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

FORM 10-K/A
Amendment No. 1

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

For the fiscal year ended December 31, 2015

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, 2015 (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 $49.5 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 2014 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 15, 2016, 8,191,289 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 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the registrant's fiscal year ended December 31, 2015, or April 29, 2016, and to be delivered to stockholders in connection with the 2016 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.

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (the "Amendment") to the Annual Report on Form 10-K of Discovery Laboratories, Inc. (the Company) for the fiscal year ended December 31, 2015, filed with the Securities and Exchange Commission on March 29, 2016 (the Original Filing), is being filed solely to correct an inadvertent error appearing in (i) Item 7. Management's Discussion and Analysis – Liquidity and Capital Resources in the second paragraph, on page 67, and (ii) Note 3 to the Company's Consolidated Financial Statements and Notes, in the second paragraph, on page F-8. In the last sentence of each of the foregoing paragraphs, the phrase "within the expected time line in the fourth quarter of 2015" has been changed to read "within the expected time line in the fourth quarter of 2016." In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended, new certifications by our principal executive officers and principal financial officer are filed as exhibits to this Amendment under Item 15 of Part IV hereof.

Except for the foregoing amended information, this Amendment does not alter or update any other information contained in the Original Filing. This Amendment does not reflect events that may have occurred subsequent to the Original Filing.

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 our development and potential regulatory plans to secure marketing authorization for AEROSURF®, if approved, and other potential future products that we may develop; 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 Aerosol Delivery System (ADS) based on our capillary aerosol generator technology 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 collaborative arrangements to develop, manufacture and market our products, and other potential strategic transactions.

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 our AEROSURF phase 2b clinical program, which is our only development program at this time, may be interrupted, delayed, or generate inconclusive or non-compelling data, or present an unacceptable benefit / risk profile due to suboptimal efficacy and / or safety profile, which would have a material adverse impact on our business and our ability to continue as a going concern;

- the risk that we will require significant additional capital to support our research and development activities and operations and have sufficient cash resources to service and repay debt, but our ability to raise such capital may be adversely impacted by: any delay or inability to complete our AEROSURF phase 2b clinical trial as planned, or if we obtain results from our clinical trial that are not sufficient to support a strategic transaction or equity financing; limitations on our ability to conduct primary offerings under our 2014 Universal Shelf, for our ATM Program or otherwise; the limited number of authorized shares available for issuance under our Amended and Restated Certificate of Incorporation, as amended, or failure to secure stockholder, if required, for a transaction involving greater than 20% of our outstanding common stock; any failure to comply with Nasdaq listing requirements, including with respect to the minimum bid price requirement, minimum market capitalization or minimum stockholders' equity; and that unfavorable credit and financial markets may adversely affect our ability to fund our activities and that additional equity financings could result in substantial equity dilution;

- 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 research and development activities, as well as in our business, our industry and other factors;

- 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, which is the drug component of AEROSURF and potentially could be developed as a separate surfactant drug product, including 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 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, including that the FDA or other regulatory authorities may not file, or may withhold or delay consideration of, any applications that we may submit, 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; or that the FDA or other regulatory authorities may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;

- the risk that we may be unable to identify and enter into strategic alliances, collaboration agreements or other strategic transactions that would provide capital to support our AEROSURF development activities and resources and expertise to support the registration and commercialization of AEROSURF in markets outside the U.S. and potentially support the development and, if approved, commercialization, of our other potential KL4 surfactant pipeline products;

- risks relating to the transfer of our manufacturing technology to contract manufacturing organizations (CMOs) and assemblers, and our CMOs' ability to manufacture our lyophilized KL4 surfactant, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for our research and development activities and, if approved, commercial applications;

- risks relating to our and our CMOs' compliance status or ability to develop and manufacture our ADS and related components for preclinical and clinical studies of our combination drug/device product candidates and, if approved, commercial activities;

- 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 product, the APIs used in the manufacture of our KL4 drug product, ADS and related components, 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 reimbursement and health care reform may adversely affect our ability to secure appropriate funding an reimbursement; or that our products will not be accepted by physicians and others in the medical community; or 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; and

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

Pharmaceutical, biotechnology and medical technology companies have suffered significant setbacks conducting clinical trials, even after obtaining promising earlier preclinical and clinical data. Moreover, data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products, and may never become profitable.

