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

FORM 10-K

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

For the fiscal year ended December 31, 2013

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

(215) 488-9300

(Registrant's telephone number, including area code)

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

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

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

None

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

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

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

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

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

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

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

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

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2013 (based on the closing price for shares of the registrant's common stock as reported on The Nasdaq Capital Market under the symbol DSCO on that date was approximately $70 million. In determining this amount, the registrant has assumed solely for this purpose that all of its directors, the executive officers named in Part III of this Annual Report on Form 10-K, and persons beneficially owning 10% or more of the outstanding shares of common stock of the registrant may be considered to be affiliates. This assumption shall not be deemed conclusive as to affiliate status for this or any other purpose.

As of March 7, 2014, 84,696,919 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, portions of the registrant's definitive Proxy Statement for its 2014 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days, or April 30, 2014, after the registrant's fiscal year ended December 31, 2013, and to be delivered to stockholders in connection with the 2014 Annual Meeting of Stockholders, are herein incorporated by reference in Part III of this Form 10-K.

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 such terms as "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 during which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans, and our expectations related to the commercialization of SURFAXIN® and our development and potential regulatory plans to secure marketing authorization for our products under development, starting with AEROSURF®, if approved; our expectations, timing and anticipated outcomes of submitting regulatory filings for our products under development; our research and development programs, including planning for development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant pipeline, our capillary aerosol generator (CAG) for delivery of aerosolized medications; plans for the manufacture of drug products, active pharmaceutical ingredients (APIs) and materials and medical devices; and plans regarding potential strategic alliances and other collaborative arrangements 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 in the near term, but may be unable to secure, significant additional capital to continue our operations, fund our debt service and support our research and development activities, including expensive and time-consuming clinical trials, until such time, if ever, that our revenues from all sources are sufficient to offset our cash outflows. To the extent that we raise such capital through additional financings, such additional financings could result in equity dilution;

- the risk that the initial and later phase of our AEROSURF phase 2 clinical program may be interrupted, delayed, or fail, which will harm our business;

- the risk that, if we fail to successfully commercialize SURFAXIN as planned, and if we do not achieve revenues consistent with our expectations, it may be more difficult to secure the additional capital we will require when needed, if at all, whether from strategic alliances or other sources, to continue our commercial and medical affairs activities, as well as our research and development programs and our operations would be impaired, which ultimately could have a material adverse effect on our business, financial condition and results of operations;

- risks relating to the ability of our sales and marketing organization to effectively introduce SURFAXIN in the United States (U.S.) and, if approved, our other product candidates, in a timely manner, if at all; and that we may not succeed in developing sufficient market awareness of our products or that our product candidates may not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;

- risks relating to the transfer of our manufacturing technology to contract manufacturing organizations (CMOs) and assemblers;

- the risk that we may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us in markets outside the U.S. with the development of our KL_4 surfactant pipeline products, beginning with AEROSURF, including development of our lyophilized KL_4 surfactant, and, if approved, commercialization of AEROSURF in markets outside the U.S.; support the commercialization of SURFAXIN in countries where regulatory approval is facilitated by the information contained in the SURFAXIN new drug application (NDA) approved by the U.S. Food and Drug Administration (FDA); and potentially support the development and, if approved, commercialization, of our other pipeline products;

- risks relating to our plans potentially 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 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 generally to our research and development activities, which among other things may involve time-consuming and expensive preclinical studies and potentially multiple clinical trials that may be subject to potentially significant delays or regulatory holds or fail;

- risks related to our efforts to gain regulatory approval, in the U.S. and elsewhere, for our drug products, medical device and combination drug/device product candidates, including AEROSURF, and our lyophilized KL_4 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™ ;

- 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;

- 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;

- 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;

- risks relating to our and our CMOs' ability to manufacture our KL_4 surfactant, in liquid and lyophilized dosage forms, 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;

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

- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems in manufacturing our KL_4 surfactant drug products and the APIs used in the manufacture of our drug products, CAG devices and other materials on a timely basis or in an amount sufficient to support our needs;

- risks relating to our pledge of substantially all of our assets to secure our obligations under our loan facility (Deerfield Loan) with affiliates of Deerfield Management Company, L.P., which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investment;

- risks that unfavorable credit and financial markets may adversely affect our ability to fund our activities, through our ATM Program or otherwise, and that our ATM Program may expire unutilized 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 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 products and medical device candidates;

- the risk that if we fail to maintain compliance with continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted and the value of our common stock decrease;

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

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

- the risk that we, our strategic partners or collaborators will be unable to attract and retain key employees, including qualified scientific, professional and other personnel, in a competitive market for skilled personnel, which could have a material adverse effect on our commercial and development activities and our operations; and

- other risks and uncertainties detailed in “Risk Factors” and elsewhere in this Annual Report on Form 10-K, and in the documents incorporated by reference in this report.

Pharmaceutical, biotechnology and medical technology companies have suffered significant setbacks conducting clinical trials, even after obtaining promising earlier preclinical and clinical data. Moreover, data obtained from 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, 2013

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 corporate website address is www.discoverylabs.com. Our common stock is listed on The Nasdaq Capital Market®, where our symbol is DSCO.

We are a specialty biotechnology company focused on creating life-saving products for critical-care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug technology produces a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of our aerosolized KL_4 surfactant. We believe that our proprietary technologies may 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.

Initial Focus – Respiratory Distress Syndrome (RDS) in Premature Infants

We are initially focused on improving 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. RDS is the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU) and can result in long-term respiratory problems, developmental delay and death.

Our first KL_4 surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL_4 surfactant in liquid form and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States (U.S.). Since November 2013, SURFAXIN has been commercially available in the U.S.

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may each result in serious respiratory conditions and other complications. To avoid such complications, many neonatologists treat infants with less severe RDS by less invasive means, typically nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of premature infants on nCPAP will not respond well (an outcome referred to as nCPAP failure) and thereafter may require delayed surfactant therapy. Since neonatologists currently cannot predict which infants will experience nCPAP failure, neonatologists are faced with difficult choices in treating infants with less severe RDS. This is because the medical outcomes for those infants who experience nCPAP failure and receive delayed surfactant therapy may be less favorable than the outcomes for infants who receive surfactant therapy in the first hours of life.

AEROSURF® is an investigational combination drug/device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). With AEROSURF, neonatologists potentially will be able to administer aerosolized KL_4 surfactant to premature infants supported with nCPAP, without having to use invasive intubation and mechanical ventilation. By enabling delivery of our KL_4 surfactant using less invasive procedures, we believe that AEROSURF will address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

We are also developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that is stored as a powder and reconstituted 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 initially developing this dosage form for use in our AEROSURF development program. We are also planning to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the U.S. and potentially in other markets.

The current RDS market for surfactants is estimated to be approximately $75 million annually in the U.S. and $250 to $300 million annually worldwide; however, we believe that this market has been constrained, in part, by the risks associated with surfactant administration. We believe that our RDS programs, including our aerosolized KL4 surfactant that potentially may be administered using less invasive means, collectively and over time, have the potential to greatly improve the management of RDS and to expand the current RDS estimated worldwide annual market to more than a $1 billion per year market opportunity.

To support the commercial introduction of SURFAXIN in the U.S. and our other KL4 surfactant pipeline products, if approved, we have established our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL4 surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL4 surfactant.

In addition, we recognize that our commercial and medical affairs team could potentially support introductions of other synergistic pipeline products, including products owned or developed by third parties for the NICU/PICU. To that end, we would consider potential transactions focused on securing commercial rights to such synergistic products, including in the form of product acquisitions, in-licensing agreements or distribution, marketing or co-marketing arrangements.

Beyond RDS

In the future, we expect that we may be able to leverage the information, data and know-how that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a potential product pipeline to address serious critical care respiratory conditions in larger children and adults in pediatric and adult intensive care units (PICUS and ICUs), including acute lung injury (ALI), chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). At the present time, however, we are focusing our resources primarily on the commercial introduction of SURFAXIN and development of AEROSURF through phase 2 clinical trials. Once we have achieved these objectives, we believe we would be in a better position to assess the potential of other development programs to address the critical care needs of patients in the PICU and ICU.

We also have developed a disposable aerosol-conducting airway connector for infants that is intended to simplify the delivery of aerosolized medications (including our aerosolized KL4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support. This device introduces aerosolized medications directly at the patient interface and minimizes the number of connections in the ventilator circuit. We have registered this device as a Class I, exempt medical device in the U.S. under the name AFECTAIR® and it is currently commercially available in the U.S.

BUSINESS STRATEGY

We 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. *See*, "– Surfactant Replacement Therapy for Respiratory Medicine – Respiratory Distress Syndrome in Premature Infants (RDS)." Our immediate goal is to successfully introduce SURFAXIN in the U.S. and advance development of our AEROSURF program. Key elements of our strategy to achieve these goals include:

- With the introduction of SURFAXIN, the first synthetic, peptide-containing surfactant approved by the FDA, we believe that hospitals in the U.S., over time, will replace animal-derived surfactants, which are derived from pig and cow lungs using a chemical extraction process, with SURFAXIN and our other clinically differentiated synthetic KL4 surfactant products.

- To support the commercial introduction of SURFAXIN, we have established our own specialty respiratory critical care commercial and medical affairs organization that has experience in respiratory critical care and is focused on neonatal / pediatric indications, beginning with SURFAXIN and, in the future, AEROSURF and our other KL4 surfactant products under development, if approved.

- We also will seek to identify other synergistic products that may be of benefit in the NICU/PICU and could be marketed through our team. To gain access to synergistic products, we would consider potential transactions focused on securing commercial rights in the U.S., including through product acquisitions or in-licensing, distribution, marketing or co-marketing arrangements. We believe that this strategy provides us direct control over our U.S. sales and marketing activities, permits us to establish a strong presence in NICUs and PICUs nationwide, and potentially optimizes the economics of our business.

· To advance our AEROSURF development program in the U.S., we are conducting a phase 2 clinical program, having opened an investigational new drug (IND) application with the FDA in the fourth quarter of 2013.

- The first part of our clinical program, phase 2a, is designed to evaluate the safety and tolerability of a single exposure of AEROSURF in an escalating dose study evaluating three doses of increasing amounts of AEROSURF. The comparator is nCPAP only. We anticipate results in the second half of 2014.

- The next phase of our clinical program, phase 2b, will have a primary objective to determine the optimal dose and define the expected efficacy margin. The results of this phase will inform the design of a potential phase 3 clinical trial focused on safety and efficacy. We currently plan to initiate phase 2b in the second half of 2014 and expect to complete it in the second half of 2015.

- Since June 2012, we have been working with Battelle Memorial Institute (Battelle), which supported us in a multi-phase development program that culminated in the manufacture of clinic-ready CAG devices and disposable AEROSURF Delivery Packs (ADPs) for our phase 2a clinical trial. Battelle has agreed to manufacture a sufficient number of CAG devices and ADPs to support our planned phase 2b clinical trial and other development activities.

- We plan to use our lyophilized KL4 surfactant in our AEROSURF program. Our contract manufacturing organization (CMO), DSM Pharmaceuticals, Inc. (DSM) has manufactured sufficient lyophilized KL4 surfactant drug product to support our phase 2a clinical trial and we expect DSM will manufacture additional product supply to support our planned phase 2b and, potentially, phase 3 clinical trials.

- To advance our AEROSURF program in the European Union (EU) and potentially other markets outside the U.S., we plan to retain regulatory consultants to assist us in engaging international regulatory authorities regarding a potential AEROSURF development plan.

· While we currently intend to retain all rights and commercialize our approved products in the U.S., an important priority for us is to secure strategic resources to support the continued development and commercial introduction of our RDS products in markets outside the U.S.

- To advance and support our AEROSURF development activities, we seek a significant strategic alliance that potentially could provide development, regulatory and commercial market expertise as well as financial resources for our AEROSURF development program, and, if approved, support the commercial introduction of AEROSURF in the EU and other selected markets outside the U.S. Financial resources provided by such alliances typically could take the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses.

- To potentially advance the introduction of SURFAXIN in markets outside the U.S. where regulatory marketing authorization is facilitated by the information contained in our new drug application (NDA) approved by the FDA, we would consider various financing or collaboration arrangements that could provide regulatory expertise and support the commercial introduction of SURFAXIN, and potentially our other FDA-approved KL4 surfactant products, in other countries. Such countries could potentially include those in Latin America, North Africa and the Middle East.

- An important priority for us is to strengthen our long-term financial position. We will require significant additional capital over time to advance our development programs, support the introduction of our approved products, support our operations and maximize stockholder value. *See*, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

    - We will require additional capital to fund our operations and development activities until such time as revenues from the sale of SURFAXIN and AEROSURF are sufficient, if ever, to fund our development activities and operations. In February 2013, we entered into a loan agreement (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) and have received advances totaling $30 million, secured by a security interest in substantially all of our assets. The proceeds of these loans are being used to meet our working capital requirements. We also entered into an At-the-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated (Stifel), under which Stifel, as our exclusive agent, may sell through an "at-the-market" program (ATM Program), at such times that we may elect in our sole discretion, during a three-year term, up to a maximum of $25,000,000 of shares of our common stock. At December 31, 2013, $23.0 million was available under the ATM Program. We plan to use any proceeds from the ATM Program to meet our working capital requirements. During 2013, we raised aggregate gross proceeds of $75.8 million through public offerings of our common stock, including under our ATM Program. We plan to continue to carefully managing our cash resources and will seek additional capital, including potentially through future debt and equity financings, as we deem necessary to maintain and strengthen our financial position.

    - In addition, as noted above, we expect that strategic alliances will play an important role in strengthening our financial position as well as our capabilities as we advance our KL4 surfactant development programs.

- We have invested, and will continue to invest, in improving our potential competitive position by protecting our exclusive rights in our KL4 surfactant technology, pipeline products and drug delivery technologies, including our CAG and aerosol-conducting airway connector, through patents, patent term restoration, trademarks and trade secrets. We believe that our development programs will provide opportunities to extend our exclusivities into the future through new patents and other intellectual property. We also hold, and will continue to seek, regulatory designations that provide post-approval market exclusivity for our pipeline products that would allow us to build our market share. *See*, "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations."

- We continue to invest in quality systems and manufacturing capabilities. We are planning for long-term continuity of supply and continued integrity and reliability of our manufacturing and quality assurance processes. We seek to build a foundation to support our anticipated long-term needs, and intend to make appropriate capital investments in the near-term, balancing the use of our available resources while maintaining flexibility in planning our long-term manufacturing activities and goals.

- While we are currently focused on RDS, we also believe that our KL4 surfactant technology could be developed into a broad product pipeline to address a variety of debilitating respiratory conditions and diseases, including pediatric and adult indications that could represent potentially significant market opportunities. From time to time, we have participated in investigator-initiated research programs and government funded research and preclinical development initiatives that explore the use of our KL4 surfactant in the treatment of a range of respiratory diseases, including CF and ALI. Although there can be no assurance, we may in the future support development activities to establish a proof-of-concept and, if successful, thereafter determine whether to seek strategic alliances or collaboration arrangements or pursue other financial alternatives to fund further development and/or worldwide commercialization of additional indications, if approved.

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; estimates from other companies with information on surfactant sales in countries where IMS data reporting is often incomplete or non-existent; 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 – KL4 SURFACTANT AND AEROSOL TECHNOLOGIES

Our KL4 Surfactant Technology

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. They 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 enough oxygen, resulting in severe respiratory diseases and disorders. In addition to lowering alveolar surface tension, surfactants contribute in other important ways to respiration including, for example, by lowering the surface tension of the conducting airways and maintaining airflow and airway patency (keeping the airways open and expanded). Many respiratory disorders are associated with surfactant deficiency or surfactant degradation. However, the use of surfactant therapy presently has limited application and is approved by the FDA only to manage RDS in premature infants.

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), a 21-amino acid peptide that closely mimics the essential attributes of the human surfactant protein B (SP-B), one of four known surfactant proteins and the most important for proper functioning of the respiratory system. Our synthetic surfactant is manufactured to approved specifications, with minimal lot-to-lot variability, and is being developed in liquid instillate, lyophilized (freeze-dried) and aerosolized dosage forms. We have 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).

We have demonstrated in preclinical studies that our KL4 surfactant may possess certain beneficial properties, including modulation of the inflammatory process, antimicrobial properties and non-immunogenicity. We believe these properties may be important attributes as we develop our KL4 surfactant technology pipeline potentially to address a broad range of respiratory conditions beyond RDS that represent significant unmet medical needs. However, the clinical relevance of such attributes has not been adequately established and, accordingly, warrants further study.

Dosage Form Flexibility

SURFAXIN is our first KL4 surfactant approved for sale in the U.S. and is a liquid instillate that is administered using the same method of administration required for animal-derived surfactants, endotracheal intubation and mechanical ventilation. As with the animal-derived surfactants currently marketed in the U.S., it must be stored in refrigerated conditions and warmed prior to use.

In addition to liquid instillate, our KL4 surfactant technology also can be produced in a lyophilized (freeze-dried) dosage form that is reconstituted to liquid form prior to administration. In several experiments, we have demonstrated that our lyophilized KL4 surfactant retains the key characteristics of our liquid instillate and may provide additional benefits in a clinical setting, including potentially:

- improved ease of use for healthcare practitioners, including potential elimination of the drug warming process allowing for shortened preparation time; 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 may reduce the frequency of transient peri-dosing events typically observed during administration of surfactants.

We have also demonstrated that we can aerosolize both liquid instillate and lyophilized dosage forms of 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.

We initially plan to develop our aerosolized KL4 surfactant to treat RDS in premature infants and thereafter potentially to address a range of indications in neonatal, pediatric and adult critical care patient populations. We believe our KL4 surfactant in liquid, lyophilized and aerosolized dosage forms, may be developed to expand the therapeutic options available to treat previously unaddressed respiratory problems in patients of all ages.

Our Aerosolization Delivery Technologies

Capillary Aerosol Generator (CAG) Technology

We have worldwide exclusive rights to our 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.

Our proprietary CAG technology is designed to produce a high-quality aerosol capable of delivering our KL4 surfactant to the lung. An aerosol is created by pumping our KL4 surfactant through a heated capillary. Upon exiting the capillary, the aerosol cools and slows in velocity, yielding a dense aerosol with a defined particle size. In studies conducted with our initial CAG device and our KL4 surfactant, we have generated an aerosolized KL4 surfactant at consistent and reproducible volumes suitable to deliver therapeutic dosages in a reasonable period of time. Preclinical studies presented in 2007 at the *Pediatric Academic Societies* Annual Congress (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. We believe that our CAG technology is capable of effectively delivering our KL4 surfactant to the lung of premature infants with RDS without having to resort to invasive procedures that are currently required to administer surfactants.

AFECTAIR Aerosol-Conducting Airway Connector

We have also developed a novel, disposable aerosol-conducting airway connector that is intended to simplify the delivery of aerosolized medications, including our aerosolized KL_4 surfactant, and inhaled therapies to infants requiring ventilatory support in the NICU and PICU. This device introduces the aerosolized medication directly at the patient interface and minimizes the number of connections in the ventilator circuit, simplifying the delivery of aerosolized medications and other inhaled therapies.

We registered this device in the U.S. under the name AFECTAIR as a Class I, exempt medical device and we have completed the European conformity (CE) marking process in the EU. Based on *in vitro* studies demonstrating that AFECTAIR improves the delivery of inhaled therapies to infants requiring ventilatory support, we believe that it has the potential to greatly improve the delivery of aerosolized medications and inhaled therapies to critical-care patients. We currently are focused on gaining information and learning from the introduction of AFECTAIR in the U.S. Thereafter, we may consider introducing AFECTAIR in markets outside the U.S.

SURFACTANT REPLACEMENT THERAPY FOR RESPIRATORY MEDICINE

Prior to the FDA's approval of SURFAXIN, the only pulmonary surfactants commercially available in the U.S. were introduced in the 1990's. All of the available pulmonary surfactants were animal-derived and approved for RDS in premature infants. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners in the U.S. 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 KL_4 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 may need surfactant 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 severe RDS currently are treated with surfactants (usually within the first hours of birth) that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may each result in serious respiratory conditions and other 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. To avoid these complications, many neonatologists will administer surfactants as an initial therapy only to premature infants with severe RDS, where the potential benefits of invasive surfactant therapy more clearly outweigh the associated risks. Unfortunately, many infants with server RDS will 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.

A common ventilatory support treatment alternative to intubation and mechanical ventilation is nCPAP, which is generally used to support all but the very low birth weight infants with severe RDS. Unfortunately, a significant number of infants do not respond adequately to nCPAP, an outcome referred to as nCPAP failure, and thereafter may require delayed surfactant therapy administered by intubation and mechanical ventilation. Several 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)). Since it currently is not possible to predict which patients will experience nCPAP failure, neonatologists are faced with difficult choices in deciding how best to treat premature infants with less severe RDS. This is because the medical outcomes for those infants who experience nCPAP failure and receive delayed surfactant therapy may be less favorable than the outcomes 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 in the U.S., major European medical markets, and Japan). In the U.S., we estimate that approximately 160,000 premature infants could benefit from surfactant therapy. However, due to the risks associated with intubation and mechanical ventilation, only approximately 45,000 of these infants currently are treated with surfactants as the initial therapy for severe RDS. The remainder primarily receive nCPAP for less severe RDS. As discussed above, a large percentage of these patients will fail nCPAP therapy and require delayed surfactant therapy administered via intubation and mechanical ventilation. We estimate this delayed surfactant therapy (post-nCPAP failure) population to be another approximately 45,000 infants, bringing the total number of premature infants in the U.S who are treated with surfactants for RDS to approximately 90,000.

Neonatologists' treatment options have not improved significantly, nor have mortality and morbidity rates for RDS meaningfully improved over the last decade. We believe that the neonatal medical community would respond favorably to the introduction of a synthetic, peptide-containing surfactant and a less-invasive method of administration.

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. SURFAXIN represents the first synthetic, peptide-containing surfactant approved for the prevention of RDS in premature infants at high risk for RDS.

Our NDA for SURFAXIN was supported by a phase 3 pivotal trial (SELECT) to evaluate the safety and efficacy of SURFAXIN for the prevention of RDS in premature infants. Co-primary endpoints were the incidence of RDS at 24 hours and RDS-related mortality at 14 days. The primary comparator was Exosurf® (colfosceril palmitate) with the intent of demonstrating superiority. SURFAXIN demonstrated a statistically significant improvement in both RDS at 24 hours and RDS-related mortality through day 14. Survanta® (beractant) served as an additional active comparator. SURFAXIN demonstrated a statistically significant reduction in RDS-related mortality through day 14 versus Survanta. We also conducted a supportive, multicenter, double-blind, active-controlled, phase 3 clinical trial (STAR) which was designed as a non-inferiority trial comparing SURFAXIN to Curosurf® (poractant alfa), a surfactant derived from pig lung.

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 indicates 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. The clinical relevance of this finding has not been adequately established and, accordingly, warrants further study. However, pharmacoeconomic analysis suggests that lower reintubation rates may result in significant hospital cost savings associated with reduction in time spent on mechanical ventilation and reduced rates of bronchopulmonary dysplasia (BPD), air leak, sepsis, necrotizing enterocolitis (NEC), or intraventricular hemorrhage (IVH).

The FDA granted marketing approval for SURFAXIN on March 6, 2012. In the third quarter of 2012, following a routine 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. We subsequently improved and validated the analytical chemistry method and submitted updated product specifications to the FDA. In November 2013, the FDA approved our submission and we initiated the commercial introduction of SURFAXIN.

To facilitate proper administration of SURFAXIN, we are making available to hospitals a 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.

AEROSURF for the Treatment of RDS in Premature Infants

AEROSURF is an investigational drug-device combination product that produces our KL4 surfactant in aerosolized form using our lyophilized KL4 surfactant with our CAG. We are developing AEROSURF to potentially reduce or eliminate the need for intubation and mechanical ventilation in the treatment of RDS. With AEROSURF, neonatologists may potentially administer our aerosolized KL4 surfactant to premature infants supported by nCPAP, without subjecting them to invasive intubation and mechanical ventilation, which are currently required to administer surfactant therapy to premature infants. With the risk of intubation reduced or eliminated, we believe that AEROSURF could enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but who are currently not treated.

By enabling delivery of our aerosolized KL4 surfactant using less invasive procedures, we believe that AEROSURF will address a serious unmet medical need, provide potentially transformative clinical and pharmacoeconomic benefits, and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated. As noted above, of the 160,000 infants that could likely benefit from surfactant therapy, approximately 115,000 currently receive nCPAP therapy as the initial therapy for RDS. We believe, and market research with clinicians suggests, that, if AEROSURF is approved, a large majority of infants who currently receive nCPAP only will instead receive aerosolized KL4 surfactant as the initial treatment for RDS. In addition, if AEROSURF is approved, of the 45,000 remaining premature infants who currently receive liquid surfactant administered using intubation and mechanical ventilation as the initial treatment, a significant number of these infants could potentially also receive aerosolized KL4 surfactant therapy as the initial treatment.

In addition to the potential clinical benefits of aerosolized KL4 surfactant, this therapy has the potential to provide significant pharmacoeconomic benefits for hospitals, payers and healthcare systems. The cost to support a mechanically ventilated RDS patient (an estimated $55,000 per patient), is much greater than the cost to manage a patient on nCPAP (an estimated $8,000 per patient). These costs increase even more when treating complications associated with intubation and mechanical ventilation such as bronchopulmonary dysplasia. By providing clinical and pharmacoeconomic benefits and enabling the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated, we estimate that AEROSURF may, over time, expand the size of the U.S. surfactant market from a current estimated $250-$300 million per year to a range of $600 million to over $1 billion per year.

We are developing AEROSURF to deliver our aerosolized KL4 surfactant using the CAG. To develop our CAG 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 assisted us with technical support and expertise and, together with our medical device engineering team, conducted a multi-phased program to finalize the design, test, and manufacture clinic-ready CAGs for our AEROSURF phase 2a clinical trial. In addition, Battelle has agreed to manufacture a sufficient number of additional CAG devices and ADPs to support our AEROSURF phase 2b clinical trial, which we anticipate could initiate in the second half of 2014. In addition to the CAG, we are developing a lyophilized KL4 surfactant dosage form that we intend to use initially for AEROSURF. *See*, "– Lyophilized KL4 Surfactant for RDS in Premature Infants." We plan to develop AEROSURF using the lyophilized dosage form of our KL4 surfactant.

To prepare for our AEROSURF development activities, we previously conducted preliminary meetings with the FDA to discuss the AEROSURF development plan. We also engaged regulatory consultants to assist us in refining and submitting our IND to implement our phase 2a clinical program. We filed with the FDA in October 2013 and opened our IND in November 2013. We currently plan to retain regulatory consultants to assist us in engaging international regulatory authorities regarding an AEROSURF development plan outside the U.S.

Our phase 2a program is currently ongoing. This initial phase of our phase 2 clinical program is designed to evaluate the safety and tolerability of a single exposure of AEROSURF in an escalating dose study evaluating three doses of increasing amounts of AEROSURF. The comparator is nCPAP only. We plan to conduct this trial in up to four medical centers in the U.S., and anticipate results in the second half of 2014.

The next phase, phase 2b, of our clinical program is expected to begin in the second half of 2014 and conclude in the second half of 2015. The primary objective of this phase will be to determine the optimal dose and define the expected efficacy margin. The design of this phase will be informed by the results of the phase 2a trial. This phase is expected to be a multicenter trial conducted in the U.S., with results to be available in the second half of 2015. The potential phase 3 efficacy clinical will be defined based in part on the results of the phase 2 trial.

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. We also have filed for a Phase II SBIR Grant that could provide up to an additional $1.88 million to support our AEROSURF clinical activities. *See*, "–Surfactant Replacement Therapy for Respiratory Medicine - Serious Respiratory Indications Associated with Inflammation of the Lungs."

Lyophilized KL_4 Surfactant for RDS in Premature Infants

We are developing a lyophilized (freeze-dried) dosage form of our KL_4 surfactant that can be stored as a powder and reconstituted to liquid form prior to use, with the objective of improving ease of use for healthcare practitioners, as well as potentially prolonging shelf life and eliminating the need for cold-chain storage. This lyophilized dosage form is intended initially to be used in our AEROSURF development program. We have completed a technology transfer of our lyophilized surfactant manufacturing process to DSM, which has expertise in lyophilized products. DSM has manufactured a supply of clinical drug product needed for the initial phase of our phase 2 program and will manufacture the clinical drug supply needed to complete our phase 2 clinical program. We also have entered into a development agreement with DSM for the further development of this lyophilized KL_4 surfactant, potentially for our AEROSURF phase 3 program and, if approved, commercial supply.

We are focused initially on developing this dosage form for use in our AEROSURF development program. We are also planning to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS, in the U.S. and potentially in other 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. For this reason, we believe that AEROSURF is a highly promising program and that, with the knowledge that we gain from our efforts to develop AEROSURF for the treatment of RDS in premature infants with RDS, we may be able to leverage our technology platform to potentially address serious respiratory conditions affecting pediatric and adult patient populations. We believe that our proprietary aerosolized KL_4 surfactant technology potentially may be effective as a preventive measure to treat patients at risk for ALI and, possibly in the future COPD and that investment in these indications could potentially address significant unmet medical needs.

