FORM 10-K

WINDTREE THERAPEUTICS INC /DE/ - WINT

Filed: March 16, 2015 (period: December 31, 2014)

Annual report with a comprehensive overview of the company

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

FORM 10-K

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

For the fiscal year ended December 31, 2014

or

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

For the transition period from to

Commission file number 000-26422

DISCOVERY LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

None

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

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

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

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

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

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

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

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

The aggregate market value of shares of voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2014 (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 $128 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 its 2013 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 6, 2015, 85,586,914 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 2015 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days, or April 30, 2015, after the registrant's fiscal year ended December 31, 2014, and to be delivered to stockholders in connection with the 2015 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 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), 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 phases of our AEROSURF phase 2 clinical program may be interrupted, delayed, or fail, which will harm our business;

- the risk that we may be unable in the near term to secure on acceptable terms, or at all, a strategic alliance or collaboration agreement for SURFAXIN in the U.S., which also would require us to negotiate a lease extension for our manufacturing facility in Totowa, NJ (Totowa Facility) and may require us to seek consent under our Deerfield Loan; in such event, we would be exposed to risks associated with the cessation of commercialization activities for SURFAXIN and termination of manufacturing activities at the Totowa Facility;

- the risk that we may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us with the development of our KL4 surfactant pipeline products in markets outside the U.S., beginning with AEROSURF, and, if approved, commercialization of AEROSURF in markets outside the U.S.; and if we are able to enter into a strategic alliance to support the commercialization of SURFAXIN in the U.S, we may be unable to identify strategic alliances and/or collaboration agreements to 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 our limited resources effectively and timely modify our business strategy as needed to respond to developments in our commercial operations and research and development activities, as well as our business, our industry and other factors;

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

- risks relating to our and our CMOs' ability to manufacture our KL4 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 our CAG device and related components and technologies for preclinical and clinical studies of our combination drug/device 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 KL4 surfactant drug products and the APIs used in the manufacture of our drug products, WARMING CRADLE® dry-block heaters, 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; moreover, we may be required to seek the consent of Deerfield to enter into certain strategic transactions;

- 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 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 KL4 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 and other interactions, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;

- 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, medical device and combination drug/device product candidates;

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

- 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;

- 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;

- 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.

DISCOVERY LABORATORIES, INC.

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For the Fiscal Year Ended December 31, 2014

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 forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of aerosolized KL_4 surfactant. We believe that our proprietary technologies may make it possible to develop a pipeline of products to address a variety of respiratory diseases for which there 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.). *See,* "– Business Strategy – SURFAXIN."

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, 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 respond poorly (an outcome referred to as nCPAP failure) and 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 received 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) technology. With AEROSURF, neonatologists potentially will be able to administer aerosolized KL_4 surfactant to premature infants supported with nCPAP alone, without having to resort to invasive intubation and mechanical ventilation. By enabling delivery of our aerosolized 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.

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, in particular our aerosolized KL_4 surfactant that potentially may be administered using less invasive means, collectively and over time, have the potential to improve the management of RDS and to expand the current RDS estimated worldwide annual market to a $600 million to a $1 billion per year market opportunity.

Beyond RDS

In the future, we expect 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 children and adults in pediatric and adult intensive care units (PICUs and ICUs). While we currently are focused primarily on the development of AEROSURF through phase 2 clinical trials, we have explored and plan in the future to explore potential opportunities to address a variety of respiratory conditions that may benefit from KL4 surfactant therapy where there are no currently approved therapies other than supportive respiratory care.

We believe that our aerosolized KL4 surfactant, alone or in combination with other pharmaceutical compounds, has the potential to be developed to address a range of serious respiratory conditions and may be an effective intervention for such conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, diseases involving mucociliary clearance disorders, such chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). We believe that we may have an opportunity to develop a broad pipeline of KL4 surfactant products to address these and other conditions.

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)." Key elements of our strategy to achieve these goals include:

- SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA. We expect that, over time, hospitals in the U.S. will replace the currently available animal-derived surfactants that are derived from pig and cow lungs using a chemical extraction process with SURFAXIN and our other synthetic KL4 surfactant products, if approved.
    - To initiate the commercial introduction of SURFAXIN in the U.S., we established our own specialty respiratory critical care commercial and medical affairs organization and made investments in manufacturing, quality systems, supply chain, and distribution capabilities. For 2014, total costs for marketing, medical and commercial capabilities, as well as manufacturing, quality systems, supply chain, distribution and related costs to support the commercialization of SURFAXIN were approximately $19 million. Notwithstanding, revenue growth has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN.
    - We also believe that our limited capital and resources should be invested in the development of aerosolized KL4 surfactant, beginning with AEROSURF, which has the potential to generate greater value for our stockholders. Therefore, we are pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN that potentially could be (i) a strategic alliance or collaboration arrangement, which we expect would require a lease extension for our manufacturing facility in Totowa, NJ (Totowa Facility) and may require consent under our Deerfield Loan, or (ii) ceasing our commercialization activities for SURFAXIN. We would prefer an alliance or collaboration arrangement with a pharmaceutical company that has existing commercial capabilities, including substantial sales, marketing and medical resources and experience in the introduction of hospital-based products. However, there can be no assurance that we will succeed in such efforts. In connection with either a strategic alliance or collaboration agreement for SURFAXIN or cessation of commercialization activities, we expect that we likely will incur one-time transition-related costs associated with such event.

- For our AEROSURF development program, we opened an investigational new drug application (IND) with the FDA and initiated a phase 2 clinical program for AEROSURF for the treatment of RDS in premature infants in November 2013.

    - The first part of our clinical program is a phase 2a open label clinical trial that is designed to evaluate the safety and tolerability of a single exposure of aerosolized KL4 surfactant administered in three escalating inhaled doses to premature infants 29 to 34 week gestational age (GA) with RDS. The comparator is nCPAP alone. We are currently enrolling the third dose group in this trial. We are also assessing (i) whether there is physiological evidence that our aerosolized KL4 surfactant is being delivered to the lung of premature infants, and (ii) the performance of the CAG in the NICU. Enrollment is expected to be completed in late first quarter/early second quarter 2015 with full results expected shortly thereafter.

    - As we anticipate completion of the initial phase 2a clinical trial, we are preparing for the next phase of the clinical trial to evaluate the safety and tolerability of aerosolized KL4 surfactant in premature infants 26 to 28 week GA.

    - We are also preparing for a planned phase 2b clinical trial in premature infants 26 to 32 week GA, with startup activities to initiate a number of additional clinical sites and investments to expand our clinical capabilities, and we are preparing to manufacture additional CAG devices and disposable AEROSURF dose packs (ADPs). The final design of the phase 2b clinical trial will be informed in part by the results of the phase 2a trial, and is expected to be a multicenter trial conducted at selected medical centers both within and outside the U.S. The primary objective of this trial will be to determine the optimal doses and define the expected efficacy margin. We expect that this trial will be completed in the second quarter of 2016. *See,* "– Surfactant Replacement Therapy for Respiratory Medicine Respiratory Distress Syndrome in Premature Infants (RDS) – AEROSURF for the Treatment of RDS in Premature Infants." Battelle Memorial Institute (Battelle), which assisted us in the development and manufacture of our clinic-ready CAG device and ADPs, is working with us to manufacture a sufficient number of CAG devices and ADPs to support our continuing development activities and our planned phase 2b clinical trial.

- We are also developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant, which is stored as a dry substance and reconstituted to liquid form just prior to use and is being developed potentially to improve ease of use, prolong shelf life and eliminate the need for cold-chain storage. We plan initially to use our lyophilized KL4 surfactant in our AEROSURF development program.

- To achieve our business objectives, we will require significant additional capital and resource capabilities over time to support our operations, advance our development programs, and manufacture and support the commercialization of our approved products in markets around the world. We continue to assess potential opportunities that could provide both capital resources and strengthen our capabilities.

    - In October 2014, we entered into a Collaboration Agreement with Battelle providing for development of our CAG device for potential use in our planned phase 3 clinical program for AEROSURF and, if approved for sale, initial commercial supply. In addition, if AEROSURF is approved for commercial sale by the FDA or other regulatory authority, we and Battelle have agreed to negotiate in good faith for the manufacture of the initial commercial supply of our CAG and ADPs. This collaboration involves a sharing of development expense and provides us the continued benefit of Battelle's particular expertise in developing and integrating aerosol devices using innovative and advanced technologies. *See,* "– Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement."

    - To advance and support our AEROSURF development activities, we are seeking 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 selected markets outside the U.S. Financial resources provided by such an alliance typically could take the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses.

- If we are able to enter into a strategic alliance for SURFAXIN in the U.S. and secure long-term utilization of our Totowa Facility to manufacture commercial drug supply, we may seek to 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. If we are unable to enter into a strategic alliance for SURFAXIN in the U.S., we currently do not plan to seek alliances in other markets.

- We plan to carefully manage our cash resources and will seek additional capital, including potentially from strategic transactions and through future debt and equity financings, as we deem necessary to maintain and strengthen our financial position.

  - In February 2013, to meet our working capital requirements, we 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. As of December 31, 2014, approximately $23.0 million was available under the ATM Program. We also would consider other financing transactions, including equity offerings or capital equipment financings.

  - We entered into a secured loan agreement with affiliates of Deerfield Management, L.P. (Deerfield), under which we have long-term debt of $30 million (Deerfield Loan). Under the terms of the related agreement, the loan is payable in three equal annual installments beginning in 2017, subject to potential deferral of the first and second payments if we achieve either certain revenues or market capitalization levels in each year. As such, the loan may not become payable until 2019. The loan agreement includes certain negative covenants that may require us to seek Deerfield's consent before entering into certain strategic transactions, which could impair our ability to enter into certain strategic transactions.

- We plan to continue prosecuting and protecting our rights in our KL4 surfactant drug products and drug delivery technologies through patents, patent term restoration, trademarks and trade secrets. We expect that, as our development programs progress, we may identify opportunities to extend the duration of our market exclusivities, through new patents and other intellectual property. We also plan to utilize and seek regulatory designations that may provide post-approval market exclusivity for our pipeline products. *See,* "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations."

- We believe that our KL4 surfactant technology has the potential to be developed into a product pipeline to address a variety of debilitating respiratory conditions and diseases that could represent potentially significant market opportunities. While we remain focused on RDS, 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. In 2014, we participated in a U.S. Government-funded study to assess whether aerosolized KL4 surfactant may mitigate radiation-induced lung injury in an animal model. 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 Item 1 – Business 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: third-party market research conducted for us by Deerfield Institute, Defined Health and Compass Consulting with U.S. and EU based neonatologists in 2014; 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. Although we believe that the information contained in these sources are reliable as of the date of this Annual Report on Form 10-K, we have not independently verified such data and do not guarantee the accuracy or completeness of such information. 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 ii 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 surface of the air sacs, or alveoli, of the lungs and the terminal conducting airways that lead to the alveoli. Surfactants 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 alveoli 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 is designed to imitate 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 currently approved in liquid instillate form and is being developed in lyophilized (freeze-dried) and aerosolized 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 previously demonstrated in preclinical studies that our KL4 surfactant may possess certain beneficial properties, including modulation of the inflammatory process, antimicrobial properties and non-immunogenicity. (Wolfson, M.R., Wu, J., Hubert, T.L., Gregory, T.J., Mazela, J., & Shaffer, T.H. (2012), "Lucinactant attenuates pulmonary inflammatory response, preserves lung structure, and improves physiologic outcomes in a preterm lamb model of RDS." *Pediatr Res*, 72(4), 375-383; Black C, Leon C, Pluim J. Bactericidal properties of the novel, peptide-containing surfactant - Surfaxin®. Pediatric Academic Societies, Honolulu, HI, May, 2008. E-PAS2008:633756.11; and Clayton RG, Cochrane CG, Gregory TJ. Surfaxin® (lucinactant) does not induce an immune response in a standardized preclinical model. Pediatric Academic Societies, Honolulu, HI, May, 2008. E-PAS2008:633756.12.) 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 Flexibility

Surfactants currently marketed in the U.S., including SURFAXIN®, must be stored in refrigerated conditions and warmed prior to use, and are administered using endotracheal intubation and mechanical ventilation.

Our KL4 surfactant also can be produced in lyophilized (freeze-dried) form that is reconstituted to a liquid form prior to administration. In several experiments, we have demonstrated that our lyophilized KL4 surfactant retains many of the key attributes and characteristics of our liquid instillate. We believe that it 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 for extended shelf life; and
- relatively lower viscosity than that of a liquid instillate, 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 the liquid and lyophilized dosage forms of our KL4 surfactant and that our aerosolized KL4 surfactant product candidate 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 using the lyophilized formulation 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 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 an 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 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 infants 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 have obtained the European conformity (CE) mark. 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 improve the delivery of aerosolized medications and inhaled therapies to critical-care infants.

We believe that our AFECTAIR technology may provide us a competitive advantage and have determined to reserve AFECTAIR for use with our AEROSURF systems and aerosol development program. Accordingly, we no longer plan to maintain a commercial distribution channel for this product.

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 in the U.S. and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. We believe that our proprietary KL_4 surfactant technology makes it possible 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 GA 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 GA. The incidence of RDS approaches 100% in babies born less than 26 weeks GA. 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 severe 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 very low birth weight infants with severe RDS. Unfortunately, a significant number of infants are not adequately supported with nCPAP alone (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 300,000 to 350,000 low birth weight premature infants are born annually in the U.S. and at risk for RDS (and approximately 500,000 to 600,000 in the U.S., major European medical markets, and Japan). In the U.S., we estimate that approximately 120,000 to 150,000 premature infants could benefit from surfactant therapy. However, due to the risks associated with intubation and mechanical ventilation, only approximately 50,000 to 60,000 of these infants currently are treated with surfactants as the initial therapy for severe RDS. Those infants with less severe RDS are usually supported with nCPAP alone. As discussed above, a large percentage of these patients experience nCPAP failure and require delayed surfactant therapy administered via intubation and mechanical ventilation. We estimate that approximately 25,000 to 35,000 infants will receive delayed surfactant therapy (post-nCPAP failure), bringing the total number of premature infants in the U.S. who are treated with surfactants for RDS to approximately 80,000 to 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 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, and was used to support the safety of SURFAXIN.

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 may require less reintubation than currently approved animal-derived surfactants. Moreover, 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).

To facilitate proper administration of SURFAXIN, we developed 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 listed with the FDA as a Class I, exempt laboratory device.

AEROSURF for the Treatment of RDS in Premature Infants

AEROSURF is an investigational drug/device combination product that delivers our KL4 surfactant in aerosolized form using the lyophilized KL4 surfactant we are developing 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, if approved, will address a serious unmet medical need, potentially provide 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 (*see,* "– Respiratory Distress Syndrome in Premature Infants"), of the 120,000 to 150,000 infants in the U.S. that likely could benefit from surfactant therapy, market research conducted with clinicians for us by third parties suggests that, if AEROSURF is approved, a significant number of these infants would receive aerosolized KL4 surfactant as the initial treatment for RDS.

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. In the U.S., for example, 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. While actual treatment and morbidity costs may vary to some degree between countries, it appears that a reduced rate of reintubation could similarly lower costs in other markets as well. Accordingly, 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 global surfactant market from a currently estimated $250-$300 million per year to a range of $600 million to over $1 billion per year.

To prepare for our AEROSURF clinical development activities, we opened our AEROSURF IND with the FDA in November 2013. We are conducting a phase 2 clinical program for AEROSURF for the treatment of RDS in premature infants. Our initial phase 2a clinical trial is an open label, single-dose study that is designed to evaluate the safety and tolerability of a single exposure of aerosolized KL4 surfactant administered in escalating inhaled doses to premature infants who are receiving nCPAP for RDS, as compared to infants receiving nCPAP alone, which is the current standard of care for these patients. We are also assessing physiological information indicating whether the drug is being effectively delivered into the lungs. The next phase of this clinical trial will be to evaluate the safety and tolerability of aerosolized KL4 surfactant in premature infants 26 to 28 week GA. *See,* "– Business Strategy."

The planned phase 2b clinical trial is expected to conclude in the second quarter of 2016. The primary objective of this trial will be to determine the optimal dose and define the expected efficacy margin of AEROSURF treatment. 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 selected medical centers both within and outside the U.S. The potential pivotal phase 3 clinical trial will be defined based in part on the results of the phase 2b clinical trial.

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. 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. Battelle has also agreed to manufacture additional CAG devices and ADPs to support our AEROSURF phase 2b clinical trial.

In October 2014, we entered into a Collaboration Agreement with Battelle providing for the further development of our CAG device for potential use in our planned phase 3 clinical program for AEROSURF. In addition, if AEROSURF is approved for commercial sale by the FDA or other regulatory authority, we and Battelle have agreed to negotiate in good faith for the manufacture of the initial commercial supply of our CAG and ADPs. *See,* "– Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement."

In addition to the CAG, we are developing a lyophilized KL4 surfactant dosage form that we intend to use with AEROSURF. *See,* "– Lyophilized KL4 Surfactant for RDS in Premature Infants."

To advance AEROSURF outside the U.S., we are seeking advice from regulatory consultants to assist us in engaging international regulatory authorities regarding requirements for an AEROSURF development plan that potentially would support marketing authorization in markets outside the U.S.

In the second quarter of 2014, we received a Phase II grant and final award from the National Institutes of Health (NIH) under a Fast Track Small Business Innovation Research (SBIR) Grant for 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 KL4 Surfactant for RDS in Premature Infants

We are developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that can be stored as a dry substance 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 an initial technology transfer of our lyophilized surfactant manufacturing process to our contract manufacturing organization (CMO), Patheon Manufacturing Services LLC (Patheon, formerly DSM Pharmaceuticals, Inc.), which manufactured a supply of clinical drug product that is currently being utilized in the initial phase of our AEROSURF phase 2 program, and is planning to manufacture a sufficient clinical drug supply needed to complete our AEROSURF phase 2 clinical program. We also have entered into a development agreement with Patheon for the further development of this lyophilized KL4 surfactant, potentially for our AEROSURF phase 3 program and, if approved, commercial supply.

We have also approached the FDA to determine if we potentially could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a plan that we believe might be both capital efficient and capable of implementation within a reasonable time. The FDA requested that we provide additional data before discussing an approval pathway for SURFAXIN LS. If, and only if we are successful in entering into a strategic alliance or collaboration agreement to support the commercialization of SURFAXIN in the U.S., we and our alliance partner may consider preclinical studies to generate the requested data and, if we agree with the FDA on an acceptable pathway, we and our alliance partner may implement such development plan for SURFAXIN LS . If SURFAXIN LS is approved, we expect that our strategic partner would introduce the product commercially in the U.S. as a life-cycle extension of SURFAXIN. If we are unable to enter into a strategic alliance or collaboration agreement to support the commercialization of SURFAXIN in the U.S., we do not plan to initiate a development program for SURFAXIN LS on our own at this time.

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 KL4 surfactant technology potentially may be effective as a preventive measure to treat patients at risk for ALI and, possibly in the future, other conditions, such as COPD. We believe 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.

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.

In 2014 we received an additional award of $1.0 million from NIAID to support continued work with University of Pennsylvania to study how KL4 surfactant may mitigate radiation induced lung injury. This grant may also potentially provide up to an additional $1 million per year in each of the next two years to support this program.

We may in the future invest in or support third-party studies of these and other 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.

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. 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 Patheon to manufacture a supply of lyophilized KL4 surfactant to support the phase 2b trial and conduct further manufacturing development work for the planned phase 3 clinical trial.

In markets outside the U.S., for AEROSURF, we plan to discuss with international regulatory authorities a potential AEROSURF development plan to advance AEROSURF in selected major markets around the world. 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. If we are successful in securing a strategic alliance or collaboration arrangement to support the commercialization of SURFAXIN in the U.S., 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.

In addition to developing our lyophilized KL4 surfactant for AEROSURF, we also have approached the FDA to explore whether it would be feasible to gain marketing authorization for a lyophilized dosage form of SURFAXIN under a plan that we believe might be both capital efficient and capable of implementation within a reasonable time. The FDA requested that we provide additional data before discussing an approval pathway for SURFAXIN LS. If, we are successful in entering into a strategic alliance or collaboration agreement to support the commercialization of SURFAXIN in the U.S., we and our alliance partner may consider preclinical studies to generate the requested data and, if we agree with the FDA on an acceptable pathway, we and our alliance partner may implement such development plan for SURFAXIN LS. If SURFAXIN LS is approved, we expect that our strategic partner would introduce the product commercially in the U.S. as a life-cycle extension of SURFAXIN. If we are unable to enter into a strategic alliance or collaboration agreement to support the commercialization of SURFAXIN in the U.S., we do not plan to initiate a development program for SURFAXIN LS on our own at this time.