The forward-looking statements contained in this report or the documents incorporated by reference herein speak only as of their respective dates. Factors or events that could cause our actual results to differ may emerge from time to time and it is not possible for us to predict them all. Except to the extent required by applicable laws, rules or regulations, we do not undertake any obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

Trademark Notice

AEROSURF®, **AFECTAIR®**, **DISCOVERYLABS®**, **INSPIRED INNOVATION®**, and **SURFAXIN®** are registered and common law trademarks of Discovery Laboratories, Inc. (Warrington, PA).

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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.[1]

We are a biotechnology company focused on developing novel KL4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies being developed to enable noninvasive administration of aerosolized KL4 surfactant. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant 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

Our core development program, AEROSURF® (lucinactant for inhalation), is focused on improving the management of respiratory distress syndrome (RDS) in premature infants, a serious respiratory condition that can result in long-term respiratory problems, developmental delay and death. Premature infants born prior to 37 weeks gestational age may not have fully developed natural lung surfactant and therefore may need surfactant therapy to sustain life. Higher incidence and severity of RDS are correlated with younger gestational ages; however, RDS can occur at any premature gestational age. RDS is the most prevalent respiratory disease in the neonatal intensive care unit (NICU). We estimate that 120,000 to 150,000 premature infants are given respiratory support after birth each year in the United States because they have or are at risk for RDS.

Surfactant therapy is a life-saving treatment for RDS and the primary therapy to address an underlying surfactant deficiency. Surfactants currently available in the U.S. are animal-derived and must be administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. Intubation is associated with airway trauma and clinical instability that can extend beyond the respiratory system such as increased intracranial pressure and risk for brain injury. Mechanical ventilation is associated with ventilator-associated lung injury, chronic lung disease and increased risk of infection. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support, such as nasal continuous positive airway pressure (nCPAP). Unfortunately, since nCPAP does not address the underlying surfactant deficiency, many premature infants respond poorly to nCPAP (typically within the first 72 hours of life) and may require intubation and delayed surfactant therapy (an outcome referred to as nCPAP failure).

In addition, many premature infants with RDS who receive surfactant therapy as initial therapy are capable of breathing without mechanical ventilation, but require surfactant therapy for RDS. Because surfactant therapy requires intubation, these infants generally are supported with mechanical ventilation for either a limited or extended period of time. If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to these premature infants without exposing them to the risks associated with intubation and mechanical ventilation.

AEROSURF is an investigational combination drug/device product that combines our proprietary KL4 surfactant with our novel aerosol delivery system (ADS), which is based primarily on our capillary aerosol generator technology. We are developing AEROSURF to enable administration of aerosolized KL4 surfactant to premature infants receiving nCPAP, without invasive intubation and mechanical ventilation. We believe that, if approved, AEROSURF will have the potential to transform the treatment of RDS, allow for earlier treatment of those premature infants who currently receive surfactants later in their course of treatment, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy as a result of nCPAP failure.

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[1] *Information concerning the shares of our common stock and related share prices in this Annual Report on Form 10-K has been adjusted to reflect a 1-for-14 reverse split of our common stock and a change in the number of shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation, as amended, that were made effective on January 22, 2016.*

The current surfactant market for RDS 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 and lack of medical innovation. Treatment options for RDS have not improved significantly, nor have mortality and morbidity rates for RDS meaningfully improved over the last few decades. We believe that the neonatal medical community would respond favorably to the introduction of a synthetic, peptide-containing (KL_4) surfactant and a less-invasive method of surfactant administration. By enabling delivery of our aerosolized KL_4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits. We believe that AEROSURF has the potential to create a worldwide annual market opportunity of $600 million to a $1 billion per year. *See,* "– Surfactant Therapy – The RDS Market."

The drug product component of our AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL_4 surfactant liquid instillate drug product that was approved by the U.S. Food and Drug Administration (FDA) in 2012 under the name SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. In the second quarter of 2015, we determined to cease commercial and manufacturing activities for SURFAXIN to focus our limited resources on advancing the AEROSURF clinical development program and our aerosolized KL_4 surfactant pipeline. We believe that gaining the approval of SURFAXIN provided us valuable experience to support the further development of our KL_4 surfactant product candidates, beginning with AEROSURF.