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.

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.

We have collaborated in research and preclinical studies to assess the use of our KL4 surfactant to potentially address ALI in an animal model. In September 2012, we announced four collaborations in a series of preclinical studies funded through various U.S. government-sponsored, biodefense-related initiatives, including collaborations with: (i) 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; (ii) University of Rochester, to evaluate the use of KL4 surfactant to protect the lung in a radiation-induced multi-organ dysfunction animal model; (iii) a facility of the U.S. Department of Defense through the NIH Office of the Director and the Countermeasures Against Chemical Threats (CounterACT) program, to assess the utility of KL4 surfactant for the treatment of chemical-induced ALI; and (iv) a program funded by NIAID, to investigate the use of KL4 surfactant as a treatment for influenza-induced ALI.

We may in the future 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. 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.

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. CF is the most common, life-threatening genetic disorder in the U.S. CF occurs in approximately one in every 3,500 Caucasian live births and affects approximately 30,000 patients in the U.S. and nearly 70,000 worldwide. Life expectancy for CF has more than doubled in the past 25 years to the mid-forties, due to significant advances in research and care.

We believe that our KL4 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, may serve as a complementary therapy to advance the treatment of CF and improve treatment outcomes for these very ill patients. In 2009, 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. In addition, we have received an orphan drug designation for CF from the FDA and the European Medicines Agency (EMA).

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 the management of RDS in premature infants. We continually evaluate our research and development priorities in light of a number of factors, including the results obtained in our preclinical research and related activities, advances in technology, and relationship of a project to our near-term objectives; our cash flow requirements, financial liquidity, and our ability to secure the necessary capital; and the potential for development partnerships and collaboration agreements. In connection with our evaluations, we modify and adapt our research and development plans from time to time and anticipate that we will continue to do so.

We plan to focus our research and development resources in the near term on our RDS programs, primarily AEROSURF. We are presently engaged in a phase 2a clinical trial for AEROSURF and are preparing to initiate a phase 2b trial, potentially in the second half of 2014. Battelle has assisted us in the development and manufactured for us a supply of clinic-ready CAG devices to support preclinical activities and our phase 2a clinical trial. We are working with Battelle to manufacture additional CAG devices to support additional research and development activities and our phase 2b clinical trial. We are also working with DSM to manufacture a supply of lyophilized KL_4 surfactant in mid-2014 to support the phase 2b trial and conduct further manufacturing development work for the planned phase 3 trial.

In addition to developing our lyophilized KL_4 surfactant for AEROSURF, we plan to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS, in the U.S. and potentially in other markets.

In markets outside the U.S., for AEROSURF, we plan to engage international regulatory authorities regarding a potential AEROSURF development plan to advance AEROSURF in the EU and potentially other markets. We also would invest in research and development activities to support a significant strategic alliance focused on the EU and/or other selected markets outside the U.S. for the development and, if approved, commercial introduction of AEROSURF. For SURFAXIN, we would consider various financing or collaboration arrangements that could provide regulatory expertise and support the commercial introduction of SURFAXIN, and potentially our other FDA-approved KL_4 surfactant products, in other countries.

To support our research and development activities, we have:

- physicians and scientists with expertise in pediatric and pulmonary medicine and extensive contacts in the neonatal medical community;
- expertise in the design and execution 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. We have our own scientific, medical, biostatistics, and trial and data management capabilities. 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 AEROSURF trials, including potentially 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 engineering team, we are engaged in a development program with Battelle to bring its significant expertise in developing and integrating aerosol device technologies to optimize our CAG device and manufacture clinic-ready CAG devices for our phase 2 AEROSURF clinical trials;
- quality operations capabilities to assure compliance with applicable regulations;
- manufacturing capabilities to manufacture our KL_4 surfactant for use in preclinical studies. We rely on CMOs to produce our lyophilized KL_4 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 year ended December 31, 2013, we invested approximately $27.7 million for research and development expense, which includes (i) product development and manufacturing, (ii) medical and regulatory operations, and (iii) direct preclinical and clinical programs.

Manufacturing and Distribution

In 2005, we acquired manufacturing operations located in a leased facility in Totowa NJ (Totowa Facility) to manufacture SURFAXIN, our liquid instillate KL4 surfactant. To support our manufacturing operations, in 2007, we established our own analytical and technical support laboratory at our headquarters in Warrington, Pennsylvania (Warrington Laboratory). We use third parties for the manufacture of our lyophilized KL4 surfactant and medical devices and related components, certain analytical and laboratory services in support of our manufacturing activities, packaging and labeling, warehousing, third-party logistics services 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. Our KL4 surfactant is a complex drug product comprised of four active pharmaceutical ingredients (APIs). It must be aseptically manufactured as a sterile, liquid suspension and requires ongoing monitoring of drug product stability and conformance to specifications. Like some other surfactants, it is stored and shipped in a refrigerated, cold-chain environment. We currently rely on single source suppliers under separate product supply agreements for KL4 and POPG, two of our APIs, and source our other APIs from single source suppliers under purchase orders that we issue from time to time. To mitigate our risk, we plan to qualify secondary suppliers for our APIs over the next 18 to 36 months. Our risk of losing a source of supply is currently somewhat mitigated by our decision to enlarge our safety stock of all APIs when we began the commercial introduction of SURFAXIN. While we generally purchase our primary packaging components and excipients from single-sources, these items are generally readily available from multiple manufacturers.

We conduct our manufacturing activities for SURFAXIN in our Totowa Facility and our analytical and technical support laboratory in our Warrington Laboratory. We have a third-party agreement for packaging and vial labeling services for our SURFAXIN drug product. Our Totowa facility consists of pharmaceutical manufacturing and development space that is designed for the manufacture and filling of sterile liquid pharmaceuticals in compliance with cGMP. *See*, "Item 2 – Properties." These operations are configured and approved to produce SURFAXIN commercial drug product. In addition, we also operate a microbiology laboratory at our Totowa Facility that supports our manufacturing activities. In our Warrington Laboratory, we conduct certain analytical development and quality control activities, including release testing of all APIs as well as release and stability testing of SURFAXIN clinical and commercial drug product supply. Our Warrington Laboratory also provides analytical testing and quality system support for our efforts to identify and protect our intellectual property, and for our lyophilized and aerosolized KL4 surfactant dosage forms as well as other potential formulations of our KL4 surfactant in support of AEROSURF and our other KL4 surfactant product candidates.

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, including our biological activity test (BAT) release and stability testing. At the present time, several of these laboratories are single-source providers. We are implementing a plan to potentially qualify over the next 12- 24 months additional sources to meet our key release testing and stability requirements.

Importantly, as we undertake the commercial introduction of SURFAXIN and the development of AEROSURF, we are planning for long-term continuity of supply and continued integrity and reliability of our manufacturing and quality assurance processes. We seek to build a foundation to support our anticipated long-term needs, and intend to make appropriate capital investments in the near-term, balancing the use of our available resources while maintaining flexibility in planning our manufacturing goals.

- The lease for our Totowa Facility currently expires on June 30, 2015. We continue to explore possible alternatives that could enable longer-term utilization of that facility for the manufacture of SURFAXIN and potentially lyophilized KL4 surfactant.

- We completed the technology transfer of our lyophilized KL4 surfactant manufacturing process to DSM in 2013 and have manufactured a sufficient clinical supply of KL4 surfactant to support the phase 2a AEROSURF clinical trial. We plan to manufacture additional clinical supply in mid-2014 to support our phase 2b clinical trial. We also have entered into a development agreement with DSM for the potential further development and manufacture of lyophilized KL4 surfactant for our AEROSURF phase 3 clinical program, as well as other potential pipeline development programs.

- To secure an additional source of SURFAXIN commercial drug product, in 2012 we initiated a technology transfer of our liquid KL4 surfactant manufacturing process to DSM and in August 2013 entered into a supply agreement with DSM that provides for the manufacture of commercial supply of SURFAXIN drug product through December 31, 2015, with such further extensions at that time as the parties may agree.

- We also have initiated a project to identify a second CMO that would manufacture clinical and commercial supply and assure a continuous and back up supply of SURFAXIN drug product. We currently are working through potential development plans with a few CMOs and thereafter plan to initiate a technology transfer of our liquid KL4 manufacturing process.

We also believe that our in-house manufacturing capabilities, including our executive management, in-house manufacturing and quality operations managers and employees, are important to our long-term success. Our management team includes executives experienced in pharmaceutical and biopharmaceutical drug product manufacturing, with extensive experience in manufacturing both small and large molecules, biological and sterile drug/device combination products in both domestic and overseas operations, and supply chain; as well as in worldwide quality operations to assure consistent and continued quality and cGMP compliance for our products, whether manufactured on our own or with a CMO. Our manufacturing operations are lead by seasoned professionals with broad technical and managerial skills in all facets of our KL4 surfactant manufacturing process, expertise built on many years of accumulated knowledge in biopharmaceutical manufacturing, facility management, process and cleaning validation, sterility assurance and microbiological analyses, clean room operation and direction of formulation and aseptic filling of our drug product. Although there can be no assurance, we believe that we can leverage the extensive experience that we have gained from having managed our own manufacturing operations since 2005 to flexibly respond over time and provide for the continued manufacture of our KL4 surfactant drug product, on our own or with our CMOs.

CAG Device and Related Componentry

AEROSURF is a combination drug-device product that producing aerosolized KL4 surfactant by combining our lyophilized KL4 surfactant with our CAG device and aerosol delivery technologies. We are developing and, if approved, will commercialize AEROSURF in the U.S. for the treatment of premature infants with RDS. We also believe that our aerosolized KL4 surfactant may be used to address a broad range of serious respiratory conditions in the NICU as well as in children and adults in the PICU and ICU.

The CAG device includes an aerosol control unit and a disposable AEROSURF delivery pack (ADP). The ADP includes the critical drug product-contact components that are either cleaned or manufactured in an environmentally-controlled, clean area. The control unit and ADPs are assembled and packaged in a clean area. Each of the ADP devices is tested for conformance to designated product specifications during assembly and each of the assembled control units must be quality control tested prior to release and monitored for conformance to designated product specifications.

In June 2012, we entered into an agreement with Battelle under which Battelle assisted in a multi-phase development program focused on design and testing of clinic-ready CAG devices for our AEROSURF phase 2a clinical trials, and then manufactured CAG devices for the phase2a clinical trial that is currently underway. In addition, we recently entered into an agreement with Battelle for the manufacture and assembly of a sufficient number of control units, ADPs and related components to support our planned phase 2b clinical trial and development activities. In the future, we expect to rely on CMOs to manufacture and assemble the CAG device and related components needed to support our development activities, planned phase 3 clinical studies and, if approved, potential commercialization of AEROSURF.

AFECTAIR Aerosol-Conducting Airway Connector

In 2012 we entered into a supply agreement (Agreement) with Lacey Manufacturing Company, a division of Precision Products, LLC (Lacey), to manufacture AFECTAIR devices through October 2015. 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 has agreed to label, package, and prepare AFECTAIR devices for shipment.

Distribution

To support the commercial introduction of SURFAXIN, we have established arrangements with ASD Specialty Healthcare Inc. (ASD) 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, returned goods, contract and accounts receivable management, certain financial management services and other similar services.

In 2012, we amended and updated our agreement with ASD, which agreed to act as our exclusive specialty distributor for SURFAXIN, WARMING CRADLE dry-block heaters and AFECTAIR devices in the U.S. and provide related services. Lacey will ship the finished product to ICS who has agreed to warehouse and provide third-party logistic services for us. ASD has agreed to act as distributor for AFECTAIR devices.

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.

General and Administrative

We have made significant investments in our sales and marketing capabilities and 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

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 (collectively, the territory). Antonio Esteve, Ph.D., a principal of Esteve, served as a member of our Board of Directors from May 2002 until January 2013. 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 2004 restructuring in which Esteve returned certain rights to us in certain territories (Former Esteve Territories), we agreed to pay Esteve 10% of any cash up front and milestone fees (up to a maximum aggregate of $20 million) that we 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

While we currently intend to retain all rights and commercialize our approved products in the U.S., we seek strategic alliances and other collaboration arrangements for the development and/or commercialization of our KL4 surfactant product candidates in markets outside the U.S.

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, 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 which is now U.S. Patent No. 8,221,772 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.

In March 2013, we filed International patent applications (PCT/US13/34364 and PCT/US13/34464 and commenced expedited examination in US and EU) directed to lyophilized pulmonary surfactant and methods of manufacture.

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

In 2008, to restructure a December 2005 strategic alliance, we entered into an Amended and Restated License Agreement with Philip Morris USA, Inc. (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). 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.

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 certain 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 are required to pay minimum royalties quarterly beginning in 2014, 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. We believe that our AEROSURF aerosolized KL_4 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.

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.

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 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 our KL4 surfactant for the treatment of RDS in premature infants. However, our indication is SURFAXIN is for the prevention, rather than treatment, of RDS, such that this designation does not apply to SURFAXIN. If we develop AEROSURF or SURFAXIN LS for the treatment of RDS, this orphan drug designation may apply for those indications. We are currently seeking the confirmation from the FDA. The FDA has also granted Orphan Drug designation to (i) KL4 surfactant 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) KL4 surfactant for the prevention of RDS in premature infants, (ii) KL4 surfactant for the treatment of RDS in premature infants, (iii) our KL4 surfactant for the treatment of ALI in adults (which in this circumstance encompasses ARDS), and (iv) 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 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/or 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 its wholly-owned subsidiary, Cornerstone Therapeutics Inc. In addition, Chiesi has published the results of a preclinical study 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). Chiesi has also initiated a first-in-human phase 2 clinical trial to study the safety and tolerability of intratracheal administration of two different single doses of its investigational synthetic surfactant in preterm neonates with RDS (clinicaltrials.gov). Survanta historically has been marketed by Abbott Nutritionals, Inc. (Abbott). However, in December 2012, Abbott distributed to its shareholder a wholly-owned subsidiary, AbbVie Inc. (AbbVie), which separated Abbott's research-based pharmaceuticals business, including Survanta, from the remainder of its businesses. 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. Chiesi has recently investigated the use of nebulized Curosurf using a Pari eFlow Neonatal Nebulizer System (CureNeb study; PAS 2013 abstract - http://www.abstracts2view.com/pas/view.php?nu=PAS13L1_3500.7). Aerogen manufactures a number of aerosolization devices, including a disposable, single patient nebulizer and a reusable, multi-patient nebulizer. Our AFECTAIR device is an aerosol-conducting airway connector that is intended to replace standard connectors in the ventilatory circuit. AFECTAIR has been shown in various studies to potentially increase the delivery of aerosolized medications. Although we are not aware of any efforts by a competitor to develop an alternative to AFECTAIR, it may be viewed as competing with companies that are developing aerosol generators with the intent of improving the delivery of aerosols to infants.

GOVERNMENT REGULATION

The development, manufacture, distribution, marketing and advertising of drug, device, and combination drug-device 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, device, or combination 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 KL_4 surfactant technology pipeline products, we must demonstrate, through experiments, preclinical studies and clinical trials that each of our drug product candidates meets the safety and efficacy standards established by the FDA and other international regulatory authorities. In addition, we and our suppliers and 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, 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 to commercialize 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 clinical 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, including for AEROSURF involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes."

Regulatory Review: The results of preclinical and clinical trials for drug products 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 standard review is approximately 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 decline to 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.

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.

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.

Combination Drug-Device Products

Combination drug products such as AEROSURF and potentially other aerosolized KL_4 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. The FDA has determined that our aerosolized KL_4 surfactant combination drug-device product will be evaluated as a drug and, therefore, 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.

Manufacturing Standards

The FDA and other international regulators establish requirements and standards and routinely inspect the quality system, facilities, equipment, processes, and analytical laboratories 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. The FDA may determine to conduct such inspections at any time and for any reason. *See*, "Item 1A – Risk Factors – Manufacturing problems potentially could cause us to experience shortages of SURFAXIN and AFECTAIR product inventories, or delay our preclinical or clinical programs, 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 harmonized. International regulators are independent and not bound by the findings of the FDA and there is a risk that foreign regulators will not accept clinical trial design/results or may require additional data or other information not requested by the FDA. Therefore, we will have to comply with both cGMP and International Conference on Harmonization (ICH) guidelines.

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 "Open Payments" law (previously referred to as "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 transparency provisions, requiring annual reporting of various types of payments to physicians and teaching hospitals. Implementation of the Open Payments provisions has been subject to delay by the U.S. Centers for Medicare and Medicaid Services (CMS). Under the current regime, applicable manufacturers were to 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 in a two-phased approach by March 31, and May 31, 2014, respectively. CMS will publish the data on a public website later in the year. Inaccurate or incomplete reports may be subject to enforcement. Like the federal Open Payments 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 KL_4 surfactant technology, our novel CAG technology, and our novel aerosol-conducting airway connector;" "– Our research and development programs, including for AEROSURF involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes," "– 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 designation, Orphan Drug designation, or other potential expedited regulatory pathway options. Each potential expedited regulatory pathway could provide for expedited FDA communication or approval, as well as additional potential benefits, such as additional market exclusivity or tax incentives. *See*, "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights – Other Regulatory Designations," and "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."

EMPLOYEES

As of March 7, 2014, we have 126 employees. Of this total, 14 (approximately 11% of our total labor force) are employed at our Totowa Facility, and are subject to a collective bargaining agreement that expires on December 3, 2015. 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 or our partners or collaborators are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products."

AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (SEC). 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 websites at http://www.DiscoveryLabs.com, www.SURFAXIN.com, and www.AFECTAIR.com. Our websites 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 in the near term, but may be unable to secure when needed, significant additional capital to support our operations, pay our debt service, commercialize our approved products and develop our products under development, including AEROSURF®, and to continue our other research and development programs. Moreover, any financings could result in substantial dilution to our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.

Our operations have consumed substantial amounts of cash since inception. As of December 31, 2013, we have an accumulated deficit of approximately $480 million and we expect to continue to incur significant, increasing operating losses over the next several years. As of December 31, 2013, we had cash and cash equivalents of approximately $86.3 million and $30 million ($18.4 million net of discount) of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P.(Deerfield). During 2013, we raised aggregate gross proceeds of $75.8 million through public offerings of our common stock, including net proceeds of approximately $1.8 million that we raised under our ATM Program. On November 8, 2013, we announced the commercial launch of SURFAXIN®. Before any additional financings, including under our ATM Program, we anticipate that we will have sufficient cash available to support our operations and debt service obligations through the third quarter of 2015.

We expect to continue to require significant additional infusions of capital to execute our business strategy until such time as the net revenues from SURFAXIN and, potentially, AEROSURF, and from potential strategic alliance and collaboration arrangements and other sources, are sufficient to offset our cash flow requirements. Even if we succeed with the commercial introduction of SURFAXIN, we expect our revenues from SURFAXIN will be modest in the first 12-24 months and then increase slowly over time. For the next several years, we expect that our cash outflows for development programs, operations and debt service will far outpace the rate at which we may generate revenues from product sales. *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; and/or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to secure capital from strategic alliances and collaboration arrangements and other similar transactions, 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. Depending on conditions in the global financial markets, we may face significant challenges accessing the capital markets at a time when we would like or require, and at an increased cost of capital. Except for our at-the-market equity program with Stifel, Nicolaus & Company, Incorporated (ATM Program), which can be cancelled at any time, we do not have in place arrangements to obtain additional capital. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. In any such event, the market price of our common stock may decline. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could delay new product development and clinical trial plans.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this Annual Report on Form 10-K should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

Our clinical development program for AEROSURF involves 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 prospects.

We are currently conducting a phase 2a clinical trial, which is an open label, single-dose study with the primary goal of evaluating the safety and tolerability of aerosolized KL_4 surfactant drug product administered in escalating inhaled doses in premature infants 29 to 32 weeks gestational age who are receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to infants receiving nCPAP alone. This initial clinical trial is the first in a series of clinical trials that will be needed to gain marketing authorization for AEROSURF. Such 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 U.S. Food and Drug Administration (FDA) or a foreign regulator on the design of any one or more of the clinical trials necessary for approval, or we may be unable to reach agreement on a single design that would permit us to conduct a single clinical program. Conditions imposed by the FDA and foreign regulators on our clinical program could significantly increase the time required to complete and the costs of conducting clinical trials. For example, we may not be successful in achieving a study design that is acceptable to both the FDA and regulators in other countries, which would cause us to limit the scope of our activities or greatly increase our investment. Like many biotechnology companies, even after obtaining promising preliminary findings or results in earlier preclinical studies and clinical trials, we may suffer significant setbacks in any stage of our clinical trials. Clinical data is 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 eligibility and enrollment criteria for the study;
- the willingness of patients' 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 in our clinical trials, we succeed in achieving our patient enrollment targets, our patients could suffer adverse medical events or side effects that are known to be associated with surfactant administration, such as a decrease in the oxygen level of the blood, or currently unknown to us. It is also possible that we, our AEROSURF Clinical Trial (ACT) Steering Committee, the Safety Review Committee (SRC), or the FDA could interrupt, delay or halt any one or more of our clinical trials for AEROSURF or any of our product candidates. If our ACT Steering Committee, the SRC, any regulator or we believe that study participants face unacceptable health risks, any one or more of our clinical 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, ACT Steering Committee and/or SRC recommendation, or business reasons.

In addition to our planned clinical program to support AEROSURF, in the future, we also may initiate or support clinical trials evaluating other KL_4 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.

If we fail to successfully commercialize SURFAXIN, or if our efforts to commercialize SURFAXIN are significantly delayed or impaired, our ability to grow our revenues and continue our development programs will be impaired, and we may be unable to secure the additional capital that we require, which would have a material adverse effect on our business, financial condition and results of operations and the price of our common stock would likely decline.

We initiated the commercial introduction of SURFAXIN in late 2013. SURFAXIN product sales are expected to constitute most, if not all, of our total revenue from product sales over the next several years. Our efforts to successfully execute the commercial introduction of SURFAXIN are subject to a variety of risks and uncertainties that could cause actual results to be materially different. The commercial success of SURFAXIN 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 hospitals to accept and employ WARMING CRADLE® dry-block heater, a device that warms drug vials at the same temperature and for the time period designated in the SURFAXIN prescribing information;
- the effectiveness of our marketing, sales and medical affairs organizations and their ability to (a) accurately describe SURFAXIN consistent with its approved labeling, and (b) educate and provide critical care providers and hospitals with medical and scientific education and information;
- our ability to gain access to the entire market with our commercial organization;
- our ability to provide hospitals acceptable evidence of the safety and efficacy of SURFAXIN and the perceived advantages of SURFAXIN, a synthetic peptide-containing surfactant, over alternative animal-derived surfactants;
- 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 impact of adding SURFAXIN and WARMING CRADLE heater to 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 RDS and the number treated with SURFAXIN;
- the growth of commercial sales;
- our ability to meet commercial demand for SURFAXIN, including through maintenance of commercial supplies of our active drug substances and other excipients, and manufacturing capabilities, by ourselves and through contract manufacturing organizations (CMOs); and commercial inventory supplies of our medical device products; and
- the sufficiency of coverage or reimbursement by third parties.

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® device must be approved for use by hospitals' materials management, and we will need to arrange with each hospital to include WARMING CRADLE on the hospital's list of approved laboratory equipment. 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 cause hospitals 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.

Our efforts to achieve formulary acceptance of SURFAXIN, and to educate the medical community and third-party payers regarding the benefits of SURFAXIN will require significant, focused and competent resources and we may not be successful in achieving our objectives. If we are unable to achieve formulary acceptance in our target hospitals, the revenues we generate from sales will be limited and we may never achieve profitability.

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

Even if we are successful in achieving formulary acceptance of SURFAXIN and, if approved, AEROSURF, and adoption of AFECTAIR device, in our target hospitals, if we do not achieve broad market acceptance of our products by physicians, respiratory therapists, nurses and other personnel in neonatal and pediatric intensive care units (NICUs and PICUS) and elsewhere in the hospital, as well as patients, healthcare payers and others in the medical community in general, 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 our approved products will depend on a number of factors, including:

- the willingness of physicians and hospitals to utilize our products and the willingness of hospitals' P&T Committees to place our products on formulary or on the list of medical devices the hospital will purchase;
- the safety and efficacy of our products, both in fact and as perceived by the medical community, regulatory agencies and insurers and other payers, on both a short and long-term basis;
- the potential advantages of our products over alternative treatments;
- the relative convenience and ease of use;
- 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.

As a company, we have limited experience in the field of marketing or selling pharmaceutical and medical device products and limited marketing capabilities, which may restrict our success in commercializing our products. We have established our own commercial and medical affairs organization to launch our 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 have limited experience in marketing or selling pharmaceutical and medical device products, although we have endeavored to hire individuals that have significant experience in neonatal indications and/or hospital-based products. We plan to rely solely on our own specialty respiratory critical care commercial and medical affairs organization to market and support SURFAXIN, and, if approved, AEROSURF and potentially SURFAXIN LS™, if approved, in the U.S. We also plan to rely on our own commercial and medical affairs organization to introduce AFECTAIR device in the U.S. We believe that AFECTAIR device will be of interest to many of the same hospitals, neonatologists and neonatal intensive care units that purchase SURFAXIN. Commercializing our products in the U.S. on our own may 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 expensive and time-consuming 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 retain, motivate and attract experienced individuals for our commercial and medical affairs organization to support the introduction, marketing 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 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 may consider strategic alliances and/or collaboration arrangements, including third-party distributors or marketing alliances, to sell our AFECTAIR device 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.

If we enter into alliances, distribution and collaboration 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 if we are unable to enter into arrangements with third parties in a timely manner when needed, 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 collaborators 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.

If we do not adequately forecast customer demand for our approved products, including SURFAXIN and, if approved, AEROSURF, our business could suffer. If we are successful, we also potentially are 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, 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 would subject 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 manufacturing strategy includes relying, at least in part in the future, on third parties to manufacture our current approved products as well as certain of our drug product candidates and medical devices, which exposes us to risks that may affect our ability to maintain supplies of our commercial products and/or delay our research and development activities, regulatory approval and commercialization of our drug product candidates.

We currently manufacture SURFAXIN at our Totowa Facility. Our strategy includes potentially manufacturing SURFAXIN in the future and our lyophilized dosage form of our KL4 surfactant, as well as our capillary aerosol generator (CAG) for AEROSURF and AFECTAIR devices, using third-party contract manufacturing organizations (CMOs). Our efforts to conduct a technology transfer of our manufacturing process and our planned future reliance on CMOs exposes us, among other things, 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 CMOs is limited and the FDA must approve any replacement CMO. This approval could require one or more pre-approval 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. This could take as long as 2 years to qualify and receive regulatory approval;
- we may implement a plan to execute a technology transfer of our manufacturing process to a CMO and, after investing significant time and resources, learn that the CMO we chose is unable to successfully complete the technology transfer and thereafter manufacture our products in accordance with our plan;
- CMOs might be unable to manufacture our products in the volume and to our specifications to meet our commercial and clinical needs, or we may have difficulty scheduling the production of drug product and devices in a timely manner to meet our timing requirements;
- CMOs may not perform as agreed, or may not remain in the CMO business for a lengthy time, or may refuse to renew an expiring agreement as expected, or may fail to produce a sufficient supply to meet our commercial and/or clinical needs;
- CMOs are subject to ongoing periodic unannounced inspection by the FDA, international health authorities, registered Notified Body(ies), 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 a CMO's compliance with these regulations and standards;
- if we desire to make our drug products and/or devices available outside the U.S. for commercial or clinical purposes, our CMOs would become subject to, and may not be able to comply with, corresponding manufacturing and quality system regulations of the various foreign regulators having jurisdiction over our activities abroad. Such failures could restrict our ability to execute our business strategies; and
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not have rights to, or may have to share, the intellectual property rights to any such innovation. We may be required to pay fees or other costs for access to such improvements.

Each of the foregoing risks and others could delay our commercial manufacturing plans and our development programs, the approval, if any, of our product candidates by the FDA or result in higher costs or deprive us of potential product revenues.

We may enter into strategic alliances, distributor, co-marketing or other collaboration arrangements, which could expose us to risks associated with the transfer of control to third parties and may require that we transfer rights to our products to our partners and collaborators.

To support our AEROSURF development program and potentially the commercial introduction of AEROSURF in markets outside the U.S., we seek a significant strategic alliance that potentially could provide development, regulatory and commercial market expertise as well as financial resources for our AEROSURF development program, and, if approved, support for the commercial introduction of AEROSURF in the EU and other selected markets outside the U.S. While 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 that we will ultimately secure such an alliance, if at all, on acceptable terms.

To support the commercial introduction of SURFAXIN and our other KL4 surfactant products, including potentially SURFAXIN LS, in markets outside the U.S., we may enter into distributor arrangements or 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 determine to distribute AFECTAIR devices in markets outside the U.S., we may enter into distributor arrangements in various countries.