To support our research and development activities, we have:

- physicians and scientists (on staff and available under consulting arrangements) 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 scientific 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 have managed our clinical trial data, supported by third-party technology systems and independent consultants, and monitored all clinical 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 working with Battelle, which brings significant expertise in developing and integrating aerosol device technologies to further optimize our CAG device. Battelle has manufactured a supply of clinic-ready CAG devices that are deployed for use in the ongoing phase 2a clinical trial. We and Battelle have agreed on a plan for Battelle to manufacture CAG devices to support the remainder of our phase 2 AEROSURF clinical trials;
- quality operations capabilities to assure compliance with applicable regulations;
- manufacturing capabilities to manufacture our KL4 surfactant for use in preclinical studies. We rely on CMOs to produce our lyophilized KL4 surfactant and WARMING CRADLE dry block heater. We plan to rely on third-party manufacturers to manufacture and assemble our CAG systems and related components; and
- our own analytical 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, 2014, we invested approximately $26.7 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 two 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 several years. Our risk of losing a source of supply is currently somewhat mitigated by our decision to enlarge our safety stock of all APIs. 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 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 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, we have been planning for our long-term needs and the continued integrity and reliability of our manufacturing and quality assurance capabilities. We intend to balance the use of our available resources while making appropriate capital investments to achieve our manufacturing goals.

- The lease for our Totowa Facility currently expires on June 30, 2015. We have explored with the landlord alternatives to secure longer-term utilization of that facility for the manufacture of SURFAXIN. However, we would likely not seek to extend this lease unless and until we are able to enter into a strategic transaction or collaboration agreement that would provide additional capital and other resources to support the continued commercialization of SURFAXIN, *see,* "– Business Strategy,".

- We completed development work for the technology transfer of our lyophilized KL4 surfactant manufacturing process to Patheon in 2013 and manufactured a sufficient clinical supply of KL4 surfactant to support the initial phase 2a AEROSURF clinical trial. We plan to manufacture additional clinical supply to support the remainder of our phase 2 clinical program and other development activities. We also have entered into a development agreement with Patheon for the potential further development and manufacture of lyophilized KL4 surfactant for our AEROSURF phase 3 clinical program. We currently are initiating a technology transfer of our manufacturing process to a new facility within Patheon where the phase 3 manufacturing development work will occur.

CAG Device and Related Componentry

AEROSURF is a combination drug/device product that produces aerosolized KL4 surfactant by combining our lyophilized KL4 surfactant with our CAG device and aerosol delivery technologies. We are developing and, if approved, plan to commercialize AEROSURF in the U.S. for the treatment of premature infants with RDS. We also believe that in the future 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 meet quality control standards prior to release and conform to designated product specifications.

Since 2012, Battelle has assisted us in a multi-phase development program focused on design and testing of clinic-ready CAG devices for our AEROSURF phase 2a clinical trials, and has manufactured CAG devices for the phase 2a clinical trial that is currently underway. We also have entered into an agreement with Battelle for the manufacture and assembly of an initial supply of control units, ADPs and related components to support our planned phase 2b clinical trial and development activities, and plan to arrange for production of additional control units, ADPs and related components, as needed. For our planned phase 3 clinical program, we and Battelle are collaborating to further develop the CAG device. We and Battelle also have agreed to negotiate in good faith the manufacture of phase 3 CAG devices for use in phase 3 clinical trials and, if approved, initial commercial distribution. *See,* "– Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement."

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 manufacturing facility that we believe to be Quality System Regulation (QSR) compliant and has significant experience with the mold injection process required to manufacture AFECTAIR devices. In addition to providing manufacturing support, Lacey agreed to label, package, and prepare AFECTAIR devices for shipment.

Distribution

To distribute SURFAXIN and the WARMING CRADLE dry block heater, we rely on 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 has been 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. ASD has acted as our exclusive specialty distributor for SURFAXIN, and WARMING CRADLE dry-block heaters in the U.S. and has provided related services. If we enter into a strategic alliance or collaboration agreement for SURFAXIN in the U.S., we will determine appropriate changes in these distribution arrangements. If we do not enter into such a transaction, we likely will wind down these relationships. In addition, since we believe that limiting AFECTAIR devices to use in our AEROSURF development program may provide competitive benefits, we no longer plan to maintain a commercial distribution channel for this product.

Our collaboration with Laboratorios del Dr. Esteve, S.A. (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.

Strategic Alliances and Collaboration Arrangements

Battelle Collaboration Agreement

On October 10, 2014, we entered into the Collaboration Agreement with Battelle providing for the further development of our CAG for potential use in our planned phase 3 clinical program for AEROSURF for the treatment of RDS in premature infants and, if AEROSURF is approved for commercial sale by the FDA or other regulatory authority, initial commercial supply.

Pursuant to the Collaboration Agreement, we and Battelle plan to (i) define the requirements of the phase 3 CAG and disposable dose packs (together, AEROSURF System) as well as a detailed project plan for the project (Stage 1), (ii) develop the AEROSURF System in accordance with the project plan (Stage 2), and (iii) complete all required testing, verification and documentation to be in a position to manufacture AEROSURF Systems (Stage 3). Upon completion of the three-stage project plan, we and Battelle intend to negotiate in good faith to enter into an agreement for the manufacture of AEROSURF Systems for the AEROSURF phase 3 clinical program, and, if AEROSURF is approved, to negotiate in good faith to enter into a supply agreement providing for an initial commercial supply of AEROSURF Systems.

A Steering Committee, comprised of an equal number of members appointed by each party, will oversee the work of the project. The foregoing notwithstanding, we will retain final decision-making authority on all matters related to the design, registration, manufacture, packaging, marketing, distribution and sale of AEROSURF Systems. We and Battelle will share equally in the costs of Stage 1 activities. Following completion of Stage 1, we and Battelle will agree on a detailed project plan, including projected costs, for Stages 2 and 3. The parties will share equally in the costs of the project plan for Stages 2 and 3 as set forth in the project plan. Battelle will bear the entire cost of any cost overruns associated with execution of the project plan and we will bear the entire cost of any increase in the agreed upon project plan costs resulting from changes in the scope of the product requirements as agreed in Stage 1 and set forth in the project plan.

In connection with the Collaboration Agreement, we issued to Battelle two warrants to purchase shares of our common stock, each having an exercise price of $5.00 per share and a term of 10 years, subject to earlier termination under certain circumstances set forth therein, including (i) a warrant to purchase up to 1.0 million shares of our common stock, exercisable upon successful completion by Battelle of the Stage 3 activities (Initial Warrant), and (ii) a warrant to purchase up to 0.5 million shares of our common stock (Additional Warrant; and together with the Initial Warrant, the Battelle Warrants), exercisable if and only if Battelle successfully completes the Stage 3 activities no later than May 31, 2016 (Milestone Date), which date may be adjusted as provided in the Collaboration Agreement. We and Battelle have agreed to execute a registration rights agreement providing for the registration of the resale of shares underlying the Battelle Warrants. The Battelle Warrants may be exercised for cash only, except that, in the event a registration statement is not effective at the time of exercise and if an exemption from registration is otherwise available at that time, the Battelle Warrants may be exercised on a cashless basis.

In addition, if Battelle successfully completes the Stage 3 activities, we have agreed to pay Battelle royalties equal to a low single-digit percentage of the worldwide net sales and license royalties on sales of AEROSURF for the treatment of RDS in premature infants, up to an aggregate limit of $25 million.

The term of the Collaboration Agreement will end at the time we fulfill our payment obligations to Battelle, unless sooner terminated by a party as provided in the Collaboration Agreement, including for a "failure of purpose" (as defined therein) or (iii) a material breach by either party.

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

We continue to enter into discussions with entities with a view to enter into strategic alliances, collaboration arrangements and other opportunities 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 was previously extended until November 17, 2014 and is now expired. 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. 6,120,795 will expire on March 4, 2017. U.S. Patent No. 6,013,764, 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 in the U.S. and a number of foreign jurisdictions, including Australia, Canada, Israel, Japan, New Zealand, South Africa, and South Korea, Singapore. 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 August 21, 2023.

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. U.S. Patent No. 7,582,312 will expire on November 15, 2025.

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. U.S. Patent No. 8,337,815 will expire on December 12, 2028.

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. U.S. Patent No 7,541,331 will expire on January 6, 2026.

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. U.S. Patent No. 8,221,772 will expire on September 19, 2027.

In March 2013, we filed International patent applications (PCT/US13/34364 and PCT/US13/34464, now entered national phase and commenced expedited examination in U.S. and EU) directed to lyophilized pulmonary surfactant and methods of manufacture. In this patent family, two U.S. Patents Nos. 8,748,396 and 8,748,397 were issued on June 10, 2014. U.S. Patents Nos. 8,748,396 and 8,748,397 will expire on March 28, 2033.

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 KL4 surfactant can be developed to potentially address a broad range of serious respiratory conditions. We are developing AEROSURF to treat premature infants with or at risk for RDS using the CAG technology.

Capillary Aerosolization Technology Patents and Patent Rights

We currently hold exclusive licenses to the CAG technology both in and outside of the U.S. for use with pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) for all respiratory diseases and conditions. In addition, under the U.S. License Agreement, our license to use the CAG technology includes certain non-surfactant drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions. The aerosolization technology patents expire on various dates beginning in May 2016 and ending in 2031, or, in some cases, possibly later.

Aerosol-Conducting Airway Connector Technology Patents and Patent Rights

In March 2009, we filed International patent application (PCT US/2009/037409, now entered national phase) directed to aerosol-conducting airway connectors and improvements of an aerosol delivery system using AFECTAIR. The claims of this application are directed to a novel ventilation circuit adaptor (an aerosol-conducting airway connector) and related aerosol circuitry that are intended to increase the efficiency of aerosol delivery to the patient by allowing more efficient delivery of aerosols to the patient, reduce drug compound dilution and wastage and result in more precise aerosol dosing. In this patent family, U.S. Patent No. 8,701,658 was issued on April 22, 2014, and several foreign patents have issued during 2011 through 2014. U.S. Patent No. 8,701,658 will expire on March 17, 2029.

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®, 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

FDA has not yet published an exclusivity determination for SURFAXIN. We believed that SURFAXIN would be eligible for either 3-year or 5-year exclusivity and submitted a letter to CDER in support of our position on July 31, 2013. If SURFAXIN receives three years of marketing exclusivity based on the data from the SELECT and STAR clinical trials, exclusivity would have expired on March 6, 2015. In line with recent FDA decisions analyzing exclusivity based on arguments similar to the arguments that we made in our submission, which is currently being challenged in court, we now believe that, while the lawsuit is pending and unless the court strikes down the FDA's position, it is unlikely that the FDA will determine that SURFAXIN qualifies as a new chemical entity, in which event, we would not be eligible for the five years of marketing exclusivity.

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 Products Development of the FDA will determine whether to designate a drug as an Orphan Drug. If a drug is designated as an Orphan Drug, it is eligible to obtain certain advantages, including, but not limited to, seven years of market exclusivity upon approval of the drug for the orphan indication, 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 confirmation from the FDA. The FDA has also granted Orphan Drug designation to (i) our KL4 surfactant for the prevention and treatment of BPD in premature infants, (ii) our KL4 surfactant for the treatment of acute respiratory distress syndrome (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) our KL4 surfactant for the prevention of RDS in premature infants of less than 37 weeks GA, (ii) our KL4 surfactant for the treatment of RDS in premature infants of less than 37 weeks GA, (iii) our KL4 surfactant for the treatment of ALI (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 may grant priority review for an NDA for a drug granted Fast Track designation if relevant criteria are met, which means that the review goal for the NDA would be 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, Chiesi USA, 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 completed a first-in-human clinical trial to study the safety and tolerability of intratracheal administration of two different single doses of its investigational synthetic surfactant in preterm infants with RDS (clinicaltrials.gov). Survanta is marketed internationally by AbbVie, Inc., created in a spin-off transaction by Abbott Nutritionals, Inc. (Abbott). ONY, Inc. markets Infasurf®, a surfactant derived from calf lung surfactant lavage, in the U.S.

With respect to our aerosolized surfactant drug delivery technologies, efforts to aerosolize animal-derived surfactants have not been very successful due to historical limitations with conventional technologies. 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, Inc. 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. Aerogen nebulizers have also been used in surfactant aerosolization clinical trials including, *see* Finer, *et al*, JAMP, Volume 23, Number 5, 2010 and in the ongoing study by Sood, *et al* (https://clinicaltrials.gov/ct2/show/NCT02294630?term=sood+surfactant&rank=1). Another potential competitor to our aerosolized surfactant drug technology may be other minimally invasive surfactant therapies (MIST). MIST is delivery of exogenous surfactant to the lung via brief catheterization of the trachea with an instillation catheter in a preterm infant, followed by reinstitution of CPAP. Currently, a phase 4 clinical trial is being conducted to assess the efficacy of this therapy versus CPAP alone (ClinicalTrials.gov Identifier: NCT02140580). Unlike AEROSURF, these approaches would still require invasion of the vocal cords with a surfactant administration apparatus.

GOVERNMENT REGULATION

In the United States, drug products, medical devices, and drug-device combination products are subject to extensive regulation by the U.S. Food and Drug Administration, or the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, clearance, labeling, promotion, advertising and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of drug products, medical devices, and drug-device combination products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve or clear pending new submissions to market drugs or devices warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. Any product that we develop must receive all relevant regulatory approvals or clearances before it may be marketed in the United States. Drug products, medical devices, and drug-device combination products are subject to extensive regulation, including premarket review and marketing authorization, by similar agencies in other countries.

Drug Product Regulations

Development Activities: To gain regulatory approval of our KL4 surfactant technology pipeline products, we must demonstrate, through experiments, preclinical studies and clinical trials that each of our drug product candidates meets the safety and efficacy standards established by the FDA and other international regulatory authorities. In addition, we and our suppliers and CMOs must demonstrate that all development-related laboratory, clinical and manufacturing practices comply with regulations of the FDA, other international regulators and local regulators. Regulations establish standards for such things as drug substances, materials and excipients; drug manufacturing operations and facilities; and analytical laboratories and 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 submitted to the FDA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. If the FDA raises questions, those questions must be resolved, which may involve additional testing and animal studies, before 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 involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice (GCP), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

Clinical trials to support new drug applications (NDAs) for marketing approval normally are conducted in three sequential phases, but the phases may overlap, 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. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible. 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 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. Clinical trials are monitored by the regulatory agencies as well as medical advisory and standards boards, which could decide at any time to reevaluate, alter, suspend, or terminate a trial if the trial is not being conducted in accordance with regulatory standards or 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 KL4 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: After completion of the required clinical testing, an NDA is prepared and submitted to the FDA, with comparable filings submitted to other international regulators. Approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,335,000, though these fees may be waived under certain conditions, such as if the NDA is for a drug that has been designated as an orphan drug. The manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding $110,000 per product and $569,000 per establishment. These fees are typically increased annually.

After the initial submission, the FDA has 60 days in which it must determine if the NDA is sufficiently complete to permit substantive review. If an NDA is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee – typically a panel that includes clinicians and other experts – for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices (cGMPs) is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

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.

In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Orphan Drugs: Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Fast Track Designation: FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

In addition to other benefits such as the ability to engage in more frequent interactions with FDA, FDA may initiate review of sections of a fast track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process. In addition, a drug that is designated as a fast track drug may be eligible for priority review, assuming relevant criteria are met.

Disclosure of Clinical Trial Information: Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The Hatch-Waxman Amendments:

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which FDA cannot approval an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase - the time between IND application and NDA submission – and all of the review phase – the time between NDA submission and approval up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of the NDA approval.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

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 medical devices. In the U.S., medical device products are subject to extensive regulation by the FDA under the FDC Act, and its implementing regulations, and certain other federal and state statutes and regulations. Medical device regulation is intended to calibrate regulatory requirements to the issues of safety and efficacy presented by specific devices. The laws and regulations govern, among other things, the design, manufacture, storage, recordkeeping, approval, clearance, labeling, promotion, post-market monitoring and reporting, distribution and import and export of medical devices. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as issuance of warning or untitled letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

Device Classification and Pre-market Authorization and Notification: Medical devices are classified into one of three classes based on the risks associated with the device and 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 Approval. Class III devices are generally the most risky, whereas Class I devices are generally the least risky. While most Class I and some Class II devices can be marketed without prior FDA authorization, most medical devices can be legally sold within the U.S. only if the FDA has: (i) approved a pre-market approval application (PMA) prior to marketing, generally applicable to Class III devices; or (ii) cleared the device in response to a premarket notification, or 510(k) submission, generally applicable to Class II devices and sometimes Class I devices.

Exempt Devices: If a manufacturer's device falls into a generic category of Class I or Class II devices that FDA has exempted by regulation, a premarket notification is not required before marketing the device in the U.S. However, a device would not be able to keep the Class I 510(k)-exempt classification if the proposed device either had a different intended use or operates using a different fundamental scientific technology. Manufacturers of Class I devices are required to register their establishments and list the generic category or classification name of their devices. Some 510(k)-exempt devices are also exempt from almost all Quality System Regulation (QSR) requirements.

Postmarket Requirements: After a device is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, the FDA's general prohibition against promoting products for unapproved or "off-label" uses, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act).

FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals already granted; and criminal prosecution.

Combination Drug-Device Products

Combination drug-device products such as AEROSURF and potentially other aerosolized KL4 surfactant drug products are similarly subject to extensive regulation by federal, state and local governmental authorities in the U.S. and in other countries. Combination products involve review of two or more regulated components that might normally be reviewed by regulatory authorities having different expertise and may involve more complicated and time-consuming regulatory coordination, approvals and clearances than a drug product alone. In order to review an application for a combination product, the FDA must decide which Center should be responsible for the review. FDA regulations require that the FDA determine the combination product's primary mode of action, or PMOA, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA becomes the lead evaluator. When evaluating an application, a lead Center may consult other Centers but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator. The FDA has determined that our aerosolized KL4 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 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 may 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 a warning letter or the suspension of our manufacturing operations, to seizing product or seeking injunctions or 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 intend to seek such approval from 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 Healthcare Laws

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 healthcare program 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.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offerer/payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the healthcare fraud statute, which prohibits knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations, or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items, or services.

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. Applicable manufacturers were to begin tracking relevant transfer-of-value data in August 2013, and reported 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. Those data were made publicly available in late 2014 via a CMS website. Going forward, manufacturers must report relevant data for a calendar year no later than March 31 of the following year, and the data will be made publicly available on an annual basis. Inaccurate or incomplete reports may be subject to enforcement, and it is expected that data will be subject to significant public scrutiny. In addition, several states have existing laws that require manufacturers to report transfers of value to select healthcare providers licensed within the state. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. Furthermore, other laws such as the federal Lanham Act and similar state laws allow competitors and others to initiate litigation relating to advertising claims. 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.

EMPLOYEES

As of March 6, 2015, we have 110 employees. Of this total, 12 (approximately 11% of our total labor force and approximately one half of those employed at our Totowa Facility) are subject to a collective bargaining agreement that expires on December 3, 2015. All of our employees are based 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 strategic 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. In addition, the SEC maintains an Internet site that contains reports, proxy and information statements, certain and other information that we may file electronically with the SEC (*http://www.sec.gov*). We also 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 our corporate website at http://www.DiscoveryLabs.com. Our website and the information contained therein or connected thereto are not incorporated into this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS.

You should carefully consider the following risks and any of the other information set forth in this Annual Report on Form 10-K and in the documents incorporated herein by reference, before deciding to invest in shares of our common stock. The risks described below are not the only ones that we face. Additional risks that are not presently known to us or that we currently deem immaterial may also impair our business operations. The following risks, among others, could cause our actual results, performance, achievements or industry results to differ materially from those expressed in our forward-looking statements contained herein and presented elsewhere by management from time to time. If any of the following risks actually occurs, our business prospects, financial condition or results of operations could be materially harmed. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you could lose all or part of your investment.