Beyond RDS

In the future, we believe that we may be able to leverage the data and know-how that we gain from our development activities for our KL_4 surfactant, in liquid, lyophilized and aerosolized dosage forms, to support a potential product pipeline of KL_4 surfactant products to address serious critical care respiratory and other conditions in children and adults in pediatric and adult intensive care units. While we remain focused on AEROSURF, we have supported and plan in the future to support potential opportunities to explore the utility of our KL_4 surfactant to address a variety of respiratory conditions. Although there can be no assurance, we would consider supporting such efforts in the future if we are able to secure separate funding, including through potential government-supported and other grant programs that are dedicated to advancing research and development initiatives.

We believe that our aerosolized KL_4 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, although there can be no assurance, we may explore opportunities to apply KL_4 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 as chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF). There can be no assurance, however, that we will secure the additional capital needed to undertake such explorations, that we will undertake such explorations or that, even if we do, that we will be successful.

BUSINESS STRATEGY

We continue to focus our drug research and development activities on the management of RDS in premature infants. We are currently conducting a clinical development program for AEROSURF for the treatment of RDS. Our strategy to achieve our goals includes:

- We are focusing our efforts on advancing the AEROSURF clinical development program and our aerosolized KL_4 surfactant pipeline candidates. 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.

- In May 2015, we announced the results of our initial AEROSURF phase 2a open label clinical trial conducted in 48 premature infants 29 to 34 week gestational age who were receiving nCPAP for RDS. The primary goal of this trial was to evaluate the safety and tolerability of a single exposure of aerosolized KL4 surfactant administered in three escalating inhaled doses (15, 30 and 45 minutes) to premature infants with RDS, compared to infants receiving nCPAP alone. In addition, a key objective of this trial was to establish proof of concept for our proprietary technology platform with (1) physiological data indicating that aerosolized KL4 surfactant is being delivered into the lung of premature infants, and (2) acceptable performance of the novel ADS in the NICU. Physiological data from this clinical trial suggest that, with AEROSURF, KL4 surfactant is being delivered to the lungs of premature infants with RDS and potentially improves gas exchange. In addition, parameters related to timing and frequency of the need for invasive surfactant therapy suggest that a single dose of AEROSURF may delay the time to invasive surfactant therapy due to nCPAP failure. Based on these encouraging results, we initiated a study to explore whether multiple or increased doses of AEROSURF may potentially reduce the need for invasive surfactant therapy.

- In October 2015, we completed enrollment in an AEROSURF phase 2a clinical expansion study in 32 premature infants 29 to 34 week gestational age who were receiving nCPAP for RDS. This trial was designed to evaluate safety and tolerability of aerosolized KL4 surfactant administered in higher (60 and 90 minutes) doses compared to infants receiving nCPAP alone. In November 2015, we announced top line data from our overall phase 2a clinical program in premature infants 29 to 34 week gestational age, including the previously announced data from the initial phase 2a clinical trial. The data suggest that aerosolized KL4 surfactant delivered to premature infants with RDS is generally safe and well tolerated and may be reducing the incidence of nCPAP failure. The reported adverse events and serious adverse events were those that are common and expected among premature infants with RDS and comparable to the control group. Through 72 hours after the start of treatment, AEROSURF treated patients, predominantly receiving a single dose, had lower rates of nCPAP failure compared to control in each of the last three dose groups studied. nCPAP failure rates were 53% in the control group (n=40) compared to 38% (n=8), 14% (n=7, excluding one patient who was inappropriately enrolled) and 38% (n=8) in the 45, 60 and 90 minute AEROSURF dose groups, respectively.

- We also are enrolling a phase 2a multicenter, randomized, open-label, controlled clinical study in 32 premature infants 26 to 28 week gestational age receiving nCPAP for RDS that is designed to evaluate safety and tolerability of aerosolized KL4 surfactant administered in two escalating (30 and 45 minutes) doses, with potential repeat doses, compared to infants receiving nCPAP alone. We anticipate completing enrollment in the second quarter of 2016 and releasing top-line results in the third quarter of 2016. As with the previous phase 2a clinical trials, the primary objective of this 2a clinical trial is to evaluate safety and tolerability and we are also assessing performance of the ADS in the NICU and available physiological data for information that indicates that aerosolized KL4 surfactant is being delivered to the lungs and potentially reducing or delaying the time to invasive surfactant therapy due to nCPAP failure.