If we succeed in entering into one or more strategic alliances, or distributor, co-marketing or other collaboration arrangements, 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 engage. Under these arrangements, our partners may control key decisions relating to the development and, if approved, 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 agreements or if our strategic partners or collaborators 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 collaborators or, in the alternative and after a potentially unacceptable delay, develop our own internal sales and marketing capabilities to commercialize our products in markets outside the U.S. If we fail to successfully develop these relationships, or if we or our partners or collaborators 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 KL_4 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 KL_4 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 arrangements.

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 own 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.

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.

We may have difficulty managing our growth.

We have experienced significant growth in the scope of our operations as we have prepared 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 potentially 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 and effectively manage 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 effectively and 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 in markets both inside and potentially 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 cash resources and 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, including increasing our investment in internal capabilities. Similarly, if a potential partner or collaborator 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, 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, if at all, 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.

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 advanced the Deerfield Loan to us, consisting of $30 million principal amount. 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 Deerfield Loan. In the event that we were to fail in the future to make any required payment under the Deerfield Loan 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.

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, AFECTAIR and, if approved, AEROSURF, we are and will be required to comply with not only the requirements of the FDA and potentially 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 continually evaluating 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."

We are currently conducting a phase 2a clinical program for AEROSURF. There can be no assurance that issues requiring protracted and time-consuming preclinical studies will not arise or that our clinical program trials will be concluded successfully. There can be no assurance that we will be successful in gaining regulatory approval for AEROSURF or, if we determine that there is a feasible development plan that can be accomplished with an acceptable investment and within an acceptable time, SURFAXIN LS, if at all.

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 relevant regulatory authorities with the goal of designing 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 program for AEROSURF is in phase 2 clinical trials. We currently are planning to seek regulatory advice from the FDA to determine if we could gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely seek to implement such a development plan. Foreign regulators have not yet approved SURFAXIN or any of our KL4 surfactant 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, including for AEROSURF, involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes.

Development risk factors include, but are not limited to, whether we, or our third-party collaborators, contract research organizations (CROs), drug substances and materials suppliers and CMOs, will be able to:

- competently execute and 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 the active pharmaceutical ingredients, 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.

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 KL_4 surfactant products, and our business strategy.

We have recently completed development of a clinic-ready CAG device that is suitable for use in our ongoing phase 2 clinical trial and currently are working to further develop our CAG device for use in our planned phase 3 clinical trial and potentially for commercial use. Our development activities are subject to certain risks and uncertainties, including, without limitation:

- We may not successfully develop a CAG device that is acceptable for use in a phase 3 program and commercial environment, if at all, on a timely basis and such inability may delay or prevent initiation of our phase 3 clinical trial.
- We will require access to sophisticated engineering capabilities. We have medical device engineering staff and we are currently working with Battelle Memorial Institute (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 commercial use and 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 KL_4 surfactant products.
- We will also require additional capital to advance our development activities and plan to seek a potential strategic partner or third-party collaborator to provide financial support and potentially 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 KL_4 surfactant products.

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

Manufacturing problems potentially could cause us to experience shortages of SURFAXIN and AFECTAIR product inventories, or delay our preclinical or clinical programs, which could have a material adverse effect on our business.

The manufacture of pharmaceutical and medical device products requires significant expertise and compliance with strictly enforced federal, state and foreign regulations. We, our 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 current good manufacturing practices (cGMP) and Quality System Requirements (QSR), or those of foreign regulators or notified bodies, 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 maintain a qualified and facility;
- 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, in-process monitoring and controls, and 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 currently manufacture our SURFAXIN drug product at our manufacturing operations in Totowa, NJ (Totowa Facility). We manufacture our lyophilized KL4 surfactant, WARMING CRADLE dry-block heaters and AFECTAIR aerosol-conducting airway connectors with CMOs. In the past, we have experienced manufacturing or quality control problems and such problems may again occur, at our Totowa Facility or at the facilities of a CMO or a manufacturer 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 CMOs or suppliers to comply with cGMP or, for devices, QSR, 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 manufacture a supply of commercial SURFAXIN drug product, or our products under development, and potentially adversely affect our research activities and our business and financial condition. Any interruption of our manufacturing at the Totowa Facility could result in a shortage of our commercial drug supply of SURFAXIN. We currently do not have a back-up facility for the Totowa Facility or our CMOs, or back-up suppliers of APIs or excipients and other materials.

A number of factors could cause interruptions, including:

- equipment malfunctions or failures;
- technology malfunctions;
- interruption of material availability;
- work stoppages or slowdowns;
- damage to or destruction of the facility;
- regional power shortages; and
- product tampering.

In connection with our drug product 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 or a CMO's 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 market and sell 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 commercial drug product 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 facility or at our Totowa Facility 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 Totowa Facility. We maintain our analytical testing and device development laboratories in Warrington, Pennsylvania. Our Totowa Facility 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 Totowa Facility, we depend upon third-party manufacturers to manufacture WARMING CRADLE dry-block heaters, our lyophilized KL_4 surfactant, our AFECTAIR device 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 any such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.

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 KL_4 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 combination drug/device product that produces our aerosolized KL_4 surfactant, we plan to rely on CMOs to manufacture and assemble the CAG and all subcomponents of the CAG to support our preclinical experiments, planned clinical trials and, if approved, commercial device. The CAG device includes an aerosol control unit and a disposable ADP. The ADP includes the critical drug product-contact components that are either cleaned or manufactured in an environmentally-controlled, clean area. The control unit and ADPs are assembled and packaged in a clean area. Each of the ADP devices is tested for conformance to designated product specifications during assembly and each of the assembled control units must be quality control tested prior to release and monitored for conformance to designated product specifications.

We have worked with Battelle to develop an optimized CAG device to support our phase 2 clinical program. As with many device development initiatives, there is a risk that, even if we are able to finalize specifications for a CAG system that is suitable for use in a phase 3 trial and, if approved, commercial applications, we may have difficulty identifying manufacturers that are able to consistently manufacture and assemble 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 KL_4 surfactant, including AEROSURF.

We are exposed to similar risks in the manufacture of our AFECTAIR device. We are reliant on our CMO for, among other things, the manufacture, packaging and labeling of our AFECTAIR device. 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, our CMO is obligated to cooperate with us, including for those defects that result in product recalls or other similar events. If our CMO is unable to manufacture to our specifications, or if our CMO 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.

Issues with product quality could have an adverse effect on 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.

Medical 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 may 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 our products will be limited and subject to continuing review.

We have successfully registered our AFECTAIR device in the U.S. This registration does not include substantial claims with respect to potential use or efficacy. If we register this product in the European Union (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 KL_4 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.

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.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our 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 ATM Program, the issuance of shares upon exercise of outstanding warrants, including those issued to Deerfield in connection with the Deerfield Loan, 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.

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 these 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.

We 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. To provide flexibility and support any future transactions we may undertake, in 2014, we plan to replace this registration statement, which expires in June 2014, with a new universal shelf registration statement.

As of March 7, 2014, we had 84,696,919 shares of common stock issued and outstanding. In addition, as of December 31, 2013, approximately (i) 14.8 million shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, (ii) 5.4 million shares of our common stock were reserved for issuance pursuant to our equity incentive plans, and (iii) 166,243 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.

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 our 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, 2013, the price of our common stock ranged between $1.50 and $3.05. 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, 2013, the average daily trading volume in our common stock was approximately 549,650 shares, and the average number of transactions per day was approximately 1,502. 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, referred to as the federal "Open Payments" law (previously referred to as the "Sunshine Law"), 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. Implementation of the sunshine provisions has been subject to delay by the U.S. Centers for Medicare and Medicaid Services (CMS). Under the current regime, applicable manufacturers were to 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 in a two-phased approach by March 31, and May 31, 2014, respectively. CMS will publish the data on a public website later in the year. 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. If we do not file our financial statements 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 or our strategic partners or collaborators are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

As we prepared for the commercial introduction of SURFAXIN, we implemented a plan to hire additional qualified personnel to support (i) the commercial introduction of SURFAXIN and AFECTAIR, and (ii) the advancement of our AEROSURF and, potentially, SURFAXIN LS development programs. In particular, we established our field-based sales and marketing and medical affairs organizations, and continue to invest in our regulatory affairs, quality control and assurance and administrative capabilities. 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.

In March 2013, we 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 March 31, 2015, subject to automatic renewal for additional one-year periods, unless a party provides notice of non-renewal at least 90 days in advance. In addition, we recently entered into new agreements with five other officers that also expire on March 31, 2015. 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 proceed with the commercial introduction of our approved products and undertake our AEROSURF phase 2 clinical program, 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.

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;
- 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. 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 and device products and 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 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 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.

Our technology platform is based solely on our proprietary KL4 surfactant technology, our novel CAG technology, and our novel aerosol-conducting airway connector.

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 combination drug-device 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 related 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 agreements containing obligations regarding intellectual property, confidentiality and noncompetition provisions 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 and proprietary information and trade secrets to third parties, as well as agreements that provide for disclosure and assignment to us of all rights to the ideas, developments, improvements, discoveries and inventions of our employees, consultants, advisors and research collaborators 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.

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.

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.

The failure to prevail in litigation or the costs of litigation, including securities class actions, product liability claims 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 the design, manufacture and marketing of 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. Product liability claims alleging inadequate disclosure and warnings in our package inserts and medical device disclosures also may arise.

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 medical device and combination drug/device products 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 Amended and Restated Certificate of Incorporation, 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, 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 Amended and Restated Certificate of Incorporation 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. This agreement expired in February 2014. The rights issued under the Shareholder Rights Agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

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 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 Warrington location our analytical and technical support laboratory that is involved predominantly in release testing of all active pharmaceutical ingredients (APIs), release and stability testing of SURFAXIN® drug product, and supporting our research and development work for our lyophilized and aerosolized KL_4 surfactant dosage forms as well as our efforts to identify and protect our intellectual property. We also maintain a medical device development laboratory at this location that is used by our development engineering team to conduct preclinical development activities for AEROSURF® and our aerosol delivery technologies. Having our own device development laboratory allows us to conduct a range of research activities while at the same time controlling the related expense and conserving our financial resources. Our laboratory space 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 (Totowa Facility), at an annual rent of $150,000. In early 2014, we extended the term of this lease such that it will now expire on June 30, 2015. This space is specifically designed for the manufacture and filling of sterile liquid pharmaceuticals in compliance with cGMP and is currently dedicated to the manufacture of SURFAXIN drug product. We currently are in discussions with the landlord potentially to enable longer-term utilization of that facility for the manufacture of SURFAXIN and potentially lyophilized KL_4 surfactant. See, “Item 1 – Business – Business Operations – Manufacturing and Distribution – KL_4 Surfactant.”

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.

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 7, 2014, we had 124 stockholders of record of shares of our common stock. We also have been advised that, as of December 13, 2013, there are approximately 20,774 beneficial owners of our common stock whose positions are held in street name. As of March 7, 2014, there were 84,696,919 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.

	2013		2012	
	High	Low	High	Low
Period:				
First Quarter	$ 2.91	$ 2.11	$ 5.39	$ 1.67
Second Quarter	$ 2.40	$ 1.50	$ 3.15	$ 2.12
Third Quarter	$ 2.23	$ 1.54	$ 3.51	$ 2.30
Fourth Quarter	$ 3.05	$ 1.90	$ 3.29	$ 1.71

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 quarter ended December 31, 2013, we issued 8,750 unregistered shares of common stock to a consultant as compensation for management consulting services rendered during the period from August 31, 2013 through November 30, 2013. The shares were issued in reliance upon the exemption from securities registration provided by Section 4(a)(2) of the Act.

ITEM 6. SELECTED FINANCIAL DATA.

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

	For the year ended December 31,				
	2013	**2012**	**2011**	**2010**	**2009**
Revenues from grants	$ 388	$ 195	$ 582	$ –	$ –
Operating expenses:					
Cost of product sales	517				
Research and development	27,661	21,570	17,230	17,136	19,077
Selling, general and administrative	16,718	16,444	7,864	8,392	10,120
Total expenses[1]	44,896	38,014	25,094	25,528	29,197
Operating loss	(44,508)	(37,819)	(24,512)	(25,528)	(29,197)
Change in fair value of common stock warrant liability	761	555	3,560	6,422	369
Other (expense) / income	(1468)	(51)	(13)	(69)	(1,043)
Net loss	$ (45,215)	$ (37,315)	$ (20,965)	$ (19,175)	$ (29,871)
Net loss per common share – basic and diluted	$ (0.82)	$ (0.95)	$ (0.93)	$ (1.65)	$ (3.89)
Weighted average number of common shares outstanding – basic and diluted	55,258	39,396	22,660	11,602	7,680

(1) Included in the net loss for 2013, 2012, 2011, 2010, and 2009 were non-cash charges for stock-based compensation and depreciation of $2.9 million, $3.3 million, $2.2 million, $2.8 million, and $4.3 million, respectively.

Consolidated Balance Sheet Data:
(in thousands)

	December 31,				
	2013	**2012**	**2011**	**2010**	**2009**
Cash and investments	$ 86,283	$ 26,892	$ 10,189	$ 10,211	$ 15,741
Working capital	75,384	16,107	(516)	2,920	176
Total assets	89,317	29,943	13,324	14,537	21,403
Long-term debt, net of discount of $11,646	18,354	–	–	–	–
Other long-term obligations, less current portion	607	591	913	935	1,118
Total stockholders' equity	$ 58,501	$ 17,653	$ 1,264	$ 6,026	$ 1,296

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, 2013, 2012 and 2011.

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

OVERVIEW

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on creating life-saving products for critical-care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug technology produces a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL_4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of our aerosolized KL_4 surfactant. We believe that our proprietary technologies may 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.

We are initially focused on improving 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. RDS is the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU) and can result in long-term respiratory problems, developmental delay and death.

Our first KL_4 surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL_4 surfactant in liquid form and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States (U.S.). Since November 2013, SURFAXIN has been commercially available in the U.S.

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may each result in serious respiratory conditions and other complications. To avoid such complications, many neonatologists treat infants with less severe RDS by less invasive means, typically nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of premature infants on nCPAP will not respond well (an outcome referred to as nCPAP failure) and thereafter may require delayed surfactant therapy. Since neonatologists currently cannot predict which infants will experience nCPAP failure, neonatologists are faced with difficult choices in treating infants with less severe RDS. This is because the medical outcomes for those infants who experience nCPAP failure and receive delayed surfactant therapy may be less favorable than the outcomes for infants who receive surfactant therapy in the first hours of life.

AEROSURF® is an investigational combination drug/device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). With AEROSURF, neonatologists potentially will be able to administer aerosolized KL_4 surfactant to premature infants supported with nCPAP, without having to use invasive intubation and mechanical ventilation. By enabling delivery of our KL_4 surfactant using less invasive procedures, we believe that AEROSURF will address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

We are also developing a lyophilized (freeze-dried) dosage form of our KL_4 surfactant that is stored as a powder and reconstituted 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 initially developing this dosage form for use in our AEROSURF development program. We are also planning to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the U.S. and potentially in other markets.

To support the commercial introduction of SURFAXIN in the U.S. and our other KL_4 surfactant pipeline products, if approved, we have established our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL_4 surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL_4 surfactant.

In addition we recognize that our commercial and medical affairs team could potentially support introductions of other synergistic pipeline products, including products owned or developed by third parties for the NICU/PICU. To that end, we would consider potential transactions focused on securing commercial rights to such synergistic products, including in the form of product acquisitions, in-licensing agreements or distribution, marketing or co-marketing arrangements.

In the future, we expect that we may be able to leverage the information, data and know-how that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a potential product pipeline to address serious critical care respiratory conditions in larger children and adults in pediatric and adult intensive care units (PICUS and ICUs), including acute lung injury (ALI), chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). At the present time, however, we are focusing our resources primarily on the commercial introduction of SURFAXIN and development of AEROSURF through phase 2 clinical trials. Once we have achieved these objectives, we believe we would be in a better position to assess the potential of other development programs to address the critical care needs of patients in the PICU and ICU.

We also have developed a disposable aerosol-conducting airway connector for infants that is intended to simplify the delivery of aerosolized medications (including our aerosolized KL_4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support. This device introduces aerosolized medications directly at the patient interface and minimizes the number of connections in the ventilator circuit. We have registered this device as a Class I, exempt medical device in the U.S. under the name AFECTAIR and it is currently commercially available in the U.S.

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

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*, "Item 8 – Note 3 – Accounting Policies and Recent Accounting Pronouncements" in the Notes to Consolidated Financial Statements for the year ended December 31, 2013, in Part IV to this Annual Report on Form 10-K.

Product Sales

Revenues from product sales are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured.

Our products are distributed in the U.S. using a specialty distributor. Under this model, the specialty distributor purchases and takes physical delivery and title of product, and then sells to hospitals. We began the commercial introduction of SURFAXIN in the fourth quarter of 2013 and, for that reason, we currently cannot make a reasonable estimate of future product returns when product is delivered to the specialty distributor. Therefore, we currently do not recognize revenue upon product shipment to the specialty distributor, even though the distributor is invoiced upon product shipment. Instead, we recognize revenue once product has been sold through to the hospital and all revenue recognition criteria have been met. Once product has been delivered to the hospital, the risk of material returns is significantly mitigated. As of December 31, 2013, we have deferred revenue recognition on all product sales since the inception of the commercial launch of SURFAXIN in November 2013. We will recognize those revenues at the point in time when all revenue recognition criteria have been met.

We will begin to recognize revenue at the time of shipment of product to our specialty distributor when we can reasonably estimate expected distributor sales deductions and returns. In developing estimates for sales returns we consider the shelf life of the product, expected demand based on market data and return rates of other surfactant products.

Product sales are recorded net of accruals for estimated chargebacks, discounts, specialty distributor deductions and returns.

- *Chargebacks.* Chargebacks are discounts that occur when contracted customers purchase directly from our specialty distributor. Contracted customers, which currently consist primarily of member hospitals of Group Purchasing Organizations, generally purchase the product at a discounted price. Our specialty distributor, in turn, charges back the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the customer. The allowance for specialty distributor chargebacks is based on known sales to contracted customers.

- *Sales discounts*: Sales discounts are offered to certain contracted customers based upon a customer's historical volume of surfactant product purchases. Customers must enter into a Letter of Participation (LOP) with us to receive sales discounts. Sales discounts are calculated on a quarterly basis based upon the customer's quarterly purchases of SURFAXIN, as provided in the LOP. The allowance for sales discounts is based on known sales to contracted customers.

- *Specialty distributor deductions.* Our specialty distributor is offered various forms of consideration including allowances, service fees and prompt payment discounts. Specialty distributor allowances and service fees are provided in our contractual agreement and are generally a percentage of the purchase price paid by the specialty distributor. The specialty distributor is offered a prompt pay discount for payment within a specified period.

- *Returns.* Sales of our products are not subject to a general right of return; however, we will accept product that is damaged or defective when shipped or for expired product up to 6 months subsequent to its expiry date. Product that has been administered to patients is no longer subject to any right of return.

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.

Inventory

Inventories, which are recorded at the lower of cost or market, include materials, labor, and other direct and indirect costs and are valued at cost using the first-in, first-out method. We capitalize inventories produced in preparation for commercial launch when it becomes probable that the related product candidate will receive regulatory approval and that the related costs will be recoverable through commercial sale of the product. Costs incurred prior to FDA approval of SURFAXIN drug product and registration of AFECTAIR device have been recorded in our statement of operations as research and development expense. Inventories are evaluated for impairment based on consideration of such factors as the net realizable value, lower of cost or market, obsolescence, and product expiry. Inventories do not have carrying values that exceed either cost or net realizable value.

We establish expiry risk by evaluating current and future product demand relative to product shelf life. We build demand forecasts based on consideration of such factors as overall market potential, market share, market acceptance and hospital ordering practices.

Deferred revenue

Deferred revenue reflects amounts related to sales of SURFAXIN to our specialty distributor, which are then deferred and recognized as revenue once product has been sold through to the hospital and all revenue recognition criteria have been met. *See*, "– Product Sales."

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 current liabilities, which are 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*, "Item 8 –Note 8 – Common Stock Warrant Liability," for a detailed description of our accounting for derivative warrant liabilities.

RESULTS OF OPERATIONS

Net Loss and Operating Loss

The net loss for the years ended December 31, 2013, 2012, and 2011 was $45.2 million (or $0.82 per share), $37.3 million (or $0.95 per share), and $21.0 million (or $0.93 per share), respectively. Included in net loss is the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.8 million, $0.6 million, and $3.6 million for 2013, 2012, and 2011, respectively.

The operating loss for the years ended December 31, 2013, 2012, and 2011 was $44.5 million, $37.8 million, and $24.5 million, respectively. The operating loss includes $2.9 million, $3.3 million, and $2.2 million for non-cash items related to depreciation and stock-based compensation for 2013, 2012, and 2011, respectively. Excluding non-cash items related to depreciation and stock-based compensation, the operating loss was $41.6 million, $34.5 million, and $22.4 million for 2013, 2012, and 2011, respectively.

The increase in operating loss from 2012 to 2013 was primarily due to (i) a $3.2 million increase in investment in AEROSURF development activities, primarily to develop and manufacture a clinic-ready CAG for use in our AEROSURF phase 2 clinical program and in the technology transfer and further development of our lyophilized KL_4 surfactant manufacturing process at DSM Pharmaceuticals, Inc. (DSM), (ii) a $3.2 million increase in investment in our specialty commercial and medical affairs organization that is focused on neonatal/pediatric respiratory critical care in NICUs/PICUs across the U.S.; and (iii) a $1.7 million increase in purchases of raw materials to manufacture drug product for SURFAXIN and our AEROSURF development program, which were partially offset by a $2.0 million one-time charge in the fourth quarter of 2012 associated with certain contractual severance obligations and stock-based compensation charges related to the resignation of our former Chief Executive Officer.

The increase in operating loss from 2011 to 2012 was primarily due to (i) a $6.5 million investment to establish our commercial and medical affairs organization; (ii) a $1.6 million investment to advance the development of our CAG for potential use in our AEROSURF phase 2 clinical program; and (iii) a $2.0 million one-time charge in the fourth quarter of 2012 associated with certain contractual severance obligations and stock-based compensation charges related to the resignation of our former Chief Executive Officer.

Product Sales

As of December 31, 2013, we have deferred revenue recognition on all product sales since the initiation of the commercial launch of SURFAXIN in November 2013. In accordance with our revenue recognition policy, we will recognize revenue once product has been sold through to the hospital and all revenue recognition criteria have been met.

Grant Revenue

We recognized grant revenue of $0.4 million, $0.2 million and $0.6 million for the years ended December 31, 2013, 2012 and 2011, respectively. The grant revenue in 2012 and 2013 represents 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 KL_4 surfactant to mitigate the effects of acute radiation exposure to the lung, including acute pneumonitis and delayed lung injury. The total amount of the Phase I award was $0.6 million and we have received and expended the full amount as of December 31, 2013.

In the future, we expect that we may be able to leverage the information, data and know-how that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a potential product pipeline to address serious critical care respiratory conditions in larger children and adults in pediatric and adult intensive care units (PICUS and ICUs), including acute lung injury (ALI), chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). While we are currently focused on RDS, we are currently, and will consider in the future, collaborating with leading research institutions to conduct preclinical studies, including those that may be funded through various U.S. government-sponsored, biodefense-related initiatives, including NIAID.

The grant revenue in 2011 represents funds received and expended under a Fast Track SBIR from NIH to support the development of aerosolized KL4 surfactant for RDS.

Cost of Product Sales

(in thousands)	Years Ended December 31,		
	2013	**2012**	**2011**
Cost of product sales	$ 517	$ –	$ –

Cost of product sales for 2013 primarily reflects inventory reserves for costs of SURFAXIN finished goods inventory that is not expected to be recoverable through commercial sale of the product during the initial launch period due to product expiration.

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 the foundation for the development of our KL4 surfactant and drug delivery technologies, they are expected to benefit more than a single project. For that reason, we cannot reasonably estimate the costs of 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) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs. We also track research and development and report 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 for the years ended December 31, 2013, 2012 and 2011 are as follows:

	Years Ended December 31,		
	2013	**2012**	**2011[1]**
		(in thousands)	
Product development and manufacturing	$ 20,471	$ 15,788	$ 12,359
Medical and regulatory operations	5,966	4,818	3,452
Direct preclinical and clinical programs	1,224	964	1,419
Total Research and Development Expenses	$ 27,661	$ 21,570	$ 17,230

(1) Certain prior year expenses have been reclassified to conform to 2013 presentation.

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $1.4 million, $1.3 million, and $1.4 million for 2013, 2012, and 2011, respectively.

For a description of the clinical programs included in research and development expenses, *See*, “Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine.”

Product Development and Manufacturing

Product development and manufacturing includes (i) the cost of our manufacturing operations, both in-house and with our CMOs, validation activities and quality assurance and analytical chemistry capabilities to support production of drug supply for our KL4 surfactant products, in conformance with current good manufacturing practices (cGMP), and medical devices, including AFECTAIR, the WARMING CRADLE®, and the CAG, in accordance with Quality System Regulations (QSR), (ii) design and development activities related to our CAG device for use in our AEROSURF phase 2 clinical program; (iii) design and development activities related to our AFECTAIR aerosol-conducting airway connector; 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 $4.7 million from 2012 to 2013 primarily due to increases in (i) investments in design and development activities related to our CAG for use in our AEROSURF phase 2 clinical trials, including work with third-party device experts and work that we began in June 2012 with Battelle Memorial Institute (Battelle), which assisted in a multi-phase project to design, test, and manufacture clinic-ready CAG devices for the AEROSURF phase 2a clinical trial; (ii) costs associated with the technical transfer and further development of our KL4 surfactant manufacturing processes at DSM; and (iii) purchases of active pharmaceutical ingredients (APIs) used in the manufacture of SURFAXIN drug product and our lyophilized KL4 surfactant, for commercial use and preclinical development activities, including to complete the technical transfer and further develop our KL4 surfactant manufacturing process at DSM, and activities to develop a clinic-ready CAG and prepare for our AEROSURF phase 2 clinical program.

Product development and manufacturing expenses increased $3.4 million from 2011 to 2012 primarily due to (i) an increase in investments in manufacturing and quality activities as we prepared 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 assisted us in a multi-phase development program focused on design, testing, and manufacturing of clinic-ready CAG devices for our AEROSURF phase 2 clinical trials, and (iii) an increase in costs associated with employee incentive compensation plans.

Product development and manufacturing expenses include non-cash charges associated with stock-based compensation and depreciation of $0.9 million, $1.0 million, and $1.2 million, for the years ended December 31, 2013, 2013 and 2011, respectively.

Consistent with our long-term strategy, in 2014 and beyond, we plan to invest in and assure long-term manufacturing development capabilities. We currently are in discussions with the landlord of our Totowa, NJ, manufacturing operations (Totowa Facility) potentially to enable longer-term utilization of that facility for the manufacture of SURFAXIN and potentially lyophilized KL4 surfactant. The lease for that facility currently expires on June 30, 2015. To assure continuity of supply, we are working with DSM to provide for the manufacture of both SURFAXIN and our lyophilized KL4 surfactant for use initially in our AEROSURF development program. We are also working to identify a second contract manufacturing organization (CMO) to potentially supply SURFAXIN commercial drug product and lyophilized KL4 surfactant. We also will continue to invest in the development of our manufacturing process for our lyophilized KL4 surfactant with DSM, and plan to manufacture drug product for preclinical and clinical activities, including for our AEROSURF phase 2 clinical program and potentially our other KL4 surfactant development programs. By manufacturing our drug products at our Totowa Facility and with CMOs, we believe that we will be able to bring our own manufacturing expertise to our CMOs, maintain an appropriate balance between capital investments and variable manufacturing expense, and remain flexible while potentially reducing the risk profile of meeting the long-term requirements for development and commercial supply of our drug products. For a discussion of our long-term business strategy to provide for the long-term continuity of supply and continued integrity and reliability of our manufacturing and quality capabilities, *see*, "Item 1 – Business – Business Operations – Manufacturing and Distribution."

Medical and Regulatory Operations

Medical and regulatory operations includes (i) medical, scientific, clinical, regulatory, data management and biostatistics activities in support of our research and development programs; and (ii) medical affairs activities to provide scientific and medical education support related primarily to SURFAXIN, 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 $1.1 million from 2012 to 2013 primarily due to a full year investment in 2013 in our medical affairs organization to support the commercial introduction of SURFAXIN and the AFECTAIR device.

Medical and regulatory operations expenses increased $1.4 million from 2011 to 2012 primarily due to (i) investment to establish 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 $0.4 million, $0.3 million, and $0.2 million for the years ended December 31, 2013, 2012, and 2011, respectively.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) development activities, including for the AEROSURF clinical program, toxicology studies and other preclinical studies to obtain data to support our investigational new drug (IND) application and, potentially, our New Drug Application (NDA) filings for AEROSURF, and potentially our other KL4 surfactant product candidates; and (ii) activities, if any, associated with conducting clinical trials, including patient enrollment costs, external site costs, clinical device and drug supply, and related external costs, such as research consultant fees and expenses.