We will require 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 product 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, 2014, we have an accumulated deficit of approximately $524 million and we expect to continue to incur significant, increasing operating losses over the next several years. As of December 31, 2014, we had cash and cash equivalents of approximately $44.7 million and $30 million of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield). In November 2013, we initiated the commercialization of SURFAXIN®. Revenue growth for SURFAXIN has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN. We also believe that our limited capital and resources should be invested in the development of aerosolized KL_4 surfactant, beginning with AEROSURF, which has the potential to generate greater value for our stockholders. Therefore, we are pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN that potentially could be (i) a strategic alliance or collaboration arrangement, which we expect would require a lease extension for our manufacturing facility in Totowa, NJ (Totowa Facility) and may require consent under our Deerfield Loan, or (ii) ceasing our commercialization activities for SURFAXIN. We would prefer an alliance or collaboration arrangement with a pharmaceutical company that has existing commercial capabilities, including substantial sales, marketing and medical resources and experience in the introduction of hospital-based products. However, there can be no assurance that we will succeed in such efforts. In connection with either a strategic alliance or collaboration agreement for SURFAXIN or cessation of commercialization activities, we expect that we likely will incur one-time transition-related costs associated with such event. Before any additional financings, and assuming that we promptly either enter into a strategic alliance or collaboration agreement for SURFAXIN or cease our commercialization activities, we anticipate that we will have sufficient cash available to support our operations and debt service obligations through the first quarter of 2016.

We expect to continue to require significant additional infusions of capital to execute our business strategy until such time as revenues from the commercialization of AEROSURF, if approved, and from potential strategic alliance and collaboration arrangements, including potentially with respect to SURFAXIN and other sources, are sufficient to offset our cash flow requirements. 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 and other cash inflows from all sources. *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 financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. In any such event, the market price of our common stock may decline. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could delay new product development and clinical trial plans.

Our 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 an initial phase 2a clinical program evaluating the safety and tolerability of aerosolized KL4 surfactant drug product administered to premature infants 26 to 34 week GA 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 development 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 severity of the disease under investigation;
- the eligibility and enrollment criteria for the study;
- the willingness of patients' parents or guardians to participate in the clinical trial;
- the perceived risks and benefits of the product candidate under study;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

If patients are enrolled in our clinical trials, they 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 Independent Safety Review Committee (ISRC), 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 ISRC, 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 ISRC 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 KL4 surfactant pipeline products. All of these clinical trials will be time-consuming and potentially costly. Should we fail to complete our clinical development programs or should such programs yield unacceptable results, such failures would have a material adverse effect on our business.

We established our own commercial and medical affairs organization to launch our products in the U.S. We believed that this strategy would greatly improve our ability to introduce our products in the U.S. However, this strategy has increased our cost to commercialize our products and exposed us to risk. As a result, we are currently considering strategic alternatives to potentially provide for the marketing and sale of SURFAXIN, which expose us to additional risks.

We initiated the commercialization of SURFAXIN with our own medical and sales organizations in the U.S. in late 2013. We believed that this strategy would allow us to focus on communicating the benefits of our KL4 surfactant products and providing education and safety in-service training as needed, while retaining all rights to and the full financial benefits of our products. However, revenue growth has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN. We also believe that our limited capital and resources should be invested in the development of aerosolized KL4 surfactant, beginning with AEROSURF. Therefore, we are pursuing, with the intention of promptly implementing, a strategic alternative that could support the commercialization of SURFAXIN, including potentially could be a strategic alliance or collaboration arrangement, which we expect would require a lease extension for our manufacturing facility in Totowa, NJ (Totowa Facility) and may require consent under our Deerfield Loan. If we are not successful in entering into a strategic alliance or collaboration arrangement for SURFAXIN in the U.S., we plan to cease our commercialization activities. If we enter into any such arrangements, the terms of any such arrangements may not be favorable to us.

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 alliance partners 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 alliance partners 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 alliance partners 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.

In addition, even if we establish or secure alliance or collaboration arrangements, 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.

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

We recently modified our business strategy to focus primarily on the development of aerosolized KL_4 surfactants, beginning with AEROSURF. We determined to either seek a strategic alliance for SURFAXIN or cease commercialization activities. We plan to continually evaluate our business 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, SURFAXIN revenue growth has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN. We also believe that our limited capital and resources should be invested in the development of aerosolized KL_4 surfactant, beginning with AEROSURF, which has the potential to generate greater value for our stockholders. We are pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN that potentially could be (i) a strategic alliance or collaboration arrangement, or (ii) ceasing our commercialization activities for SURFAXIN. In the future, if we determine that an alternative approach or structure would allow us to improve the profitability of our products, we will consider adopting such other approaches. 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.

We have limited resources, which could impair our ability to manage our diverse activities and accomplish our business objectives.

The demands on our management team have grown over time. In addition to working on the further development of our KL4 surfactant pipeline, beginning with AEROSURF, and the commercialization of SURFAXIN in the U.S., we have also devoted resources to identifying potential strategic partnerships, collaboration arrangements and similar transactions, in the U.S. and EU and in other selected markets. These activities have 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 financial, operational and other internal controls. From time to time, we will be required to make difficult decisions on how to best allocate our resources. For example, as a result of our limited resources, we determined to either seek a strategic alliance for SURFAXIN or cease commercialization activities.

If our discussions with potential strategic partners are successful, we will require additional management resources and controls to implement alliance structures, and potentially add a layer of complexity to our operations. We plan to distribute our products, if approved, in the U.S. 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 infrastructure and capabilities, and providing adequate training and supervision to maintain high quality standards. We believe that the significant challenges associated with these potential activities will include our ability to recruit, train and integrate skilled management, scientific, medical and operations 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 these challenges would cause our business, financial condition and results of operations to suffer.

Our manufacturing strategy includes potentially relying 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.

Our manufacturing strategy includes potentially manufacturing our lyophilized dosage form of our KL4 surfactant, as well as our capillary aerosol generator (CAG) for AEROSURF, 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 transfer to a 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. To qualify and receive regulatory approval for a new manufacturer could take as long as 2 years;

- 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 timely 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/or corresponding state agencies to ensure strict compliance with cGMP and/or QSR and other government regulations and corresponding foreign standards. Although we do not have control over the day-to-day operations of any CMO we may use, we are responsible for ensuring 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;

- 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. Such an event could limit our ability to conduct technology transfers to alternate and successor manufacturers. We may be required to pay fees or other costs for access to such improvements; and

- we may have difficulty implementing changes or modifications to our manufacturing processes that may be required by the FDA or foreign regulator, if, for example, such changes would burden our CMO or otherwise disrupt operations, or our CMO could impose significant financial terms to implement any such change that could adversely affect our business. Failure to achieve such required changes or modifications could delay or prevent our gaining regulatory approval for our product candidates, or prevent us from continuing to market our approved products, which would have a material adverse effect on our business, financial condition and operations.

Each of the foregoing risks and others could delay our commercial manufacturing plans and our development programs, limit our ability to maintain continuity of supply for our approved products, delay or impair the approval, if any, of our product candidates by the FDA, or result in higher costs or deprive us of potential product revenues.

Manufacturing problems potentially could cause us to experience shortages of active pharmaceutical ingredients, our commercial or lyophilized KL4 surfactant drug products, medical devices, and other 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 cGMP and QSR requirements, or those of foreign regulators or notified bodies, which is necessary to continue manufacturing of our drug products, materials, drug substances, or medical devices. Other problems that may be encountered include:

- the need to make necessary modifications to maintain a qualified 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 Totowa Facility. We manufacture our lyophilized KL4 surfactant product candidate, WARMING CRADLE dry-block heaters and our aerosol-conducting airway connector with CMOs. We have in the past 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 or our CMOs' manufacturing operations or by the manufacturing operations of any of our suppliers to comply with applicable regulatory manufacturing standards 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 produce 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 active pharmaceutical ingredients 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 Totowa Facility 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 most 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.

For the development and, if approved, commercialization of AEROSURF, we will depend upon the manufacturers and assemblers of our CAG devices. If we are unable to identify qualified manufacturers and assemblers, the timeline of our plans for the development and, if approved, commercialization of AEROSURF and any other aerosolized KL4 surfactant products, could suffer.

In connection with the development of AEROSURF, which is a combination drug/device product candidate that delivers our aerosolized KL4 surfactant reconstituted from our lyophilized formulation, we plan to rely on CMOs to manufacture and assemble the CAG and all subcomponents of the CAG to support any preclinical experiments, our ongoing and planned clinical trials and, if approved, commercial device. 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.

We have worked with Battelle to develop a clinic-ready CAG device to support our phase 2 clinical program and currently are collaborating to develop a phase 3/commercial CAG device. 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 CAG system and, if developed, later versions of our CAG systems, or we may not be able to enter into agreements with them on terms and conditions favorable and acceptable to us. In addition, the manufacturers and assemblers that we identify may be unable to timely comply with FDA, or other foreign regulatory agency, regulatory manufacturing requirements. If we do not successfully identify and enter into contractual agreements with manufacturers and assemblers that have the required expertise to produce our CAG devices as and when needed, it will adversely affect our timeline for the development and, if approved, commercialization of our aerosolized KL4 surfactant, including AEROSURF.

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 enter into strategic alliances, 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 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.

Revenue growth has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN. At the same time, we believe that our limited capital and resources should be invested in the development of aerosolized KL4 surfactant, beginning with AEROSURF. Therefore, we are pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN that potentially could be (i) a strategic alliance or collaboration arrangement, which we expect would require a lease extension for our manufacturing facility in Totowa, NJ (Totowa Facility) and may require consent under our Deerfield Loan, or (ii) ceasing our commercialization activities for SURFAXIN. In addition, if we are able to secure a strategic alliance or collaboration agreement for SURFAXIN in the U.S., we also may seek strategic alliances and/or collaboration arrangements potentially to gain regulatory approval for SURFAXIN and, if approved, SURFAXIN LS, and support the commercial introduction of these products in countries where regulatory marketing authorization is facilitated by an FDA-approved NDA.

If we succeed in entering into one or more strategic alliances, or 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 Laboratorios del Dr. Esteve, S.A. (Esteve) for SURFAXIN and certain other of our drug product candidates is focused on Andorra, Greece, Italy, Portugal and Spain (Esteve Territory). We have limited influence over the decisions made by Esteve or its sublicensees or the resources that they may devote to the marketing and distribution of our KL4 surfactant products in their licensed territory, and Esteve or its sublicensees may not meet their obligations in this regard. Our marketing and distribution arrangement with Esteve may not be successful, and, as a result, we may not receive any revenues from it. In addition, we may not be able to enter into marketing and sales agreements for our KL4 surfactant pipeline products on acceptable terms, if at all, in territories not covered by the Esteve agreement, or for any of our other drug product candidates. If Esteve or we should fail to conduct our respective collaboration-related activities in a timely manner, or otherwise breach or terminate the agreements that make up our collaboration arrangements, or if a dispute should arise under our collaboration arrangements, such events could impair our ability to commercialize or develop our products in the Esteve Territory. In that event, we may need to seek other partners and/or collaboration arrangements, or we may have to develop our own internal capabilities to market the covered products in the Esteve Territory.

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. Among other things, 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, and it is likely that we would have no recourse against our partners or collaborators.

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 the cost or timing of clinical programs, product approval, production and supply dates, commercial launch dates, and other financial or operational matters) reflect numerous assumptions developed 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 existing and future debt obligations could impair our liquidity and financial condition, and if we are unable to meet our debt obligations, the lenders could foreclose on our assets.

In connection with the Deerfield Loan, we received from Deerfield $30 million principal amount, which accrues interest at an annual rate of 8.75%, payable in cash quarterly, and which is secured by a security interest on substantially all of our assets. Principal repayments are required beginning in February 2017, subject to certain potential deferrals. 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;
- impose restrictions on us with respect to our ability to license our products in the U.S. as well as other markets around the world;
- 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.

Should we fail in the future to make any required payment under the Deerfield Loan or fail to comply with the covenants contained in the loan agreement and other related agreements, we would be in default regarding that indebtedness. Since we have pledged substantially all of our assets to secure our obligations under the Deerfield Loan, 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.

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 Nasdaq, we could face severe consequences from those authorities. In either case, there could result a material adverse effect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. We can give no assurance that 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 Nasdaq, 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.

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 pass inspection and/or be approved or licensed prior to production and remain subject to inspection at any time thereafter. Failure to comply with the requirements of the FDA or other regulatory authorities, including a failed inspection or a failure in our post-marketing reporting, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of our products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could damage our reputation and have a material adverse effect on our sales. In addition, requirements of the FDA and other regulatory authorities may change and implementing any additional compliance requirements may increase our costs, or force us or our third-party providers to suspend production, which could result in a shortage of our approved product or delays in the commercial introduction of our new product candidates, if approved.

With the commercial launch of SURFAXIN and, 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.

Before we can market our products, 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 and planning a phase 2b clinical trial 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. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. As a result, data we obtain from our phase 2a clinical program may not accurately predict phase 2b or phase 3 results due to many factors such as differences in sample size, study arms, duration, endpoints and features of the CAG device used. In addition, if the CAG device to be used in phase 3 program differs in potentially important ways from that used in phase 2, we may be required to conduct bridging studies or repeat important studies conducted with the earlier version. With regard to SURFAXIN LS, if we and our SURFAXIN alliance partner determine to proceed with development, we expect to conduct additional CMC and preclinical work before we can design and initiate a clinical program. There can be no assurance that we will be successful in gaining regulatory approval for AEROSURF or potentially SURFAXIN LS, if at all.

For AEROSURF, we plan to pursue clinical development in the U.S. and potentially in other markets, and, if approved, market and sell our products in the U.S. and potentially in 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 FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons, which may include:

- the FDA or a foreign regulator may disagree with the design or implementation of one or more clinical trials;
- the FDA or a foreign regulator may not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;
- the FDA or a foreign regulator may not find the data from preclinical studies and clinical trials sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;
- the FDA or a foreign regulator may disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other applicable regulatory filing;
- the FDA or a foreign regulator may require additional preclinical studies or clinical trials; for example, FDA has requested further preclinical studies to characterize physicochemical properties of SURFAXIN LS to demonstrate comparability to the liquid formulation;
- the FDA or a foreign regulator may identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- the FDA or a foreign regulator may grant approval contingent on the performance of costly additional post-approval clinical trials;
- the FDA or a foreign regulator also may approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested;
- the FDA or a foreign regulator may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- the FDA or a foreign regulator may not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract; or
- the FDA or a foreign regulator may change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

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 Fast Track designation, the FDA may not approve them at all or any sooner than other product candidates that do not have Fast Track designation.

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. Instead, Fast Track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review. Our products may cease to qualify for Fast Track designation and our other product candidates may fail to qualify for Fast Track designation. 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.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or biologics for relatively small patient populations as Orphan Drugs. Under the Orphan Drug Act, the FDA may designate a product as an Orphan Drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

The FDA has granted Orphan Drug designation for our KL4 surfactant for the treatment of RDS in premature infants. However, our indication for SURFAXIN is for the prevention, rather than treatment, of RDS, which means that this designation does not apply to SURFAXIN. If we develop AEROSURF or SURFAXIN LS product candidates for the treatment of RDS, this Orphan Drug designation may apply for those indications. We are currently seeking the confirmation from FDA, and FDA may determine that our Orphan Drug designation does not apply to these product candidates. Then, the only option for obtaining an Orphan Drug designation is to submit a new Orphan Drug designation request for each formulation, which FDA may not grant.

If a drug that has Orphan Drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan Drug marketing exclusivity generally prevents the FDA from approving an NDA to market a drug containing the same active moiety for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is clinically superior to the approved drug. A drug is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan Drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We may not be able to obtain new chemical entity exclusivity for SURFAXIN.

The FDA approved SURFAXIN on March 6, 2012, but it has not yet published an exclusivity determination for SURFAXIN. The FDA may determine SURFAXIN is eligible for 5-year exclusivity, 3-year exclusivity, or no exclusivity. On July 31, 2013, we submitted a letter to CDER requesting that FDA grant a 5-year exclusivity to SURFAXIN as a new chemical entity. Since then, the FDA recently determined a drug product did not qualify as a new chemical entity, denying it 5-year exclusivity, because at least one of the constituents of the complex mixture that made up the drug was an active moiety that had been approved by the FDA in another NDA. This decision by the FDA has been challenged in court, and the lawsuit is pending. The active ingredient in SURFAXIN is lucinactant, which is a mixture of four constituents, of which at least one has been previously approved in another NDA. Therefore, it is unlikely that the FDA will determine that SURFAXIN qualifies as a new chemical entity while this lawsuit is pending and unless the court strikes down the FDA's position. However, we cannot predict with certainty what action the FDA will take, what action the court will take, or how the FDA will respond once the court makes a decision. Alternatively, the data from the SELECT and STAR clinical trials may support an FDA determination of 3-year exclusivity; however, such exclusivity would have expired on March 6, 2015. If we are unable to obtain 5-year new chemical entity exclusivity, since we have no unexpired patents for SURFAXIN listed in the Orange Book, SURFAXIN may face generic competition sooner than expected, which could harm our business. However, we rely on patents for manufacturing SURFAXIN and KL4 peptide to provide exclusivity until March 2017.

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 2a clinical trials. We have approached the FDA to determine whether we could gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, under a development plan that we believe might be both capital efficient and capable of implementation within a reasonable time. If feasible and if we have been successful in securing a strategic alliance or collaboration agreement to support the commercialization of SURFAXIN in the U.S., we may potentially seek to implement such a development plan with a strategic partner. Foreign regulators have not yet approved SURFAXIN or any of our KL4 surfactant products under development. (If we are unable to enter into a strategic alliance or collaboration agreement to support the commercialization of SURFAXIN in the U.S., we do not plan to initiate a development program for SURFAXIN LS on our own at this time.) Without regulatory approval, we would not be able to market these products in those markets. 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 potentially 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:

- our substantial reliance on third-party collaborators, CROs, CMOs and suppliers;
- 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 KL4 surfactant products, and our business strategy.

We have developed 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 KL4 surfactant products.

- We will also require additional capital to advance our development activities and plan to seek a potential strategic partner or third-party collaborator to provide financial support and potentially medical device development and commercialization expertise. There can be no assurance, however, that we will successfully identify or be able to enter into agreements with such potential partners or collaborators on terms and conditions that are favorable to us. If we are unable to secure the necessary medical device development expertise to support our development program, this could impair our ability to commercialize or develop AEROSURF or other aerosolized KL4 surfactant products.

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

The commercial success of our products will depend in large part upon the degree of market acceptance by physicians, patients, and others in the medical community.

Even if SURFAXIN and , if approved, AEROSURF are accepted on formulary by our target hospitals, if our products do not achieve broad market acceptance 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 and others in the medical community in general, we may not generate sufficient revenues, either directly, or indirectly through alliance or collaboration agreements, 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' Pharmacy and Therapeutics (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.

Our post-marketing activities, including promotion, marketing and manufacturing, are subject to continuing review.

We have received marketing authorization in the United States for SURFAXIN. Our approved labeling contains, among other things, data from our pivotal phase 3 clinical trial, but there are limitations that affect the manner in which we may promote, market and sell our SURFAXIN drug product. For SURFAXIN, any promotion, marketing and sales efforts must be based on the content of our labeling, although certain scientific information that speaks to the benefits of our KL4 surfactant may be provided by our medical affairs representatives in response to unsolicited requests for information.

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 promotional materials for our products, including labeling, training or other marketing or educational activities, constitute promotion of an unapproved use, it could issue to us and our alliance partner a warning or untitled letter or direct our alliance partner to cease using or modify training or promotional materials, or subject us or our alliance partner to serious regulatory enforcement actions. For example, on March 6, 2015, we received an untitled letter from FDA regarding promotional materials alleged to contain unsubstantiated claims of the superiority of SURFAXIN to animal-derived surfactants and broaden the intended use of SURFAXIN by implying that it is approved for the treatment of RDS in premature infants when it is only approved for the prevention of RDS in premature infants. We expect to promptly implement a plan to respond to the concerns raised in the letter and to reply within the time period set forth therein. It is also possible that other federal, state or foreign enforcement authorities could take action if they consider that we or our alliance partners have engaged in activities that 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.