- Based on the safety and tolerability profile observed in the phase 2a clinical program, we initiated the AEROSURF phase 2b clinical trial in premature infants 26 to 32 weeks gestational age receiving nCPAP for RDS. The trial is a multicenter, randomized, controlled study with masked treatment assignment in approximately 240 premature infants and is designed to evaluate the safety and tolerability of aerosolized KL4 surfactant (including with potential repeat doses) administered in two dose groups (25 and 50 minutes), compared to infants receiving nCPAP alone. We plan to evaluate the following endpoints: time to nCPAP failure (defined as the need for intubation and delayed surfactant therapy), incidence of nCPAP failure and physiological parameters indicating the effectiveness of lung function. The trial is expected to be conducted in up to 60 clinical sites in the U.S., Canada, Europe and Latin America. Enrollment is beginning with premature infants 29 to 32 week gestational age, and will include premature infants 26 to 28 weeks gestational age after completion of the ongoing phase 2a clinical trial in this age group. We anticipate completing enrollment for this clinical trial by the end of 2016 and releasing top-line results in the first quarter of 2017.

- We are also planning for the manufacture of a sufficient number of ADSs to support the AEROSURF phase 2b clinical trial. We are working with Battelle Memorial Institute (Battelle), which assisted us in the development and manufacture of our phase 2a clinic-ready ADS to manufacture a sufficient number of ADSs to support our continuing development activities and our phase 2b clinical trial. The ADS has been demonstrated to produce consistent and controlled output rates, particle size, and other aerosol characteristics throughout extended KL4 surfactant dosing periods. We believe the ADS represents a robust platform to support reliable and reproducible clinical development, potential commercialization of our AEROSURF combination drug / device product, if approved, and, in the future, further life-cycle product development.

- 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 just prior to use and is being developed potentially to improve ease of use for healthcare providers, prolong shelf life and reduce the need for cold-chain storage. We are developing lyophilized KL4 surfactant initially for our AEROSURF development program. In the first quarter of 2015, we completed a technology transfer of our lyophilized surfactant manufacturing process to our contract manufacturing organization (CMO), Patheon Manufacturing Services LLC (Patheon), which manufactured a sufficient supply of clinical drug product to support our AEROSURF phase 2 clinical program. We are currently engaged in a second technology transfer to a new facility at Patheon. We also have entered into a manufacturing 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.

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

    - In October 2014, we entered into a Collaboration Agreement with Battelle providing for further development of our ADS for use in our planned AEROSURF phase 3 clinical program and, if AEROSURF is approved, initial commercial supply. The collaboration involves a sharing of development expense and provides us the continued benefit of Battelle's expertise in developing and integrating aerosol devices using innovative and advanced technologies. *See,* "– Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement."

    - We plan in the future to seek opportunities to enter into a significant strategic alliance, collaboration or other strategic transaction that would support our AEROSURF development activities, potentially by providing development, regulatory and commercial market expertise as well as financial resources, and, if approved, support the commercial introduction of AEROSURF in selected markets outside the U.S. Financial resources provided by such an alliance could take the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses.

- We plan to closely 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. However, with our current market capitalization, we may be constrained in our efforts by several factors, including: (i) our ability to conduct primary offerings, including under the ATM Program, is constrained by a restriction under our universal shelf registration statement on Form S-3 (File No. 333-196420), which was declared effective on June 13, 2014 (2014 Universal Shelf), that limits the value of primary securities offerings we may conduct in any 12-month period to no more than one-third of our public float; (ii) the number of authorized shares currently available for issuance under our Amended and Restated Certificate of Incorporation, as amended, likely would be insufficient to fund our activities through equity offerings; (iii) if in a financing, we seek to issue more than 20% of our outstanding shares of common stock, we may be required to first seek approval of our stockholders, a time-consuming and expensive process; (iv) if we fail to maintain compliance with Nasdaq listing requirements, including without limitation the minimum bid price, minimum market capitalization or minimum stockholders' equity requirements, our common stock may be subject to delisting, which could affect the liquidity and value of our common stock.