Direct preclinical and clinical programs expenses increased $0.3 million from 2012 to 2013 primarily due to investments in activities to prepare for our AEROSURF phase 2 clinical program. Such activities included manufacture of a sufficient number of clinic-ready CAG devices to support our phase 2a clinical trial, implementation of clinical data management systems and selection of clinical site locations. Costs in 2012 included a $0.5 million charge related to a milestone payment that became payable to Johnson and Johnson (J&J) upon FDA approval of SURFAXIN in March 2012.

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 a Complete Response Letter received from the FDA in 2009 (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.

We anticipate that direct clinical program costs associated with conducting the AEROSURF phase 2 clinical program will be approximately $8 -10 million for 2014 through the anticipated completion of the AEROSURF phase 2 program in 2015.

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,		
	2013	**2012**	**2011**
Salaries & Benefits	$ 11,213	$ 9,986	$ 8,231
Contracted Services	8,248	6,332	3,317
Raw Materials & Supplies	3,633	1,652	1,871
Rents & Utilities	1,186	1,366	1,531
Depreciation	659	841	1,141
Contract Manufacturing	1,441	15	143
Travel	447	316	188
Stock-Based Compensation	784	488	289
All Other	50	574	519
Total	$ 27,661	$ 21,570	$ 17,230

The increase in salaries and benefits from 2012 to 2013 and from 2011 to 2012 is primarily due to the establishment of our medical affairs organization primarily to support the commercial introduction of SURFAXIN and AFECTAIR, increased benefit costs and employee incentive payments.

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 2012 to 2013 and 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 our AEROSURF phase 2a clinical trial, and investments in our manufacturing and quality activities as we prepare for the commercial introduction of SURFAXIN.

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 connector. The increase in raw materials and supplies from 2012 to 2013 is primarily due to a $1.6 million increase in purchases of raw materials to manufacture drug product for SURFAXIN commercial supply and to support manufacturing development activities. 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**.**

Rents and utilities are costs related to our leased manufacturing, laboratory, and corporate facilities. The decrease from 2012 to 2013 is primarily due to (i) decreased rent for our corporate and laboratory facility in Warrington, PA in connection with an amended lease agreement executed in January 2013, and (ii) decreased utility costs at our manufacturing facility. The decrease from 2011 to 2012 is primarily due to decreased utility costs at our manufacturing facility due to decreased manufacturing activity for SURFAXIN.

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 the Totowa Facility. The decrease from 2012 to 2013 and from 2011 to 2012 is primarily due to capitalized assets becoming fully depreciated.

Contract manufacturing represents costs related to the technology transfer of our liquid and lyophilized KL4 surfactant manufacturing processes to a CMO. The increase in contract manufacturing from 2012 to 2013 was due to an increase in activities to transfer our KL4 manufacturing processes for our lyophilized KL4 surfactant as well as SURFAXIN. The decrease in contract manufacturing costs from 2011 to 2012 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.

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 relate to investments in our research and development projects, for which we incurred $66.5 million in expenses for the three-year period ended December 31, 2013. 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.

In addition to the risks and uncertainties affecting our research and development projects discussed in this MD&A, including those 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 to commercialize our products;" "– Our research and development activities involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes;" "– Our clinical trials may be delayed, or fail, which will harm our business," "– Manufacturing problems potentially could cause us to delay preclinical or clinical programs, or, if our products are approved, product launch, or cause us to experience shortages of products inventories, which could have a material adverse effect on our business;" as well as elsewhere in this Annual Report on Form 10-K.

Our lead development projects initially are focused on the management of RDS in premature infants, including (i) SURFAXIN liquid instillate, which has been approved by the FDA for the prevention of RDS at high risk for RDS, (ii) our lyophilized KL4 surfactant, which we are developing initially for use in our AEROSURF development program and, if we determine that we could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a development plan that would be both capital efficient and capable of implementation within a reasonable time, we would likely implement such a plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS; and (iii) our aerosol delivery technology, including preparation of a clinic-ready CAG device to support our AEROSURF phase 2 clinical program.

With respect to activities in support of our AEROSURF development program, from 2012 through December 2013, we invested approximately $7 million to develop the CAG and complete the technology transfer and further develop our lyophilized KL4 surfactant manufacturing process at DSM, in preparation for initiation of the AEROSURF phase 2 program. In addition, as noted above, we anticipate that direct clinical program costs associated with conducting the AEROSURF phase 2 clinical program will be approximately $8 - 10 million for 2014 through the anticipated completion of the AEROSURF phase 2 program in 2015.

The status of our lead projects and our other pipeline candidates, including the potential timing and milestones for each, is discussed in "Item 1 – Business – Surfactant Replacement Therapy for Respiratory Medicine." *See also*, "Item 1 – Business – Business Strategy," and "Item 1A – Risk Factors – We may not successfully develop and market our products, and even if we do, we may not become profitable," "– We will require significant additional capital to continue our planned research and development activities and continue to operate as a going concern. Moreover, such additional financing could result in equity dilution."

In the future, we expect that we may be able to leverage the information, data and know-how that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a potential product pipeline to address serious critical care respiratory conditions in larger children and adults in pediatric and adult intensive care units (PICUS and ICUs), including Acute Lung Injury (ALI), Chronic Obstructive Pulmonary Disorder (COPD) and Cystic Fibrosis (CF). At the present time, we are focusing our resources primarily on the commercial introduction of SURFAXIN and development of AEROSURF through phase 2 clinical trials. Once we have achieved these objectives, we believe we would be in a better position to assess the potential of other development programs to address the critical care needs of patients in the PICU and ICU. *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,		
	2013	**2012**	**2011**
Selling, General and Administrative Expenses	$ 16,718	$ 16,444	$ 7,864

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

Selling, general and administrative expenses increased $0.3 million from 2012 to 2013 primarily due to an increase in investments in our marketing and field-based sales force to execute the commercial introduction of SURFAXIN and the AFECTAIR device for infants. Selling, general and administrative expenses in 2012 include a $2.0 million 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.

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 to support the anticipated commercial introduction of SURFAXIN; (ii) marketing-related activities primarily for SURFAXIN; (iii) a $2.0 million 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) increased costs associated with employee incentive compensation plans.

Selling, general and administrative expenses include non-cash charges associated with stock-based compensation and depreciation of $1.5 million, $2.0 million, and $0.7 million, for the years ended December 31, 2013, 2012 and 2011, respectively. The 2012 amount includes $0.8 million of stock-based compensation charges related to the resignation of our former Chief Executive Officer.

In addition to developing our commercial marketing and sales organization, we have made additional investments to enhance certain of our general and administrative resources, including in legal, finance and accounting, and information technologies, to support the commercial introduction of our products. 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,		
	2013	**2012**	**2011**
Change in fair value of common stock warrant liability	$ 761	$ 555	$ 3,560

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"*, 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 form of warrant agreement for 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) 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. Although by their express terms, these warrants are not subject to potential cash settlement, 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) Other Income / (Expense):	Years Ended December 31, 2013	2012	2011
Interest income	$ 3	$ 3	$ 13
Interest expense	(1,471)	(13)	(20)
Other income / (expense)	–	(41)	(6)
Other income / (expense), net	$ (1,468)	$ (51)	$ (13)

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 U.S. treasury-based money market funds.

Interest expense in 2013 consists of interest expense associated with the Deerfield Loan (*see*, "– Liquidity and Capital Resources – Deerfield Loan") and interest expense incurred under our equipment financing facilities. Interest expense for 2012 and 2011 consists of interest expense incurred under our equipment loan.

The following amounts comprise the Deerfield Loan interest expense for the periods presented:

(in thousands)	Years Ended December 31, 2013	2012	2011
Cash interest expense	$ 911	$ –	$ –
Non-cash amortization of debt discounts	534	–	–
Amortization of debt costs	18	–	–
Total Deerfield Loan interest expenses	$ 1,463	$ –	$ –

Cash interest expense represents interest at an annual rate of 8.75% calculated on the outstanding principal amount for the period, paid in cash on a quarterly basis. Non-cash amortization of debt discount represents the amortization of transaction fees and the fair value of the Deerfield Warrants. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan.

LIQUIDITY AND CAPITAL RESOURCES

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, and, more recently, commercialization and medical affairs 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, debt facilities, strategic alliances, the use of committed equity financing facilities (CEFFs) and at-the-market equity programs, and capital equipment financings.

As of December 31, 2013, we had cash and cash equivalents of $86.3 million and $30 million ($18.4 million net of discount) of long-term debt under our Deerfield Loan with affiliates of Deerfield Management Company, L.P. (Deerfield). *See*, "– Deerfield Loan." During 2013, we raised aggregate gross proceeds of $75.8 million through public offerings of our common stock, including under our ATM Program (*see*, "– At-the-Market Program (ATM Program)"). In February 2013, we entered into the Deerfield Loan and, upon execution of the agreement, Deerfield advanced to us $10 million ($9.85 million net of transaction fee). In May 2013, we completed a public offering of 10.847 million shares of common stock, including 1.347 million shares under an option granted to and exercised by the underwriters, at an offering price of $1.50 per share, resulting in gross proceeds of $16.3 million ($15.1 million net of commissions, discounts and expenses). In October 2013, we completed an offering under the ATM Program and issued 713,920 shares of our common stock resulting in net proceeds to us of approximately $1.8 million (net of commissions). In November 2013, we completed a public offering of 28.75 million shares of common stock, including 3.75 million shares under an option granted to and exercised by the underwriters for over-allotments, at an offering price of $2.00 per share resulting in gross proceeds of $57.5 million ($53.9 million net of commissions, discounts and expenses). In December 2013, we received an additional $20 million under the Deerfield Loan ($19.7 million net of transaction fee), which became available under the Deerfield Loan upon the first commercial sale of SURFAXIN. Before any additional financings, including under our ATM Program, we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the third quarter of 2015.

Our future capital requirements depend upon many factors, primarily the success of our efforts to (i) execute the commercial introduction of SURFAXIN in the U.S.; (ii) advance the AEROSURF development program to completion of the phase 2 clinical program as planned in the second half of 2015; and (iii) secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, commercial introduction of AEROSURF and potentially SURFAXIN in markets outside the U.S. We believe that, if we are able to complete the AEROSURF phase 2 clinical program on a timely basis and obtain encouraging results, and if we are able to successfully advance the commercial introduction of SURFAXIN, our ability to enter into a significant strategic alliance will be enhanced. 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.

Even if we succeed with the commercial introduction of SURFAXIN, given the time required to secure formulary acceptance at our target hospitals, we expect our revenues from SURFAXIN to be modest in the first 12-24 months and then increase slowly over time. For the next several years, we expect that our cash outflows for marketing, commercial and medical activities, development programs, operations and debt service will far outpace the rate at which we may generate revenues. Therefore, to execute our business strategy and fund our operations over the long term, we will require significant additional infusions of capital until such time as the net revenues from the sale of approved products, from potential strategic alliances and from other sources are sufficient to offset our cash flow requirements. To secure the necessary capital to fund our development programs, we would prefer to enter into strategic alliances or collaboration arrangements with partners having broad experience in markets outside the U.S., including regulatory and product-development expertise as well as an ability to commercialize our products, if approved. Such alliances typically would also provide financial resources, in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. Collaboration, co-marketing and other similar arrangements would provide, in addition to an ability to introduce our products in markets outside the U.S., a sharing of revenues. Under our ATM Program, subject to market conditions, we may sell up to approximately $23 million of common stock at such times and in such amounts that we deem appropriate, subject to a 3% commission. However, use of the ATM Program is subject to market and other conditions and the ATM Program could be cancelled at any time by either party. We also may consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions. There can be no assurance, however, that our AEROSURF and other research and development projects will be successful, that our products under development will obtain necessary regulatory approval in the U.S. and other markets, that any approved product, including SURFAXIN, will be commercially viable, that the ATM Program will be available when needed, if at all, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

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

As of December 31, 2013, 150 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, and approximately 42.1 million shares of common stock were available for issuance and not otherwise reserved.

In addition, as of December 31, 2013, we had outstanding warrants to purchase approximately 14.8 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, 7 million warrants were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share. The Deerfield Warrants may be exercised for cash or on a cashless basis. In lieu of paying cash upon exercise, the holders also may elect to reduce the principal amount of the Deerfield loan in an amount sufficient to satisfy the exercise price of the Deerfield Warrants. In addition to the Deerfield Warrants, we have outstanding warrants to purchase approximately 4.8 million shares of common stock that were issued in February 2011, are exercisable for five-years, and 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. These warrants were originally issued with an exercise price of $3.20 per share and thereafter adjusted downward, first to $2.80 per share in March 2012 and then to $1.50 per share following a public offering in May 2013. If the market price of our common stock should exceed $1.50 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 receive up to $7.3 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 successfully execute our business strategy, there can be no assurance that we will be successful. We will require significant additional capital to satisfy debt obligations and sustain operations, and to complete the development and support the commercial introduction of our products. 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, 2013, 2012 and 2011, we had cash and cash equivalents of $86.3 million, $26.9 million and $10.2 million. Cash outflows before financing activities for 2013 consisted of $40.5 million used for ongoing operating activities and $0.6 million for purchases of property and equipment. During 2013, we raised aggregate net proceeds of $100.4 million, including a $30 million ($29.6 million net of expenses) advanced under the Deerfield Loan, $15.1 million and $53.9 million of net proceeds from registered public offerings that we completed in May 2013 and November 2013, respectively, and $1.8 million of net proceeds from a financing under the ATM Program.

Operating Activities

Net cash used in operating activities was $40.5 million, $32.9 million, and $22.7 million for the years ended December 31, 2013, 2012 and 2011, respectively. Net cash used in operating activities is a result of our net losses for the period, adjusted for non-cash items and changes in working capital.

The increase in net cash used in operating activities from 2012 to 2013 is primarily due to (i) investment in our specialty commercial and medical affairs organization that is focused on neonatal/pediatric respiratory critical care in NICUs/PICUs across the U.S., and manufacturing and quality activities in preparation for the commercial introduction of SURFAXIN; (ii) costs to develop and manufacture clinic-ready CAGs for the AEROSURF phase 2a clinical trial, including work with third party device experts and work that began June 2012 with Battelle, which assisted in a multi-phase project to design, test, and manufacture clinic-ready CAG devices; and (iii) purchases of APIs used in the manufacture of SURFAXIN drug product and our lyophilized KL_4 surfactant, for commercial use and preclinical development activities, including to complete the technical transfer and further develop our KL_4 surfactant manufacturing process at DSM, and activities to develop a clinic-ready CAG and prepare for our AEROSURF phase 2 clinical program.

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; (ii) costs to develop and manufacture clinic-ready CAGs for the AEROSURF phase 2a clinical trial, including work with third party device experts and work that began June 2012 with Battelle, which assisted in a multi-phase project to design, test, and manufacture clinic-ready CAG devices; and (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.

Investing Activities

Net cash used in investing activities primarily represents capital expenditures of $0.6 million, $0.6 million, and $0.1 million for the years ended December 31, 2013, 2012, and 2011, respectively.

Financing Activities

Net cash provided by financing activities was $100.5 million, $50.2 million, and $22.8 million for the years ended December 31, 2013, 2012, and 2011, respectively, summarized as follows:

(in millions)	Years Ended December 31,		
	2013	**2012**	**2011**
Financings pursuant to common stock offerings	$ 69.0	$ 42.1	$ 21.6
Proceeds from issuance of long-term debt, net	29.6	–	–
Financings under the 2010 CEFF	–	–	1.3
Exercise of common stock warrants and options	0.2	6.7	–
Financings under the ATM Programs	1.8	3.0	–
Debt service payments	(0.1)	(0.1)	(0.1)
Cash flows from financing activities, net	$ 100.5	$ 50.2	$ 22.8

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.

Registered Public Offerings

On November 5, 2013, we completed a registered public offering of 25,000,000 shares of our common stock, at a price of $2.00 per share resulting in gross proceeds of $50.0 million ($46.8 million net proceeds). We also granted the underwriters a 30-day option to purchase up to an additional 3,750,000 shares of common stock at an offering price of $2.00 per share. On November 8, 2013, the underwriters exercised their option in full, resulting in additional gross proceeds of $7.5 million ($7.1 million net proceeds).

On May 10, 2013, we completed a registered public offering of 9,500,000 shares of our common stock, at a price of $1.50 per share resulting in gross proceeds of $14.3 million ($13.2 million net proceeds). We also granted the underwriters a 30-day option to purchase up to an additional 1,425,000 shares of common stock at an offering price of $1.50 per share. On May 28, 2013, the underwriters exercised their option to purchase 1,347,000 shares of common stock at a price of $1.50 per share, resulting in additional gross proceeds of $2.0 million ($1.9 million net proceeds).

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 offerings in March 2012 and May 2013, the exercise price of the five-year warrants was adjusted downward to a price per share of $2.80 and $1.50, respectively.

In addition, 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)

From 2004 through June 2013, we maintained one or more Committed Equity Financing Facilities (CEFFs) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, under which Kingsbridge was committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFFs allowed us, at our discretion, to raise capital, at the time and in amounts deemed suitable to us, to support our business plans. We were not obligated to utilize any of the funds available under any CEFF and our ability to access funds at any time was subject to certain conditions, including stock price and volume limitations.

As of December 31, 2013, we have no CEFF agreements. Three CEFF agreements, dated May 22, 2008, December 12, 2008, and June 11, 2010 (2010 CEFF) expired in June 2011, February 2011, and June 2013, respectively. There were no financings under the May 2008 CEFF or December 2008 CEFF during 2013, 2012 and 2011.

The 2010 CEFF Agreement originally provided for the purchase of the lesser of up to 2.1 million shares or a maximum of $35 million, and expired in June 2013. There were no financings completed under the 2010 CEFF in 2012 and 2013.

In 2011, we received $1.3 million of gross proceeds from the issuance of 514,990 shares at an average discounted price of $2.56 per share under the 2010 CEFF.

Warrants

During the year ended December 31, 2013, holders of the February 2011 five-year warrants exercised warrants to purchase 113,800 shares of our common stock at an exercise price of $1.50 per share, resulting in proceeds to us of $170,700.

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 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 11 – Stockholders' Equity – Common Shares Reserved for Future Issuance – Common shares reserved for potential future issuance upon exercise of warrants."

At-the-Market Program (ATM Program)

Stifel ATM Program

On February 11, 2013, we entered into an At-the-Market Equity Sales Agreement (ATM Agreement) with Stifel, 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 (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 ATM Agreement by notice to the other party.

The ATM Agreement will terminate upon the earliest of: (1) the sale of all shares subject to the ATM Agreement, (2) February 11, 2016 or (3) the termination of the ATM Agreement in accordance with its terms. Either party may terminate the ATM Agreement at any time upon written notification to the other party in accordance with the ATM Agreement, and upon such termination, the offering will terminate.

We agreed to pay Stifel a commission equal to 3.0% of the gross sales price of any shares sold pursuant to the ATM 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.

On October 15, 2013, we completed an offering under the ATM Program and issued 713,920 shares of our common stock for an aggregate purchase price of approximately $2.0 million, resulting in net proceeds to us of approximately $1.8 million, after deducting commissions. As of December 31, 2013, approximately $23 million remained available under the ATM Program.

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, at our discretion and at such times that we may determine from time to time, could sell over a two-year period up to a maximum of $15,000,000 of shares of our common stock 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 under the Lazard ATM Program. We also agreed to reimburse Lazard for certain expenses incurred in connection with entering into the Agency Agreement and provided Lazard with customary representations, warranties and indemnification rights. 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.

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.

Deerfield Loan

On February 13, 2013, we entered into a secured loan facility (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for up to $30 million in secured financing in 2013. As of December 31, 2013, long-term debt consists solely of amounts due under this facility as follows:

(in thousands)		
Note Payable	$	30,000
Unamortized discount		(11,646)
Long-term debt, net of discount	$	18,354

Under the terms of the related agreement, Deerfield advanced funds to us in two separate disbursements. Deerfield made the first disbursement, in the amount of $10 million, on February 13, 2013, upon execution of the related agreement (First Disbursement). Deerfield made the second disbursement, in the amount of $20 million, on December 3, 2013 (Second Disbursement), following the first commercial sale of SURFAXIN.

The amount received and outstanding under the Deerfield Loan will accrue interest at an annual rate of 8.75%, payable quarterly in cash. The Deerfield Loan agreement contains customary terms and conditions but does not require us to meet minimum financial and revenue performance covenants. In connection with each advance, we paid Deerfield a transaction fee equal to 1.5% of the amount disbursed. The Deerfield Loan agreement also contains various representations and warranties and affirmative and negative covenants customary for financings of this type, including restrictions on our ability to incur additional indebtedness and grant additional liens on our assets. In addition, all amounts outstanding under the Deerfield Loan may become immediately due and payable upon (i) an “Event of Default,” as defined in the Deerfield Loan agreement, in which case Deerfield would have the right to require us to repay the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the occurrence of certain events as defined in the facility agreement, including, among other things, the consummation of a change of control transaction or the sale of more than 50% of our assets (a Major Transaction).

In connection with the execution of the Deerfield Loan and receipt of the First Disbursement, we issued to Deerfield warrants to purchase approximately 2.3 million shares of our common stock at an exercise price of $2.81 per share. Upon receipt of the Second Disbursement, we issued to Deerfield warrants to purchase an additional 4.7 million shares of our common stock at an exercise price of $2.81 per share (together with the warrants issued in connection with the First Disbursement, the Deerfield Warrants). The number of shares of common stock into which the Deerfield Warrants are exercisable and the exercise price of any Deerfield Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock. The Deerfield Warrants will expire on the sixth anniversary of the facility agreement, February 13, 2019, and contain certain limitations that generally prevent the holder from acquiring shares upon exercise of the Deerfield Warrants or any part thereof that would result in the number of shares beneficially owned by such holder to exceed 9.985% of the total number of shares of our common stock then issued and outstanding. For a discussion of additional rights of the holders, see, “Item 8 – Notes to consolidated financial statements – Note 9 – Deerfield Loan.”

We have recorded the loan as long-term debt at its face value of $30.0 million less debt discounts and issuance costs consisting of (i) $11.7 million fair value of the Deerfield Warrants issued upon the First Disbursement and the Second Disbursement (7 million warrants in total), and (ii) a $450,000 transaction fee. The discount is being accreted to the $30 million loan over its term using the effective interest method. The Deerfield Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815 *“Derivatives and Hedging – Contracts in Entity’s Own Equity”* (ASC 815) and have been classified as equity.

Equipment Loan

In September 2008, we entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department), 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 November 2013 for a waiver, the Department granted us an extension through December 31, 2014 to come into compliance with the Jobs Covenant and has waived any interest adjustment until that date.

Contractual Obligations and Commitments

Future payments due under contractual obligations at December 31, 2013 are as follows:

(in thousands)	2014	2015	2016	2017	2018	There-after	Total
Operating lease obligations	1,087	1,024	934	936	158	–	4,139
Equipment loan obligations [1]	79	69	–	–	–	–	148
Total	$ 1,166	$ 1,093	$ 934	$ 936	$ 158	$ –	$ 4,287

[1] *See*, Note 10 – Equipment Loan

Operating Lease Agreements

We lease our headquarters location in Warrington, Pennsylvania. The facility consists of 39,594 square feet and also serves as the main operating location for drug and device development, regulatory, analytical technical services, research and development, and administration. In January 2013, we entered into an lease amendment to extend the term an additional five years, from February 2013 through 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 also lease approximately 21,000 square feet of space at our Totowa Facility, our only manufacturing facility, at an annual rent of $150,000. We have secured an extension of the lease, which was originally scheduled to expire in December 2014, until June 30, 2015. We currently are in discussions with the landlord potentially to extend the lease through the end of 2016. We are also exploring possible alternatives that could enable longer-term utilization of the Totowa Facility for the manufacture of SURFAXIN drug product and potentially lyophilized KL4 surfactant. The total aggregate payments over the term of the lease are $1.4 million. *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 of the years ended December 31, 2013, 2012 and 2011, respectively.

Severance Arrangements

On September 13, 2013, our Board of Directors approved an employee severance and retention plan for employees at the Totowa Facility to take effect in the event that we are unable to secure long-term utilization of the Totowa Facility beyond the scheduled lease expiration on June 30, 2015. The retention plan is intended to minimize employee turnover by providing severance and retention bonuses that encourage employees to stay with us through facility closing date (and beyond for certain employees). The plan has two components: (1) plant management (three individuals) has received an award of stock options that will vest in full, and will be eligible for a retention bonus payable in June 2016, provided that they remain employed with us in June 2016; and (2) provided that they remain employed with us through the successful closure of the Totowa Facility, non-union employees (nine individuals) will be eligible to receive both severance and a retention bonus payable upon such closure. The total cash amount expected to be paid for severance and retention through June 2016 is approximately $1.0 million. The plan-related expense incurred during 2013 is $0.1 million and is included in research and development expense. The related liability is $0.1 million as of December 31, 2013.

In addition, there are 14 employees at the Totowa Facility who are subject to a collective bargaining agreement and will be eligible to receive severance upon closure of the Totowa Facility. The plan-related expense incurred during 2013 is $30,000 and is included in research and development expense. The related liability is $0.5 million as of December 31, 2013.

In December 2012, we entered into a separation agreement (CEO Agreement) with our former Chief Executive Officer and Chairman of the Board of Directors. Pursuant to the CEO Agreement, the executive 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 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. We also agreed to pay the executive's attorneys' fees incurred in connection with negotiating the CEO Agreement.

In July 2011, we entered into a separation agreement (EVP Agreement) with a former executive who served as our Executive Vice President, General Counsel and Corporate Secretary. Pursuant to the EVP Agreement, the 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 obligation (as defined in the RSA), (iii) extended health benefits for up to 18 months, and, (iv) depending on the circumstances, outplacement services. In addition, 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 Agreement also contained a general release by both 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, 2013, 2012 or 2011, 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 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, 2013. 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 1992 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, 2013.

Our independent registered public accounting firm has audited our internal control over financial reporting, and issued an unqualified opinion dated March 17, 2014 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, 2013 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, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (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 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, 2013, 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, 2013 and 2012, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the three years in the period ended December 31, 2013 and our report dated March 17, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young

Philadelphia, Pennsylvania
March 17, 2014

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 17, 2014

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

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

Signature	Name & Title	Date
/s/ John G. Cooper	John G. Cooper Director, President, Chief Executive Officer and Chief Financial Officer (Principal Executive and Principal Financial Officer)	March 17, 2014
/s/ John Tattory	John Tattory Vice President, Finance, and Chief Accounting Officer (Principal Accounting Officer)	March 17, 2014
/s/ John R. Leone	John R. Leone Director (Chairman of the Board)	March 17, 2014
/s/ Joseph M. Mahady	Joseph M. Mahady Director	March 17, 2014
/s/ Bruce A. Peacock	Bruce A. Peacock Director	March 17, 2014
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 17, 2014

INDEX TO EXHIBITS

The following exhibits are included with this Annual Report on Form 10-K.

Exhibit No.	Description	Method of Filing
3.1	Amended and Restated Certificate of Incorporation filed as of August 1, 2013, including amendments reflected in a Certificate of Amendment to the Restated Certificate of Incorporation of Discovery filed on December 27, 2010, and in 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 on Form 10-Q, as filed with the SEC on August 8, 2013.
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 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.
4.3	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.
4.4	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.
4.5	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.
4.6	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
4.7	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.
4.8	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.
4.9	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.
4.10	Form of Warrant dated February 13, 2013, issued to affiliates of 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, as filed with the SEC on June 14, 2013.
4.11	Form of Warrant dated December 3, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) on December 3, 2013 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, as filed with the SEC on December 6, 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.
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*	Discovery's 2007 Long Term Incentive Plan	Incorporated by reference to Exhibit 1.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 28, 2007.

Exhibit No.	Description	Method of Filing
10.7*	Form of 2007 Long-Term Incentive Plan Stock Option Agreement	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, as filed with the SEC on August 9, 2007.
10.8*	Discovery's 2011 Long-Term Incentive Plan	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).
10.9*	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.
10.10*	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.
10.11*	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.
10.12*	Employment Agreement dated as of April 1, 2013, between Discovery Laboratories, Inc. 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 April 2, 2013.
10.13*	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.
10.14*	Employment Agreement dated as of April 1, 2013, between Discovery Laboratories, Inc. and Thomas F. Miller, Ph.D., MBA	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 2, 2013.
10.15*	Employment Agreement dated as of April 1, 2013, between Discovery Laboratories, Inc. and Russell G. Clayton	Filed herewith.
10.16*	Employment Agreement dated as of April 1, 2013, between Discovery Laboratories, Inc. and Mary B. Templeton	Filed herewith.

Exhibit No.	Description	Method of Filing
10.17	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.
10.18	Extension, dated as of July 16, 2013, of Lease dated as of December 3, 2004, between Discovery, as successor-in-interest to Laureate Pharma, Inc., and Norwell Land Company, with respect to property at 710 Union Blvd., Totowa, NJ 07512	Incorporated by reference to Exhibit 10.1 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on August 8, 2013.
10.19	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, by and between TR Stone Manor Corp. and Discovery	Incorporated by reference to Exhibits 10.1 and 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 6, 2007.
10.20	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.
10.21	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.
10.22	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.
10.23	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.
10.24	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.
10.25	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.