We expect to provide our AFECTAIR device with our AEROSURF drug-device product candidate. If AEROSURF is approved, the FDA may determine that AFECTAIR is no longer a Class I, 510(k)-exempt medical device. During the development of AEROSURF, we expect to discuss with the FDA the regulatory status of AFECTAIR.

In addition, we will have to comply with reporting requirements applicable to drug products and medical devices, 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.

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.

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.

Adverse safety events or restrictions on use and safety warnings for our products can negatively affect our business, product sales and stock price.

Adverse safety events involving our marketed products may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market, and the imposition of fines or criminal penalties. Adverse safety events may also damage physician and patient confidence in our products and our reputation. Any of these could result in liabilities, loss of revenue, material write-offs of inventory, material impairments of intangible assets, goodwill and fixed assets, material restructuring charges and other adverse impacts on our results of operations.

Regulatory authorities are making greater amounts of stand-alone safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events involving our products or products similar to ours or any public rumors about such events may give rise to claims against us and may also adversely affect our ability to market our products and conduct our clinical development programs.

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.

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 source 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.

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 products generally, but other provisions of the Health Care Reform Law could affect us adversely. The changes contemplated by the health care reform law are subject to timelines that extend for several years, and further federal and state proposals for healthcare reform are likely. 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 reported 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. That data was made publicly available in late 2014 via a CMS website. Similarly, manufacturers must report relevant data for all of 2014 no later than March 31, 2015. Inaccurate or incomplete reports may be subject to enforcement, and it is expected that data will be subject to significant public scrutiny. 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, 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. At the present time, the effect of this tax on our business is not material. However, as U.S. net sales are expected to be a significant portion of our worldwide net sales in the coming years, beginning with AEROSURF, 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.

Additionally, in the next several years regulations and guidance implementing the Health Care Reform Law, as well as additional healthcare reform proposals, may have a financial impact on our business.

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

For our commercial products, development programs, operations and administration, we need extensive information technology (IT) systems in virtually all aspects of our business. In selecting the appropriate software packages and systems to manage and support our activities, we consider both in-house development and specialty software and system packages offered by third party vendors, service providers and consultants. There can be no assurance that the systems we selected or may 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. For all of our systems, we take precautionary measures to prevent unanticipated problems. Nevertheless, we may experience damage 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 assurance 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.

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.

The increasing use of social media platforms presents new risks and challenges.

At the present time, we have not established channels of communication using social media, but we are nevertheless exposed to risks that derive from the use of social media by other. Social media is increasingly being used to communicate about drug products and related diseases. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear or responsive to the changing technological environment. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend ourselves or the public's legitimate interests in the face of political or market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

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 anticipated FDA approval for SURFAXIN, we implemented a plan to hire additional qualified personnel to support (i) the commercial introduction of SURFAXIN, (ii) the advancement of AEROSURF development and potentially SURFAXIN LS development, as well as our other KL4 surfactant products under development programs. In particular, we enhanced our regulatory affairs, quality control and assurance and administrative capabilities and established our own sales, and marketing and medical organization. We have competed and will continue to compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is significant and attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us.

We are highly dependent upon the members of our executive management team and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these individuals have been involved with us for many years, have played integral roles in our progress and we believe that they continue to provide value to us. A loss of any of our key personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs.

We have entered into employment agreements with six executive officers, including, in March 2013, our President and Chief Executive Officer; the Senior Vice President and Chief Operating Officer; the Senior Vice President, General Counsel and Corporate Secretary; and the Senior Vice President, Human Resources; and in March 2014, the Senior Vice President and Chief Financial Officer; and in December 2014, the Senior Vice President and Chief Development Officer. These agreements were recently extended through March 31, 2017. In addition, we have agreements with five other officers that if not renewed will 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 conduct our AEROSURF phase 2 clinical program, and prepare to conduct a phase 3 clinical trial, we will need to attract and retain highly-qualified personnel to join our management, medical, development and operations 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 professional, scientific and management personnel and our ability to recruit 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, and technology 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 receiving FDA or foreign regulatory approval or commercializing products and obtaining patent protection 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. For the sale of commercial products, 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 competitive forces frequently and aggressively seek patent protection and licensing arrangements to collect royalties for technologies that they develop. 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. 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. Certain of such patents related to lyophilized KL4 surfactant have issued in the U.S. and will expire in March 2033. 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 consists solely of 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 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, Philip Morris USA Inc. (PMUSA), Philip Morris Products S.A. (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 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, 2014, the price of our common stock ranged between $0.99 and $2.77. 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, 2014, the average daily trading volume in our common stock was approximately 427,402 shares, and the average number of transactions per day was approximately 1,496. 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.

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 in connection with a public financing, under the ATM Program, in connection with our compensation programs, and upon exercise of outstanding warrants 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 future 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. 333-196420) on May 30, 2014 (which was declared effective on June 13, 2014) for the proposed offering from time to time of up to $250 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing. We may issue securities pursuant to this shelf registration statement in the future in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

As of March 6, 2015, there were 85,586,914 shares of common stock issued and outstanding. In addition, as of December 31, 2014, approximately (i) 15.5 million shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, (ii) 6.6 million shares of our common stock were reserved for issuance pursuant to our equity incentive plans, and (iii) 6,130 shares of our common stock were reserved for issuance pursuant to our 401(k) Plan. The exercise of stock options and other securities could cause our stockholders to experience substantial dilution. Moreover, holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

If we fail to adhere to the strict listing requirements of Nasdaq, 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 Nasdaq, the liquidity of our securities likely would be impaired.

Our common stock currently trades on Nasdaq 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 Nasdaq. Any failure at any time to meet the continuing Nasdaq listing requirements could have an adverse impact on the value of and trading activity in our common stock.

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, including in clinical trials, may expose us to product liability claims. 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.

Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated By-Laws 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 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. As a result, our Board of Directors could issue large blocks of preferred stock or 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.

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 KL4 surfactant dosage forms as well as our efforts to identify and protect our intellectual property. We also maintain a controlled 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.

We lease approximately 21,000 square feet of space for our manufacturing operations in Totowa, New Jersey (Totowa Facility), at an annual rent of $525,000. In early 2014, we entered into an amendment to extend the lease through 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 assessing our strategic alternatives and thereafter may enter into discussions with the landlord potentially to enable longer-term utilization of that facility for the manufacture of SURFAXIN. See, “Item 1 – Business – Business Operations – Manufacturing and Distribution – KL4 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® (Nasdaq) under the symbol "DSCO." As of March 6, 2015, we had 117 stockholders of record of shares of our common stock. We also have been advised that, as of December 14, 2014, there are approximately 18,295 beneficial owners of our common stock whose positions are held in street name. As of March 6, 2015, there were 85,586,914 shares of our common stock issued and outstanding.

The following table sets forth the quarterly sales price ranges of our common stock for the periods indicated, as reported by Nasdaq.

	2014		2013	
	High	Low	High	Low
Period:				
First Quarter	$ 2.77	$ 2.10	$ 2.91	$ 2.11
Second Quarter	$ 2.34	$ 1.51	$ 2.40	$ 1.50
Third Quarter	$ 2.03	$ 1.51	$ 2.23	$ 1.54
Fourth Quarter	$ 2.01	$ 0.99	$ 3.05	$ 1.90

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.

ITEM 6. SELECTED FINANCIAL DATA.

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

	For the year ended December 31,				
	2014	**2013**	**2012**	**2011**	**2010**
Revenues:					
Product sales	$ 312	$ –	$ –	$ –	$ –
Grant revenue	2,523	388	195	582	–
	2,835	388	195	582	–
Operating expenses:					
Cost of product sales	2,671	517	–	–	–
Research and development	26,690	27,661	21,570	17,230	17,136
Selling, general and administrative	16,732	16,718	16,444	7,864	8,392
	46,093	44,896	38,014	25,094	25,528
Operating loss	(43,258)	(44,508)	(37,819)	(24,512)	(25,528)
Change in fair value of common stock warrant liability	3,791	761	555	3,560	6,422
Other (expense) / income	(4,591)	(1,468)	(51)	(13)	(69)
Net loss	$ (44,058)	$ (45,215)	$ (37,315)	$ (20,965)	$ (19,175)
Net loss per common share					
Basic	$ (0.52)	$ (0.82)	$ (0.95)	$ (0.93)	$ (1.65)
Diluted	$ (0.56)	$ (0.82)	$ (0.95)	$ (0.93)	$ (1.65)
Weighted average number of common shares outstanding					
Basic	85,095	55,258	39,396	22,660	11,602
Diluted	86,025	55,258	39,396	22,660	11,602

Included in the net loss for 2014, 2013, 2012, 2011, and 2010 were non-cash charges for stock-based compensation and depreciation of $3.7 million, $2.9 million, $3.3 million, $2.2 million, and $2.8 million, respectively.

Consolidated Balance Sheet Data:
(in thousands)

	December 31,				
	2014	**2013**	**2012**	**2011**	**2010**
Cash and investments	$ 44,711	$ 86,283	$ 26,892	$ 10,189	$ 10,211
Working capital	37,730	75,384	16,107	(516)	2,920
Total assets	47,499	89,317	29,943	13,324	14,537
Long-term debt, $30,000 net of discount of $9,698 at December 31, 2014 and $11,646 at December 31, 2013	20,302	18,354	–	–	–
Other long-term obligations, less current portion	169	607	591	913	935
Total stockholders' equity	$ 19,199	$ 58,501	$ 17,653	$ 1,264	$ 6,026

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 for the year ending December 31, 2014 and notes thereto (Notes) included in this Annual Report of Form 10-K. *See,* "Item 8 – Financial Statements and Supplementary Data." 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, 2014, 2013 and 2012.
- **Liquidity and Capital Resources**: this section provides a discussion of our capital resources, future capital requirements, cash flows, committed equity financing facilities, historical financing transactions, outstanding debt arrangements and commitments.

OVERVIEW

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a specialty biotechnology company focused on creating life-saving products for critical-care patients with respiratory disease and improving the standard of care in pulmonary medicine. Our proprietary drug technology produces a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL4 surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel aerosol drug delivery technologies potentially to enable efficient delivery of our aerosolized KL4 surfactant. We believe that our proprietary technologies may make it possible to develop a pipeline of products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our development programs have been focused initially 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 KL4 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 KL4 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.). SURFAXIN has been commercially available in the U.S. since November 2013. *See,* "Item 1 – Business – Business Strategy – SURFAXIN."

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, 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 respond poorly (an outcome referred to as nCPAP failure) and 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 received surfactant therapy in the first hours of life.

AEROSURF® is an investigational combination drug/device product that combines our KL4 surfactant with our proprietary capillary aerosol generator (CAG) technology. With AEROSURF, neonatologists potentially will be able to administer aerosolized KL4 surfactant to premature infants supported with nCPAP alone, without having to resort to invasive intubation and mechanical ventilation. By enabling delivery of our aerosolized KL4 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.

To initiate the commercial introduction of SURFAXIN in the U.S., we established our own specialty respiratory critical care commercial and medical affairs organization and made investments in manufacturing, quality systems, supply chain, and distribution capabilities. For 2014, total costs for marketing, medical and commercial capabilities, as well as manufacturing, quality systems, supply chain, distribution and related costs to support the commercialization of SURFAXIN were approximately $19 million. Notwithstanding, revenue growth has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN.

We also believe that our limited capital and resources should be invested in the development of aerosolized KL4 surfactant, beginning with AEROSURF, which has the potential to generate greater value for our stockholders. Therefore, we are pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN that potentially could be (i) a strategic alliance or collaboration arrangement, which we expect would require a lease extension for our manufacturing facility in Totowa, NJ (Totowa Facility) and may require consent under our Deerfield Loan, or (ii) ceasing our commercialization activities for SURFAXIN. We would prefer an alliance or collaboration arrangement with a pharmaceutical company that has existing commercial capabilities, including substantial sales, marketing and medical resources and experience in the introduction of hospital-based products. However, there can be no assurance that we will succeed in such efforts. In connection with either a strategic alliance or collaboration agreement for SURFAXIN or cessation of commercialization activities, we expect that we likely will incur one-time transition-related costs associated with such event.

In the future, we expect 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 children and adults in pediatric and adult intensive care units (PICUs and ICUs). While we currently are focused primarily on the development of AEROSURF through phase 2 clinical trials, we have explored and plan in the future to explore potential opportunities to address a variety of respiratory conditions that may benefit from KL4 surfactant therapy where there are no currently approved therapies other than supportive respiratory care.

We believe that our aerosolized KL4 surfactant, alone or in combination with other pharmaceutical compounds, has the potential to be developed to address a range of serious respiratory conditions and may be an effective intervention for such conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, diseases involving mucociliary clearance disorders, such chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). We believe that we have an opportunity to develop a broad pipeline of KL4 surfactant products to address these and other conditions.

The reader is referred to, and encouraged to read in its entirety "Item 1 – Business – Company Overview" and "– Business Strategy," in this Annual Report on Form 10-K, which contains a discussion of our Business and Business Strategy, as well as information concerning our proprietary technologies and our current and planned KL4 pipeline programs.

CRITICAL ACCOUNTING POLICIES

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

We believe the following accounting policies are the most critical for an understanding of our financial condition and results of operations. For further discussion of our accounting policies, *see,* "Item 8 – Notes to consolidated financial statements – Note 3 – Accounting Policies and Recent Accounting Pronouncements."

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 we currently cannot make a reasonable estimate of future product returns 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 a hospital, we believe the risk of material returns is significantly mitigated. 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 primarily consist of Group Purchasing Organizations member hospitals, 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 periodically adjusted on a prospective basis based upon the customer's 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 for 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 six months subsequent to its expiry date.

Research and development

We account for research and development expense by the following categories: (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 all regulatory approvals needed to enable the commercial launch of the product are received and the related costs will be recoverable through the commercial sale of the product. Costs incurred prior to FDA approval of drug products and registration of medical devices is recorded in our statement of operations as research and development expense. Inventories are 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.

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. Depending on the terms of a warrant agreement, we use the Black-Scholes or trinomial pricing models to value the related derivative warrant liabilities. Changes in the fair value of the warrants are reflected in the consolidated statement of operations as "Change in fair value of common stock warrant liability." *See,* "Item 8 – Notes to consolidated financial statements – 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, 2014, 2013, and 2012 was $44.1 million (or $0.52 basic net loss per share), $45.2 million (or $0.82 basic net loss per share), and $37.3 million (or $0.95 basic net loss per share), respectively. The operating loss for the years ended December 31, 2014, 2013, and 2012 was $43.3 million, $44.5 million, and $37.8 million, respectively.

Product Sales

In accordance with our revenue recognition policy, we recognize revenue on product sales once product has been sold through to the hospital and all revenue recognition criteria have been met. For the year ended December 31, 2014, we recognized revenue in the amount of $312,000. SURFAXIN revenue growth continues to be slower than expected and we are now considering potential strategic alternatives for SURFAXIN, including potentially (i) a strategic alliance or collaboration arrangement, which we expect would require a lease extension for our Totowa Facility and may require consent under our Deerfield Loan, or (ii) ceasing commercialization activities. No product sales revenue was recognized for the years ended December 31, 2013 and 2012.

Grant Revenue

We recognized grant revenue of $2.5 million for the year ended December 31, 2014 under two grants discussed below.

During the second quarter of 2014, we were awarded the final $1.9 million of a $2.4 million Fast Track Small Business Innovation Research (SBIR) Grant from the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). This award provides support for the ongoing phase 2a clinical trial for AEROSURF. We received and expended $1.8 million in 2014 under this award. We previously received and expended $0.6 million in 2011 under this grant to support development activities related to our capillary aerosol generator technology.

During the third quarter of 2014, we were awarded a Phase II SBIR grant of $1.0 million from the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH to support the development of our aerosolized KL4 surfactant as a medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury. We received $0.7 million in 2014 under this award. Over the next two years, we may be awarded up to an additional $2.0 million as part of this grant. Phase I of this grant was awarded in 2012 for $0.6 million and we previously received and expended $0.4 million in 2013 and $0.2 million in 2012.

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), such as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, and diseases involving mucociliary clearance disorders, such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). We believe that we may have an opportunity to develop a broad pipeline of KL4 surfactant products to address these and other conditions.

Cost of Product Sales

(in thousands)	Years Ended December 31,		
	2014	2013	2012
Cost of product sales	$ 2,671	$ 517	$ –

Since October 4, 2013, the date the FDA approved updated SURFAXIN product specifications, which enabled the commercial introduction of SURFAXIN, we have capitalized inventories produced to support the commercial launch. Cost of product sales for 2014 and 2013 includes $2.4 million and $0.5 million, respectively, of 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. The increase in cost of product sales from 2013 to 2014 is due to the manufacture of additional commercial production in 2014.

Research and Development Expenses

Our research and development expenses are charged to operations as incurred and we account for 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 account for research and development and report by major expense category as follows: (i) salaries and benefits, (ii) contracted services, (iii) raw materials, aerosol devices and supplies, (iv) rents and utilities, (v) depreciation, (vi) contract manufacturing, (vii) travel, (viii) stock-based compensation and (ix) other.

Research and development expenses by category for the years ended December 31, 2014, 2013, and 2012 are as follows:

(in thousands)	Years Ended December 31,		
	2014	2013	2012
Product development and manufacturing	$ 14,920	$ 20,471	$ 15,788
Medical and regulatory operations	8,126	5,966	4,818
Direct preclinical and clinical programs	3,644	1,224	964
Total Research and Development Expenses	$ 26,690	$ 27,661	$ 21,570

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $1.8 million, $1.4 million, and $1.3 million for 2014, 2013, and 2012, 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) manufacturing operations, both in-house and with CMOs, validation activities, quality assurance and analytical chemistry capabilities that support the manufacture of our KL4 surfactant used in research and development activities, and our medical devices, including our CAG, (ii) design and development activities related to our CAG device for use in our AEROSURF clinical program; and (iii) pharmaceutical and manufacturing 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 decreased $5.6 million from 2013 to 2014, primarily due to (i) investments in 2013 of $3.5 million to complete development activities related to our CAG for use in our AEROSURF phase 2a clinical trial, 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) a $1.4 million reduction in CMO costs related to activities in 2013 to transfer our KL4 surfactant manufacturing process to a CMO, and (iii) a $1.0 million reduction in purchases of APIs used in the manufacture of SURFAXIN commercial drug product and our lyophilized KL4 surfactant for use in preclinical and clinical development activities, including the technology transfer of our lyophilized KL4 surfactant manufacturing process to Patheon, and activities to support our AEROSURF phase 2 clinical program.

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 with Battelle to develop a clinic-ready CAG device for use in our AEROSURF phase 2 clinical trials; (ii) costs associated with a technical transfer and further development of our KL4 surfactant manufacturing processes at Patheon; 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 lyophilized KL4 surfactant manufacturing process at Patheon, and activities to develop a clinic-ready CAG and prepare for our AEROSURF phase 2 clinical program.

We plan to continue investments in the development of our manufacturing process for our lyophilized KL4 surfactant with Patheon, and plan to manufacture drug product for preclinical and clinical activities, including for our AEROSURF clinical programs and 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 $2.2 million from 2013 to 2014 primarily due to (i) a $0.8 million increase in employee-related costs as we strengthen our clinical leadership team and regulatory capabilities to support our AEROSURF development program, (ii) a $0.5 million increase related to our medical affairs capabilities to support the commercialization of SURFAXIN, and (iii) a $0.4 million severance charge (*see,* "Item 8 – Notes to consolidated financial statements – Note 13 – Commitments").

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.

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, clinical site costs, clinical device and drug supply, and related external costs, such as consultant fees and expenses.

Direct preclinical and clinical programs expenses increased $2.4 million from 2013 to 2014 primarily due to (i) a $1.5 million increase in AEROSURF clinical trial activities, including the initial Phase 2a clinical trial and manufacturing of clinic-ready CAG devices to support further clinical activities and the planned AEROSURF Phase 2b clinical trial, and (ii) a $0.9 million increase in preclinical activities in connection with the two NIH grants we were awarded in 2014 and work related to our the lyophilized KL4 surfactant.

Direct preclinical and clinical programs expenses increased $0.3 million from 2012 to 2013 primarily due to increased 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 initial 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.

If our early clinical results are encouraging, we anticipate that our direct clinical program costs will increase significantly over the next few years as we refine our development plan for AEROSURF and execute the later stages of the AEROSURF clinical development program. If successful, we estimate incurring $15 to $20 million in 2015 and 2016 on direct clinical program costs for the AEROSURF Phase 2 program.