    - We continue to pursue non-dilutive funding opportunities, including in the form of U.S. Government-funded research and preclinical development initiatives that explore the use of our KL4 surfactant in the treatment of a range of respiratory diseases. Since 2012, we have received $4.1 million in funding, including approximately $1.9 million to fund our AEROSURF phase 2a clinical program.

- In July 2015, we completed a registered public offering of 1,791,667 Series A units and 3,000,000 Series B units each at a price per unit of $8.40, resulting in gross proceeds of $40.25 million ($37.6 million net after underwriting discount and expenses). The proceeds included $5.0 million in non-cash consideration from affiliates of Deerfield Management, L.P. (Deerfield) in the form of a reduction in future interest payments due under the Deerfield Loan (discussed below). Each Series A unit consists of one share of common stock and a Series A warrant to purchase one share of common stock at an exercise price of $9.80 per share. Each Series B unit consists of a fully paid pre-funded Series B warrant to purchase one share of common stock at an exercise price of $8.40 per share, and a Series B warrant to purchase one share of common stock at an exercise price of $9.80 per share. *See,* Item 7 – Management Discussion and Analysis – Liquidity and Capital Resources – Financings Pursuant to Common Stock Offerings – Registered Public Offerings."

- In February 2013, we entered into an At-the-Market Equity Offering Sales Agreement (Sales Agreement) with Stifel, Nicolaus & Company, Incorporated (Stifel), pursuant to which Stifel, as our exclusive agent, may sell through an "at-the-market" program (ATM Program), at such times that we may elect during a three-year term, up to a maximum of $25,000,000 of shares of our common stock. In February 2016, we entered into an amendment to the Sales Agreement to extend the term three years to February 11, 2019. As of December 31, 2015, approximately $23.0 million remains available under the ATM Program.

- In February 2013, we entered into a secured loan agreement with Deerfield, under which we secured long-term debt of $30 million (Deerfield Loan). In July 2015, we entered into two amendments to the loan agreement, pursuant to which we prepaid $5 million of the outstanding principal amount, eliminated the initial principal payment due in February 2017; increased each of the remaining principal payments due in February 2018 (which may be deferred one year if we achieve a market capitalization milestone) and February 2019 to $12.5 million; agreed to pay $5 million in satisfaction of future interest obligations through issuance to Deerfield of $5 million securities in the July 2015 public offering; and reduced the rate of any remaining interest accruing under the Deerfield Loan from 8.75% to 8.25%. The loan agreement also 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. *See*, "Item 7 – Management Discussion and Analysis – Liquidity and Capital Resources – Deerfield Loan."

- 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 we advance our development programs, 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 approved products. *See,* "– Licensing, Patents and Other Proprietary Rights and Regulatory Designations."

- We believe that our KL4 surfactant technology may potentially support 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. For example, since 2012, we have 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, if approved, commercialization of additional KL4 surfactant indications.

Although we currently believe that we will be successful in completing our ongoing AEROSURF clinical trials within the time frames set forth above and that the results will support our planned AEROSURF phase 3 clinical program and registration of AEROSURF in the U.S.; that we will be able to manufacture a sufficient supply of lyophilized KL4 surfactant and ADSs and related components to support our AEROSURF clinical program; and that we will be able to secure the additional capital that we will require to achieve our business objectives, including through a strategic alliance or other strategic transaction, there can be no assurance that we will be successful. Our activities involve significant risks and uncertainties that could cause the results of our efforts to differ from our expectations. *See,* "Item 1A – Risk Factors."

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, 2013; IMS Midas Data MAT, December 2013; HCUP Hospital Discharge data, 2013; Obstetric and Neonatal Care Practices for Infants 501 to 1500 g From 2000 to 2009; *Pediatrics,* July 2013, Soll; Hospital Insurance Claim Database, 2009; Management and Outcomes of Very Low Birth Weight, *New England Journal of Medicine* (NEJM), 2008, Eichenwald, Stark; Cost of hospitalization for preterm and low birth weight infants in the United States, *Pediatrics* 2007, Russell RB; 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 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."

SURFACTANT THERAPY

The RDS Market

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 was the first synthetic, peptide-containing surfactant approved for use in neonatal medicine in the U.S.