Exhibit No.	Description	Method of Filing
10.26	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.
10.27	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.
10.28	Pharmaceutical Manufacturing and Supply Agreement dated August 7, 2013 between Discovery and DSM Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on August 8, 2013.
10.29	Master Services Agreement dated October 24, 2013 between Discovery and DSM	Incorporated by reference to Exhibit 10.2 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 12, 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, 2013, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2013, December 31, 2012 and December 31, 2011, (ii) Statements of Operations for the years ended December 31, 2013, December 31, 2012, and December 31, 2011, (iii) Statements of Changes in Equity for the years ended December 31, 2013, December 31, 2012, and December 31, 2011, (iv) Statements of Cash Flows for the years ended December 31, 2013, December 31, 2012, and December 31, 2011, and (v) Notes to consolidated financial statements.	
101.INS	Instance Document	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith.

Exhibit No.	Description	Method of Filing
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

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

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

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Contents

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Discovery Laboratories, Inc.

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary as of December 31, 2013 and 2012, 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, 2013. 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, 2013 and 2012, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Discovery Laboratories, Inc. and subsidiary's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated March 17, 2014 expressed an unqualified opinion thereon.

/s/ Ernst and Young LLP

Philadelphia, Pennsylvania
March 17, 2014

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 86,283	$ 26,892
Accounts receivable	67	–
Inventory, net	112	195
Prepaid expenses and other current assets	777	719
Total current assets	87,239	27,806
Property and equipment, net	1,656	1,737
Restricted cash	325	400
Other assets	97	–
Total assets	89,317	29,943
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,433	$ 1,166
Accrued expenses	4,785	4,159
Deferred revenue	139	–
Common stock warrant liability	5,425	6,305
Equipment loans, current portion	73	69
Total current liabilities	11,855	11,699
Long-term debt, net of discount of $11,646 at December 31, 2013 and $0 at December 31, 2012	18,354	–
Equipment loans, non-current portion	69	148
Other liabilities	538	443
Total liabilities	$ 30,816	$ 12,290
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 150,000,000 and 100,000,000 shares authorized at December 31, 2013 and 2012, respectively; 84,659,111 and 43,673,636 shares issued at December 31, 2013 and 2012, respectively; 84,638,219 and 43,652,744 shares outstanding at December 31, 2013 and 2012, respectively	85	44
Additional paid-in capital	541,420	455,398
Accumulated deficit	(479,950)	(434,735)
Treasury stock (at cost); 20,892 shares at December 31, 2013 and 2012	(3,054)	(3,054)
Total stockholders' equity	$ 58,501	$ 17,653
Total liabilities & stockholders' equity	$ 89,317	$ 29,943

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,		
	2013	**2012**	**2011**
Grant revenue	$ 388	$ 195	$ 582
Expenses:			
Cost of product sales	517	-	-
Research & development	27,661	21,570	17,230
Selling, general & administrative	16,718	16,444	7,864
Total expenses	44,896	38,014	25,094
Operating loss	(44,508)	(37,819)	(24,512)
Change in fair value of common stock warrant liability	761	555	3,560
Other income / (expense):			
Interest and other income	3	6	13
Interest and other expense	(1,471)	(57)	(26)
Other income / (expense), net	(1,468)	(51)	(13)
Net loss	$ (45,215)	$ (37,315)	$ (20,965)
Net loss per common share – basic and diluted	$ (0.82)	$ (0.95)	$ (0.93)
Weighted average number of common shares outstanding – basic and diluted	55,258	39,396	22,660

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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, 2011	**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**
Net loss	–	–	–	(45,215)	–	–	(45,215)
Issuance of common stock, May 2013 financing	10,847	11	15,102	–	–	–	15,113
Issuance of common stock, November 2013 financing	28,750	29	53,836	–	–	–	53,865
Issuance of common stock, ATM financing	714	1	1,795	–	–	–	1,796
Issuance of common stock warrants, Deerfield	–	–	11,729	–	–	–	11,729
Issuance of common stock, 401(k) Plan employer match	510	–	959	–	–	–	959
Exercise of common stock warrants	114	–	290	–	–	–	290
Exercise of stock options for cash	18	–	34	–	–	–	34
Issuance of common stock, consultants	32	–	67	–	–	–	67
Stock-based compensation expense	–	–	2,210	–	–	–	2,210
Balance – December 31, 2013	**84,659**	**$ 85**	**$ 541,420**	**$ (479,950)**	**(21)**	**$ (3,054)**	**$ 58,501**

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2013	**2012**	**2011**
Cash flows from operating activities:			
Net loss	$ (45,215)	$ (37,315)	$ (20,965)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	707	1,150	1,234
Provision for excess inventory	514	–	–
Stock–based compensation and 401(k) Plan employer match	3,236	3,270	1,364
Fair value adjustment of common stock warrants	(761)	(555)	(3,560)
Amortization of discount of long-term debt	534	–	–
Loss on disposal of equipment	–	42	45
Reduction in required restricted cash under lease agreement	75	–	–
Changes in:			
Inventory	(431)	(195)	–
Accounts receivable	(67)	–	–
Prepaid expenses and other current assets	(58)	(277)	(157)
Accounts payable	267	55	(574)
Accrued expenses	626	1,187	(314)
Deferred revenue	139	–	–
Other assets	(115)	–	174
Other liabilities	95	(246)	55
Net cash used in operating activities	(40,454)	(32,884)	(22,698)
Cash flows from investing activities:			
Purchase of property and equipment	(608)	(636)	(106)
Net cash used in investing activities	(608)	(636)	(106)
Cash flows from financing activities:			
Proceeds from issuance of securities, net of expenses	70,774	43,551	22,927
Proceeds from issuance of long-term debt	30,000	–	–
Payment of debt issuance costs	(450)	–	–
Proceeds from exercise of common stock warrants and options	204	6,747	–
Principal payments under equipment loans	(75)	(75)	(145)
Net cash provided by financing activities	100,453	50,223	22,782
Net increase / (decrease) in cash and cash equivalents	59,391	16,703	(22)
Cash and cash equivalents – beginning of year	26,892	10,189	10,211
Cash and cash equivalents – end of year	$ 86,283	$ 26,892	$ 10,189
Supplementary disclosure of cash flows information:			
Interest paid	$ 920	$ 13	$ 20

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 our aerosolized KL_4 surfactant. We believe that our proprietary technologies may 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.

We are initially focused on improving 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. RDS is the most prevalent respiratory disease in the Neonatal Intensive Care Unit (NICU) and can result in long-term respiratory problems, developmental delay and death.

Our first KL_4 surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the United States Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL_4 surfactant in liquid form and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States (U.S.). Since November 2013, SURFAXIN has been commercially available in the U.S.

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may each result in serious respiratory conditions and other complications. To avoid such complications, many neonatologists treat infants with less severe RDS by less invasive means, typically nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of premature infants on nCPAP will not respond well (an outcome referred to as nCPAP failure) and thereafter may require delayed surfactant therapy. Since neonatologists currently cannot predict which infants will experience nCPAP failure, neonatologists are faced with difficult choices in treating infants with less severe RDS. This is because the medical outcomes for those infants who experience nCPAP failure and receive delayed surfactant therapy may be less favorable than the outcomes for infants who receive surfactant therapy in the first hours of life.

AEROSURF® is an investigational combination drug/device product that combines our KL_4 surfactant with our proprietary capillary aerosol generator (CAG). With AEROSURF, neonatologists potentially will be able to administer aerosolized KL_4 surfactant to premature infants supported with nCPAP, without having to use invasive intubation and mechanical ventilation. By enabling delivery of our KL_4 surfactant using less invasive procedures, we believe that AEROSURF will address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

We are also developing a lyophilized (freeze-dried) dosage form of our KL_4 surfactant that is stored as a powder and reconstituted 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 initially developing this dosage form for use in our AEROSURF development program. We are also planning to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and would plan to introduce it commercially as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the U.S. and potentially in other markets.

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To support the commercial introduction of SURFAXIN in the U.S. and our other KL4 surfactant pipeline products, if approved, we have established our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL4 surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL4 surfactant.

In addition, we recognize that our commercial and medical affairs team could potentially support introductions of other synergistic pipeline products, including products owned or developed by third parties for the NICU/PICU. To that end, we would consider potential transactions focused on securing commercial rights to such synergistic products, including in the form of product acquisitions, in-licensing agreements or distribution, marketing or co-marketing arrangements.

In the future, we expect that we may be able to leverage the information, data and know-how that we gain from our development efforts with SURFAXIN and AEROSURF to support development of a potential product pipeline to address serious critical care respiratory conditions in larger children and adults in pediatric and adult intensive care units (PICUS and ICUs), including Acute Lung Injury (ALI), Chronic Obstructive Pulmonary Disorder (COPD) and Cystic Fibrosis (CF). At the present time, however, we are focusing our resources primarily on the commercial introduction of SURFAXIN and development of AEROSURF through phase 2 clinical trials. Once we have achieved these objectives, we believe we would be in a better position to assess the potential of other development programs to address the critical care needs of patients in the PICU and ICU.

We also have developed a disposable aerosol-conducting airway connector for infants that is intended to simplify the delivery of aerosolized medications (including our aerosolized KL4 surfactant) and other inhaled therapies to critical-care patients requiring ventilatory support. This device introduces aerosolized medications directly at the patient interface and minimizes the number of connections in the ventilator circuit. We have registered this device as a Class I, exempt medical device in the U.S. under the name AFECTAIR® and it is currently commercially available in the U.S.

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business" of this Annual Report on Form 10-K for the year ended December 31, 2013, 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.

Note 2 – Liquidity Risks and Management's Plans

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, and, more recently, commercialization and medical affairs 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, debt facilities, strategic alliances, the use of committed equity financing facilities (CEFFs) and at-the-market equity programs, and capital equipment financings.

As of December 31, 2013, we had cash and cash equivalents of $86.3 million and $30 million ($18.4 million net of discount) of long-term debt under our Deerfield Loan with affiliates of Deerfield Management Company, L.P. (Deerfield). *See*, "Note 9 – Deerfield Loan." During 2013, we raised aggregate gross proceeds of $75.8 million through public offerings of our common stock, including under our ATM Program. In February 2013, we entered into the Deerfield Loan and, upon execution of the agreement, Deerfield advanced to us $10 million ($9.85 million net of transaction fee). In May 2013, we completed a public offering of 10.847 million shares of common stock, including 1.347 million shares under an option granted to and exercised by the underwriters, at an offering price of $1.50 per share, resulting in gross proceeds of $16.3 million ($15.1 million net of commissions, discounts and expenses). In October 2013, we completed an offering under the ATM Program and issued 713,920 shares of our common stock resulting in net proceeds to us of approximately $1.8 million (net of commissions). In November 2013, we completed a public offering of 28.75 million shares of common stock, including 3.75 million shares under an option granted to and exercised by the underwriters for over-allotments, at an offering price of $2.00 per share resulting in gross proceeds of $57.5 million ($53.9 million net of commissions, discounts and expenses). In December 2013, we received an additional $20 million under the Deerfield Loan ($19.7 million net of transaction fee), which became due under the Deerfield Loan upon the first commercial sale of SURFAXIN. Before any additional financings, including under our ATM Program, we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the third quarter of 2015.

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Our future capital requirements depend upon many factors, primarily the success of our efforts to (i) execute the commercial introduction of SURFAXIN in the U.S.; (ii) advance the AEROSURF development program to completion of the phase 2 clinical program as planned in the second half of 2015; and (iii) secure one or more strategic alliances or other collaboration arrangements to support the development and, if approved, commercial introduction of AEROSURF and potentially SURFAXIN in markets outside the U.S. We believe that, if we are able to complete the AEROSURF phase 2 clinical program on a timely basis and obtain encouraging results, and if we are able to successfully advance the commercial introduction of SURFAXIN, our ability to enter into a significant strategic alliance will be enhanced. 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.

Even if we succeed with the commercial introduction of SURFAXIN, given the time required to secure formulary acceptance at our target hospitals, we expect our revenues from SURFAXIN to be modest in the first 12-24 months and then increase slowly over time. For the next several years, we expect that our cash outflows for marketing, commercial and medical activities, development programs, operations and debt service will far outpace the rate at which we may generate revenues. Therefore, to execute our business strategy and fund our operations over the long term, we will require significant additional infusions of capital until such time as the net revenues from the sale of approved products, from potential strategic alliances and from other sources are sufficient to offset our cash flow requirements. To secure the necessary capital to fund our development programs, we would prefer to enter into strategic alliances or collaboration arrangements with partners having broad experience in markets outside the U.S., including regulatory and product-development expertise as well as an ability to commercialize our products, if approved. Such alliances typically would also provide financial resources, in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. Collaboration, co-marketing and other similar arrangements would provide, in addition to an ability to introduce our products in markets outside the U.S., a sharing of revenues. Under our ATM Program (*see*, “Note 11 – Stockholders' Equity – At-the-Market Program (ATM Program)”), subject to market conditions, we may sell up to approximately $23 million of common stock at such times and in such amounts that we deem appropriate, subject to a 3% commission. However, use of the ATM Program is subject to market and other conditions and the ATM Program could be cancelled at any time by either party. We also may consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions. There can be no assurance, however, that our AEROSURF and other research and development projects will be successful, that our products under development will obtain necessary regulatory approval in the U.S. and other markets, that any approved product, including SURFAXIN, will be commercially viable, that the ATM Program will be available when needed, if at all, or that we will be able to obtain additional capital when needed on acceptable terms, if at all. Even if we succeed in raising additional capital and developing and subsequently commercializing product candidates, we may never achieve sufficient sales revenue to achieve or maintain profitability.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. For the next several years, our ability to continue as a going concern will be dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations, including debt service, on a timely basis. If we are unable to successfully raise sufficient additional capital when needed, 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 our programs and consider other means of creating value for our stockholders, such as licensing the development and commercialization of products that we consider valuable and would otherwise likely develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders’ interests and, in such event, the market price of our common stock may decline. The balance sheets do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

As of December 31, 2013, 150 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation and approximately 42.1 million shares of common stock were available for issuance and not otherwise reserved.

In addition, as of December 31, 2013, we had outstanding warrants to purchase approximately 14.8 million shares of our common stock at various prices, exercisable on different dates into 2019. Of these warrants, 7 million warrants were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share. The Deerfield Warrants may be exercised for cash or on a cashless basis. In lieu of paying cash upon exercise, the holders also may elect to reduce the principal amount of the Deerfield loan in an amount sufficient to satisfy the exercise price of the Deerfield Warrants. In addition to the Deerfield Warrants, we have outstanding warrants to purchase approximately 4.8 million shares of common stock that were issued in February 2011, are exercisable for five-years, and 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. These warrants were originally issued with an exercise price of $3.20 per share and thereafter adjusted downward, first to $2.80 per share in March 2012 and then to $1.50 per share following a public offering in May 2013. If the market price of our common stock should exceed $1.50 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 receive up to $7.3 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 successfully execute our business strategy, there can be no assurance that we will be successful. We will require significant additional capital to satisfy debt obligations and sustain operations, and to complete the development and support the commercial introduction of our products. 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

Cash and cash equivalents are held in U.S. banks and consist of liquid investments and money market funds with a maturity from date of purchase of 90 days or less that are readily convertible into cash.

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, 2013 and 2012, respectively. Other financial instruments, including accounts payable and accrued expenses, are carried at cost, which we believe approximates fair value.

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Accounts receivable

Trade accounts receivable are recorded net of allowances for prompt payment discounts and doubtful accounts.

Inventory

Inventories, which are recorded at the lower of cost or market, include materials, labor, and other direct and indirect costs and are valued at cost using the first-in, first-out method. The Company capitalizes inventories produced in preparation for commercial launches when the related product candidates receive regulatory approval and that the related costs will be recoverable through the commercial sale of the product. Costs incurred prior to FDA approval of SURFAXIN drug product and registration of our initial AFECTAIR device have been recorded in our statement of operations as research and development expense. Inventory is evaluated for impairment through consideration of factors such as the net realizable value, lower of cost or market, obsolescence, and expiry. Inventories do not have carrying values that exceed either cost or net realizable value.

We evaluate our expiry risk by evaluating current and future product demand relative to product shelf life. We build demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and hospital ordering practices.

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.

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 and amended January 3, 2013 for our headquarters location in Warrington, Pennsylvania (*See*, Note 14 – Commitments, for further discussion on our leases). Under terms of the lease agreement, the required restricted cash balance was reduced to $325,000 in October 2013.

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, 2013, 2012, and 2011 as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable.

Financing costs related to long-term debt

Costs associated with obtaining long-term debt, including the fair value of warrants issued in connection with the debt and transaction fees, are amortized over the term of the related debt using the effective interest method.

Deferred revenue

Deferred revenue reflects amounts related to SURFAXIN sales to our specialty distributor, which are deferred and recognized as revenue once product has been sold through to the hospital and all revenue recognition criteria have been met.

Product Sales

Revenues from product sales are recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured.

Our products are distributed in the U.S. using a specialty distributor. Under this model, the specialty distributor purchases and takes physical delivery and title of product, and then sells to hospitals. We began the commercial introduction of SURFAXIN in the fourth quarter of 2013 and, for that reason, we currently cannot make a reasonable estimate of future product returns when product is delivered to the specialty distributor. Therefore, we currently do not recognize revenue upon product shipment to the specialty distributor, even though the distributor is invoiced upon product shipment. Instead, we recognize revenue once product has been sold through to the hospital and all revenue recognition criteria have been met. Once product has been delivered to the hospital, the risk of material returns is significantly mitigated. As of December 31, 2013, we have deferred revenue recognition on all product sales since the inception of the commercial launch of SURFAXIN in November 2013. We will recognize those revenues at the point in time when all revenue recognition criteria have been met.

We will begin to recognize revenue at the time of shipment of product to our specialty distributor when we can reasonably estimate expected distributor sales deductions and returns. In developing estimates for sales returns we consider the shelf life of the product, expected demand based on market data and return rates of other surfactant products.

Product sales are recorded net of accruals for estimated chargebacks, discounts, specialty distributor deductions and returns.

- *Chargebacks.* Chargebacks are discounts that occur when contracted customers purchase directly from our specialty distributor. Contracted customers, which currently consist primarily of member hospitals of Group Purchasing Organizations, generally purchase the product at a discounted price. Our specialty distributor, in turn, charges back the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the customer. The allowance for specialty distributor chargebacks is based on known sales to contracted customers.

- *Sales discounts*: Sales discounts are offered to certain contracted customers based upon a customer's historical volume of surfactant product purchases. Customers must enter into a Letter of Participation (LOP) with us to receive sales discounts. Sales discounts are calculated on a quarterly basis based upon the customer's quarterly purchases of SURFAXIN, as provided in the LOP. The allowance for sales discounts is based on known sales to contracted customers.

- *Specialty distributor deductions.* Our specialty distributor is offered various forms of consideration including allowances, service fees and prompt payment discounts. Specialty distributor allowances and service fees are provided in our contractual agreement and are generally a percentage of the purchase price paid by the specialty distributor. The specialty distributor is offered a prompt pay discount for payment within a specified period.

- *Returns.* Sales of our products are not subject to a general right of return; however, we will accept product that is damaged or defective when shipped or for expired product up to 6 months subsequent to its expiry date. Product that has been administered to patients is no longer subject to any right of return.

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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.

We recognized $0.4 million and $0.2 million of grant revenue for the years ended December 31, 2013 and 2012, respectively, for funds received and expended under a $0.6 million 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.

For the year ended December 31, 2011, grant revenue represents funds received and expended under a $0.6 million Fast Track SBIR from the NIH to support the development of aerosolized KL4 surfactant for 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 12 – 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 current liabilities, which are 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, 2013, 2012, and 2011, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 20.2 million, 11.9 million and 15.4 million shares, respectively. As a result of the 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. We do not have any components of other comprehensive income (loss).

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. 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.

Major customer and concentration of credit risk

We currently sell our products to one exclusive pharmaceutical specialty distributor in the U.S. We periodically assess the financial strength of our specialty distributor and establish allowances for anticipated uncollectible amounts, if necessary. As of December 31, 2013, we have not recorded an allowance for doubtful accounts.

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

The Company did not adopt any new accounting pronouncements during 2013 that had a material effect on the Company's consolidated financial statements.

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.

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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, 2013 and 2012:

(in thousands)	Fair Value December 31, 2013	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 86,283	$ 86,283	$ –	$ –
Certificate of deposit	325	325	–	–
Total Assets	$ 86,608	$ 86,608	$ –	$ –
Liabilities:				
Common stock warrants	$ 5,425	$ $ –	$ –	$ 5,425

(in thousands)	Fair Value December 31, 2012	Fair value measurement using Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 26,892	$ 26,892	$ –	$ –
Certificate of deposit	400	400	–	–
Total Assets	$ 27,292	$ 27,292	$ –	$ –
Liabilities:				
Common stock warrants	$ 6,305	$ $ –	$ –	$ 6,305

The following table summarizes changes in the fair value of the common stock warrants measured on a recurring basis using Level 3 inputs for 2012 and 2013:

(in thousands)	
Balance at January 1, 2012	**$ 6,996**
Issuance of common stock warrants	(136)
Change in fair value of common stock warrant liability	(555)
Balance at December 31, 2012	**$ 6,305**
Exercise of warrants [1]	(119)
Change in fair value of common stock warrant liability	(761)
Balance at December 31, 2013	**$ 5,425**

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

The significant unobservable inputs used in the fair value measurement of the common stock warrants measured on a recurring basis 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, certain fair value measurements also take 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, may result in significantly higher or lower fair value measurements.

Significant Unobservable Input Assumptions of Level 3 Valuations	December 31, 2013	2012
Historical volatility	62% -76%	56% -80%
Expected term (in years)	0.4 – 2.1	1.4 – 3.2
Risk-free interest rate	0.08% - 0.44%	0.16% - 0.36%

Fair Value of Long-Term Debt

At December 31, 2013, the estimated fair value of the Company's Deerfield Loan was $23.6 million compared to a carrying value, net of discounts, of $18.4 million. We had no long-term debt as of December 31, 2012. The estimated fair value of the Deerfield Loan was based on discounting the future contractual cash flows to the present value. This analysis utilizes certain Level 3 unobservable inputs, including current cost of capital. Considerable judgment is required to interpret market data and to develop estimates of fair value. The estimates presented are not necessarily indicative of amounts we could realize in a current market exchange. The use of alternative market assumptions and estimation methodologies could have a material effect on these estimates of fair value.

Note 5 – Inventory

Inventory is comprised of the following:

(in thousands)	December 31, 2013	2012
Raw materials	$ 52	$ 195
Finished goods	60	–
	$ 112	$ 195

Raw materials costs in inventory of $52,000 as of December 31, 2013 consisted of the portion of raw materials anticipated to be used in the manufacture of commercial product that were purchased after October 4, 2013, the date the FDA agreed to our updated product specifications for SURFAXIN that allowed us to proceed with the commercial introduction of SURFAXIN. Raw materials on hand as of December 31, 2013 that were purchased prior to October 4, 2013 were $1.6 million. These raw materials have a carrying value of zero, as the costs to purchase this material were expensed as research and development expense in the period purchased, and accordingly are not reflected in the inventory balances shown above. The majority of these raw materials are anticipated to be used in manufacturing development and research and development activities. The remaining portion of these raw materials are anticipated to be used in the manufacture of commercial product.

Raw materials costs in inventory of $195,000 as of December 31, 2012 consisted of the portion of raw materials anticipated to be used in the manufacture of commercial product that were purchased after the FDA agreed granted us marketing approval for SURFAXIN (March 2012). Due to a delay in commercial availability of SURFAXIN drug product until the fourth quarter of 2013, previously capitalized raw material costs of $195,000 as of December 31, 2012 were charged to research and development expense in the first quarter of 2013, as these raw materials were no longer expected to be used in the manufacture of commercial product.

Inventory reserves were $0.5 million as of December 31, 2013 and $0 as of December 31, 2012. The inventory reserves in 2013 primarily reflect costs of SURFAXIN related finished goods inventories that are not anticipated to be recoverable through the commercial sale of the product during the initial launch period due to product expiration. These reserves ensure that the inventory carrying values do not exceed net realizable value.

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Note 6 – Property and Equipment

Property and equipment is comprised of the following:

(in thousands)	December 31, 2013	2012
Manufacturing, laboratory & office equipment	$ 8,383	$ 7,775
Furniture & fixtures	816	816
Leasehold improvements	2,711	2,711
Subtotal	11,910	11,302
Accumulated depreciation and amortization	(10,254)	(9,565)
Property and equipment, net	$ 1,656	$ 1,737

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 June 2015.

Depreciation expense on property and equipment for the years ended December 31, 2013, 2012, and 2011 was $0.7 million, $0.9 million, and $1.3 million, respectively.

Note 7 – Accrued Expenses

Accrued expenses are comprised of the following:

(in thousands)	December 31, 2013	2012
Salaries, bonus & benefits	$ 1,849	$ 1,206
Manufacturing operations	1,707	926
Research and development	270	734
Professional fees	393	428
Sales and marketing	161	279
All other	405	586
Total accrued expenses	$ 4,785	$ 4,159

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 form of warrant agreement for 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.

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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) 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. Although by their express terms, these warrants are not subject to potential cash settlement, 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	Fair Value of Warrants (in thousands) Value at Issuance Date	December 31, 2013	December 31, 2012
5/13/2009	466,667	$ 17.25	5/13/2014	$ 3,360	$ –	$ –
2/23/2010	916,669	12.75	2/23/2015	5,701	6	104
2/22/2011	4,834,950	1.50	2/22/2016	8,004	5,419	6,201
					$ 5,425	$ 6,305

In addition, the February 2011 five-year 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 at issuance of $3.20 was adjusted downward to $2.80 per share at the time of the March 2012 public offering and to $1.50 per share at the time of the May 2013 public offering.

During the year ended December 31, 2013, holders of the February 2011 five-year warrants exercised warrants to purchase 113,800 shares of common stock for total proceeds of $170,700. 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.

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 –Deerfield Loan

On February 13, 2013, we entered into a secured loan facility (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for up to $30 million in secured financing in 2013. As of December 31, 2013, long-term debt consists solely of amounts due under this facility as follows:

(in thousands)	
Note Payable	$ 30,000
Unamortized discount	(11,646)
Long-term debt, net of discount	$ 18,354

Under the terms of the related agreement, Deerfield advanced funds to us in two separate disbursements. Deerfield made the first disbursement, in the amount of $10 million, on February 13, 2013, upon execution of the related agreement (First Disbursement). Deerfield made the second disbursement, in the amount of $20 million, on December 3, 2013 (Second Disbursement), following the first commercial sale of SURFAXIN.

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The loan may be prepaid in whole or in part without penalty at any time. In addition, the principal amount of the loan may be reduced to the extent that holders of the notes elect to apply all or a portion of the principal amount outstanding under the loan to satisfy the exercise price of all or a portion of the Deerfield Warrants (discussed below) upon exercise. The principal amount of the loan is payable in equal annual installments on the fourth, fifth and sixth anniversaries of the Deerfield Loan agreement, provided that the amount payable on the fourth anniversary shall be deferred for one year if either (i) our "Net Sales" (defined below) for the immediately preceding 12-month period are at least $20 million, or (ii) our "Equity Value" (defined below) is at least $200 million; and provided further, that the amount payable on the fifth anniversary (together with any amount deferred on the fourth anniversary) shall be deferred until the sixth anniversary if either (i) our "Net Sales" for the immediately preceding 12-month period are at least $30 million, or (ii) our "Equity Value" is at least $250 million. For the purposes of the foregoing deferrals of principal, "Net Sales" means, without duplication, the gross amount invoiced by us or on our behalf, any of our subsidiaries or any direct or indirect assignee or licensee for products, sold globally in bona fide, arm's length transactions, less customary deductions determined without duplication in accordance with generally accepted accounting principles; and "Equity Value" means, with respect to each measurement date, the product of (x) the number of issued and outstanding shares of our common stock on such measurement date multiplied by (y) the per share closing price of our common stock on such measurement date. Accordingly, if the milestones are achieved in each year, payment of the principal amount could be deferred until the sixth anniversary date of the loan, on February 13, 2019.

The amount received and outstanding under the Deerfield Loan will accrue interest at an annual rate of 8.75%, payable quarterly in cash. The Deerfield Loan agreement contains customary terms and conditions but does not require us to meet minimum financial and revenue performance covenants. In connection with each advance, we paid Deerfield a transaction fee equal to 1.5% of the amount disbursed. The Deerfield Loan agreement also contains various representations and warranties and affirmative and negative covenants customary for financings of this type, including restrictions on our ability to incur additional indebtedness and grant additional liens on our assets. In addition, all amounts outstanding under the Deerfield Loan may become immediately due and payable upon (i) an "Event of Default," as defined in the Deerfield Loan agreement, in which case Deerfield would have the right to require us to repay the outstanding principal amount of the loan, plus any accrued and unpaid interest thereon, or (ii) the occurrence of certain events as defined in the facility agreement, including, among other things, the consummation of a change of control transaction or the sale of more than 50% of our assets (a Major Transaction).