In addition to developing our aerosolized KL4 surfactant for AEROSURF, we have approached the FDA to determine if we potentially could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a plan that we believe might be both capital efficient and capable of implementation within a reasonable time. If achievable, and if we are successful in entering into a strategic alliance or collaboration agreement to support SURFAXIN commercialization in the U.S., we may consider implementing such a development plan with our strategic partner or other third parties. If SURFAXIN LS is approved, we expect that our strategic partner would introduce the product commercially in the U.S. as a life-cycle extension of SURFAXIN. If we are unable to enter into a strategic alliance or collaboration agreement to support the commercialization of SURFAXIN in the U.S., we do not plan to initiate a development program for SURFAXIN LS on our own at this time.

Research and Development Expense by Major Expense Category

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

(in thousands)	Years Ended December 31,		
	2014	**2013**	**2012**
Salaries & benefits	$ 12,755	$ 11,213	$ 9,986
Contracted services	7,064	8,248	6,332
Raw materials, aerosol devices and supplies	3,969	3,633	1,652
Rents and utilities	1,431	1,186	1,366
Depreciation	755	659	841
Contract manufacturing	87	1,441	15
Travel	749	447	316
Stock-based compensation	1,014	784	488
All other	1,315	670	574
Allocation to batch production	(2,449)	(620)	–
Total	$ 26,690	$ 27,661	$ 21,570

The increase in salaries and benefits from 2013 to 2014 is primarily due to (i) strengthening our clinical leadership team and regulatory capabilities to support our AEROSURF development program, (ii) continuing to develop our medical affairs capabilities to support the commercial introduction of SURFAXIN, and (iii) an employee severance and retention plan for employees at our manufacturing facility initially intended to retain our personnel in the event that we are unable to secure long-term utilization of the facility beyond the scheduled lease expiration on June 30, 2015. The increase from 2012 to 2013 is primarily due to the establishment of our medical affairs organization primarily to support the commercial introduction of SURFAXIN, 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 stability and release testing of our drug product, consulting services, aerosol device design and engineering services, etc. The decrease from 2013 to 2014 is primarily due to the completion of our work with Battelle for a clinic-ready CAG device to be used in our initial AEROSURF phase 2a clinical trial. The increase from 2012 to 2013 is primarily due to costs associated with initiation in June 2012 of our work with Battelle to prepare a clinic-ready CAG to be used in our initial AEROSURF phase 2a clinical trial, and investments in our manufacturing and quality activities as we prepared for the commercial introduction of SURFAXIN.

Raw materials, aerosol devices 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. Raw materials, aerosol devices and supplies purchases increased from 2013 to 2014 primarily due to an increase in purchases of aerosol devices and supplies for use in the AEROSURF phase 2a clinical trial, partially offset by a decrease in purchases of raw materials. The increase in raw materials, aerosol devices 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.

Rents and utilities are costs related to our leased manufacturing, laboratory, and corporate facilities. The increase from 2013 to 2014 is primarily due to (i) increased rent for our manufacturing facility in Totowa, NJ in accordance with an agreement to extend our lease effective in the third quarter of 2013 and (ii) increased utility costs at our manufacturing facility. The decrease from 2012 to 2013 is primarily due to (i) decreased rent for our corporate and laboratory facility in Warrington, PA in accordance with an agreement to amend and extend our lease executed in January 2013, and (ii) decreased utility costs at our manufacturing facility.

Contract manufacturing represents costs related to the technology transfer of our liquid and lyophilized KL4 surfactant manufacturing processes to a CMO. The costs in 2013 related to activities to transfer our KL4 manufacturing processes to a CMO.

The category “All other” consists primarily of ongoing research and development costs such as insurance, taxes, education and training and software licenses. The increase from 2013 to 2014 includes $0.3 million for royalties due to Philip Morris USA and Philip Morris Products, S.A. under our license agreements for our CAG technology.

Allocation to batch production represents manufacturing, quality and analytical testing costs related to SURFAXIN batch production for commercial supply, medical affairs programs and other development activities.

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 $75.9 million in expenses for the three-year period ended December 31, 2014. Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete individual projects in development are not reasonably estimable. With every phase of a development project, there are unknowns that may significantly affect cost projections and timelines. In view 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, other risks could arise that may affect our ability to estimate projections and timelines. (*See,* “Item 1 – Business – Government Regulation,” and “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. 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;” “- 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.”)

Our lead research and development projects have been focused initially on the management of RDS in premature infants. They include (i) SURFAXIN liquid instillate, which was approved by the FDA in 2012 and introduced commercially in 2013, (ii) lyophilized KL_4 surfactant, which we are developing initially for use in our AEROSURF development program and potentially SURFAXIN LS; (iii) our aerosol delivery technologies, in particular the development and manufacture of a clinic-ready CAG device to support our AEROSURF phase 2 clinical program and initiation of a program to further develop and improve our CAG device for use in a potential Phase 3 clinical program and, if approved initial commercial supply; and (iv) AEROSURF phase 2 clinical trial activities and preparatory work for the planned AEROSURF phase 3 clinical program.

To prepare for initiation of our planned AEROSURF phase 2b clinical trial and the phase 3 clinical program, we plan to make additional investments in our development capabilities, including for manufacturing development of our lyophilized KL_4 surfactant, further development of our CAG device under our collaboration with Battelle, and the conduct of the planned clinical trials. In particular, we anticipate that direct clinical program costs for AEROSURF will increase significantly over the next few years as we complete our phase 2a clinical trial, assess the results and execute the later stages of the planned AEROSURF clinical development program.

At the present time, we are focusing our development efforts primarily on RDS and the development of AEROSURF through the phase 2 clinical trials to the planned phase 3 clinical program. In the future, we expect 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 children and adults in pediatric and adult intensive care units (PICUs and ICUs). We believe that our aerosolized KL_4 surfactant, alone or in combination with other pharmaceutical compounds, may be an effective intervention for people at risk for, or with, manifestations of, acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, we may explore opportunities to apply KL_4 surfactant therapies to treat conditions such as chronic sinusitis, complications of certain major surgeries, and mechanical ventilator-induced lung injury (often referred to as VILI), severe acute respiratory syndrome (SARS), pneumonia and sepsis.

The status of our lead projects and our other pipeline candidates, including the potential timing and milestones for each, is also discussed in "Item 1 – Business – 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,		
	2014	**2013**	**2012**
Selling, General and Administrative Expenses	$ 16,732	$ 16,718	$ 16,444

Selling, general and administrative expenses consist primarily of the costs of 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 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. Excluding these charges, selling, general, and administrative expense increased $2.3 million from 2012 to 2013 due to an increase in costs in our marketing and field-based sales force to support the commercial introduction of SURFAXIN.

Selling, general and administrative expenses include non-cash charges associated with stock-based compensation and depreciation of $2.0 million, $1.5 million, and $2.0 million, for the years ended December 31, 2014, 2013 and 2012, respectively.

In addition to developing our commercial marketing and sales organization, we have made 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,		
	2014	2013	2012
Change in fair value of common stock warrant liability	$ 3,791	$ 761	$ 555

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 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, 2014	2013	2012
Interest income	$ 6	$ 3	$ 3
Interest expense	(4,597)	(1,471)	(13)
Other income / (expense)	–	–	(41)
Other income / (expense), net	$ (4,591)	$ (1,468)	$ (51)

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 2014 and 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 consists of interest expense incurred under our equipment loan.

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

(in thousands)	December 31, 2014	2013	2012
Cash interest expense	$ 2,625	$ 911	$ –
Non-cash amortization of debt discounts	1,948	534	–
Amortization of debt costs	19	18	–
Total Deerfield Loan interest expense	$ 4,592	$ 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, committed equity financing facilities (CEFFs), at-the-market equity programs, and capital equipment financings.

As of December 31, 2014, we had cash and cash equivalents of $44.7 million and long-term debt of $30 million under our loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (see, "Item 8 – Notes to consolidated financial statements – Note 9 – Deerfield Loan"). For the next several years, we expect that our cash outflow requirements, for development programs, operations and debt service, will outpace the rate at which we may generate revenues. Therefore, to execute our business strategy, advance our development programs, pay debt obligations and fund our operations, we will require significant additional infusions of capital until such time as we are able to generate sufficient revenues from the sale of approved products, from potential strategic alliances and commercialization agreements, and from other sources that are sufficient to offset our cash flow requirements. Following the approval of SURFAXIN, we established our own specialty respiratory critical care commercial and medical affairs organization and made investments in manufacturing, quality systems, supply chain, and distribution capabilities. Notwithstanding, revenue growth has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN. We also believe that our limited capital and resources should be invested in the development of aerosolized KL4 surfactant, beginning with AEROSURF. Therefore, we are pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN that potentially could be (i) a strategic alliance or collaboration arrangement, which we expect would require a lease extension for our Totowa Facility and may require consent under our Deerfield Loan, or (ii) ceasing commercialization activities for SURFAXIN. We would prefer an alliance or collaboration arrangement with a pharmaceutical company that has existing commercial capabilities, including substantial sales, marketing and medical resources and experience in the introduction of hospital-based products. However, there can be no assurance that we will succeed in such efforts. In connection with either a strategic alliance or collaboration agreement for SURFAXIN or cessation of commercialization activities, we expect that we likely will incur one-time transition-related costs associated with such event. Before any additional financings and taking into account our plan to quickly reduce cash outflows related to SURFAXIN through either (i) a strategic alliance or, in the event we are unable to secure a strategic alliance in the near term, (ii) ceasing commercial activities, we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the first quarter of 2016.

To secure the necessary capital to fund our development programs, an important priority for us is to identify strategic transactions that could provide additional capital and strategic resources to support the continued development and commercial introduction of our RDS products in markets outside the U.S. For our AEROSURF development program, we seek a significant strategic alliance with a partner that has broad experience in markets outside the U.S., including regulatory and product-development expertise and, if AEROSURF is approved, an ability to support the commercial introduction of AEROSURF in the EU and other selected markets outside the U.S. Such alliances typically also provide financial resources, in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. If our efforts to secure an alliance for SURFAXIN in the U.S. are successful, we may seek a strategic alliance that could provide regulatory expertise in designated markets where regulatory marketing authorization is facilitated by the information contained in our new drug application (NDA) approved by the FDA, support the commercial introduction of SURFAXIN in such markets and provide for a sharing of revenues. Under our Battelle Collaboration Agreement, at our discretion from time to time, we may elect to defer payment of amounts due to Battelle in respect of our share of development costs for up to 12 months. We currently have deferred certain payments and may continue to defer payments through the completion of the development project. In addition, 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. We also may consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions.

Our future capital requirements will depend upon many factors, including our efforts to (i) advance the AEROSURF development program to completion of the phase 2 clinical trials as planned; (ii) reduce or eliminate our capital and resources allocated to the commercialization of SURFAXIN in the U.S. (iii) assure long-term continuity of supply for our KL4 surfactant drug product, potentially at our manufacturing facility in Totowa, NJ (Totowa Facility) and with CMOs, (iv) further the development of our CAG for use in a planned phase 3 clinical program and, if approved, early commercial activities, (v) prepare for and conduct an AEROSURF phase 3 clinical program, and (vi) secure one or more strategic alliances or other collaboration arrangements to support our development programs and commercialization of our approved products, if any, in markets outside the U.S. We believe that we will be better positioned to enter into a significant strategic alliance for AEROSURF if we obtain encouraging results from the AEROSURF phase 2 clinical program.

Given the uncertainty associated with our business strategy as planned, there can be no assurance (i) that our AEROSURF development program will be successful within our anticipated time frame, if at all, (ii) that any of our approved products will be commercially viable, (iii) that we will be able to execute our long-term manufacturing plan to secure continuity of drug product supply, (iv) that we will be able to secure regulatory marketing authorization for AEROSURF and our other potential KL4 surfactant product candidates in the U.S. and other markets, or (v) that the ATM Program will be available when needed, if at all, or (vi) that we otherwise will be able to obtain additional capital when needed and on acceptable terms. We will require significant additional capital to execute our business strategy, pay debt service and sustain operations. Failure to secure the necessary additional capital when needed would have a material adverse effect on our business, financial condition and results of operations. Even if we succeed in our efforts and subsequently commercialize our products, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of December 31, 2014, we had outstanding warrants to purchase approximately 15.5 million shares of our common stock at various prices, exercisable on different dates into 2024. This includes warrants to purchase 7 million shares that were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share (Deerfield Warrants). 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 issued in February 2011 to purchase approximately 4.6 million shares of common stock that expire in February 2016 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 currently have an exercise price of $1.50 per share. 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 approximately $6.8 million. There can be no assurance that the price of our common stock will achieve the needed level, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. 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.

As of December 31, 2014, 250 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 135.7 million shares of common stock were available for issuance and not otherwise reserved.

Cash Flows

As of December 31, 2014, 2013, and 2012, we had cash and cash equivalents of $44.7 million, $86.3 million and $26.9 million. Cash outflows before financing activities for 2014 consisted of $41.2 million used for ongoing operating activities and $0.8 million for purchases of property and equipment.

Operating Activities

Net cash used in operating activities was $41.2 million, $40.5 million, and $32.9 million for the years ended December 31, 2014, 2013, and 2012, 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 U.S. specialty commercial and medical affairs organizations to support, and manufacturing and quality activities in preparation for, the commercial introduction of SURFAXIN; (ii) costs to develop and manufacture clinic-ready CAGs for the initial AEROSURF phase 2a clinical trial, including work that began in 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 KL4 surfactant, for commercial use and preclinical development activities, including to complete the technical transfer and further develop our KL4 surfactant manufacturing process at Patheon, and activities to develop a clinic-ready CAG and prepare for our AEROSURF phase 2 clinical program.

Investing Activities

Net cash used in investing activities was $0.8 million, $0.6 million, and $0.6 million for the years ended December 31, 2014, 2013, and 2012, respectively, and represents capital expenditures.

Financing Activities

Net cash provided by financing activities was $0.4 million, $100.5 million, and $50.2 million for the years ended December 31, 2014, 2013, and 2012, respectively, summarized as follows:

(in millions)	Years Ended December 31,		
	2014	2013	2012
Financings pursuant to common stock offerings	$ –	$ 69.0	$ 42.1
Proceeds from issuance of long-term debt, net	–	29.6	–
Exercise of common stock warrants and options	0.5	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	$ 0.4	$ 100.5	$ 50.2

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 that we will continue to fund, our business operations through various sources, including financings in the form of common stock offerings. In May 2014, we filed a universal shelf registration statement on Form S-3 (No. 333-196420) (2014 Universal Shelf) with the SEC that was declared effective on June 13, 2014 for the proposed offering from time to time of up to $250 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing, on terms and conditions that will be determined at the time of an offering. The 2014 Universal Shelf replaces an expired 2011 Universal Shelf. As of December 31, 2014, after reserves for outstanding unexercised warrants and amounts remaining available under our ATM Program, approximately $199.0 million remained available under the 2014 Universal Shelf. The 2014 Universal Shelf will expire in June 2017.

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.

Warrants

During the year ended December 31, 2014, holders of the February 2011 five-year warrants exercised warrants to purchase 284,850 shares of our common stock at an exercise price of $1.50 per share, resulting in proceeds to us of $0.4 million.

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 $0.2 million.

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 $0.2 million. For a listing of outstanding warrants, *see,* "Item 8 – Notes to consolidated financial statements – Note 10 – 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, 2014, 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 could sell 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 (i) to pay Lazard a commission equal to 3.0% of the gross proceeds of any sales, and (ii) to reimburse Lazard for certain expenses incurred. 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

Long-term debt consists solely of amounts due under a $30 million loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for the periods presented:

(in thousands)	December 31, 2014	December 31, 2013
Note payable	$ 30,000	$ 30,000
Unamortized discount	(9,698)	(11,646)
Long-term debt, net of discount	$ 20,302	$ 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 accrues 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* and have been classified as equity.

Contractual Obligations and Commitments

Future payments due under contractual obligations at December 31, 2014 are as follows:

(in thousands)	2015	2016	2017	2018	2019	There-after	Total
Operating lease obligations	$ 1,239	$ 961	$ 943	$ 158	$ –	$ –	$ 3,301
Equipment loan obligations	69	–	–	–	–	–	69
Total	$ 1,308	$ 961	$ 943	$ 158	$ –	$ –	$ 3,370

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 $525,000. This space is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. The lease expires on June 30, 2015. *See,* "Item 1 – Business – Business Strategy," and "– Business Operations – Manufacturing and Distribution," in this Annual Report on Form 10-K.

Rent expense under these leases was $1.2 million for the year ended December 31, 2014 and $1.0 million for each of the years ended December 31, 2013, and 2012.

Battelle Collaboration

In October 2014, we entered into a collaboration agreement with Battelle providing for the further development of our CAG for potential use in our planned phase 3 clinical program for AEROSURF for the treatment of RDS in premature infants and, if AEROSURF is approved for commercial sale by the FDA or other regulatory authority, initial commercial supply. Under our agreement, we and Battelle plan to design, develop, and complete the testing, verification, and documentation of an improved AEROSURF system, and share equally in the related development costs. If this development project is successfully completed, based upon our current estimates, we expect to incur development costs of approximately $6.0 million through 2016. *See,* "Item 8 – Notes to consolidated financial statements – Note 12 – Corporate Partnership, Licensing and Research Funding Agreements."

Severance Arrangements

Effective November 30, 2014 we and our Senior Vice President, Research and Development (the Executive) agreed to terminate his employment under his existing Employment Agreement dated April 1, 2013 (Employment Agreement). In connection therewith, upon execution by the Executive of a plenary release in form satisfactory to us, he became entitled under his Employment Agreement to certain severance and other benefits. In addition to any benefits that were otherwise due under our vested plans or other policies, the Executive will receive the following payments and benefits: (i) a pro rata bonus equal to that percent of the Executive's Annual Bonus Amount (as defined in the Employment Agreement) that corresponds to that percent of days that the Executive was employed by us in 2014, reduced to reflect the same percent of his pro rata Annual Bonus Amount that corresponds to the percent of the aggregate Annual Bonus Amounts actually paid to other contract executives with respect to 2014, payable at the time that our other contract executives are paid bonuses; (ii) a severance amount equal to the sum of the Executive's base salary then in effect and his Annual Bonus Amount, payable in equal installments from November 30, 2014 to November 30, 2015 (the Severance Period); and (iii) all vested stock options, restricted stock grants and other similar equity awards held by the Executive shall continue to be exercisable during the Severance Period. From and after the effective date of termination, all of the Executive's unvested stock options were forfeited in accordance with the terms of our 2011 Long-Term Incentive Plan. In addition, the Executive also is subject to non-competition and non-solicitation restrictions for 12 months and 18 months, respectively, after the date of termination under a separate confidentiality agreement. All of our obligations under the Employment Agreement will cease if at any time during the Severance Period the executive engages in a material breach of the Employment Agreement and fails to cure such breach within five business days after receipt from us of notice of such breach.

On September 13, 2013, our Board of Directors approved an employee severance and retention plan for employees at the Totowa Facility that initially was intended to retain our manufacturing personnel should we be unable to secure long-term utilization of the Facility beyond the scheduled lease expiration on June 30, 2015. The retention plan provides severance and retention bonuses that encourage employees to stay with us through the 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 in June 2016, and will be eligible for a retention bonus payable in June 2016, provided that they remain employed with us at that time; and (2) non-union employees (eight individuals) will be eligible to receive both severance and retention bonuses, payable upon closure of the Totowa Facility, provided that they remain employed with us through the date of closure. If we secure an extension of our lease for the Totowa Facility beyond June 30, 2015, plant management bonuses nevertheless will be paid as provided in the plan in June 2016, and non-union employees will remain eligible to receive severance and retention bonuses under the plan upon the eventual closure of the Facility, provided they remain employed with us through the date of closure. The total cash amount expected to be paid for severance and retention through June 2016 is approximately $0.9 million. The plan-related expense incurred during the years ended December 31, 2014 and 2013 is $0.5 million and $0.1 million, respectively, and is included in research and development expense and cost of product sales. The related liability as of December 31, 2014 and 2013 is $0.6 million and $0.1 million, respectively.