We estimate that approximately 300,000 to 350,000 low birth weight premature infants are born annually in the U.S. (and approximately 500,000 to 600,000 in the major U.S., European and Japanese medical markets). In addition, our current market data suggests that the number of low birth weight premature infants born annually in the Latin America, Asia and the Pacific markets may represent opportunities similar to Europe and Japan and we plan to conduct further market research on this topic. In the U.S., we estimate that approximately 120,000 to 150,000 premature infants are given respiratory support because they have or are at risk for RDS. Approximately 40% (50,000 to 60,000) of these infants currently are treated with surfactant as the initial therapy for RDS, usually within the first hours of life, generally because the perceived benefits of surfactant therapy for these very fragile infants outweigh the increased risks associated with invasive intubation and mechanical ventilation. The remaining infants are usually initially supported with nCPAP alone. As discussed above, a large percentage of these patients (approximately 25%) experience nCPAP failure and require delayed surfactant therapy administered via intubation and mechanical ventilation. We estimate that approximately 20,000 to 25,000 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 70,000 to 85,000.

Market research conducted with clinicians for us by third parties suggests that, if AEROSURF were approved, a significant number of the 120,000 to 150,000 premature infants given respiratory support because they have or are at risk for RDS would receive aerosolized KL_4 surfactant as the initial treatment for RDS.

We estimate the surfactant market 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 and lack of medical innovation. By enabling delivery of aerosolized KL4 surfactant using noninvasive means, we believe that, over time, AEROSURF has the potential to expand the current RDS estimated worldwide annual market to a $600 million to a $1 billion per year market opportunity. *See,* "– Potential Pharmacoeconomic Benefits of AEROSURF.")

Potential Pharmacoeconomic Benefits of AEROSURF

In addition to the potential clinical benefits of aerosolized KL4 surfactant, AEROSURF 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 premature infant (an estimated $55,000 per patient), is much greater than the cost to manage a premature infant who does not need mechanical ventilation (an estimated $8,500 per patient). These costs increase even more if complications associated with intubation and mechanical ventilation should develop, including bronchopulmonary dysplasia. Other healthcare system costs include the need to transport RDS patients who require intubation and mechanical ventilation to tertiary care neonatal intensive care units as well as family relocation costs. Accordingly, by providing clinical and pharmacoeconomic benefits through the reduction or elimination of the need for intubation and mechanical ventilation to treat RDS, we estimate that AEROSURF may, over time, expand the size of the global surfactant market.

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 developing AEROSURF, we may be able to apply 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 and CF.

Acute lung injury (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 a number of preclinical studies funded through various U.S. government-sponsored, biodefense-related initiatives, including without limitation: (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 (award number R44AI102308); (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's contract with 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; (iv) a program funded by NIAID, to investigate the use of KL4 surfactant as a treatment for influenza-induced ALI. We received additional awards of $1.0 million each from NIAID to support continued work with University of Pennsylvania to study (i) in 2014, how KL4 surfactant may mitigate radiation-induced lung injury, and in 2015, to support continued development of our aerosolized KL4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury. We recently received from NIAID $225,000 fixed-price contract (contract HHSN272201500027C) to study KL4 surfactant aerosol to reduce influenza lung injury. The foregoing content concerning these initiatives is solely the responsibility of Discovery Labs and does not necessarily represent the official views of the NIH.

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 would 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 we will secure the necessary capital, whether through government-sponsored grants or otherwise, 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.

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, surfactant therapy is currently 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 rigorous specifications, with minimal lot-to-lot variability, is currently approved by the FDA in liquid instillate form, and is being developed in lyophilized (freeze-dried) and aerosolized forms. We hold an exclusive worldwide license and sublicense to this technology, which was invented at The Scripps Research Institute and exclusively licensed to Johnson & Johnson, Inc. (J&J) and further developed by an affiliate of (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 seek to develop our KL4 surfactant technology pipeline potentially to address a broad range of respiratory conditions that represent significant unmet medical needs. However, the clinical relevance of such attributes has not been adequately established and, accordingly, warrants further study.