In connection with the execution of the Deerfield Loan and receipt of the First Disbursement, we issued to Deerfield warrants to purchase approximately 2.3 million shares of our common stock at an exercise price of $2.81 per share. Upon receipt of the Second Disbursement, we issued to Deerfield warrants to purchase an additional 4.7 million shares of our common stock at an exercise price of $2.81 per share (together with the warrants issued in connection with the First Disbursement, the Deerfield Warrants). The number of shares of common stock into which the Deerfield Warrants are exercisable and the exercise price of any Deerfield Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock.

The Deerfield Warrants will expire on the sixth anniversary of the facility agreement, February 13, 2019, and contain certain limitations that generally prevent the holder from acquiring shares upon exercise of the Deerfield Warrants or any part thereof that would result in the number of shares beneficially owned by such holder to exceed 9.985% of the total number of shares of our common stock then issued and outstanding. A holder of the Deerfield Warrants may exercise all or a portion of such Deerfield Warrants either for cash or on a cashless basis. In connection with a Major Transaction, as defined in the Deerfield 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 Deerfield Warrants or that portion of the Deerfield Warrant for cash in an amount equal to the Black-Scholes value (as defined in the Deerfield Warrants) of the Deerfield Warrants or that portion of the Deerfield Warrants 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 Deerfield Warrants and receive therefor that number of shares of Common Stock that equals the Black-Scholes value of the Deerfield Warrants or that portion of the Deerfield Warrants exercised. Prior to a holder exercising the Deerfield Warrants for shares in such transactions, the Company may elect to terminate the Deerfield Warrants or that portion of the Deerfield Warrants being exercised and pay the holder cash in an amount equal to the Black-Scholes value of the Deerfield Warrants.

We have recorded the loan as long-term debt at its face value of $30.0 million less debt discounts and issuance costs consisting of (i) $11.7 million fair value of the Deerfield Warrants issued upon the First Disbursement and the Second Disbursement (7 million warrants in total), and (ii) a $450,000 transaction fee. The discount is being accreted to the $30 million loan over its term using the effective interest method. The Deerfield Warrants are derivatives that qualify for an exemption from liability accounting as provided for in ASC Topic 815 *"Derivatives and Hedging – Contracts in Entity's Own Equity"* (ASC 815) and have been classified as equity.

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The fair value of the Deerfield Warrants at issuance was calculated using the Black-Scholes option-pricing model. The significant Level 3 unobservable inputs used in valuing the Deerfield Warrants are the historical volatility of our common stock market price, expected term of the warrants, and the risk-free interest rate based on the U.S. Treasury yield curve in effect at the measurement date. Any significant increases or decreases in the unobservable inputs, with the exception of the risk-free interest rate, would have resulted in a significantly higher or lower fair value measurement.

Significant Unobservable Input Assumptions of Level 3 Valuations	
Historical volatility	101%
Expected term (in years)	5.2 – 6.0
Risk-free interest rate	1.2% – 1.5%

The following amounts comprise the Deerfield Loan interest expense for the periods presented:

(in thousands)	December 31, 2013	2012	2011
Cash interest expense	$ 911	$ –	$ –
Non-cash amortization of debt discounts	534	–	–
Amortization of debt costs	18	–	–
Total Deerfield Loan interest expenses	$ 1,463	$ –	$ –

Cash interest expense represents interest at an annual rate of 8.75% on the outstanding principal amount for the period, paid in cash on a quarterly basis. Non-cash amortization of debt discount represents the amortization of transaction fees and the fair value of the warrants issued in connection with the Deerfield Loan. The amortization of debt costs represents legal costs incurred in connection with the Deerfield Loan.

Note 10 – Equipment Loan

Our equipment loan comprises the following:

(in thousands)	December 31, 2013	2012
Short-term	73	69
Long-term	69	148
	$ 142	$ 217

In September 2008, we entered into a Loan Agreement and Security Agreement with the Commonwealth of Pennsylvania, Department of Community and Economic Development (Department), 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 in November 2013 for a waiver, the Department granted us an extension through December 31, 2014 to come into compliance with the Jobs Covenant and has waived any interest adjustment until that date.

For the years ended December 31, 2013, 2012, and 2011, we incurred interest expense of $9,000, $13,000 and $20,000, respectively, on our outstanding equipment loan.

Note 11 – Stockholders' Equity

Registered Public Offerings

On November 5, 2013, we completed a registered public offering of 25,000,000 shares of our common stock, at a price of $2.00 per share resulting in gross proceeds of $50.0 million ($46.8 million net proceeds). We also granted the underwriters a 30-day option to purchase up to an additional 3,750,000 shares of common stock at an offering price of $2.00 per share. On November 8, 2013, the underwriters exercised their option in full, resulting in additional gross proceeds of $7.5 million ($7.1 million net proceeds).

On May 10, 2013, we completed a registered public offering of 9,500,000 shares of our common stock, at a price of $1.50 per share resulting in gross proceeds of $14.3 million ($13.2 million net proceeds). We also granted the underwriters a 30-day option to purchase up to an additional 1,425,000 shares of common stock at an offering price of $1.50 per share. On May 28, 2013, the underwriters exercised their option to purchase 1,347,000 shares of common stock at a price of $1.50 per share, resulting in additional gross proceeds of $2.0 million ($1.9 million net proceeds).

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 offerings in March 2012 and May 2013, the exercise price of the five-year warrants was adjusted downward to a price per share of $2.80 and $1.50, respectively.

In addition, 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.

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At-the-Market Program (ATM Program)

Stifel ATM Program

On February 11, 2013, we entered into an At-the-Market Equity Sales Agreement (ATM Agreement) with Stifel, 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 (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 ATM Agreement by notice to the other party.

The ATM Agreement will terminate upon the earliest of: (1) the sale of all shares subject to the ATM Agreement, (2) February 11, 2016 or (3) the termination of the ATM Agreement in accordance with its terms. Either party may terminate the ATM Agreement at any time upon written notification to the other party in accordance with the ATM Agreement, and upon such termination, the offering will terminate.

We agreed to pay Stifel a commission equal to 3.0% of the gross sales price of any shares sold pursuant to the ATM 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.

On October 15, 2013, we completed an offering under the ATM Program and issued 713,920 shares of our common stock for an aggregate purchase price of approximately $2.0 million, resulting in net proceeds to us of approximately $1.8 million, after deducting commissions. As of December 31, 2013, approximately $23 million remained available under the ATM Program.

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, at our discretion and at such times that we may determine from time to time, could sell over a two-year period up to a maximum of $15,000,000 of shares of our common stock 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 under the Lazard ATM Program. We also agreed to reimburse Lazard for certain expenses incurred in connection with entering into the Agency Agreement and provided Lazard with customary representations, warranties and indemnification rights. 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.

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.

Committed Equity Financing Facility (CEFF)

From 2004 through June 2013, we maintained one or more Committed Equity Financing Facilities (CEFFs) with Kingsbridge Capital Limited (Kingsbridge), a private investment group, under which Kingsbridge was committed to purchase, subject to certain conditions, newly-issued shares of our common stock. The CEFFs allowed us, at our discretion, to raise capital, at the time and in amounts deemed suitable to us, to support our business plans. We were not obligated to utilize any of the funds available under any CEFF and our ability to access funds at any time was subject to certain conditions, including stock price and volume limitations.

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As of December 31, 2013, we did not have an active CEFF. Three CEFF agreements, dated May 22, 2008, December 12, 2008, and June 11, 2010 (2010 CEFF) expired in June 2011, February 2011, and June 2013, respectively. There were no financings under the May 2008 CEFF or December 2008 CEFF during 2013, 2012 and 2011. The 2010 CEFF Agreement originally provided for the purchase of the lesser of up to 2.1 million shares or a maximum of $35 million, and expired in June 2013. There were no financings completed under the 2010 CEFF in 2012 and 2013. In 2011, we received $1.3 million of gross proceeds from the issuance of 514,990 shares at an average discounted price of $2.56 per share under the 2010 CEFF.

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 by issuing shares of common stock that 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, 2013, 2012 and 2011, the match resulted in the issuance of 510,047, 316,543, and 265,185, shares of common stock, respectively. Expenses associated with the 401(k) match for the years ended December 31, 2013, 2012, and 2011 were $1.0 million, $0.8 million and $0.5 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, 2013	December 31, 2012	Exercise Price	Expiration Date
Deerfield – 2013 loan	7,000	–	$ 2.81	2/13/2019
Former employee	30	30	$ 3.20	3/18/2016
Investors – February 2011 financing	4,835	4,949	$ 1.50	2/22/2016
PharmaBio – October 2010 financing	79	79	$ 4.10	10/13/2015
Investors – June 2010 financing	1,190	1,190	$ 6.00	6/22/2015
Kingsbridge – June 2010 CEFF	83	83	$ 6.69	12/11/2015
PharmaBio – April 2010 financing	135	135	$ 10.59	4/30/2015
Investors – February 2010 financing	917	917	$ 12.75	2/23/2015
Investors – 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	$ 37.59	11/22/2013
Total	14,781	7,950		

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 Long-Term 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 become available for issuance under the 1998 Plan or the 2011 Plan.

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Stock options and awards outstanding and available for future issuance as of December 31, 2013 and 2012 are as follows:

	As of December 31, 2013	2012
Stock Options Outstanding		
2011 Plan[1]	4,919	3,365
2007 Plan	258	277
1998 Plan	251	355
Total Outstanding	5,428	3,997
Available for Future Grants under 2011 Plan	2,894	2,966
Total	8,322	6,963

(1) *See*, Note 12 – Stock Options and Stock-based Employee Compensation – Long-Term Incentive Plans.

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

As of December 31, 2013 and 2012, we had 166,243 and 26,290, respectively, reserved for potential future issuance under the 401(k) Plan.

Note 12 – 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 11 – 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 7.8 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 awards (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, 2013, under the 2011 Plan, there were 4,919,333 stock options outstanding, 18,936 restricted stock units ("RSUs") that vest in June 2014 and 2,894,374 shares available for grant. No SARs, RSAs, other performance and stock-based awards, or 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.

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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, 2010	943	$ 56.06	
Granted	1,771	1.84	
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	
Granted	1,928	2.30	
Exercised	(18)	1.85	
Forfeited or expired	(479)	28.09	
Outstanding at December 31, 2013	5,428	$ 6.51	8.0
Exercisable at December 31, 2013	2,346	$ 12.01	6.9

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Yrs)
Outstanding at December 31, 2012	–	$ –	
Awarded	19	–	
Outstanding at December 31, 2013	19	$ –	0.4
Exercisable at December 31, 2013	–	$ –	0.0

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, 2013, 2012, and 2011 was $1.79, $2.02, and $1.45, respectively. The weighted-average grant-date fair value of RSUs granted during the year ended December 31, 2013 was $1.69. There were no RSUs granted during the years ended December 31, 2012 and 2011. For the year ended December 31, 2013, there were 18,208 options exercised, resulting in approximately $34,000 in proceeds. 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 year ended December 31, 2011. The total intrinsic value of options outstanding, vested, and exercisable as of December 31, 2013 is $0.8 million, $0.5 million, and $0.5 million, respectively.

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The following table provides detail with regard to options outstanding, vested and exercisable at December 31, 2013:

(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	5,428	$ 6.51	8.0 Years	2,346	$ 12.01	6.9 Years

Stock-Based Compensation

We recognized stock-based compensation expense in accordance ASC Topic 718 for the years ended December 31, 2013, 2012, and 2011, of $2.2 million, $2.4 million and $0.9 million, respectively.

Stock-based compensation expense was classified as follows:

(in thousands)	December 31, 2013	2012	2011
Research and development	$ 784	$ 487	$ 289
Selling, general and administrative	1,426	1,924	578
Total	$ 2,210	$ 2,411	$ 867

On December 31, 2012, our former Chief Executive Officer resigned from his position and as a member of our Board. Under the terms of a separation agreement that we entered into with the former CEO, all of the former CEO's outstanding options vested immediately and all such options shall remain exercisable to the end of their stated terms. We 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, 2013	2012	2011
Weighted average expected volatility	109%	111%	113%
Weighted average expected term	4.7 years	4.6 years	4.8 years
Weighted average risk-free interest rate	0.73%	0.74%	1.08%
Expected dividends	–	–	–

The total fair value of the underlying shares of the options vested during 2013, 2012, and 2011, equals $1.9 million, $2.2 million and $0.6 million, respectively. As of December 31, 2013, there was $4.0 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the 2011 Plan. That cost is expected to be recognized over a weighted-average vesting period of 1.7 years.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 13 – 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 principal of Esteve, served as a member of our Board of Directors from May 2002 until January 2013. 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 2004 restructuring in which Esteve returned certain rights to us in certain territories (Former Esteve Territories), we agreed to pay Esteve 10% of any cash up front and milestone fees (up to a maximum aggregate of $20 million) that we 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 the CAG 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 quarterly beginning in 2014, 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 license agreement) of licensed products sold by us or sublicensees, or, if greater, a percentage of royalty income from sublicensees in the low double digits.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 14 – Commitments

Future payments due under contractual obligations at December 31, 2013 are as follows:

(in thousands)	2014	2015	2016	2017	2018	There-after	Total
Operating lease obligations	1,087	1,024	934	936	158	–	4,139
Equipment loan obligations [1]	79	69	–	–	–	–	148
Total	$ 1,166	$ 1,093	$ 934	$ 936	$ 158	$ –	$ 4,287

[1] *See*, Note 10 – Equipment Loan

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 drug and device development, regulatory, analytical technical services, research and development, and administration. In January 2013, the lease was amended to extend the term an additional five years through 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 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. We have secured an extension of the lease, which was scheduled to expire in December 2014, until to June 30, 2015 for aggregate base rental payments of $306,250 under the extension period. 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 these leases was $1.0 million for each of the years ended December 31, 2013, 2012, and 2011, respectively.

Retention Plan

On September 13, 2013, our Board of Directors approved an employee severance and retention plan for employees at the Totowa Facility to take effect in the event that we are unable to secure long-term utilization of the Totowa Facility beyond the scheduled lease expiration on June 30, 2015. The retention plan is intended to minimize employee turnover by providing severance and retention bonuses that encourage employees to stay with us through facility closing date (and beyond for certain employees). The plan has two components: (1) plant management (three individuals) has received an award of stock options that will vest in full, and will be eligible for a retention bonus payable in June 2016, provided that they remain employed with us in June 2016; and (2) provided that they remain employed with us through the successful closure of the Totowa Facility, non-union employees (nine individuals) will be eligible to receive both severance and a retention bonus payable upon such closure. The total cash amount expected to be paid for severance and retention through June 2016 is approximately $1.0 million. The plan-related expense incurred during 2013 is $0.1 million and is included in research and development expense. The related liability is $0.1 million as of December 31, 2013.

In addition, there are 14 employees at the Totowa Facility who are subject to a collective bargaining agreement and will be eligible to receive severance upon closure of the Totowa Facility. The plan-related expense incurred during 2013 is $30,000 and is included in research and development expense. The related liability is $0.5 million as of December 31, 2013.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 15 – Litigation

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

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

Note 16 – Income Taxes

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

The reconciliation of the income tax benefit computed at the Federal statutory rates to our recorded tax benefit for the years ended December 31, 2013, 2012, and 2011 is as follows:

(in thousands)	December 31,		
	2013	2012	2011
Income tax benefit, statutory rates	$ 15,373	$ 12,687	$ 7,128
State taxes on income, net of Federal benefit	2,922	2,288	1,633
Research and development tax credit	517	332	662
Employee related	(766)	(988)	(1,758)
Warrant valuation related	259	189	1,210
Income tax benefit	18,305	14,508	8,875
Valuation allowance	(18,305)	(14,508)	(8,875)
Income tax benefit	$ –	$ –	$ –

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2013 and 2012, are as follows:

(in thousands)	December 31,	
	2013	2012
Long-term deferred tax assets:		
Net operating loss carryforwards (Federal and state)	$ 175,258	$ 160,522
Research and development tax credits	10,604	9,412
Compensation expense on stock	3,276	3,154
Charitable contribution carryforward	7	7
Inventory reserve	198	–
Deferred revenue	53	–
Other accrued	1,024	524
Depreciation	2,714	2,665
Capitalized research and development	1,326	1,516
Total long-term deferred tax assets	194,460	177,800
Less: valuation allowance	(194,460)	(177,800)
Deferred tax assets, net of valuation allowance	$ –	$ –

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

We are in a net deferred tax asset position at December 31, 2013 and 2012 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 our policy to classify interest and penalties recognized on uncertain tax positions as a component of income tax expense. There was neither interest nor penalties accrued as of December 31, 2013 or 2012, nor were any incurred in 2013, 2012, or 2011.

At December 31, 2013 and 2012, we had available carryforward net operating losses for Federal tax purposes of $432.1 million and $396.7 million, respectively, and a research and development tax credit carryforward of $10.6 million and $9.4 million, respectively. The Federal net operating loss and research and development tax credit carryforwards began to expire in 2008 and will continue through 2033.

At December 31, 2013, 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, 2013 and 2012, we had available carryforward losses of approximately $433.7 million and $392.6 million, respectively, for state tax purposes. Of the $433.7 million state tax carryforward losses, $399.5 million is associated with the state of Pennsylvania, with the remainder associated with the other 10 states within which we have established tax nexus.

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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 17 – Selected Quarterly Financial Data (Unaudited)

The following table contains unaudited statement of operations information for each quarter of 2013 and 2012. The operating results for any quarter are not necessarily indicative of results for any future period.

2013 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Grant revenues	$ 72	$ 182	$ 60	$ 74	$ 388
Expenses:					
Cost of sales	–	–	–	517	517
Research and development	8,472	6,863	6,574	5,752	27,661
Selling, General and administrative	4,220	4,129	4,299	4,070	16,718
Total expenses	12,692	10,992	10,873	10,339	44,896
Operating loss	(12,620)	(10,810)	(10,813)	(10,265)	(44,508)
Change in fair value of common stock warrant liability	162	2,525	(1,059)	(867)	761
Other expense, net	(177)	(342)	(352)	(597)	(1,468)
Net loss	$ (12,635)	$ (8,627)	$ (12,224)	$ (11,729)	$ (45,215)
Net loss per common share - basic	$ (0.29)	$ (0.18)	$ (0.22)	$ (0.16)	$ (0.82)
Net loss per common share - diluted	(0.29)	(0.22)	(0.22)	(0.16)	(0.82)
Weighted average number of common shares outstanding - basic	43,657	49,135	54,792	73,129	55,258
Weighted average number of common shares outstanding - diluted	43,657	49,866	54,792	73,129	55,258

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
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

Exhibit 10.15

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of April 1, 2013, by and between Discovery Laboratories, Inc., a Delaware corporation (the "Company"), and Russell G. Clayton ("Executive"), subject to the terms and conditions defined in this Agreement.

WHEREAS, the Company and Executive desire that Executive be employed by the Company to act as the Company's Senior Vice President, Research and Development, subject to the terms and conditions set forth in this Agreement. Executive's employment shall also be subject to such policies and procedures as the Company may from time to time implement;

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and Executive hereby agree as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through March 31, 2015; provided, however, that commencing on April 1, 2015 and on each April 1 thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such renewal date, either party shall have given notice that such party does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions hereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the expiration date of the then-current Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination. On the Date of Termination, Executive hereby resigns all employment and related job duties and responsibilities with the Company, including, without limitation any and all positions on any committees or boards of the Company or any affiliated company. Executive agrees to sign all documentation evidencing the foregoing as may be presented to Executive for signature by the Company.

3. Executive's Duties and Obligations.

(a) Duties. Executive shall serve as the Company's Senior Vice President, Research and Development. Executive shall be responsible for all duties customarily associated with a Senior Vice President, Research and Development in a publicly-traded company.

(b) Location of Employment. Executive's principal place of business shall be at the Company's headquarters to be located within thirty (30) miles of Warrington, Pennsylvania. In addition, Executive acknowledges and agrees that the performance by Executive of Executive's duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Matters. In consideration of the covenants contained herein, Executive has executed and agrees to be bound by the Company's standard form of Proprietary Information and Inventions, Non-Solicitation and Non-Competition Agreement (the "Confidentiality Agreement"), a form of which is attached to this Agreement as Exhibit B. Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During Executive's employment with the Company, Executive shall devote substantially all of Executive's time, attention and efforts to the proper performance of Executive's implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During Executive's employment with the Company, Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board of Directors of the Company (the "Board").

(c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity compete with the Company in the business of developing or commercializing (i) pulmonary surfactants or any other category of compounds which form the basis of the Company's material drug products, or (ii) any material medical device products under development by the Company, including without limitation the Company's capillary aerosol generator, series of aerosol-conducting airway connectors and related componentry, and similar medical devices; in each case, as determined in good faith by the Board on the Date of Termination. During the Term and for 18 months from the Date of Termination, Executive shall not solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the six (6) months preceding the Date of Termination; provided, that nothing herein shall prevent Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of Executive or (ii) if such discussions shall be held as a result of, or any employment shall be the result of, the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor.

(d) Injunctive Relief. In the event that Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to Executive (i) base annual compensation ("Base Salary"), effective as of April 1, 2013, of $288,500, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the Company. Executive's Base Salary shall not be subject to reduction from the level in effect hereunder from time to time, other than pursuant to a salary reduction program of general application to contract executives of the Company.

(b) Bonuses. During the Term, Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, based upon a target Annual Bonus Amount of 30% of Base Salary, as may be awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of a similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives of a similar level or to other employees (including, without limitation, profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. If a conflict should exist between similar benefits afforded under any Company policy and the benefits afforded under this Agreement, the Company policy shall control, except to the extent that this Agreement shall provide for greater benefits, in which event the terms of this Agreement shall control. Anything contained herein to the contrary notwithstanding, throughout the Term, Executive shall be entitled to receive life insurance on behalf of Executive's named beneficiaries in an amount equal to the lesser of (i) Executive's then current annual salary for the Term of this Agreement and (ii) if less, the maximum amount available under the Company's insurance program, at no cost to Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such insurance.

(d) Vacations. During the Term, Executive shall be entitled to 25 days paid vacation per year, or such greater amount as may be earned under the Company's standard vacation policy, to be earned ratably throughout the year. Vacation days may be carried from one year to the next in accordance with the Company vacation policy.

(e) Reimbursement of Business Expenses. Executive is authorized to incur reasonable expenses in carrying out Executive's duties and responsibilities under this Agreement and the Company shall reimburse Executive for all such expenses, in accordance with reasonable policies of the Company.

6. Change of Control Benefits.

(a) Bonus. Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period that is at least equal to the Annual Bonus Amount; provided, that Executive is employed on the last day of such fiscal year. Such bonuses will be paid no later than the 15th day of the third month following the end of such fiscal year.

(b) Options. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested and, with respect to restricted stock, all restrictions shall be lifted upon the Change of Control Date. In the case of any Change of Control in which holders of the Company's common stock receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) Executive shall be permitted to exercise Executive's options at a time and in a fashion that will entitle Executive to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by Executive without Good Reason, Death or Disability.

(i) In the event of a termination of Executive's employment by the Company for Cause, a termination by Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of Executive, Executive shall be entitled to any unpaid compensation accrued through the last day of Executive's employment, a lump sum payment in respect of all accrued but unused vacation days at Executive's Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to Executive but not yet paid, less any amounts owed by Executive to the Company. Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or Disability, notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms.

(b) Termination by the Company without Cause or by Executive for Good Reason. If (x) Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) Executive terminates employment with Good Reason, then Executive will receive the amounts set forth in Section 7(a)(i) and, on the condition that the Executive signs a separation agreement containing a plenary release of claims in a form acceptable to the Company within fifty (50) days after the Date of Termination (or such shorter period specified in such plenary release) and such plenary release becomes final, binding and irrevocable, the Executive shall also be entitled to receive the following from the Company:

(i) A pro rata bonus equal to the Executive's Annual Bonus Amount (A) multiplied by the fraction obtained by dividing the aggregate amount of actual bonuses paid to the Company's other employment contract executives for the year that includes the Date of Termination by such employment contract executives' aggregate target bonuses for the year that includes the Date of Termination, multiplied by (B) the fraction obtained by dividing the number of days in the year through the Date of Termination by 365, which amount shall be paid when the Company's other employment contract executives are paid;

(ii) An amount equal to 1 times the sum of (A) Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Annual Bonus Amount, payable in equal installments in accordance with the Company's regular payroll schedule, from the Date of Termination to the date that is 12 months after the Date of Termination (the "Severance Period") provided, however, that each installment payable before the plenary release becomes final, binding and irrevocable shall not be paid to the Executive until such plenary release becomes final, binding and irrevocable;

(iii) During the Severance Period, if Executive elects to continue Company medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Company shall continue to pay the Company's costs of such benefits as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company. If for any reason COBRA coverage is unavailable at any time during the Severance Period, the Company shall reimburse Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for Executive to purchase medical and dental coverage for Executive and Executive's dependents that is substantially equivalent to the medical and dental coverage that Executive and Executive's dependents were receiving immediately prior to the Date of Termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under the Company's plans. Company's obligation under this Section 7(b)(iii) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(iv) Upon the date that the plenary release becomes final, binding and irrevocable, notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and the Executive, all vested stock options to acquire Company stock and all other similar equity awards held by the Executive as of the Date of Termination shall continue to be exercisable during the Severance Period; and

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company.

Notwithstanding the foregoing, if Executive engages in a material breach of any provision of this Agreement or the Executive's Confidentiality Agreement during the Severance Period, and such breach is not cured within five business days after receipt from the Company of notice thereof, then the Company's continuing obligations under this Section 7(b) shall cease as of the date of the breach and the Executive shall be entitled to no further payments hereunder.

(c) Termination in connection with a Change of Control. If Executive's employment is terminated by the Company other than for Cause or by Executive for Good Reason during the Effective Period, then Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Annual Bonus Amount multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to 1.5 times the sum of (A) Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Annual Bonus Amount; provided, however, that if Executive's employment is terminated prior to the consummation of a Change of Control but under circumstances that would cause the Change of Control Date to precede the date that the Change of Control is consummated, such amount will be paid in equal installments in accordance with the Company's regular payroll schedule over the Severance Period described in Section 7(b)(ii);

(iv) If Executive elects to continue Company medical benefits under COBRA, for a period of 18 months following the Date of Termination (the "Benefit Period"), the Company shall continue to pay the Company's costs of such benefits as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company. If for any reason COBRA coverage is unavailable at any time during the Benefit Period, the Company shall reimburse Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for Executive to purchase medical and dental coverage for Executive and Executive's dependents that is substantially equivalent to the medical and dental coverage that Executive and Executive's dependents were receiving immediately prior to the Date of Termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under the Company's plans. Company's obligation under this Section 7(b)(iii) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms; and

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company.

Notwithstanding the foregoing, if Executive engages in a material breach of any provision of this Agreement or Executive's Confidentiality Agreement during the Severance Period, and such breach is not cured within five business days after receipt from the Company of notice thereof, then the Company's continuing obligations under this Section 7(c) shall cease as of the date of the breach and the Executive shall be entitled to no further payments or benefits hereunder.

8. Notice of Termination.

(a) Any termination of Executive's employment by the Company for Cause, or by Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination (at least 30 days in the case of Notice of Termination given by Executive for Good Reason), (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of Executive will not be deemed to be for Good Reason unless Executive gives the Notice of Termination provided for herein within 12 months after Executive has actual knowledge of the act or omission of the Company constituting such Good Reason and Executive gives the Company a 30 day cure period to rectify or correct the condition or event that constitutes Good Reason.

9. Mitigation of Damages. Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by Executive as the result of self-employment or employment by another employer or otherwise.

10. Excess Parachute Excise Tax.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), the Company will automatically reduce such Payments to the extent, but only to the extent, necessary so that no portion of the remaining Payments will be subject to the Excise Tax, unless the amount of such Payments that the Executive would retain after payment of the Excise Tax and all applicable Federal, state and local income taxes without such reduction would exceed the amount of such Payments that the Executive would retain after payment of all applicable Federal, state and local taxes after applying such reduction. Unless otherwise elected by the Executive, to the extent permitted under Code Section 409A, such reduction shall first be applied to any stock options, restricted stock or any other form of equity compensation (Equity Compensation") that is subject to exercise at a price per share that exceeds the closing price of the Company's common stock on the trading day immediately preceding the Change of Control, and thereafter pro rata among (i) severance payments payable to the Executive under this Agreement in reverse order of receipt, (ii) any remaining compensation in respect of Equity Compensation provided under this Agreement, starting with those options with the smallest spread between fair market value and exercise price first, and any restricted stock or restricted stock units, and (iii) any compensation related to continuation of benefits in reverse order of receipt.