In addition, there are 12 employees at the Totowa Facility (approximately 11% of our total labor force) who are subject to a collective bargaining agreement and will be eligible to receive severance upon closure of the Totowa Facility. The related liability is $0.4 million as of December 31, 2014 and 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.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2014, 2013, or 2012, 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 (principal executive officer) and our Senior Vice President and Chief Financial Officer (principal financial officer), do 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 our Senior Vice President and Chief Financial Officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our President and Chief Executive Officer and our Senior Vice President 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 our Senior Vice President 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 our Senior Vice President and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2014. 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 2013 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, 2014.

Our independent registered public accounting firm has audited our internal control over financial reporting, and issued an unqualified opinion dated March 16, 2015 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, 2014 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, 2014, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 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, 2014, 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, 2014 and 2013, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the three years in the period ended December 31, 2014 and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young

Philadelphia, Pennsylvania
March 16, 2015

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 2014 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 16, 2015

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

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

Signature	Name & Title	Date
/s/ John G. Cooper	John G. Cooper Director, President, and Chief Executive Officer (Principal Executive)	March 16, 2015
/s/ John Tattory	John Tattory Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2015
/s/ John R. Leone	John R. Leone Director (Chairman of the Board)	March 16, 2015
/s/ Joseph M. Mahady	Joseph M. Mahady Director	March 16, 2015
/s/ Bruce A. Peacock	Bruce A. Peacock Director	March 16, 2015
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 16, 2015

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 on 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 Amendment to Amended and Restated Certificate of Incorporation filed on June 10, 2014	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 10, 2014.
3.3	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.
3.4	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	Form of Warrant to Purchase Common Stock dated April 30, 2010, by and between Discovery and PharmaBio Development Inc. (PharmaBio)	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 28, 2010.
4.2	Form of Warrant dated June 11, 2010, by and between Kingsbridge Capital Limited and Discovery	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2010.
4.3	Form of Series I Warrant to Purchase Common Stock issued on June 22, 2010	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 17, 2010.
4.4	Warrant to Purchase Common Stock dated October 14, 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.
4.5	Form of Series I Warrant to Purchase Common Stock issued on February 22, 2011	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 16, 2011.
4.6+	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.

Exhibit No.	Description	Method of Filing
4.7+	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.
4.8+	Form of Warrant to Purchase Common Stock dated October 10, 2014, by and between Discovery and Battelle Memorial Institute	Incorporated by reference to Exhibit 4.11 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014.
4.9+	Form of Warrant to Purchase Common Stock dated October 10, 2014, by and between Discovery and Battelle Memorial Institute	Incorporated by reference to Exhibit 4.12 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014.
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.
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.

Exhibit No.	Description	Method of Filing
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 of Non-Employee Director Option 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*	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under Discovery's 2011 Long-Term Incentive Plan	Filed herewith.
10.12*	Employment Agreement dated as of April 1, 2013, by and 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 April 2, 2013.
10.13*	Employment Agreement dated as of April 1, 2013, by and between Discovery 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.
10.14*	Employment Agreement dated as of April 1, 2013, by and between Discovery and Mary B. Templeton	Incorporated by reference to Exhibit 10.16 to Discovery's Annual Report on Form 10-K, as filed with the SEC on March 17, 2014.
10.15*	Employment Agreement dated as of March 21, 2014, by and between Discovery and John A. Tattory	Incorporated by reference to Exhibit 10.1 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on May 12, 2014.
10.16*	Amendment dated December 29, 2014 to Employment Agreement dated as of April 1, 2013, by and between Discovery and John G. Cooper	Filed herewith.
10.17*	Amendment dated December 29, 2014 to Employment Agreement dated as of April 1, 2013, by and between Discovery and Thomas F. Miller, Ph.D., MBA	Filed herewith.
10.18*	Amendment dated December 29, 2014 to Employment Agreement dated as of April 1, 2013, by and between Discovery and Mary B. Templeton	Filed herewith.
10.19*	Amendment dated December 29, 2014 to Employment Agreement dated as of March 21, 2014, by and between Discovery and John A. Tattory	Filed herewith.

Exhibit No.	Description	Method of Filing
10.20	Assignment of Lease and Termination and Option Agreement, dated as of December 30, 2005, between Laureate Pharma, Inc. and Discovery with respect to property at 710 Union Blvd., Totowa, NJ 07512 (Totowa Facility)	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.
10.21	Extension of Lease, dated as of July 16, 2013, of Lease dated as of December 3, 2004, between Discovery and Norwell Land Company, with respect to the Totowa Facility	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.
10.22	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, by and between TR Stone Manor Corp. and Discovery	Incorporated by reference to Exhibits 10.1 and 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 6, 2007.
10.23	Second 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.
10.24+	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.
10.25+	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.
10.26+	Collaboration Agreement made as of October 10, 2014, by and between Discovery and Battelle Memorial Institute	Incorporated by reference to Exhibit 10.1 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on November 7, 2014.
10.27+	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.
10.28	Registration Rights Agreement dated as of February 13, 2013, between Discovery and Deerfield	Incorporated by reference to Exhibit 10.2 to Discovery's Current Report on Form 8-K/A, as filed with the SEC on March 15, 2013.
10.29	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.
10.30	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.

Exhibit No.	Description	Method of Filing
10.31+	Master Services Agreement dated October 24, 2013 between Discovery and DSM Pharmaceuticals, Inc. (now known as Patheon Manufacturing Services LLC)	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, 2014, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2014, December 31, 2013 and December 31, 2012, (ii) Statements of Operations for the years ended December 31, 2014, December 31, 2013, and December 31, 2012, (iii) Statements of Changes in Equity for the years ended December 31, 2014, December 31, 2013, and December 31, 2012, (iv) Statements of Cash Flows for the years ended December 31, 2014, December 31, 2013, and December 31, 2012, and (v) Notes to consolidated financial statements.	
101.INS	Instance Document	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema Document	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

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

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

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Contents

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Discovery Laboratories, Inc.

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. and subsidiary as of December 31, 2014 and 2013, 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, 2014. 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, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 16, 2015 expressed an unqualified opinion thereon.

/s/ Ernst and Young LLP

Philadelphia, Pennsylvania
March 16, 2015

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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

	December 31, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 44,711	$ 86,283
Accounts receivable	–	67
Inventory, net	27	112
Prepaid expenses and other current assets	821	777
Total current assets	45,559	87,239
Property and equipment, net	1,637	1,656
Restricted cash	225	325
Other assets	78	97
Total assets	47,499	89,317
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 350	$ 1,433
Accrued expenses	6,116	4,785
Deferred revenue	43	139
Common stock warrant liability	1,258	5,425
Equipment loans, current portion	62	73
Total current liabilities	7,829	11,855
Long-term debt, $30,000 net of discount of $9,698 at December 31, 2014 and $11,646 at December 31, 2013	20,302	18,354
Equipment loans, non-current portion	–	69
Other liabilities	169	538
Total liabilities	$ 28,300	$ 30,816
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 250,000,000 and 150,000,000 shares authorized at December 31, 2014 and 2013, respectively; 85,607,806 and 84,659,111 shares issued at December 31, 2014 and 2013, respectively; 85,586,914 and 84,638,219 shares outstanding at December 31, 2014 and 2013, respectively	86	85
Additional paid-in capital	546,175	541,420
Accumulated deficit	(524,008)	(479,950)
Treasury stock (at cost); 20,892 shares at December 31, 2014 and 2013	(3,054)	(3,054)
Total stockholders' equity	$ 19,199	$ 58,501
Total liabilities & stockholders' equity	$ 47,499	$ 89,317

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,		
	2014	**2013**	**2012**
Revenues:			
Product sales	$ 312	$ –	$ –
Grant revenue	2,523	388	195
	2,835	388	195
Expenses:			
Cost of product sales	2,671	517	–
Research and development	26,690	27,661	21,570
Selling, general, and administrative	16,732	16,718	16,444
	46,093	44,896	38,014
Operating loss	(43,258)	(44,508)	(37,819)
Change in fair value of common stock warrant liability	3,791	761	555
Other income / (expense):			
Interest and other income	6	3	6
Interest and other expense	(4,597)	(1,471)	(57)
Other income / (expense), net	(4,591)	(1,468)	(51)
Net loss	$ (44,058)	$ (45,215)	$ (37,315)
Net loss per common share			
Basic	$ (0.52)	$ (0.82)	$ (0.95)
Diluted	$ (0.56)	$ (0.82)	$ (0.95)
Weighted average number of common shares outstanding			
Basic	85,095	55,258	39,396
Diluted	86,025	55,258	39,396

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, 2012	**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**
Net Loss	–	–	–	(44,058)	–	–	(44,058)
Issuance of common stock, 401(k) Plan employer match	593	1	943	–	–	–	944
Exercise of common stock warrants	285	–	803	–	–	–	803
Exercise of stock options for cash	17	–	30	–	–	–	30
Issuance of common stock, consultants	18	–	38	–	–	–	38
Stock-based compensation expense	36	–	2,941	–	–	–	2,941
Balance – December 31, 2014	**85,608**	**$ 86**	**$ 546,175**	**$ (524,008)**	**(21)**	**$ (3,054)**	**$ 19,199**

See notes to consolidated financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Cash flows from operating activities:			
Net loss	$ (44,058)	$ (45,215)	$ (37,315)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	818	707	1,150
Provision for excess inventory	1,873	514	–
Stock–based compensation and 401(k) Plan employer match	3,923	3,236	3,270
Fair value adjustment of common stock warrants	(3,791)	(761)	(555)
Amortization of discount of long-term debt	1,948	534	–
Loss on disposal of equipment	–	–	42
Reduction in required restricted cash under lease agreement	100	75	–
Changes in:			
Inventory	(1,788)	(431)	(195)
Accounts receivable	67	(67)	–
Prepaid expenses and other current assets	(44)	(58)	(277)
Accounts payable	(1,083)	267	55
Accrued expenses	1,331	626	1,187
Deferred revenue	(96)	139	–
Other assets	–	(115)	–
Other liabilities	(369)	95	(246)
Net cash used in operating activities	(41,169)	(40,454)	(32,884)
Cash flows from investing activities:			
Purchase of property and equipment	(780)	(608)	(636)
Net cash used in investing activities	(780)	(608)	(636)
Cash flows from financing activities:			
Proceeds from issuance of securities, net of expenses	–	70,774	43,551
Proceeds from issuance of long-term debt	–	30,000	–
Payment of debt issuance costs	–	(450)	–
Proceeds from exercise of common stock warrants and options	457	204	6,747
Principal payments under equipment loans	(80)	(75)	(75)
Net cash provided by financing activities	377	100,453	50,223
Net increase / (decrease) in cash and cash equivalents	(41,572)	59,391	16,703
Cash and cash equivalents – beginning of year	86,283	26,892	10,189
Cash and cash equivalents – end of year	$ 44,711	$ 86,283	$ 26,892
Supplementary disclosure of cash flows information:			
Interest paid	$ 2,630	$ 920	$ 13

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 aerosol drug delivery technologies potentially to enable efficient delivery of our aerosolized KL_4 surfactant. We believe that our proprietary technologies may make it possible to develop a pipeline of products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our development programs have been focused initially 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.). SURFAXIN has been commercially available since November 2013. However, revenue growth has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN. Therefore, we are pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN. *See,* "Note 2 – Liquidity Risks and Management's Plans."

Premature infants with severe RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, 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 respond poorly (an outcome referred to as nCPAP failure) and 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 received 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) technology. With AEROSURF, neonatologists potentially will be able to administer aerosolized KL_4 surfactant to premature infants supported with nCPAP alone, without having to resort to invasive intubation and mechanical ventilation. By enabling delivery of our aerosolized 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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

In the future, we expect 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 children and adults in pediatric and adult intensive care units (PICUs and ICUs). While we currently are focused primarily on the development of AEROSURF through phase 2 clinical trials, we have explored and plan in the future to explore potential opportunities to address a variety of respiratory conditions that may benefit from KL4 surfactant therapy where there are no currently approved therapies other than supportive respiratory care.

We believe that our aerosolized KL4 surfactant, alone or in combination with other pharmaceutical compounds, has the potential to be developed to address a range of serious respiratory conditions and may be an effective intervention for such conditions as acute lung injury (ALI), including acute radiation exposure to the lung (acute pneumonitis and delayed lung injury), chemical-induced ALI, and influenza-induced ALI. In addition, we may explore opportunities to apply KL4 surfactant therapies to treat conditions such as chronic rhinosinusitis, complications of certain major surgeries, mechanical ventilator-induced lung injury (often referred to as VILI), pneumonia, diseases involving mucociliary clearance disorders, such chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). We believe that we have an opportunity to develop a broad pipeline of KL4 surfactant products to address these and other conditions.

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, committed equity financing facilities (CEFFs), at-the-market equity programs, and capital equipment financings.

As of December 31, 2014, we had cash and cash equivalents of $44.7 million and long-term debt of $30 million under our loan with affiliates of Deerfield Management Company, L.P. (Deerfield) (see, "Note 9 – Deerfield Loan"). For the next several years, we expect that our cash outflow requirements, for development programs, operations and debt service, will outpace the rate at which we may generate revenues. Therefore, to execute our business strategy, advance our development programs, pay debt obligations and fund our operations, we will require significant additional infusions of capital until such time as we are able to generate sufficient revenues from the sale of approved products, from potential strategic alliances and commercialization agreements, and from other sources that are sufficient to offset our cash flow requirements. Following the approval of SURFAXIN, we established our own specialty respiratory critical care commercial and medical affairs organization and made investments in manufacturing, quality systems, supply chain, and distribution capabilities. Notwithstanding, revenue growth has been slower than expected and we currently believe that more of our capital and resources than previously anticipated would have to be allocated to SURFAXIN. We also believe that our limited capital and resources should be invested in the development of aerosolized KL4 surfactant, beginning with AEROSURF. Therefore, we are pursuing, with the intention of promptly implementing, a strategic alternative for SURFAXIN that potentially could be (i) a strategic alliance or collaboration arrangement, which we expect would require a lease extension for our Totowa Facility and may require consent under our Deerfield Loan, or (ii) ceasing commercialization activities for SURFAXIN. We would prefer an alliance or collaboration arrangement with a pharmaceutical company that has existing commercial capabilities, including substantial sales, marketing and medical resources and experience in the introduction of hospital-based products. However, there can be no assurance that we will succeed in such efforts. In connection with either a strategic alliance or collaboration agreement for SURFAXIN or cessation of commercialization activities, we expect that we likely will incur one-time transition-related costs associated with such event. Before any additional financings and taking into account our plan to quickly reduce cash outflows related to SURFAXIN through either (i) a strategic alliance or, in the event we are unable to secure a strategic alliance in the near term, (ii) ceasing commercial activities, we anticipate that we will have sufficient cash available to fund our operations and debt service obligations through the first quarter of 2016.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

To secure the necessary capital to fund our development programs, an important priority for us is to identify strategic transactions that could provide additional capital and strategic resources to support the continued development and commercial introduction of our RDS products in markets outside the U.S. For our AEROSURF development program, we seek a significant strategic alliance with a partner that has broad experience in markets outside the U.S., including regulatory and product-development expertise and, if AEROSURF is approved, an ability to support the commercial introduction of AEROSURF in the EU and other selected markets outside the U.S. Such alliances typically also provide financial resources, in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. If our efforts to secure an alliance for SURFAXIN in the U.S. are successful, we may seek a strategic alliance that could provide regulatory expertise in designated markets where regulatory marketing authorization is facilitated by the information contained in our new drug application (NDA) approved by the FDA, support the commercial introduction of SURFAXIN in such markets and provide for a sharing of revenues. Under our Battelle Collaboration Agreement, at our discretion from time to time, we may elect to defer payment of amounts due to Battelle in respect of our share of development costs for up to 12 months. We currently have deferred certain payments and may continue to defer payments through the completion of the development project. In addition, 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. We also may consider public and private equity offerings or other financing transactions, including potentially secured equipment financing facilities or other similar transactions.

Our future capital requirements will depend upon many factors, including our efforts to (i) advance the AEROSURF development program to completion of the phase 2 clinical trials as planned; (ii) reduce or eliminate our capital and resources allocated to the commercialization of SURFAXIN in the U.S. (iii) assure long-term continuity of supply for our KL4 surfactant drug product, potentially at our manufacturing facility in Totowa, NJ (Totowa Facility) and with CMOs, (iv) further the development of our CAG for use in a planned phase 3 clinical program and, if approved, early commercial activities, (v) prepare for and conduct an AEROSURF phase 3 clinical program, and (vi) secure one or more strategic alliances or other collaboration arrangements to support our development programs and commercialization of our approved products, if any, in markets outside the U.S. We believe that we will be better positioned to enter into a significant strategic alliance for AEROSURF if we obtain encouraging results from the AEROSURF phase 2 clinical program.

Given the uncertainty associated with our business strategy as planned, there can be no assurance (i) that our AEROSURF development program will be successful within our anticipated time frame, if at all, (ii) that any of our approved products will be commercially viable, (iii) that we will be able to execute our long-term manufacturing plan to secure continuity of drug product supply, (iv) that we will be able to secure regulatory marketing authorization for AEROSURF and our other potential KL4 surfactant product candidates in the U.S. and other markets, or (v) that the ATM Program will be available when needed, if at all, or (vi) that we otherwise will be able to obtain additional capital when needed and on acceptable terms. We will require significant additional capital to execute our business strategy, pay debt service and sustain operations. Failure to secure the necessary additional capital when needed would have a material adverse effect on our business, financial condition and results of operations. Even if we succeed in our efforts and subsequently commercialize our products, we may never achieve sufficient sales revenue to achieve or maintain profitability.

As of December 31, 2014, we had outstanding warrants to purchase approximately 15.5 million shares of our common stock at various prices, exercisable on different dates into 2024. This includes warrants to purchase 7 million shares that were issued to Deerfield in connection with the Deerfield Loan at an exercise price of $2.81 per share (Deerfield Warrants). 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 issued in February 2011 to purchase approximately 4.6 million shares of common stock that expire in February 2016 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 currently have an exercise price of $1.50 per share. 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 approximately $6.8 million. There can be no assurance that the price of our common stock will achieve the needed level, that holders of the Deerfield Warrants would choose to exercise their warrants for cash, or that holders of any of our outstanding warrants would choose to exercise any or all of their warrants prior to the applicable warrant expiration dates. 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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

As of December 31, 2014, 250 million shares of common stock were authorized under our Amended and Restated Certificate of Incorporation, as amended, and approximately 135.7 million shares of common stock were available for issuance and not otherwise reserved.

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 U. S.

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 U. S., 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, 2014 and 2013, respectively. Warrants classified as liabilities are recorded at their fair market value. Other financial instruments, including accounts payable and accrued expenses, are carried at cost, which we believe approximates fair value.

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. We capitalize inventories produced in preparation for commercial launch when all regulatory approvals needed to enable the commercial launch of the product are received and the related costs will be recoverable through the commercial sale of the product. Costs incurred prior to FDA approval of drug products and registration of medical devices is recorded in our statement of operations as research and development expense. Inventories are 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 13 – Commitments, for further discussion on our leases). Under terms of the lease agreement, the required restricted cash balance was reduced by $100,000 to $225,000 in October 2014.

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, 2014, 2013, and 2012 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 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.

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 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 a hospital, the risk of material returns is significantly mitigated. 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 primarily consist of Group Purchasing Organizations member hospitals, 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 periodically adjusted on a prospective basis based upon the customer's 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 for 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 six months subsequent to its expiry date.

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.

Research and development

We account for research and development expense by the following categories: (a) product development and manufacturing, (b) medical and regulatory operations, and (c) direct preclinical and clinical programs. Research and development expense includes personnel, facilities, manufacturing and quality operations, pharmaceutical and device development, research, clinical, regulatory, other preclinical and clinical activities and medical affairs. Research and development costs are charged to operations as incurred.

Stock-based compensation

Stock-based compensation is accounted for under the fair value recognition provisions of Accounting Standards Codification (ASC) Topic 718 "Stock Compensation" (ASC Topic 718). See, Note 11 – Stock Options and Stock-based Employee Compensation, for a detailed description of our recognition of stock-based compensation expense. The fair value of stock option grants is recognized evenly over the vesting period of the options or over the period between the grant date and the time the option becomes non-forfeitable by the employee, whichever is shorter.

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. Depending on the terms of a warrant agreement, we use the Black-Scholes or trinomial pricing models to value the related 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.