KL4 Surfactant Dosage Forms

Surfactants currently marketed in the U.S. are liquid instillate and must be stored in refrigerated conditions, warmed prior to use, and administered using endotracheal intubation and mechanical ventilation. Our KL4 surfactant can be lyophilized (freeze-dried) and reconstituted to a liquid just prior to administration. We have demonstrated in laboratory experiments 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 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 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 are using lyophilized KL4 surfactant to develop aerosolized KL4 surfactant in our AEROSURF development program to treat RDS in premature infants. Thereafter, we potentially will be able to address a range of indications in neonatal, pediatric and adult critical care patient populations.

The Safety and Efficacy Profile of SURFAXIN for the Prevention of RDS in Premature Infants at High Risk for RDS

Our new drug application (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).

SURFAXIN was approved by the FDA in 2012. In the second quarter of 2015, we decided to cease our commercial and manufacturing activities for SURFAXIN and focus our capital resources on advancing the AEROSURF clinical development program and our aerosolized KL4 surfactant pipeline.

Our Aerosolization Delivery Technologies

Aerosol Delivery System (ADS)

We have worldwide exclusive rights to our ADS, which consists of a capillary aerosol generator and related components, 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 this technology for use with non-surfactant drugs to treat certain other pediatric and adult respiratory indications in hospitals and other health care institutions. Our ADS is protected by a portfolio of patents covering the core components of the system.

Our proprietary ADS is designed to aerosolize our KL4 surfactant. An aerosol is created by pumping our KL4 surfactant through a heated capillary, after which the aerosol cools and slows in velocity, yielding a dense aerosol with a defined particle size suitable for respiration. In studies conducted with our initial capillary aerosol generator and our KL4 surfactant, we generated aerosolized KL4 surfactant at consistent and reproducible volumes that could support delivery of therapeutic doses in reasonable periods of time. In our AEROSURF phase 2a clinical program, we assessed physiological data suggesting that AEROSURF may be delivering surfactant into the lung (where it needs to act) and reducing the incidence of nCPAP failure. We believe that our ADS is capable of delivering our KL4 surfactant to the lung of premature infants with RDS without having to resort to invasive intubation and mechanical ventilation, procedures that are currently required to administer surfactants.

AFECTAIR® *Aerosol-Conducting Airway Connector*

We also developed AFECTAIR, a novel 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. *In vitro* studies have demonstrated that this connector improves the delivery of inhaled therapies to infants requiring ventilatory support. We therefore believe that using our AFECTAIR device with our ADS will improve the delivery of our KL4 surfactant to premature infants. Although we initially implemented a plan in 2013 to separately market AFECTAIR, we later concluded that it may provide a potential competitive advantage and decided to reserve AFECTAIR for use with our ADS in our AEROSURF development program.

BUSINESS OPERATIONS

Research and Development

Our research and development activities are focused on developing our proprietary KL4 surfactant, ADS, and aerosol delivery technologies into a series of KL4 surfactant 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 reassess our research and development priorities in light of a number of factors, including the results obtained in our clinical trials, preclinical research and related activities, advances in technology and progress in our device development programs, and relationship of a project to our near-term objectives; our cash flow requirements, financial liquidity and ability to secure necessary capital; and the potential for development partnerships, collaboration agreements and other strategic transactions. As part of our assessments, we expect to modify and adapt our research and development plans from time to time and anticipate that we will continue to do so in the future.

Our research and development resources are focused in the near term primarily on our AEROSURF development program to address RDS. We are presently engaged in a phase 2 clinical programs and have initiated our phase 2b clinical trial. Battelle assisted us in the development of a phase 2 clinic-ready ADS and has manufactured and will continue to manufacture a supply of ADS to support our preclinical activities and our phase 2 clinical program. We also are working with Battelle under a collaboration agreement to develop a phase 3 clinic-ready ADS to support additional research and development activities, our phase 3 clinical program and potential commercial supply. We are also working with Patheon to manufacture a supply of lyophilized KL4 surfactant to support our phase 2 activities and conduct further manufacturing development work for the planned phase 3 clinical trial.

In markets outside the U.S., for AEROSURF, we plan to seek regulatory advice and 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.