(b) All determinations required to be made under this Section 10, including the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and Executive within 15 business days of the receipt of notice from Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. If the Accounting Firm determines that no Excise Tax is payable by Executive, it shall furnish Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and Executive.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

if to the Board or the Company:

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976
Attn: General Counsel

if to Executive:

The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this Agreement or any dispute or claim between Executive and the Company or its officers, directors, agents, or employees (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand." Such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The Dispute shall be resolved by a single arbitrator in an arbitration administered by the American Arbitration Association in accordance with its Employment Arbitration Rules and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The decision of the arbitrator shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrator may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Employment Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrator shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrator, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrator hereunder.

(iii) The arbitrator shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory and punitive damages if authorized by applicable law.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney’s fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge Executive with or without Cause.

18. Section 409A of the Code. The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from, Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be construed and interpreted in accordance with such intent. Executive's termination of employment (or words to similar effect) shall not be deemed to have occurred for purposes of this Agreement unless such termination of employment constitutes a "separation from service" within the meaning of Code Section 409A and the regulations and other guidance promulgated thereunder.

(a) Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed on the date of Executive's termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B) and using the identification methodology selected by the Company from time to time, or if none, the default methodology set forth in Code Section 409A, then with regard to any payment or the providing of any benefit that constitutes "non-qualified deferred compensation" pursuant to Code Section 409A and the regulations issued thereunder that is payable due to Executive's separation from service, to the extent required to be delayed in compliance with Code Section 409A(a)(2)(B), such payment or benefit shall not be made or provided to Executive prior to the earlier of (i) the expiration of the six (6) month period measured from the date of Executive's separation from service, and (ii) the date of Executive's death (the "Delay Period"). On the first day of the seventh month following the date of Executive's separation from service or, if earlier, on the date of Executive's death, all payments delayed pursuant to this Section 18(a) shall be paid or reimbursed to Executive in a lump sum, and any remaining payments and benefits due to Executive under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(b) To the extent any reimbursement of costs and expenses provided for under this Agreement constitutes taxable income to Executive for Federal income tax purposes, such reimbursements shall be made no later than December 31 of the calendar year next following the calendar year in which the expenses to be reimbursed are incurred. With regard to any provision herein that provides for reimbursement of expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year. Any tax gross-ups provided for under this Agreement shall in no event be paid to Executive later than the December 31 of the calendar year following the calendar year in which the taxes subject to gross-up are incurred or paid by Executive.

(c) If any amount under this Agreement is to be paid in two or more installments, for purposes of Code Section 409A each installment shall be treated as a separate payment.

19. Executive Acknowledgement. Executive hereby acknowledges that Executive has read and understands the provisions of this Agreement, that Executive has been given the opportunity for Executive's legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that Executive has received a copy of this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Employment Agreement to be executed as of the date first above written.

Discovery Laboratories, Inc.

By: /s/ Kathryn A. Cole
Name: Kathryn A. Cole
Title: Senior Vice President, Human Resources

/s/ Russell Clayton
04/01/13

EXHIBIT A

(a) **"Annual Bonus Amount"** means the current year's target annual bonus amount for the Executive.

(b) **"Beneficiary"** means any individual, trust or other entity named by Executive to receive the payments and benefits payable hereunder in the event of the death of Executive. Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by Executive, or if no designated Beneficiary survives Executive, then the payment and benefits provided under this Agreement, if any, will be paid to Executive's estate, which shall be deemed to be Executive's Beneficiary.

(c) **"Cause"** means: (i) Executive's willful and continued neglect of Executive's duties with the Company (other than as a result of Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to Executive by the Company which specifically identifies the manner in which the Company believes that Executive has neglected his duties; (ii) the final conviction of Executive of, or an entering of a guilty plea or a plea of no contest by Executive to, a felony; or (iii) Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of Executive shall be considered "willful" unless it is done, or omitted to be done, by Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board, or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interests of the Company.

(d) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly (x) acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing more than 50% of the combined voting power of the Company's then outstanding securities or; (y) acquires within a 12 consecutive month period "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who comprise a majority of the Board are replaced during any 12 consecutive month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of such appointment or election;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, 50% or more of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) any "person" (as defined in Sections 13(d) and 14(d) of the Exchange Act) acquires all or substantially all of the assets of the Company within any 12 consecutive month period.

Notwithstanding the foregoing, none of the foregoing events shall constitute a Change of Control of the Company unless such event also constitutes a change in ownership of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(v), a change in the effective control of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(vi) or a change in ownership of a substantial portion of the assets of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(vii).

(e) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(f) **"Code"** means the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

(g) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(h) **"Disability"** means a mental or physical condition that renders Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give Executive at least 30 days' written notice that it considers the time period for disability to be running.

(i) **"Effective Period"** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.

(j) **"Good Reason"** means, unless Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to Executive of any duties materially inconsistent with Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a material reduction in Executive's Base Salary by the Company; (iii) the relocation of Executive's office to a location more than 30 miles from Warrington, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); or (v) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

EXHIBIT B

FORM OF
PROPRIETARY INFORMATION AND INVENTIONS,
NON-SOLICITATION AND
NON-COMPETITION AGREEMENT

The following is an agreement ("Agreement") between Discovery Laboratories, Inc., a Delaware corporation (the "Company"), and any successor in interest, and me, [Executive], and this Agreement is a material part of the consideration for my employment by the Company:

1. Job Title and Responsibility: I understand that my job title with the Company will be Senior Vice President, Research and Development and that the Company may change this title at any time. My job duties and responsibilities will be those assigned to me by the Company from time to time.

2. Consideration. I understand that the consideration to me for entering into this Agreement is my employment with the Company at my base salary of $288,750, and I agree that this consideration is fully adequate to support this Agreement.

3. Proprietary Information. I recognize that the Company is engaged in a continuous program of research, development and production. I also recognize that the Company possesses or has rights to secret, private, confidential information and processes (including processes and information developed by me during my employment by the Company) which are valuable, special and unique assets of the Company and which have commercial value in the Company's business ("Proprietary Information"). By way of illustration, this Proprietary Information includes, but is not limited to, information and details regarding the Company's business, trade or business secrets, inventions, intellectual property, systems, policies, records, reports, manuals, documentation, models, data and data bases, products, processes, operating systems, manufacturing techniques, research and development techniques and processes, devices, methods, formulas, compositions, compounds, projects, developments, plans, research, financial data, personnel data, internal business information, strategic and staffing plans and practices, business, marketing, promotional or sales plans, practices or programs, training practices and programs, costs, rates and pricing structures and business methods, computer programs and software, customer and supplier identities, information and lists, confidential information regarding customers and suppliers, and contacts at or knowledge of Company suppliers and customers or of prospective or potential customers of the Company.

4. Obligation of Confidentiality. I understand and agree that my employment creates a relationship of confidence and trust between the Company and me with respect to (i) all Proprietary Information, and (ii) the confidential information of others with which the Company has a business relationship. At all times, both during my employment by the Company and after the termination of my employment (whether voluntary or involuntary), I will keep in confidence and trust all such information, and I will not use, reveal, communicate, or disclose any such Proprietary Information or confidential information to anyone or any entity, without the written consent of the Company, unless I am ordered to make disclosure by a court of competent jurisdiction.

5. Ownership, Disclosure and Assignment of Proprietary Information and Inventions. In addition, I hereby agree as follows:

(a) Ownership and Assignment. All Proprietary Information is, and shall be, the sole and exclusive property of the Company and its assigns, and the Company and its assigns shall be the sole and exclusive owner of all Proprietary Information, including, but not limited to, trade secrets, inventions, patents, trademarks, copyrights, and all other rights in connection with such Proprietary Information. I agree that I have no rights in such Proprietary Information. I hereby assign, and shall assign, to the Company and its assigns any and all rights, title and interest I may have or acquire in such Proprietary Information. Any copyrightable work prepared in whole or in part by me in the course of my employment shall be deemed "a work made for hire" under applicable copyright laws, and the Company and its assigns shall own all of the rights in any copyright.

(b) Return of Materials and Property. All documents, records, apparatus, equipment, data bases, data and information stored in computers or on electronic disks, and other electronic, computer, intellectual, and physical property ("Materials and Property"), whether or not pertaining to Proprietary Information, furnished to me by the Company or produced by me or others in connection with employment, shall be and remain the sole and exclusive property of the Company. I shall return to the Company all such Materials and Property as and when requested by the Company. Even if the Company does not so request, I shall return all such Materials and Property upon termination of employment by me or by the Company for any reason, and I will not take with me any such Materials or Property, or any reproduction thereof, upon such termination.

(c) Notification. During the term of my employment and for one (1) year thereafter, I will promptly disclose to the Company, or any persons designated by it, all improvements, inventions, intellectual property, works of authorship, formulas, ideas, processes, techniques, discoveries, developments, designs, innovations, know-how and data, and creative works in which copyright and/or unregistered design rights will subsist in various media (all collectively called herein, "Inventions"), whether or not such Inventions are patentable, which I make or conceive, contribute to, reduce to practice, or learn, either alone or jointly with others.

(d) Ownership of Inventions. I agree and acknowledge that all Inventions which I make, conceive, develop, or reduce to practice (in whole or in part, either alone or jointly with others) at any time during my employment by the Company, and (i) which were created using the equipment, supplies, facilities or trade secret information of the Company, or (ii) which were developed during the hours for which I was compensated by the Company, or (iii) which relate, at the time of conception, creation, development or reduction to practice, to the business of the Company or to its actual or demonstrably anticipated research and development, or (iv) which result from any work performed by me for the Company, shall be the sole and exclusive property of the Company and its assigns (and to the fullest extent permitted by law shall be deemed works made for hire), and the Company and its assigns shall be the sole and exclusive owner of all Inventions, patents, copyrights and all other rights in connection therewith. I hereby assign to the Company any and all rights I may have or acquire in such Inventions. I agree that any Invention required to be disclosed under paragraph (c), above, within one (1) year after the termination of my employment shall be presumed to have been conceived or made during my employment with the Company and will be assigned to the Company unless and until I prove and establish to the contrary.

(e) Assistance and Cooperation. With respect to Inventions described in paragraph (d), above, I will assist the Company in every proper way (but at the Company's expense) to obtain, and from time to time enforce, patents, copyrights or other rights on these Inventions in any and all countries, and will execute all documents reasonably necessary or appropriate for this purpose. This obligation shall survive the termination of my employment. In the event that the Company is unable for any reason whatsoever to secure my signature to any document reasonably necessary or appropriate for any of the foregoing purposes (including renewals, extensions, continuations, divisions or continuations in part), I hereby irrevocably designate and appoint the Company, and its duly authorized officers and agents, as my agents and attorneys-in-fact to act for and in my behalf and instead of me, but only for the purpose of executing and filing any such document and doing all other lawfully permitted acts to accomplish the foregoing purposes with the same legal force and effect as if executed by me.

(f) Exempt Inventions. I understand that this Agreement does not require assignment of an Invention for which no equipment, supplies, facilities, resources, or trade secret information of the Company was used and which was developed entirely by me on my own time, unless the invention relates, (i) directly to the business of the Company, or (ii) to the Company's actual or demonstrably anticipated research or development. However, I will disclose to the Company any Inventions I claim are exempt, as required by paragraph (c), above, in order to permit the Company to determine such issues as may arise. Such disclosure shall be received in confidence by the Company.

6. Prior Inventions. As a matter of record I attach hereto as Exhibit A a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company which have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment with the Company, that I desire to remove from the operation of this Agreement, and I covenant that such list is complete. If no such list is attached to this Agreement, I represent that I have no such inventions and improvements at the time of my signing this Agreement.

7. Other Business Activities. So that the Company may be aware of the extent of any other demands upon my time and attention, I will disclose to the Company (such disclosure to be held in confidence by the Company) the nature and scope of any other business activity in which I am or become engaged during the term of my employment. During the term of my employment, I will not engage in any business activity or employment which is in competition with, or is related to, the Company's business or its actual or demonstrably anticipated research and development, or that will affect in any manner my ability to perform fully all of my duties and responsibilities for the Company.

8. Non-Interference and Non-Solicitation of Employees, Customers and Others. I will not now or at any time in the future disrupt, damage, impair or interfere with the business of the Company, whether by way of interfering with or raiding its employees, disrupting its relationships with customers, agents, vendors, distributors or representatives, or otherwise. During my employment with the Company and for eighteen (18) months thereafter, I will not directly or indirectly induce, encourage or solicit any employee of the Company to leave the Company for any reason, unless specifically requested to take such action in writing by the Company.

9. Non-Competition During and After Employment. I agree that the time and activity restrictions in this paragraph are wholly necessary and are reasonable to protect the legitimate business interests of the Company. During my employment with the Company or at any time within a period of one (1) year after the termination of my employment (whether the termination is by me or the Company), I will not directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity, compete with the Company in the business of developing or commercializing pulmonary surfactants.

10. Obligations to Former Employers. I represent that my execution of this Agreement, my employment with the Company, and my performance of my duties and proposed duties to the Company will not violate any obligations or agreements I have, or may have, with any former employer or any other third party, including any obligations and agreements requiring me not to compete or to keep confidential any proprietary or confidential information. I have not entered into, and I will not enter into, any agreement which conflicts with this Agreement or that would, if performed by me, cause me to breach this Agreement. I further represent that I have no knowledge of any pending or threatened litigation to which the Company may become a party by virtue of my association with the Company. I further agree to immediately inform the Company of any such pending or threatened litigation should it come to my attention during the course of my employment. I also agree that I provided to the Company for its inspection before I signed this Agreement all confidentiality, non-compete, non-solicitation, and all other employment-related agreements that I am party to or which involve me.

11. Confidential Information of, and Agreements with, Former Employers. In the course of performing my duties to the Company, I will not utilize any trade secrets, proprietary or confidential information of or regarding any former employer or business affiliate, nor violate any written or oral, express or implied agreement with any former employer or business affiliate.

12. United States Government Obligations. I acknowledge that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to be bound by all such obligations and restrictions which are made known to me and to take all action necessary to discharge the obligations of the Company under such agreements.

13. Remedies. I acknowledge that my failure to comply with, or my breach of, any of the terms and conditions of this Agreement shall irreparably harm the Company, and that money damages would not adequately compensate the Company for this harm. Accordingly, I acknowledge that in the event of a threatened or actual breach by me of any provision of this Agreement, in addition to any other remedies the Company may have at law, the Company shall be entitled to equitable relief in the form of specific performance, temporary restraining order, temporary or permanent injunction or any other equitable remedy then available, without requiring the Company to post any bond. I agree that nothing herein contained shall be construed as prohibiting the Company from pursuing any other remedies available to it for such threatened or actual breach, including money damages, and I agree that the Company shall be entitled to recover from me any attorney's fees it incurs in enforcing the terms of this Agreement.

14. Not an Employment Agreement. I acknowledge and agree that this Agreement is not a contract of employment, that it should not be construed as a guarantee of my employment for any period of time, and that I am employed by the Company at will and my employment may be terminated by the Company for any lawful reason or no reason.

15. Miscellaneous.

(a) Reformation and Severability. If any provision of this Agreement is held to be invalid or unenforceable under applicable law, such provision shall be reformed and/or construed, if possible, to be enforceable under applicable law; otherwise, such provision shall be excluded from this Agreement and the balance of the Agreement shall remain fully enforceable and valid in accordance with its terms.

(b) No Waiver. No delay or omission by the Company in exercising any right hereunder will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(c) Reassignment. I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employment I may be transferred, without the necessity that this Agreement be reassigned at the time of such transfer.

(d) Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania (but not the law or principles of conflict of laws), and the parties submit to the jurisdiction of the courts of Pennsylvania.

(e) Effective Date. This Agreement shall be effective as of the first day of my employment by the Company, shall be binding upon me, my heirs, executors, assigns and administrators, and shall inure to the benefit of the Company, its successors and assigns.

(f) Entire Agreement. This Agreement contains the entire agreement of the parties relating to the subject matter herein, and may not be waived, changed, extended or discharged except by an agreement in writing signed by both parties.

(g) ACKNOWLEDGEMENT. I acknowledge and agree that I have fully read and that I understand all of the terms and provisions of this Agreement, that I have had the opportunity to consult with an attorney and to discuss this Agreement with an attorney, that I have had any questions regarding the effect of this Agreement or the meaning of its terms answered to my satisfaction, and, intending to be legally bound hereby, I freely and voluntarily sign this Agreement.

Accepted and Agreed to:	DISCOVERY LABORATORIES, INC.
Name: _____	By: _____
Date: _____	Name: _____
SS#: _____	Title: _____

EXHIBIT A

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976

Attn:

1. The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by Discovery Laboratories, Inc. (the "Company") that have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment by the Company that I desire to remove from the operation of the Company's Proprietary Information and Inventions, Non-Solicitation and Non-Competition Agreement.

_____ No inventions or improvements.

_____ See below: Any and all inventions regarding

_____ Additional sheets attached.

2. I propose to bring to my employment the following materials and documents of a former employer:

_____ No materials or documents.

_____ See below:

_____

_____
Date

Exhibit 10.16

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made as of April 1, 2013, by and between Discovery Laboratories, Inc., a Delaware corporation (the "Company"), and Mary B. Templeton ("Executive"), subject to the terms and conditions defined in this Agreement.

WHEREAS, the Company and Executive desire that Executive be employed by the Company to act as the Company's Senior Vice President, General Counsel and Corporate Secretary, subject to the terms and conditions set forth in this Agreement. Executive's employment shall also be subject to such policies and procedures as the Company may from time to time implement;

NOW, THEREFORE, in consideration of the covenants contained herein, and for other valuable consideration, the Company and Executive hereby agree as follows:

1. Certain Definitions. Certain definitions used herein shall have the meanings set forth on Exhibit A attached hereto.

2. Term of the Agreement. The term ("Term") of this Agreement shall commence on the date first above written and shall continue through March 31, 2015; provided, however, that commencing on April 1, 2015 and on each April 1 thereafter, the term of this Agreement shall automatically be extended for one additional year, unless at least 90 days prior to such renewal date, either party shall have given notice that such party does not wish to extend this Agreement. Upon the occurrence of a Change of Control during the term of this Agreement, including any extensions hereof, this Agreement shall automatically be extended until the end of the Effective Period if the end of the Effective Period is after the expiration date of the then-current Term. Notwithstanding the foregoing, this Agreement shall terminate prior to the scheduled expiration date of the Term on the Date of Termination. On the Date of Termination, Executive hereby resigns all employment and related job duties and responsibilities with the Company, including, without limitation any and all positions on any committees or boards of the Company or any affiliated company. Executive agrees to sign all documentation evidencing the foregoing as may be presented to Executive for signature by the Company.

3. Executive's Duties and Obligations.

(a) Duties. Executive shall serve as the Company's Senior Vice President, General Counsel and Corporate Secretary. Executive shall be responsible for all duties customarily associated with a Senior Vice President, General Counsel and Corporate Secretary in a publicly-traded company.

(b) Location of Employment. Executive's principal place of business shall be at the Company's headquarters to be located within thirty (30) miles of Warrington, Pennsylvania. In addition, Executive acknowledges and agrees that the performance by Executive of Executive's duties shall require frequent travel including, without limitation, overseas travel from time to time.

(c) Proprietary Information and Inventions Matters. In consideration of the covenants contained herein, Executive has executed and agrees to be bound by the Company's standard form of Proprietary Information and Inventions, Non-Solicitation and Non-Competition Agreement (the "Confidentiality Agreement"), a form of which is attached to this Agreement as Exhibit B. Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

4. Devotion of Time to Company's Business.

(a) Full-Time Efforts. During Executive's employment with the Company, Executive shall devote substantially all of Executive's time, attention and efforts to the proper performance of Executive's implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

(b) No Other Employment. During Executive's employment with the Company, Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board of Directors of the Company (the "Board").

(c) Non-Competition During and After Employment. During the Term and for 12 months from the Date of Termination, Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity compete with the Company in the business of developing or commercializing (i) pulmonary surfactants or any other category of compounds which form the basis of the Company's material drug products, or (ii) any material medical device products under development by the Company, including without limitation the Company's capillary aerosol generator, series of aerosol-conducting airway connectors and related componentry, and similar medical devices; in each case, as determined in good faith by the Board on the Date of Termination. During the Term and for 18 months from the Date of Termination, Executive shall not solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the six (6) months preceding the Date of Termination; provided, that nothing herein shall prevent Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of Executive or (ii) if such discussions shall be held as a result of, or any employment shall be the result of, the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor.

(d) Injunctive Relief. In the event that Executive breaches any provisions of Section 4(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 4(c) or the Confidentiality Agreement, Executive shall not urge as a defense that there is an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

(e) Reformation. To the extent that the restrictions imposed by Section 4(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

5. Compensation and Benefits.

(a) Base Compensation. During the Term, the Company shall pay to Executive (i) base annual compensation ("Base Salary"), effective as of April 1, 2013, of $267,800, payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 5. Executive's Base Salary shall be reviewed annually and may be increased based on an assessment of Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that any increase in Base Salary shall be solely within the discretion of the Company. Executive's Base Salary shall not be subject to reduction from the level in effect hereunder from time to time, other than pursuant to a salary reduction program of general application to contract executives of the Company.

(b) Bonuses. During the Term, Executive shall be eligible for such year-end bonus, which may be paid in either cash or equity, or both, based upon a target Annual Bonus Amount of 30% of Base Salary, as may be awarded solely at the discretion of the Compensation Committee of the Board after consultation with the Company's Chief Executive Officer, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year. Any such equity bonus shall contain such rights and features as are typically afforded to other Company employees of a similar level in connection with comparable equity bonuses awarded by the Company.

(c) Benefits. During the Term, Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives of a similar level or to other employees (including, without limitation, profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfunded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. If a conflict should exist between similar benefits afforded under any Company policy and the benefits afforded under this Agreement, the Company policy shall control, except to the extent that this Agreement shall provide for greater benefits, in which event the terms of this Agreement shall control. Anything contained herein to the contrary notwithstanding, throughout the Term, Executive shall be entitled to receive life insurance on behalf of Executive's named beneficiaries in an amount equal to the lesser of (i) Executive's then current annual salary for the Term of this Agreement and (ii) if less, the maximum amount available under the Company's insurance program, at no cost to Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such insurance.

(d) Vacations. During the Term, Executive shall be entitled to 25 days paid vacation per year, or such greater amount as may be earned under the Company's standard vacation policy, to be earned ratably throughout the year. Vacation days may be carried from one year to the next in accordance with the Company vacation policy.

(e) Reimbursement of Business Expenses. Executive is authorized to incur reasonable expenses in carrying out Executive's duties and responsibilities under this Agreement and the Company shall reimburse Executive for all such expenses, in accordance with reasonable policies of the Company.

6. Change of Control Benefits.

(a) Bonus. Executive shall be awarded an annual cash bonus for each fiscal year of the Company ending during the Effective Period that is at least equal to the Annual Bonus Amount; provided, that Executive is employed on the last day of such fiscal year. Such bonuses will be paid no later than the 15th day of the third month following the end of such fiscal year.

(b) Options. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested and, with respect to restricted stock, all restrictions shall be lifted upon the Change of Control Date. In the case of any Change of Control in which holders of the Company's common stock receive cash, securities or other consideration in exchange for, or in respect of, their Company common stock, (i) Executive shall be permitted to exercise Executive's options at a time and in a fashion that will entitle Executive to receive, in exchange for any shares acquired pursuant to any such exercise, the same per share consideration as is received by the other holders of the Company's common stock, and (ii) if Executive shall elect not to exercise all or any portion of such options, any such unexercised options shall terminate and cease to be outstanding following such Change of Control, except to the extent assumed by a successor corporation (or its parent) or otherwise expressly continued in full force and effect pursuant to the terms of such Change of Control.

7. Termination of Employment.

(a) Termination by the Company for Cause or Termination by Executive without Good Reason, Death or Disability.

(i) In the event of a termination of Executive's employment by the Company for Cause, a termination by Executive without Good Reason, or in the event this Agreement terminates by reason of the death or Disability of Executive, Executive shall be entitled to any unpaid compensation accrued through the last day of Executive's employment, a lump sum payment in respect of all accrued but unused vacation days at Executive's Base Salary in effect on the date such vacation was earned, and payment of any other amounts owing to Executive but not yet paid, less any amounts owed by Executive to the Company. Executive shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

(ii) In the case of a termination due to death or Disability, notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms.

(b) Termination by the Company without Cause or by Executive for Good Reason. If (x) Executive's employment is terminated by the Company other than for Cause, death or Disability (i.e., without Cause) or (y) Executive terminates employment with Good Reason, then Executive will receive the amounts set forth in Section 7(a)(i) and, on the condition that the Executive signs a separation agreement containing a plenary release of claims in a form acceptable to the Company within fifty (50) days after the Date of Termination (or such shorter period specified in such plenary release) and such plenary release becomes final, binding and irrevocable, the Executive shall also be entitled to receive the following from the Company:

(i) A pro rata bonus equal to the Executive's Annual Bonus Amount (A) multiplied by the fraction obtained by dividing the aggregate amount of actual bonuses paid to the Company's other employment contract executives for the year that includes the Date of Termination by such employment contract executives' aggregate target bonuses for the year that includes the Date of Termination, multiplied by (B) the fraction obtained by dividing the number of days in the year through the Date of Termination by 365, which amount shall be paid when the Company's other employment contract executives are paid;

(ii) An amount equal to 1 times the sum of (A) Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Annual Bonus Amount, payable in equal installments in accordance with the Company's regular payroll schedule, from the Date of Termination to the date that is 12 months after the Date of Termination (the "Severance Period") provided, however, that each installment payable before the plenary release becomes final, binding and irrevocable shall not be paid to the Executive until such plenary release becomes final, binding and irrevocable;

(iii) During the Severance Period, if Executive elects to continue Company medical benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), the Company shall continue to pay the Company's costs of such benefits as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company. If for any reason COBRA coverage is unavailable at any time during the Severance Period, the Company shall reimburse Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for Executive to purchase medical and dental coverage for Executive and Executive's dependents that is substantially equivalent to the medical and dental coverage that Executive and Executive's dependents were receiving immediately prior to the Date of Termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under the Company's plans. Company's obligation under this Section 7(b)(iii) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(iv) Upon the date that the plenary release becomes final, binding and irrevocable, notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and the Executive, all vested stock options to acquire Company stock and all other similar equity awards held by the Executive as of the Date of Termination shall continue to be exercisable during the Severance Period; and

(v) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company.

Notwithstanding the foregoing, if Executive engages in a material breach of any provision of this Agreement or the Executive's Confidentiality Agreement during the Severance Period, and such breach is not cured within five business days after receipt from the Company of notice thereof, then the Company's continuing obligations under this Section 7(b) shall cease as of the date of the breach and the Executive shall be entitled to no further payments hereunder.

(c) Termination in connection with a Change of Control. If Executive's employment is terminated by the Company other than for Cause or by Executive for Good Reason during the Effective Period, then Executive shall be entitled to receive the following from the Company:

(i) All amounts and benefits described in Section 7(a)(i) above;

(ii) Within 10 days after the Date of Termination, a lump sum cash payment equal to the Annual Bonus Amount multiplied by the fraction obtained by dividing the number of days in the year through the Date of Termination by 365;

(iii) Within 10 days after the Date of Termination, a lump sum cash payment in an amount equal to 1.5 times the sum of (A) Executive's Base Salary then in effect (determined without regard to any reduction in such Base Salary constituting Good Reason) and (B) the Annual Bonus Amount; provided, however, that if Executive's employment is terminated prior to the consummation of a Change of Control but under circumstances that would cause the Change of Control Date to precede the date that the Change of Control is consummated, such amount will be paid in equal installments in accordance with the Company's regular payroll schedule over the Severance Period described in Section 7(b)(ii);

(iv) If Executive elects to continue Company medical benefits under COBRA, for a period of 18 months following the Date of Termination (the "Benefit Period"), the Company shall continue to pay the Company's costs of such benefits as Executive elects to continue under the same plans and on the same terms and conditions as such benefits are provided to active employees of the Company. If for any reason COBRA coverage is unavailable at any time during the Benefit Period, the Company shall reimburse Executive no less frequently than quarterly in advance an amount which, after taxes, is sufficient for Executive to purchase medical and dental coverage for Executive and Executive's dependents that is substantially equivalent to the medical and dental coverage that Executive and Executive's dependents were receiving immediately prior to the Date of Termination and that is available to comparable active employees, reduced by the amount that would be paid by comparable active employees for such coverage under the Company's plans. Company's obligation under this Section 7(b)(iii) shall terminate or be reduced to the extent that substantially similar coverages (determined on a benefit-by-benefit basis) are provided by a subsequent employer;

(v) Notwithstanding any provision to the contrary in any stock option or restricted stock agreement between the Company and Executive, all shares of stock and all options to acquire Company stock held by Executive shall accelerate and become fully vested upon the Date of Termination (and all options shall thereupon become fully exercisable), and all stock options shall continue to be exercisable for the remainder of their stated terms; and

(vi) Any other additional benefits then due or earned in accordance with applicable plans and programs of the Company.