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Collaborative arrangements

We account for collaborative arrangements in accordance with applicable accounting guidance provided in ASC Topic 808 Collaborative Arrangements (ASC Topic 808). See, " – Note 12 – Corporate Partnership, Licensing and Research Funding Agreements – Battelle Memorial Institute," for a description of our accounting for the Battelle Collaboration Agreement.

Income taxes

We account for income taxes in accordance with ASC Topic 740, "*Accounting for Income Taxes"* (ASC Topic 740), which 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. Diluted net loss per common share is computed by giving effect to all potentially dilutive securities outstanding for the period. For the years ended December 31, 2014, 2013, and 2012, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 22.0 million, 20.2 million and 11.9 million shares, respectively. As of December 31, 2014, 2013, and 2012, there were 17.4 million, 15.4 million, and 7.0 million shares, respectively, of common stock potentially issuable upon the exercise of stock options and warrants excluded from the computation of diluted net loss per common share because their impact would have been anti-dilutive.

In accordance with ASC Topic 260, "Earnings per Share," when calculating diluted net loss per common share, a gain associated with the decrease in the fair value of warrants classified as derivative liabilities results in an adjustment to the net loss; and the dilutive impact of the assumed exercise of these warrants results in an adjustment to the weighted average common shares outstanding. We utilize the treasury stock method to calculate the dilutive impact of the assumed exercise of warrants classified as derivative liabilities. For the year ended December 31, 2014, the effect of the adjustments for warrants classified as derivative liabilities was dilutive. For the years ended December 31, 2013 and 2012, the effect of the adjustments for warrants classified as derivative liabilities was anti-dilutive.

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The table below provides information pertaining to the calculation of diluted net loss per common share for the periods presented:

(in thousands)	December 31, 2014	2013	2012
Numerator:			
Net loss as reported	$ (44,058)	$ (45,215)	$ (37,315)
Less: income from change in fair value of warrant liability	(3,791)	–	–
Numerator for diluted net loss per common share	$ (47,849)	$ (45,215)	$ (37,315)
Denominator:			
Basic weighted average common shares outstanding	85,095	55,258	39,396
Dilutive common shares from assumed warrant exercises	930	–	–
Diluted weighted average common shares outstanding	86,025	55,258	39,396

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, 2014 and 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

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, which requires an entity to recognize revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. generally accepted accounting principles (GAAP) when it becomes effective. The new standard is effective for us in the annual period ending December 31, 2017, including interim periods within that annual period. Early application is not permitted. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

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In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements – Going Concern*, which requires management to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The standard defines substantial doubt as when it is probable (i.e., likely) that the entity will be unable to meet its obligations as they become due within one year of the date the financial statements are issued (or available to be issued, when applicable). The ASU is effective for the annual period ending December 31, 2016 and interim periods thereafter. Early application is permitted. We are evaluating the effect that ASU 2014-15 will have on our consolidated financial statements and related disclosures. The standard permits the use of either the retrospective or cumulative effect transition method. We have not yet selected a transition method nor determined the effect of the standard on our financial reporting.

Note 4 – Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

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

- Level 1 – Quoted prices in active markets for identical assets and liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Fair Value on a Recurring Basis

Assets and liabilities measured at fair value on a recurring basis are categorized in the table below as of December 31, 2014 and 2013:

	Fair Value	Fair value measurement using		
(in thousands)	December 31, 2014	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 44,711	$ 44,711	$ –	$ –
Certificate of deposit	225	225	–	–
Total Assets	$ 44,936	$ 44,936	$ –	$ –
Liabilities:				
Common stock warrants	$ 1,258	$ –	$ –	$ 1,258

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(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

The following table summarizes changes in the fair value of the common stock warrants measured on a recurring basis using Level 3 inputs for 2013 and 2014:

(in thousands)	
Balance at January 1, 2013	**$ 6,305**
Exercise of warrants (1)	(119)
Change in fair value of common stock warrant liability	(761)
Balance at December 31, 2013	**$ 5,425**
Exercise of warrants (1)	(376)
Change in fair value of common stock warrant liability	(3,791)
Balance at December 31, 2014	**$ 1,258**

(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 certain of the warrants. 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, 2014	2013
Historical volatility	55% – 84%	62% –76%
Expected term (in years)	0.1 – 1.1	0.4 – 2.1
Risk-free interest rate	0.03% – 0.31%	0.08% – 0.44%

Fair Value of Long-Term Debt

At December 31, 2014, the estimated fair value of the Deerfield Loan (*see*, Note 9 – Deerfield Loan) was $22.2 million compared to a carrying value, net of discounts, of $20.3 million. At December 31, 2013, the estimated fair value of the Deerfield Loan was $23.6 million compared to a carrying value, net of discounts, of $18.4 million. The estimated fair value of the Deerfield Loan is based on discounting the future contractual cash flows to the present value at the valuation date. 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. 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.

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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.

Note 5 – Inventory

Inventory is comprised of the following:

(in thousands)	December 31, 2014	2013
Raw materials	$ –	$ 52
Finished goods, net of reserves	27	60
Total inventories, net	$ 27	$ 112

As of December 31, 2014, there was $0.5 million of raw materials purchased prior to October 4, 2013, the date the FDA approved updated SURFAXIN product specifications and enabled the commercial introduction of SURFAXIN. These raw materials have a carrying value of zero, as the costs to purchase this material were expensed in the period of purchase as research and development expense, and accordingly are not reflected in the inventory balances shown above. These raw materials are anticipated to be used in manufacturing development, research and development activities and in the manufacture of commercial product.

Inventory reserves as of December 31, 2014 and December 31, 2013 were $2.4 million and $0.5 million, respectively. Inventory reserves reflect costs of SURFAXIN 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. Inventory reserves are recorded as a component of cost of goods sold.

Note 6 – Property and Equipment

Property and equipment is comprised of the following:

(in thousands)	December 31, 2014	2013
Manufacturing, laboratory & office equipment	$ 9,154	$ 8,383
Furniture & fixtures	817	816
Leasehold improvements	2,718	2,711
Subtotal	12,689	11,910
Accumulated depreciation and amortization	(11,052)	(10,254)
Property and equipment, net	$ 1,637	$ 1,656

Depreciation expense on property and equipment for the years ended December 31, 2014, 2013, and 2012 was $0.8 million, $0.7 million, and $0.9 million, respectively.

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Note 7 – Accrued Expenses

Accrued expenses are comprised of the following:

(in thousands)	December 31, 2014	2013
Salaries, bonus & benefits	$ 2,332	$ 1,849
Research and development	1,641	270
Manufacturing operations	876	1,707
Professional fees	376	393
Sales and marketing	318	161
All other	573	405
Total accrued expenses	$ 6,116	$ 4,785

Note 8 – Common Stock Warrant Liability

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 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 offering 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 warrants, the holder may exercise the warrants on a cashless basis. Notwithstanding the availability of cashless exercise, under GAAP, 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, issuing freely-tradable registered 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 February 2010 warrants have been classified as a derivative liability 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 warrants that we issued in the February 2011 public offering (February 2011 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 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. 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.

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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, 2014	December 31, 2013
2/23/2010	916,669	12.75	2/23/2015	$ 5,701	$ –	$ 6
2/22/2011	4,550,100	1.50	2/22/2016	8,004	1,258	5,419
					$ 1,258	$ 5,425

During the year ended December 31, 2014, holders of the February 2011 five-year warrants exercised warrants to purchase 284,850 shares of common stock for total proceeds of $0.4 million. 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 $0.2 million.

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

Long-term debt consists solely of amounts due under a $30 million loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for the periods presented:

(in thousands)	December 31, 2014	December 31, 2013
Note payable	$ 30,000	$ 30,000
Unamortized discount	(9,698)	(11,646)
Long-term debt, net of discount	$ 20,302	$ 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 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 three $10 million annual installments beginning in February 2017, provided that the amount payable in February 2017 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 in February 2018 (together with any amount deferred in February 2017) shall be deferred until February 2019 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.

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The amount received and outstanding under the Deerfield Loan accrues 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 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.

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.

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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, 2014	2013	2012
Cash interest expense	$ 2,625	$ 911	$ –
Non-cash amortization of debt discounts	1,948	534	–
Amortization of debt costs	19	18	–
Total Deerfield Loan interest expenses	$ 4,592	$ 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 – 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.

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, Nicolaus & Company, Incorporated (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.

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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, 2014, 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 could sell 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 (i) to pay Lazard a commission equal to 3.0% of the gross proceeds of any sales, and (ii) to reimburse Lazard for certain expenses incurred. 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.

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, 2014, 2013, and 2012, the match resulted in the issuance of 593,198, 510,047, and 316,543, shares of common stock, respectively. Expenses associated with the 401(k) match for the years ended December 31, 2014, 2013, and 2012 were $1.0 million, $1.0 million and $0.8 million, respectively.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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, 2014	December 31, 2013	Exercise Price	Expiration Date
Battelle – 2014 collaboration agreement(1)	1,500	–	$ 5.00	10/10/2024
Deerfield – 2013 loan	7,000	7,000	$ 2.81	2/13/2019
Former employee	30	30	$ 3.20	3/18/2016
Investors – February 2011 financing	4,550	4,835	$ 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	$ 17.25	5/13/2014
Kingsbridge – December 2008 CEFF	–	45	$ 22.70	6/12/2014
Total	15,484	14,781		

(1) See Note 12 for further details on the Battelle collaboration agreement

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

As of December 31, 2014 and 2013, we had 6.7 million and 2.9 million shares, respectively, available for potential future issuance under the 2011 Long-Term Incentive Plan (the 2011 Plan).

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

As of December 31, 2014 and 2013, we had 6,130 and 166,243, respectively, reserved for potential future issuance under the 401(k) Plan.

Note 11 – Stock Options and Stock-based Employee Compensation

Long-Term Incentive Plans

We have the 2011 Plan that provides for the grant of long-term equity and cash incentive compensation awards and replaced a 2007 Long-Term Incentive Plan (the 2007 Plan). Awards outstanding under the 2007 and an earlier 1998 Plan (expired) will continue to be governed by the terms of the plans and award agreements under which they were granted.

Under the 2011 Plan, we may grant awards for up to 12.8 million shares of our common stock. Additionally, 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. 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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Stock options and restricted stock units (RSUs) outstanding and available for future issuance are as follows:

	December 31, 2014	2013
Stock Options and RSUs Outstanding		
2011 Plan	6,113	4,919
2007 Plan	257	258
1998 Plan	182	251
Total Outstanding	6,552	5,428
Available for Future Grants under 2011 Plan	6,667	2,894

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.

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 January 1, 2014	5,428	$ 6.51	
Granted	1,786	2.39	
Exercised	(17)	1.83	
Forfeited or expired	(663)	15.57	
Outstanding at December 31, 2014	6,534	$ 4.50	7.3
Exercisable at December 31, 2014	3,599	$ 6.23	6.3

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2014	19	$ 1.69
Awarded	36	$ 1.71
Vested	(36)	$ 1.70
Unvested at December 31, 2014	19	$ 1.71

Based upon application of the Black-Scholes option-pricing formula described below, the weighted-average grant-date fair value of options granted during the years ended December 31, 2014, 2013, and 2012 was $1.82, $1.79, and $2.02, respectively. The weighted-average grant-date fair value of RSUs granted during the years ended December 31, 2014 and 2013 was $1.71 and $1.69, respectively. There were no RSUs granted during the year ended December 31, 2012. The total intrinsic value of options outstanding, vested, and exercisable as of December 31, 2014 are each $0.

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Stock-Based Compensation

We recognized stock-based compensation expense in accordance ASC Topic 718 for the years ended December 31, 2014, 2013, and 2012, of $2.9 million, $2.2 million and $2.4 million, respectively.

Stock-based compensation expense was classified as follows:

(in thousands)	December 31, 2014	2013	2012
Research and development	$ 1,014	$ 784	$ 487
Selling, general and administrative	1,927	1,426	1,924
Total	$ 2,941	$ 2,210	$ 2,411

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, 2014	2013	2012
Weighted average expected volatility	100%	109%	111%
Weighted average expected term	5.4 years	4.7 years	4.6 years
Weighted average risk-free interest rate	1.65%	0.73%	0.74%
Expected dividends	–	–	–

The total fair value of the underlying shares of the options vested during 2014, 2013, and 2012, equals $3.1 million, $1.9 million and $2.2 million, respectively. As of December 31, 2014, there was $3.4 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 1.6 years.

Note 12 – Corporate Partnership, Licensing and Research Funding Agreements

Licensing and Research Funding Agreements

Battelle Memorial Institute

In October 2014, we entered into a collaboration agreement with Battelle providing for the further development of our CAG for potential use in our planned phase 3 clinical program for AEROSURF for the treatment of RDS in premature infants and, if AEROSURF is approved for commercial sale by the FDA or other regulatory authority, initial commercial supply. Under our agreement, we and Battelle plan to design, develop, and complete the testing, verification, and documentation of an improved AEROSURF system, and share equally in the related development costs. These costs are recognized in research and development expense as incurred and were $0.3 million for the year ended December 31, 2014.

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In connection with the collaboration agreement, we issued to Battelle two warrants to purchase shares of our common stock, each having an exercise price of $5.00 per share and a term of 10 years, subject to earlier termination under certain circumstances set forth therein, including (i) a warrant to purchase up to 1.0 million shares of our common stock, exercisable upon successful completion by Battelle of development activities described above (Initial Warrant), and (ii) a warrant to purchase up to 0.5 million shares of our common stock (Additional Warrant; and together with the Initial Warrant, the Battelle Warrants), exercisable if and only if Battelle successfully completes the development activities no later than May 31, 2016, which date may be adjusted as provided in the Collaboration Agreement. We and Battelle have agreed to execute a registration rights agreement providing for the registration of the resale of shares underlying the Battelle Warrants. The Battelle Warrants may be exercised for cash only, except that, in the event a registration statement is not effective at the time of exercise and if an exemption from registration is otherwise available at that time, the Battelle Warrants may be exercised on a cashless basis. The Battelle Warrants were issued pursuant to an exemption from registration contained in Regulation D, Rule 506. The Battelle Warrants are accounted for as equity instruments under the applicable accounting guidance of ASC Topic 815.

If Battelle successfully completes their activities under the agreement, we have agreed to pay Battelle royalties equal to a low single-digit percentage of the worldwide net sales and license royalties on sales of AEROSURF for the treatment of RDS in premature infants, up to an aggregate limit of $25 million.

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. We paid the minimum royalty of $300,000 in 2014 related to these license agreements.

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.

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.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

Note 13 – Commitments

Future payments due under contractual obligations at December 31, 2014 are as follows:

(in thousands)	2015	2016	2017	2018	2019	There-after	Total
Operating lease obligations	$ 1,239	$ 961	$ 943	$ 158	$ –	$ –	$ 3,301
Equipment loan obligations	69	–	–	–	–	–	69
Total	$ 1,308	$ 961	$ 943	$ 158	$ –	$ –	$ 3,370

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 $525,000. This space is specifically designed for the manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only manufacturing facility. The lease expires on June 30, 2015. 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 $1.2 million for the year ended December 31, 2014 and $1.0 million for each of the years ended December 31, 2013 and 2012.

Battelle Collaboration

In accordance with terms of the Battelle agreement (*See,* – Note 12 – Corporate Partnership, Licensing and Research Funding Agreements), we and Battelle plan to design, develop, and complete the testing, verification, and documentation of an improved AEROSURF system, and share equally in the development plan costs. If this project is successfully completed in accordance with the development plan, based upon current estimates, we expect to incur development costs of approximately $6.0 million through 2016.

Retention Plan

On September 13, 2013, our Board of Directors approved an employee severance and retention plan for employees at the Totowa Facility that initially was intended to retain our manufacturing personnel should we be unable to secure long-term utilization of the Facility beyond the scheduled lease expiration on June 30, 2015. The retention plan provides severance and retention bonuses that encourage employees to stay with us through the 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 in June 2016, and will be eligible for a retention bonus payable in June 2016, provided that they remain employed with us in June 2016; and (2) non-union employees (eight individuals) will be eligible to receive both severance and retention bonuses, payable upon closure of the Totowa Facility, provided that they remain employed with us through the date of closure. If we secure an extension of our lease for the Totowa Facility beyond June 30, 2015, plant management bonuses nevertheless will be paid as provided in the plan in June 2016, and non-union employees will remain eligible to receive severance and retention bonuses under the plan upon the eventual closure of the Facility, provided they remain employed with us through the date of closure. The total cash amount expected to be paid for severance and retention through June 2016 is approximately $0.9 million. The plan-related expense incurred during the years ended December 31, 2014 and 2013 is $0.5 million and $0.1 million, respectively, and is included in research and development expense and cost of product sales. The related liability as of December 31, 2014 and 2013 is $0.6 million and $0.1 million, respectively.

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In addition, there are 12 employees at the Totowa Facility (approximately 11% of our total labor force) who are subject to a collective bargaining agreement and will be eligible to receive severance upon closure of the Totowa Facility. The related liability is $0.4 million as of December 31, 2014 and 2013.

Note 14 – Litigation

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

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

Note 15 – Income Taxes

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

The reconciliation of the income tax benefit computed at the Federal statutory rates to our recorded tax benefit for the years ended December 31, 2014, 2013, and 2012 is as follows:

(in thousands)	December 31,		
	2014	2013	2012
Income tax benefit, statutory rates	$ 14,980	$ 15,373	$ 12,687
State taxes on income, net of Federal benefit	2,871	2,922	2,288
Research and development tax credit	1,472	517	332
Employee related	(2,131)	(766)	(988)
Warrant valuation related	1,289	259	189
Income tax benefit	18,481	18,305	14,508
Valuation allowance	(18,481)	(18,305)	(14,508)
Income tax benefit	$ –	$ –	$ –

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2014 and 2013, are as follows:

(in thousands)	December 31,	
	2014	2013
Long-term deferred tax assets:		
Net operating loss carryforwards (Federal and state)	$ 191,643	$ 175,258
Research and development tax credits	12,927	10,604
Compensation expense on stock	2,588	3,276
Charitable contribution carryforward	7	7
Inventory reserve	907	198
Deferred revenue	16	53
Other accrued	1,088	1,024
Depreciation	2,630	2,714
Capitalized research and development	1,123	1,326
Total long-term deferred tax assets	212,929	194,460
Less: valuation allowance	(212,929)	(194,460)
Deferred tax assets, net of valuation allowance	$ –	$ –

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We are in a net deferred tax asset position at December 31, 2014 and 2013 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, 2014 or 2013, nor were any incurred in 2014, 2013, or 2012.

At December 31, 2014 and 2013, we had available carryforward net operating losses for Federal tax purposes of $473.3 million and $432.1 million, respectively, and a research and development tax credit carryforward of $12.9 million and $10.6 million, respectively. The Federal net operating loss and research and development tax credit carryforwards began to expire in 2008 and will continue through 2034.

At December 31, 2014, 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, 2014 and 2013, we had available carryforward losses of approximately $470.4 million and $433.7 million, respectively, for state tax purposes. Of the $470.4 million state tax carryforward losses, $436.0 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.

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Note 16 – Selected Quarterly Financial Data (Unaudited)

The following tables contain unaudited statement of operations information for each quarter of 2014 and 2013. The operating results for any quarter are not necessarily indicative of results for any future period.

2014 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues:					
Product sales	$ 28	$ 42	$ 106	$ 136	$ 312
Grant revenues	3	1,051	421	1,048	2,523
Total revenues	31	1,093	527	1,184	2,835
Expenses:					
Cost of sales	781	731	257	902	2,671
Research and development	5,590	6,858	6,471	7,771	26,690
Selling, General and administrative	4,423	4,446	4,126	3,737	16,732
Total expenses	10,794	12,035	10,854	12,410	46,093
Operating loss	(10,763)	(10,942)	(10,327)	(11,226)	(43,258)
Change in fair value of common stock warrant liability	378	1,448	173	1,792	3,791
Other expense, net	(1,091)	(1,129)	(1,170)	(1,201)	(4,591)
Net loss	$ (11,476)	$ (10,623)	$ (11,324)	$ (10,635)	$ (44,058)
Net loss per common share - basic	$ (0.14)	$ (0.12)	$ (0.13)	$ (0.12)	$ (0.52)
Net loss per common share - diluted	(0.14)	(0.14)	(0.13)	(0.15)	(0.56)
Weighted average number of common shares outstanding - basic	84,728	85,061	85,209	85,358	85,095
Weighted average number of common shares outstanding - diluted	84,728	85,882	85,209	85,560	86,025

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

Exhibit 10.11

FORM OF RESTRICTED STOCK UNIT AWARD AGREEMENT

RESTRICTED STOCK UNIT AWARD AGREEMENT (this "Agreement") dated as of June 18, 2014 (the "Effective Date"), between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and _____, a Non-Employee Director of the Company ("Participant").