Notwithstanding the foregoing, if Executive engages in a material breach of any provision of this Agreement or Executive's Confidentiality Agreement during the Severance Period, and such breach is not cured within five business days after receipt from the Company of notice thereof, then the Company's continuing obligations under this Section 7(c) shall cease as of the date of the breach and the Executive shall be entitled to no further payments or benefits hereunder.

8. Notice of Termination.

(a) Any termination of Executive's employment by the Company for Cause, or by Executive for Good Reason shall be communicated by a Notice of Termination to the other party hereto given in accordance with Section 12. For purposes of this Agreement, a "Notice of Termination" means a written notice which: (i) is given at least 10 days prior to the Date of Termination (at least 30 days in the case of Notice of Termination given by Executive for Good Reason), (ii) indicates the specific termination provision in this Agreement relied upon, (iii) to the extent applicable, sets forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, and (iv) specifies the employment termination date. The failure to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Good Reason or Cause will not waive any right of the party giving the Notice of Termination hereunder or preclude such party from asserting such fact or circumstance in enforcing its rights hereunder.

(b) A Termination of Employment of Executive will not be deemed to be for Good Reason unless Executive gives the Notice of Termination provided for herein within 12 months after Executive has actual knowledge of the act or omission of the Company constituting such Good Reason and Executive gives the Company a 30 day cure period to rectify or correct the condition or event that constitutes Good Reason.

9. Mitigation of Damages. Executive will not be required to mitigate damages or the amount of any payment or benefit provided for under this Agreement by seeking other employment or otherwise. Except as otherwise provided in Sections 7(b)(iv) and 7(c)(iv), the amount of any payment or benefit provided for under this Agreement will not be reduced by any compensation or benefits earned by Executive as the result of self-employment or employment by another employer or otherwise.

10. Excess Parachute Excise Tax.

(a) Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment, award, benefit or distribution (including any acceleration) by the Company or any entity which effectuates a transaction described in Section 280G(b)(2)(A)(i) of the Code to or for the benefit of Executive (whether pursuant to the terms of this Agreement or otherwise, but determined without regard to any additional payments required under this Section 10) (a "Payment") would be subject to the excise tax imposed by Section 4999 of the Code or any interest or penalties are incurred with respect to such excise tax by Executive (such excise tax, together with any such interest and penalties, are hereinafter collectively referred to as the "Excise Tax"), the Company will automatically reduce such Payments to the extent, but only to the extent, necessary so that no portion of the remaining Payments will be subject to the Excise Tax, unless the amount of such Payments that the Executive would retain after payment of the Excise Tax and all applicable Federal, state and local income taxes without such reduction would exceed the amount of such Payments that the Executive would retain after payment of all applicable Federal, state and local taxes after applying such reduction. Unless otherwise elected by the Executive, to the extent permitted under Code Section 409A, such reduction shall first be applied to any stock options, restricted stock or any other form of equity compensation (Equity Compensation") that is subject to exercise at a price per share that exceeds the closing price of the Company's common stock on the trading day immediately preceding the Change of Control, and thereafter pro rata among (i) severance payments payable to the Executive under this Agreement in reverse order of receipt, (ii) any remaining compensation in respect of Equity Compensation provided under this Agreement, starting with those options with the smallest spread between fair market value and exercise price first, and any restricted stock or restricted stock units, and (iii) any compensation related to continuation of benefits in reverse order of receipt.

(b) All determinations required to be made under this Section 10, including the assumptions to be utilized in arriving at such determination, shall be made by the Company's independent auditors or such other certified public accounting firm of national standing reasonably acceptable to Executive as may be designated by the Company (the "Accounting Firm") which shall provide detailed supporting calculations both to the Company and Executive within 15 business days of the receipt of notice from Executive that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. If the Accounting Firm determines that no Excise Tax is payable by Executive, it shall furnish Executive with a written opinion to such effect, and to the effect that failure to report the Excise Tax, if any, on Executive's applicable federal income tax return will not result in the imposition of a negligence or similar penalty. Any determination by the Accounting Firm shall be binding upon the Company and Executive.

11. Legal Fees. All reasonable legal fees and related expenses (including costs of experts, evidence and counsel) paid or incurred by Executive pursuant to any claim, dispute or question of interpretation relating to this Agreement shall be paid or reimbursed by the Company if Executive is successful on the merits pursuant to a legal judgment or arbitration. Except as provided in this Section 11, each party shall be responsible for its own legal fees and expenses in connection with any claim or dispute relating to this Agreement.

12. Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand or mailed within the continental United States by first class certified mail, return receipt requested, postage prepaid, addressed as follows:

if to the Board or the Company:

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976
Attn: General Counsel

if to Executive:

The address on file with the records of the Company

Addresses may be changed by written notice sent to the other party at the last recorded address of that party.

13. Withholding. The Company shall be entitled to withhold from payments due hereunder any required federal, state or local withholding or other taxes.

14. Entire Agreement. This Agreement contains the entire agreement between the parties with respect to the subject matter hereof and supersedes the Employment Agreement and all other prior agreements, written or oral, with respect thereto.

15. Arbitration.

(a) If the parties are unable to resolve any dispute or claim relating directly or indirectly to this Agreement or any dispute or claim between Executive and the Company or its officers, directors, agents, or employees (a "Dispute"), then either party may require the matter to be settled by final and binding arbitration by sending written notice of such election to the other party clearly marked "Arbitration Demand." Such Dispute shall be arbitrated in accordance with the terms and conditions of this Section 15. Notwithstanding the foregoing, either party may apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm.

(b) The Dispute shall be resolved by a single arbitrator in an arbitration administered by the American Arbitration Association in accordance with its Employment Arbitration Rules and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The decision of the arbitrator shall be final and binding on the parties, and specific performance giving effect to the decision of the arbitrator may be ordered by any court of competent jurisdiction.

(c) Nothing contained herein shall operate to prevent either party from asserting counterclaim(s) in any arbitration commenced in accordance with this Agreement, and any such party need not comply with the procedural provisions of this Section 15 in order to assert such counterclaim(s).

(d) The arbitration shall be filed with the office of the American Arbitration Association ("AAA") located in New York, New York or such other AAA office as the parties may agree upon (without any obligation to so agree). The arbitration shall be conducted pursuant to the Employment Arbitration Rules of AAA as in effect at the time of the arbitration hearing, such arbitration to be completed in a 60-day period. In addition, the following rules and procedures shall apply to the arbitration:

(i) The arbitrator shall have the sole authority to decide whether or not any Dispute between the parties is arbitrable and whether the party presenting the issues to be arbitrated has satisfied the conditions precedent to such party's right to commence arbitration as required by this Section 15.

(ii) The decision of the arbitrator, which shall be in writing and state the findings, the facts and conclusions of law upon which the decision is based, shall be final and binding upon the parties, who shall forthwith comply after receipt thereof. Judgment upon the award rendered by the arbitrator may be entered by any competent court. Each party submits itself to the jurisdiction of any such court, but only for the entry and enforcement to judgment with respect to the decision of the arbitrator hereunder.

(iii) The arbitrator shall have the power to grant all legal and equitable remedies (including, without limitation, specific performance) and award compensatory and punitive damages if authorized by applicable law.

(iv) Except as provided in Section 11, the parties shall bear their own costs in preparing for and participating in the resolution of any Dispute pursuant to this Section 15, and the costs of the arbitrator(s) shall be equally divided between the parties.

(v) Except as provided in the last sentence of Section 15(a), the provisions of this Section 15 shall be a complete defense to any suit, action or proceeding instituted in any federal, state or local court or before any administrative tribunal with respect to any Dispute arising in connection with this Agreement. Any party commencing a lawsuit in violation of this Section 15 shall pay the costs of the other party, including, without limitation, reasonable attorney’s fees and defense costs.

16. Miscellaneous.

(a) Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the State of New York without regard to the application of choice of law rules.

(b) Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

(c) Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the beneficiaries, heirs and representatives of Executive (including the Beneficiary) and the successors and assigns of the Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, reorganization, consolidation, acquisition of property or stock, liquidation, or otherwise) to all or substantially all of its assets, by agreement in form and substance satisfactory to Executive, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform this Agreement if no such succession had taken place. Regardless whether such agreement is executed, this Agreement shall be binding upon any successor of the Company in accordance with the operation of law and such successor shall be deemed the Company for purposes of this Agreement.

(e) Successors and Assigns. Except as provided in Section16(d) in the case of the Company, or to the Beneficiary in the case of the death of Executive, this Agreement is not assignable by any party and no payment to be made hereunder shall be subject to anticipation, alienation, sale, transfer, assignment, pledge, encumbrance or other charge.

(f) Remedies Cumulative; No Waiver. No remedy conferred upon either party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given hereunder or now or hereafter existing at law or in equity. No delay or omission by either party in exercising any right, remedy or power hereunder or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in such party's sole discretion.

(g) Survivorship. Notwithstanding anything in this Agreement to the contrary, all terms and provisions of this Agreement that by their nature extend beyond the termination of this Agreement shall survive such termination.

(h) Entire Agreement. This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior agreements, promises, covenants or arrangements, whether oral or written, with respect thereto.

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

17. No Contract of Employment. Nothing contained in this Agreement will be construed as a right of Executive to be continued in the employment of the Company, or as a limitation of the right of the Company to discharge Executive with or without Cause.

18. Section 409A of the Code. The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from, Section 409A of the Code and, accordingly, to the maximum extent permitted, this Agreement shall be construed and interpreted in accordance with such intent. Executive's termination of employment (or words to similar effect) shall not be deemed to have occurred for purposes of this Agreement unless such termination of employment constitutes a "separation from service" within the meaning of Code Section 409A and the regulations and other guidance promulgated thereunder.

(a) Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed on the date of Executive's termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B) and using the identification methodology selected by the Company from time to time, or if none, the default methodology set forth in Code Section 409A, then with regard to any payment or the providing of any benefit that constitutes "non-qualified deferred compensation" pursuant to Code Section 409A and the regulations issued thereunder that is payable due to Executive's separation from service, to the extent required to be delayed in compliance with Code Section 409A(a)(2)(B), such payment or benefit shall not be made or provided to Executive prior to the earlier of (i) the expiration of the six (6) month period measured from the date of Executive's separation from service, and (ii) the date of Executive's death (the "Delay Period"). On the first day of the seventh month following the date of Executive's separation from service or, if earlier, on the date of Executive's death, all payments delayed pursuant to this Section 18(a) shall be paid or reimbursed to Executive in a lump sum, and any remaining payments and benefits due to Executive under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(b) To the extent any reimbursement of costs and expenses provided for under this Agreement constitutes taxable income to Executive for Federal income tax purposes, such reimbursements shall be made no later than December 31 of the calendar year next following the calendar year in which the expenses to be reimbursed are incurred. With regard to any provision herein that provides for reimbursement of expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year. Any tax gross-ups provided for under this Agreement shall in no event be paid to Executive later than the December 31 of the calendar year following the calendar year in which the taxes subject to gross-up are incurred or paid by Executive.

(c) If any amount under this Agreement is to be paid in two or more installments, for purposes of Code Section 409A each installment shall be treated as a separate payment.

19. Executive Acknowledgement. Executive hereby acknowledges that Executive has read and understands the provisions of this Agreement, that Executive has been given the opportunity for Executive's legal counsel to review this Agreement, that the provisions of this Agreement are reasonable and that Executive has received a copy of this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Employment Agreement to be executed as of the date first above written.

Discovery Laboratories, Inc.

By: /s/ Kathryn A. Cole
Name: Kathryn A. Cole
Title: Senior Vice President, Human Resources

/s/ Mary B. Templeton
Mary B. Templeton

EXHIBIT A

(a) **"Annual Bonus Amount"** means the current year's target annual bonus amount for the Executive.

(b) **"Beneficiary"** means any individual, trust or other entity named by Executive to receive the payments and benefits payable hereunder in the event of the death of Executive. Executive may designate a Beneficiary to receive such payments and benefits by completing a form provided by the Company and delivering it to the General Counsel of the Company. Executive may change his designated Beneficiary at any time (without the consent of any prior Beneficiary) by completing and delivering to the Company a new beneficiary designation form. If a Beneficiary has not been designated by Executive, or if no designated Beneficiary survives Executive, then the payment and benefits provided under this Agreement, if any, will be paid to Executive's estate, which shall be deemed to be Executive's Beneficiary.

(c) **"Cause"** means: (i) Executive's willful and continued neglect of Executive's duties with the Company (other than as a result of Executive's incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to Executive by the Company which specifically identifies the manner in which the Company believes that Executive has neglected his duties; (ii) the final conviction of Executive of, or an entering of a guilty plea or a plea of no contest by Executive to, a felony; or (iii) Executive's willful engagement in illegal conduct or gross misconduct which is materially and demonstrably injurious to the Company.

For purposes of this definition, no act or failure to act on the part of Executive shall be considered "willful" unless it is done, or omitted to be done, by Executive in bad faith or without a reasonable belief that the action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board, or the advice of counsel to the Company, will be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interests of the Company.

(d) **"Change of Control"** means the occurrence of any one of the following events:

(i) any "person" (as defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), other than the Company, any trustee or other fiduciary holding securities under an employee benefit plan of the Company, an underwriter temporarily holding securities pursuant to an offering of such securities or any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company, directly or indirectly (x) acquires "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing more than 50% of the combined voting power of the Company's then outstanding securities or; (y) acquires within a 12 consecutive month period "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act) of securities representing 35% of the combined voting power of the Company's then outstanding securities;

(ii) persons who comprise a majority of the Board are replaced during any 12 consecutive month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of such appointment or election;

(iii) the consummation of a reorganization, merger, statutory share exchange, consolidation or similar corporate transaction (each, a "Business Combination") other than a Business Combination in which all or substantially all of the individuals and entities who were the beneficial owners of the Company's voting securities immediately prior to such Business Combination beneficially own, directly or indirectly, 50% or more of the combined voting power of the voting securities of the entity resulting from such Business Combination (including, without limitation, an entity which as a result of the Business Combination owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership of the Company's voting securities immediately prior to such Business Combination; or

(iv) any "person" (as defined in Sections 13(d) and 14(d) of the Exchange Act) acquires all or substantially all of the assets of the Company within any 12 consecutive month period.

Notwithstanding the foregoing, none of the foregoing events shall constitute a Change of Control of the Company unless such event also constitutes a change in ownership of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(v), a change in the effective control of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(vi) or a change in ownership of a substantial portion of the assets of the Company within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(vii).

(e) **"Change of Control Date"** means any date after the date hereof on which a Change of Control occurs; provided, however, that if a Change of Control occurs and if Executive's employment with the Company is terminated or an event constituting Good Reason (as defined below) occurs prior to the Change of Control, and if it is reasonably demonstrated by Executive that such termination or event (i) was at the request of a third party who has taken steps reasonably calculated to effect the Change of Control, or (ii) otherwise arose in connection with or in anticipation of the Change of Control then, for all purposes of this Agreement, the Change of Control Date shall mean the date immediately prior to the date of such termination or event.

(f) **"Code"** means the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

(g) **"Date of Termination"** means the date specified in a Notice of Termination pursuant to Section 8 hereof, or Executive's last date as an active employee of the Company before a termination of employment due to death, Disability or other reason, as the case may be.

(h) **"Disability"** means a mental or physical condition that renders Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three or more consecutive months or for a total of six months during any 12 consecutive months; provided, that during such period the Company shall give Executive at least 30 days' written notice that it considers the time period for disability to be running.

(i) **"Effective Period"** means the period beginning on the Change of Control Date and ending 24 months after the date of the related Change of Control.

(j) **"Good Reason"** means, unless Executive has consented in writing thereto, the occurrence of any of the following: (i) the assignment to Executive of any duties materially inconsistent with Executive's position, including any change in status, title, authority, duties or responsibilities or any other action which results in a material diminution in such status, title, authority, duties or responsibilities; (ii) a material reduction in Executive's Base Salary by the Company; (iii) the relocation of Executive's office to a location more than 30 miles from Warrington, Pennsylvania; (iv) the failure of the Company to comply with the provisions of Section 6(a); or (v) the failure of the Company to obtain the assumption in writing of the Company's obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 15 days after a Business Combination or a sale or other disposition of all or substantially all of the assets of the Company.

EXHIBIT B

FORM OF
PROPRIETARY INFORMATION AND INVENTIONS,
NON-SOLICITATION AND
NON-COMPETITION AGREEMENT

The following is an agreement ("Agreement") between Discovery Laboratories, Inc., a Delaware corporation (the "Company"), and any successor in interest, and me, [Executive], and this Agreement is a material part of the consideration for my employment by the Company:

1. Job Title and Responsibility: I understand that my job title with the Company will be Senior Vice President, General Counsel and Corporate Secretary and that the Company may change this title at any time. My job duties and responsibilities will be those assigned to me by the Company from time to time.

2. Consideration. I understand that the consideration to me for entering into this Agreement is my employment with the Company at my base salary of $267,800, and I agree that this consideration is fully adequate to support this Agreement.

3. Proprietary Information. I recognize that the Company is engaged in a continuous program of research, development and production. I also recognize that the Company possesses or has rights to secret, private, confidential information and processes (including processes and information developed by me during my employment by the Company) which are valuable, special and unique assets of the Company and which have commercial value in the Company's business ("Proprietary Information"). By way of illustration, this Proprietary Information includes, but is not limited to, information and details regarding the Company's business, trade or business secrets, inventions, intellectual property, systems, policies, records, reports, manuals, documentation, models, data and data bases, products, processes, operating systems, manufacturing techniques, research and development techniques and processes, devices, methods, formulas, compositions, compounds, projects, developments, plans, research, financial data, personnel data, internal business information, strategic and staffing plans and practices, business, marketing, promotional or sales plans, practices or programs, training practices and programs, costs, rates and pricing structures and business methods, computer programs and software, customer and supplier identities, information and lists, confidential information regarding customers and suppliers, and contacts at or knowledge of Company suppliers and customers or of prospective or potential customers of the Company.

4. Obligation of Confidentiality. I understand and agree that my employment creates a relationship of confidence and trust between the Company and me with respect to (i) all Proprietary Information, and (ii) the confidential information of others with which the Company has a business relationship. At all times, both during my employment by the Company and after the termination of my employment (whether voluntary or involuntary), I will keep in confidence and trust all such information, and I will not use, reveal, communicate, or disclose any such Proprietary Information or confidential information to anyone or any entity, without the written consent of the Company, unless I am ordered to make disclosure by a court of competent jurisdiction.

5. Ownership, Disclosure and Assignment of Proprietary Information and Inventions. In addition, I hereby agree as follows:

(a) Ownership and Assignment. All Proprietary Information is, and shall be, the sole and exclusive property of the Company and its assigns, and the Company and its assigns shall be the sole and exclusive owner of all Proprietary Information, including, but not limited to, trade secrets, inventions, patents, trademarks, copyrights, and all other rights in connection with such Proprietary Information. I agree that I have no rights in such Proprietary Information. I hereby assign, and shall assign, to the Company and its assigns any and all rights, title and interest I may have or acquire in such Proprietary Information. Any copyrightable work prepared in whole or in part by me in the course of my employment shall be deemed "a work made for hire" under applicable copyright laws, and the Company and its assigns shall own all of the rights in any copyright.

(b) Return of Materials and Property. All documents, records, apparatus, equipment, data bases, data and information stored in computers or on electronic disks, and other electronic, computer, intellectual, and physical property ("Materials and Property"), whether or not pertaining to Proprietary Information, furnished to me by the Company or produced by me or others in connection with employment, shall be and remain the sole and exclusive property of the Company. I shall return to the Company all such Materials and Property as and when requested by the Company. Even if the Company does not so request, I shall return all such Materials and Property upon termination of employment by me or by the Company for any reason, and I will not take with me any such Materials or Property, or any reproduction thereof, upon such termination.

(c) Notification. During the term of my employment and for one (1) year thereafter, I will promptly disclose to the Company, or any persons designated by it, all improvements, inventions, intellectual property, works of authorship, formulas, ideas, processes, techniques, discoveries, developments, designs, innovations, know-how and data, and creative works in which copyright and/or unregistered design rights will subsist in various media (all collectively called herein, "Inventions"), whether or not such Inventions are patentable, which I make or conceive, contribute to, reduce to practice, or learn, either alone or jointly with others.

(d) Ownership of Inventions. I agree and acknowledge that all Inventions which I make, conceive, develop, or reduce to practice (in whole or in part, either alone or jointly with others) at any time during my employment by the Company, and (i) which were created using the equipment, supplies, facilities or trade secret information of the Company, or (ii) which were developed during the hours for which I was compensated by the Company, or (iii) which relate, at the time of conception, creation, development or reduction to practice, to the business of the Company or to its actual or demonstrably anticipated research and development, or (iv) which result from any work performed by me for the Company, shall be the sole and exclusive property of the Company and its assigns (and to the fullest extent permitted by law shall be deemed works made for hire), and the Company and its assigns shall be the sole and exclusive owner of all Inventions, patents, copyrights and all other rights in connection therewith. I hereby assign to the Company any and all rights I may have or acquire in such Inventions. I agree that any Invention required to be disclosed under paragraph (c), above, within one (1) year after the termination of my employment shall be presumed to have been conceived or made during my employment with the Company and will be assigned to the Company unless and until I prove and establish to the contrary.

(e) Assistance and Cooperation. With respect to Inventions described in paragraph (d), above, I will assist the Company in every proper way (but at the Company's expense) to obtain, and from time to time enforce, patents, copyrights or other rights on these Inventions in any and all countries, and will execute all documents reasonably necessary or appropriate for this purpose. This obligation shall survive the termination of my employment. In the event that the Company is unable for any reason whatsoever to secure my signature to any document reasonably necessary or appropriate for any of the foregoing purposes (including renewals, extensions, continuations, divisions or continuations in part), I hereby irrevocably designate and appoint the Company, and its duly authorized officers and agents, as my agents and attorneys-in-fact to act for and in my behalf and instead of me, but only for the purpose of executing and filing any such document and doing all other lawfully permitted acts to accomplish the foregoing purposes with the same legal force and effect as if executed by me.

(f) Exempt Inventions. I understand that this Agreement does not require assignment of an Invention for which no equipment, supplies, facilities, resources, or trade secret information of the Company was used and which was developed entirely by me on my own time, unless the invention relates, (i) directly to the business of the Company, or (ii) to the Company's actual or demonstrably anticipated research or development. However, I will disclose to the Company any Inventions I claim are exempt, as required by paragraph (c), above, in order to permit the Company to determine such issues as may arise. Such disclosure shall be received in confidence by the Company.

6. Prior Inventions. As a matter of record I attach hereto as Exhibit A a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company which have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment with the Company, that I desire to remove from the operation of this Agreement, and I covenant that such list is complete. If no such list is attached to this Agreement, I represent that I have no such inventions and improvements at the time of my signing this Agreement.

7. Other Business Activities. So that the Company may be aware of the extent of any other demands upon my time and attention, I will disclose to the Company (such disclosure to be held in confidence by the Company) the nature and scope of any other business activity in which I am or become engaged during the term of my employment. During the term of my employment, I will not engage in any business activity or employment which is in competition with, or is related to, the Company's business or its actual or demonstrably anticipated research and development, or that will affect in any manner my ability to perform fully all of my duties and responsibilities for the Company.

8. Non-Interference and Non-Solicitation of Employees, Customers and Others. I will not now or at any time in the future disrupt, damage, impair or interfere with the business of the Company, whether by way of interfering with or raiding its employees, disrupting its relationships with customers, agents, vendors, distributors or representatives, or otherwise. During my employment with the Company and for eighteen (18) months thereafter, I will not directly or indirectly induce, encourage or solicit any employee of the Company to leave the Company for any reason, unless specifically requested to take such action in writing by the Company.

9. Non-Competition During and After Employment. I agree that the time and activity restrictions in this paragraph are wholly necessary and are reasonable to protect the legitimate business interests of the Company. During my employment with the Company or at any time within a period of one (1) year after the termination of my employment (whether the termination is by me or the Company), I will not directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity, compete with the Company in the business of developing or commercializing pulmonary surfactants.

10. Obligations to Former Employers. I represent that my execution of this Agreement, my employment with the Company, and my performance of my duties and proposed duties to the Company will not violate any obligations or agreements I have, or may have, with any former employer or any other third party, including any obligations and agreements requiring me not to compete or to keep confidential any proprietary or confidential information. I have not entered into, and I will not enter into, any agreement which conflicts with this Agreement or that would, if performed by me, cause me to breach this Agreement. I further represent that I have no knowledge of any pending or threatened litigation to which the Company may become a party by virtue of my association with the Company. I further agree to immediately inform the Company of any such pending or threatened litigation should it come to my attention during the course of my employment. I also agree that I provided to the Company for its inspection before I signed this Agreement all confidentiality, non-compete, non-solicitation, and all other employment-related agreements that I am party to or which involve me.

11. Confidential Information of, and Agreements with, Former Employers. In the course of performing my duties to the Company, I will not utilize any trade secrets, proprietary or confidential information of or regarding any former employer or business affiliate, nor violate any written or oral, express or implied agreement with any former employer or business affiliate.

12. United States Government Obligations. I acknowledge that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to be bound by all such obligations and restrictions which are made known to me and to take all action necessary to discharge the obligations of the Company under such agreements.

13. Remedies. I acknowledge that my failure to comply with, or my breach of, any of the terms and conditions of this Agreement shall irreparably harm the Company, and that money damages would not adequately compensate the Company for this harm. Accordingly, I acknowledge that in the event of a threatened or actual breach by me of any provision of this Agreement, in addition to any other remedies the Company may have at law, the Company shall be entitled to equitable relief in the form of specific performance, temporary restraining order, temporary or permanent injunction or any other equitable remedy then available, without requiring the Company to post any bond. I agree that nothing herein contained shall be construed as prohibiting the Company from pursuing any other remedies available to it for such threatened or actual breach, including money damages, and I agree that the Company shall be entitled to recover from me any attorney’s fees it incurs in enforcing the terms of this Agreement.

14. Not an Employment Agreement. I acknowledge and agree that this Agreement is not a contract of employment, that it should not be construed as a guarantee of my employment for any period of time, and that I am employed by the Company at will and my employment may be terminated by the Company for any lawful reason or no reason.

15. Miscellaneous.

(a) Reformation and Severability. If any provision of this Agreement is held to be invalid or unenforceable under applicable law, such provision shall be reformed and/or construed, if possible, to be enforceable under applicable law; otherwise, such provision shall be excluded from this Agreement and the balance of the Agreement shall remain fully enforceable and valid in accordance with its terms.

(b) No Waiver. No delay or omission by the Company in exercising any right hereunder will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(c) Reassignment. I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employment I may be transferred, without the necessity that this Agreement be reassigned at the time of such transfer.

(d) Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania (but not the law or principles of conflict of laws), and the parties submit to the jurisdiction of the courts of Pennsylvania.

(e) Effective Date. This Agreement shall be effective as of the first day of my employment by the Company, shall be binding upon me, my heirs, executors, assigns and administrators, and shall inure to the benefit of the Company, its successors and assigns.

(f) Entire Agreement. This Agreement contains the entire agreement of the parties relating to the subject matter herein, and may not be waived, changed, extended or discharged except by an agreement in writing signed by both parties.

(g) ACKNOWLEDGEMENT. I acknowledge and agree that I have fully read and that I understand all of the terms and provisions of this Agreement, that I have had the opportunity to consult with an attorney and to discuss this Agreement with an attorney, that I have had any questions regarding the effect of this Agreement or the meaning of its terms answered to my satisfaction, and, intending to be legally bound hereby, I freely and voluntarily sign this Agreement.

Accepted and Agreed to:	DISCOVERY LABORATORIES, INC.
Name: _____	By: _____
Date: _____	Name: _____
SS#: _____	Title: _____

EXHIBIT A

Discovery Laboratories, Inc.
2600 Kelly Road, Suite 100
Warrington, PA 18976

Attn:

1. The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by Discovery Laboratories, Inc. (the "Company") that have been made or conceived or first reduced to practice by me, alone or jointly with others, prior to my employment by the Company that I desire to remove from the operation of the Company's Proprietary Information and Inventions, Non-Solicitation and Non-Competition Agreement.

_____ No inventions or improvements.

_____ See below: Any and all inventions regarding

_____ Additional sheets attached.

2. I propose to bring to my employment the following materials and documents of a former employer:

_____ No materials or documents.

_____ See below:

_____

_____
Date

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, Form S-3 No. 333-174786, Form S-3 No. 333-187934 and Form S-3 No. 333-193490) of Discovery Laboratories, Inc. and in related Prospectuses

(2) Registration Statement (Form S-8 No. 333-180497, Form S-8 No. 333-184277 and Form S-8 No. 333-189966) pertaining to the Discovery Laboratories, Inc. 2011 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, Form S-8 No.333-180497, Form S-8 No. 333-187486 and Form S-8 No. 333-191502) pertaining to the 401(k) Plan of Discovery Laboratories, Inc.

of our reports dated March 17, 2014, 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. and subsidiary, included in this Annual Report (Form 10-K) for the year ended December 31, 2013.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 17, 2014

Exhibit 31.1

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 17, 2014

/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, 2013 ("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 17, 2014

/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.