WHEREAS, in order to generate an increased incentive to contribute to the Company's future success and prosperity, the Company has agreed to award to Participant that number of restricted stock units (the "Restricted Stock Units") representing on a one-for-one basis the same number of Shares of the Company;

NOW, THEREFORE, in consideration of the above premises and the mutual covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

SECTION 1. General.

(a) All capitalized terms used in this Agreement without definition shall have the meanings ascribed to them in the Discovery Laboratories, Inc., 2011 Long-Term Incentive Plan ("the "Plan").

(b) The Award is subject to the terms, conditions and restrictions set forth in this Agreement, the Plan (the terms of which are incorporated in this Agreement by reference), and the Notice of Award of Restricted Stock Units issued by the Company (the "Notice"). In the event of any inconsistency between the Plan, this Agreement or the Notice, the terms of the Plan shall control.

SECTION 2. Award and Vesting of Restricted Stock Units. Effective as of the Grant Date set forth in the Notice, the Company hereby grants to Participant named in the Notice an award of Restricted Stock Units, as set forth in the Notice. Subject to the earlier vesting or forfeiture of Restricted Stock Units as provided in Section 4 below, the Restricted Stock Units awarded to Participant shall vest and the Shares shall be delivered to Participant as set forth in the Notice.

SECTION 3. Restrictions. The Restricted Stock Units are bookkeeping entries only. The Participant shall have no rights as a stockholder of the Company, no dividend rights and no voting rights with respect to the Restricted Stock Units. Participant is an unsecured general creditor of the Company:

(a) Subject to Section 4, the Restricted Stock Units shall vest and restrictions shall lapse in accordance with the vesting schedule set forth in the Notice. Participant shall not be entitled to delivery of the certificate or certificates for the Shares pursuant to Section 5 hereof until the applicable vesting date and upon the satisfaction of all other applicable conditions.

(b) Participant shall not, without the prior written consent of the Company, offer, transfer, sell, pledge, assign, hypothecate or otherwise encumber or dispose of or attempt to dispose of any unvested Restricted Stock Units otherwise than by will or by the laws of descent and distribution. Any attempt by the Participant to offer, transfer, sell, pledge, assign, hypothecate or otherwise encumber or dispose of unvested Restricted Stock Units or any interest in such Restricted Stock Units in a manner contrary to the restrictions set forth in this Agreement shall be void and of no effect.

SECTION 4. Acceleration; Forfeiture of Restricted Stock.

(a) If Participant's Service as a member of the Board of Directors of the Company (the "Board") is terminated due to Participant's death or Disability, then Participant shall be entitled to the immediate full vesting on the date of termination of all Restricted Stock Units. Upon the occurrence of a Corporate Transaction or Change in Control, all Restricted Stock Units that have not then vested shall vest as of the effective date of such Corporate Transaction or Change in Control in accordance with the provisions of the Plan including, without limitation, Section 13 of the Plan.

(b) If Participant's Service as a member of the Board terminates for any reason other than as set forth in Section 4(a) above, all unvested Restricted Stock Units granted hereunder shall automatically be forfeited as of the date of termination and reacquired for no additional consideration and without the need for any further action on behalf of the Company. In the event of any such forfeiture, all such forfeited Restricted Stock Units shall be returned to the Plan in accordance with Section 8(e) of the Plan.

SECTION 5. Book Entry Form; Conditions to Issuance of Certificates; Tax Withholding.

(a) The Restricted Stock Units will be recorded in the name of the Participant in the books and records of the Company.

(b) Upon vesting of any Restricted Stock Units granted hereby and the satisfaction of all other applicable conditions, the Company shall (i) cause certificates representing the Shares to be issued to the Participant or (ii) credit the Shares to which Participant is entitled to Participant's (or designee's) balance account with the Depository Trust Company (DTC) through its Deposit / Withdrawal At Custodian (DWAC) system; provided, however, that the Company shall not be required to issue or deliver any such certificate(s) or credit for any Shares prior to the fulfillment of all of the following conditions:

1. In such rare circumstances in which tax withholding is applicable to the vesting of the Restricted Stock Units or distribution of the Shares, the Participant or his legal representative shall pay to the Company the full amount of all federal and state withholding or other taxes applicable to the taxable income of Participant resulting from the grant of Restricted Stock Units or the lapse or removal of the restrictions. The Committee shall be authorized, in its sole discretion, to establish such rules and procedures relating to the use of Shares to satisfy tax withholding obligations as it deems necessary or appropriate to facilitate and promote the conformity of Participant's transactions under the Plan and this Agreement with Rule 16b-3 under the 1934 Act, as amended, if such Rule is applicable to a transaction by Participant;

2. The completion and continued effectiveness of any registration or other qualification of the Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or other governmental regulatory body, which the Committee shall, in its sole and absolute discretion, deem necessary and advisable;

3. The obtaining of any approval or other clearance from any state or federal governmental agency that the Committee shall, in its absolute discretion, determine to be necessary or advisable; and

4. The lapse of any such reasonable period of time following the date the restrictions lapse as the Committee may from time to time establish for reasons of administrative convenience.

SECTION 6. Representations and Warranties.

(a) Participant hereby represents to the Company that Participant has read in their entirety and fully understands the provisions of this Agreement and the Plan, has had an opportunity to obtain the advice of counsel, and fully understands all provisions of this Agreement and the Plan, and the Participant acknowledges that Participant is relying solely on his or her own advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences of this Award. Participant understands that Participant (and not the Company) shall be responsible for Participant's own tax liability that may arise as result of the transactions contemplated by this Agreement.

(b) Participant acknowledges and agrees that the vesting of Restricted Stock Units pursuant to this Agreement is earned only through his or her continued and satisfactory service as a member of the Board and not through the award of Restricted Stock Units hereunder.

(c) Participant hereby accepts this Agreement subject to all of the terms and provisions hereof.

(d) Participant acknowledges that, as a condition to the vesting of the Restricted Stock Units, the representations and warranties of this Section 6 shall be true and correct as of the vesting date or the date of receipt of any distributions with respect to the Restricted Stock Units, as applicable, as if they had been made on such date with respect to vested Restricted Stock Units or any such other distributions, as applicable.

SECTION 7. Notices. Any notice required to be given or delivered to the Company under the terms of this Agreement shall be in writing and addressed to the Company at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, Attention: Legal Department, or to such other address as shall be provided in writing to Participant. Any notice required to be given or delivered to Participant shall be in writing and addressed to the most recent address of Participant as set forth in the books and records of the Company. All notices shall be deemed effective one day after being sent by Federal Express or similar overnight delivery or three days after being mailed registered or certified mail, postage prepaid, and properly addressed to the party to be notified.

SECTION 8. Miscellaneous.

(a) Assignment; Binding Agreement. This Agreement shall be binding upon and inure to the benefit of the heirs and representatives of the Participant and the assigns and successors of the Company, but neither this Agreement nor any rights hereunder shall be assignable or otherwise subject to hypothecation by the Participant.

(b) Entire Agreement; Amendment. This Agreement represents the entire agreement of the parties with respect to the subject matter hereof, except that the provisions of the Plan are incorporated in this Agreement in their entirety. In the event of any conflict between the provisions of this Agreement and the Plan, the provisions of the Plan shall control. This Agreement may be amended by the Committee without the consent of the Participant except in the case of an amendment adverse to the Participant (except as may be permitted under Section 16(b) of the Plan), in which case the Participant's consent shall be required.

(c) Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of laws principles of such state.

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

(e) Conformity to Securities Laws. The Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act of 1933, as amended, and the 1934 Act, and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, including without limitation Rule 16b-3 under the 1934 Act. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Awards are granted, only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by applicable law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.

(f) Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the 1934 Act, the Plan and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the 1934 Act (including any amendment to Rule 16b-3 of the 1934 Act) that are requirements for the application of such exemptive rule. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

(g) No Strict Construction. No rule of strict construction shall be implied against the Company, the Committee or any other person in the interpretation of any of the terms of the Plan, this Agreement or any rule or procedure established by the Committee.

(h) Use of the Word "Participant". Wherever the word "Participant" is used in any provision of this Agreement under circumstances where the provision should logically be construed to apply to the executors, the administrators, or the person or persons to whom the Restricted Stock Units may be transferred by will or the laws of descent and distribution, the word "Participant" shall be deemed to include such person or persons.

(i) Further Assurances. The Participant agrees, upon demand of the Company or the Committee, to do all acts and execute, deliver and perform all additional documents, instruments and agreements (including, without limitation, stock powers with respect to Shares issued as a dividend or distribution on Restricted Stock Units) which may be reasonably required by the Company or the Committee, as the case may be, to implement the provisions and purposes of this Agreement and the Plan.

Exhibit 10.16

December 29, 2014

John G. Cooper
c/o Discovery Laboratories, Inc.
2600 Kelly Road
Suite 100
Warrington, PA 18976

Re: Amendment to Employment Agreement

Dear Mr. Cooper,

This amendment is attached to and made part of the Employment Agreement dated as of April 1, 2013 between you and Discovery Laboratories, Inc. (the "Agreement"). Effective as of April 1, 2015, the parties hereby agree that certain provisions of the Agreement are revised as set forth below. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Agreement.

1. The first sentence of Section 2 is hereby amended and restated in its entirety to read as follows:

   "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 renewal date thereafter, the term of this Agreement shall automatically be extended for two additional years, unless at least 90 days prior to any such renewal date, either party shall have given notice that such party does not wish to extend this Agreement."

2. Section 6(b) of the Agreement ("Change of Control Benefits – Options") is hereby amended and restated in its entirety to read as follows:

   "Awards. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock award between the Company and Executive, in the event of a Change of Control, all vested and unvested shares of stock and all vested and unvested options to acquire Company stock held by Executive shall be assumed by the successor entity or parent or subsidiary of the successor entity; and further, if the Company is not the surviving entity, Executive shall be entitled to receive in exchange for, or in respect of, all shares of stock and all options in the Company's common stock, shares and options to acquire shares of the successor entity or parent or subsidiary of the successor entity, or other similar rights that are substantially the economic equivalent of the Executive's shares and stock options in the Company's common stock immediately prior to the Change of Control."

3. Clause (v) of Section 7(c) ("Termination of Employment – Termination in connection with a Change of Control") is hereby amended in its entirety to read as follows:

   "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 (or shares and options to acquire shares of a successor entity or parent or subsidiary of the successor entity issued or substituted for shares and options to acquire Company stock pursuant to Section 6(b) hereof) held by Executive shall accelerate and become fully vested upon the Date of Termination (and shall thereupon become fully exercisable) and all shares of stock shall become fully vested upon the Date of Termination and all restrictions thereon shall be lifted, and all stock options shall continue to be exercisable for the remainder of their stated terms."

Except as amended herein, the remaining terms and conditions of the Agreement shall remain in full force and effect. This amendment confirms an agreement between you and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and mutual promises made in connection therewith. Please indicate your acceptance of the terms contained herein by signing both copies of this amendment, retaining one copy for your records, and forwarding the remaining copy to the Company no later than December 31, 2014.

DISCOVERY LABORATORIES, INC.

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

Accepted and Agreed to:

/s/ John G. Cooper Date:
Name: John G. Cooper

Exhibit 10.17

December 29, 2014

Thomas F. Miller, Ph.D.
c/o Discovery Laboratories, Inc.
2600 Kelly Road
Suite 100
Warrington, PA 18976

Re: Amendment to Employment Agreement

Dear Dr. Miller,

This amendment is attached to and made part of the Employment Agreement dated as of April 1, 2013 between you and Discovery Laboratories, Inc. (the "Agreement"). Effective as of April 1, 2015, the parties hereby agree that certain provisions of the Agreement are revised as set forth below. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Agreement.

1. The first sentence of Section 2 is hereby amended and restated in its entirety to read as follows:

   "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 renewal date thereafter, the term of this Agreement shall automatically be extended for two additional years, unless at least 90 days prior to any such renewal date, either party shall have given notice that such party does not wish to extend this Agreement."

2. Section 6(b) of the Agreement ("Change of Control Benefits – Options") is hereby amended and restated in its entirety to read as follows:

   "Awards. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock award between the Company and Executive, in the event of a Change of Control, all vested and unvested shares of stock and all vested and unvested options to acquire Company stock held by Executive shall be assumed by the successor entity or parent or subsidiary of the successor entity; and further, if the Company is not the surviving entity, Executive shall be entitled to receive in exchange for, or in respect of, all shares of stock and all options in the Company's common stock, shares and options to acquire shares of the successor entity or parent or subsidiary of the successor entity, or other similar rights that are substantially the economic equivalent of the Executive's shares and stock options in the Company's common stock immediately prior to the Change of Control."

3. Clause (v) of Section 7(c) ("Termination of Employment – Termination in connection with a Change of Control") is hereby amended in its entirety to read as follows:

   "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 (or shares and options to acquire shares of a successor entity or parent or subsidiary of the successor entity issued or substituted for shares and options to acquire Company stock pursuant to Section 6(b) hereof) held by Executive shall accelerate and become fully vested upon the Date of Termination (and shall thereupon become fully exercisable) and all shares of stock shall become fully vested upon the Date of Termination and all restrictions thereon shall be lifted, and all stock options shall continue to be exercisable for the remainder of their stated terms."

Except as amended herein, the remaining terms and conditions of the Agreement shall remain in full force and effect. This amendment confirms an agreement between you and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and mutual promises made in connection therewith. Please indicate your acceptance of the terms contained herein by signing both copies of this amendment, retaining one copy for your records, and forwarding the remaining copy to the Company no later than December 31, 2014.

DISCOVERY LABORATORIES, INC.

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

Accepted and Agreed to:

/s/ Thomas F. Miller Date:
Name: Thomas F. Miller, Ph.D.

Exhibit 10.18

December 29, 2014

Mary B. Templeton
c/o Discovery Laboratories, Inc.
2600 Kelly Road
Suite 100
Warrington, PA 18976

Re: Amendment to Employment Agreement

Dear Ms. Templeton,

This amendment is attached to and made part of the Employment Agreement dated as of April 1, 2013 between you and Discovery Laboratories, Inc. (the "Agreement"). Effective as of April 1, 2015, the parties hereby agree that certain provisions of the Agreement are revised as set forth below. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Agreement.

1. The first sentence of Section 2 is hereby amended and restated in its entirety to read as follows:

   "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 renewal date thereafter, the term of this Agreement shall automatically be extended for two additional years, unless at least 90 days prior to any such renewal date, either party shall have given notice that such party does not wish to extend this Agreement."

2. Section 6(b) of the Agreement ("Change of Control Benefits – Options") is hereby amended and restated in its entirety to read as follows:

   "Awards. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock award between the Company and Executive, in the event of a Change of Control, all vested and unvested shares of stock and all vested and unvested options to acquire Company stock held by Executive shall be assumed by the successor entity or parent or subsidiary of the successor entity; and further, if the Company is not the surviving entity, Executive shall be entitled to receive in exchange for, or in respect of, all shares of stock and all options in the Company's common stock, shares and options to acquire shares of the successor entity or parent or subsidiary of the successor entity, or other similar rights that are substantially the economic equivalent of the Executive's shares and stock options in the Company's common stock immediately prior to the Change of Control."

3. Clause (v) of Section 7(c) ("Termination of Employment – Termination in connection with a Change of Control") is hereby amended in its entirety to read as follows:

   "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 (or shares and options to acquire shares of a successor entity or parent or subsidiary of the successor entity issued or substituted for shares and options to acquire Company stock pursuant to Section 6(b) hereof) held by Executive shall accelerate and become fully vested upon the Date of Termination (and shall thereupon become fully exercisable) and all shares of stock shall become fully vested upon the Date of Termination and all restrictions thereon shall be lifted, and all stock options shall continue to be exercisable for the remainder of their stated terms."

Except as amended herein, the remaining terms and conditions of the Agreement shall remain in full force and effect. This amendment confirms an agreement between you and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and mutual promises made in connection therewith. Please indicate your acceptance of the terms contained herein by signing both copies of this amendment, retaining one copy for your records, and forwarding the remaining copy to the Company no later than December 31, 2014.

DISCOVERY LABORATORIES, INC.

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

Accepted and Agreed to:

/s/ Mary B. Templeton Date:
Name: Mary B. Templeton

Exhibit 10.19

December 29, 2014

John Tattory
c/o Discovery Laboratories, Inc.
2600 Kelly Road
Suite 100
Warrington, PA 18976

Re: Amendment to Employment Agreement

Dear Mr. Tattory,

This amendment is attached to and made part of the Employment Agreement dated as of March 21, 2014 between you and Discovery Laboratories, Inc. (the "Agreement"). Effective as of April 1, 2015, the parties hereby agree that certain provisions of the Agreement are revised as set forth below. Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to such terms as set forth in the Agreement.

1. The first sentence of Section 2 is hereby amended and restated in its entirety to read as follows:

   "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 renewal date thereafter, the term of this Agreement shall automatically be extended for two additional years, unless at least 90 days prior to any such renewal date, either party shall have given notice that such party does not wish to extend this Agreement."

2. Section 6(b) of the Agreement ("Change of Control Benefits – Options") is hereby amended and restated in its entirety to read as follows:

   "Awards. Notwithstanding any provision to the contrary in any of the Company's long-term incentive plans or in any stock option or restricted stock award between the Company and Executive, in the event of a Change of Control, all vested and unvested shares of stock and all vested and unvested options to acquire Company stock held by Executive shall be assumed by the successor entity or parent or subsidiary of the successor entity; and further, if the Company is not the surviving entity, Executive shall be entitled to receive in exchange for, or in respect of, all shares of stock and all options in the Company's common stock, shares and options to acquire shares of the successor entity or parent or subsidiary of the successor entity, or other similar rights that are substantially the economic equivalent of the Executive's shares and stock options in the Company's common stock immediately prior to the Change of Control."

3. Clause (v) of Section 7(c) ("Termination of Employment – Termination in connection with a Change of Control") is hereby amended in its entirety to read as follows:

   "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 (or shares and options to acquire shares of a successor entity or parent or subsidiary of the successor entity issued or substituted for shares and options to acquire Company stock pursuant to Section 6(b) hereof) held by Executive shall accelerate and become fully vested upon the Date of Termination (and shall thereupon become fully exercisable) and all shares of stock shall become fully vested upon the Date of Termination and all restrictions thereon shall be lifted, and all stock options shall continue to be exercisable for the remainder of their stated terms."

Except as amended herein, the remaining terms and conditions of the Agreement shall remain in full force and effect. This amendment confirms an agreement between you and the Company with respect to the subject matter hereof and is a material part of the consideration stated in the Agreement and mutual promises made in connection therewith. Please indicate your acceptance of the terms contained herein by signing both copies of this amendment, retaining one copy for your records, and forwarding the remaining copy to the Company no later than December 31, 2014.

DISCOVERY LABORATORIES, INC.

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

Accepted and Agreed to:

/s/ John Tattory Date:
Name: John Tattory

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. 333-187934, Form S-3 No. 333-193490, and 333-196420) of Discovery Laboratories, Inc. and in related Prospectuses

(2) Registration Statement (Form S-8 No. 333-180497, Form S-8 No. 333-184277 Form S-8 No. 333-189966, and Form S-8 No. 333-197139) 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. 333-110412, 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, Form S-8 No. 333-191502, Form S-8 No. 333-197139 and Form S-8 No. 333-201478) pertaining to the 401(k) Plan of Discovery Laboratories, Inc.

of our reports dated March 16, 2015, 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, 2014.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 16, 2015

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 16, 2015

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

Exhibit 31.1

CERTIFICATIONS

I, John Tattory, 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 16, 2015

/s/ John Tattory

John Tattory
Senior Vice President and
Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS

Pursuant to 18 U.S.C. § 1350, each of the undersigned officers of Discovery Laboratories, Inc. (the "Company") hereby certifies that our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 ("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 16, 2015

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

/s/ John A. Tattory
John A. Tattory
Senior Vice President and Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.

This certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.