To support our research and development activities, we have:

- physicians and scientists on staff and available under consulting arrangements who have 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 and collaborate with 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 have retained contract research organizations (CROs) to support our ongoing multi-center AEROSURF trials, including in the U.S., EU, Latin America and Canada;

- 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 ADS and aerosol delivery technologies. In addition to our collaboration with Battelle, which has significant expertise in developing and integrating aerosol device technologies, we have our own engineering team that is focused on further optimizing our ADS;

- quality operations capabilities to assure compliance of our drug and device development activities with applicable regulations;

- we rely on CMOs to produce our lyophilized KL4 surfactant, APIs and other materials for our drug product. We plan to rely on third-party manufacturers to manufacture and assemble our ADS and related components; and

- our own analytical testing laboratory and 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 in support of our manufacturing activities.

Research and development costs are charged to operations as incurred. During the years ended December 31, 2015, and December 31, 2014, we invested approximately $28.9 million and 26.7 million, respectively, 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

We use third parties for the manufacture of our lyophilized KL4 surfactant, ADS and related components, AFECTAIR aerosol-conducting airway connector and related components, certain analytical and laboratory services in support of our manufacturing activities, clinical supply labeling, packaging warehousing and distribution. To support our manufacturing operations, we maintain our own analytical and technical support laboratory at our headquarters in Warrington, Pennsylvania (Warrington Laboratory).

KL4 Surfactant

We believe that our KL4 surfactant product is 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 that requires ongoing monitoring of drug product stability and conformance to specifications. We currently rely on single source suppliers under separate product supply agreements for KL4 and POPG, two of our APIs, and source the other two APIs from a single source supplier 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.

We manufacture our lyophilized KL4 surfactant at Patheon under a development agreement that expires October 24, 2016. We completed development work for the technology transfer of our lyophilized KL4 surfactant manufacturing process to Patheon in 2013. We have since manufactured a sufficient clinical supply of KL4 surfactant to support our phase 2 clinical program and other development activities. During the fourth quarter of 2014, we began a technology transfer of our lyophilized KL4 surfactant manufacturing process to another facility at Patheon, where we expect to manufacture our lyophilized KL4 surfactant for use in our AEROSURF phase 3 clinical program. Under our arrangement with Patheon, we provide the APIs and Patheon purchases excipients and other materials required to manufacture our lyophilized KL4 surfactant.

In our Warrington Laboratory, we conduct certain analytical development and quality control activities, including release testing of all APIs and release and stability testing of our lyophilized KL4 surfactant clinical drug product. Our Warrington Laboratory also provides analytical testing and quality system support for our lyophilized and aerosolized KL4 surfactant dosage forms, our research to identify and protect our intellectual property, including studying other potential formulations of our KL4 surfactant and other potential KL4 surfactant product candidates.

We also 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. At the present time, several of these laboratories are single-source providers.

We previously manufactured our commercial supply of SURFAXIN, our KL4 surfactant in liquid instillate form, at our manufacturing operations located in a leased facility in Totowa New Jersey (Totowa Facility). In connection with our decision to cease commercialization activities for SURFAXIN, we allowed our lease for this facility to expire in June 2015. Our Totowa facility consisted of pharmaceutical manufacturing space that was designed for the manufacture and filling of sterile liquid pharmaceuticals in compliance with cGMP. To support our manufacturing activities, we also operated a microbiology laboratory at our Totowa Facility.

Aerosol Delivery System (ADS)

AEROSURF is an investigational combination drug/device product that produces aerosolized KL4 surfactant by combining our lyophilized KL4 surfactant with our 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 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 ADS includes a durable, reusable 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 ADPs 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.

Beginning in 2012, Battelle assisted us in a multi-phase development program focused on design and testing of clinic-ready ADS for use in our AEROSURF phase 2 clinical trials, and manufactured a sufficient number of ADSs for the phase 2a clinical trial in premature infants 29 to 34 week gestational age. Battelle also agreed to manufacture and assemble a sufficient supply of control units, ADPs and related components to support our ongoing phase 2a clinical trial in premature infants 26 to 28 week gestational age, our phase 2b clinical trial in premature infants 26 to 32 week gestational age and development activities. We expect to arrange for additional control units, ADPs and related components from Battelle, as needed. For our planned phase 3 clinical program, we and Battelle are collaborating to further develop the phase 2 ADS. Under our Collaboration Agreement, we and Battelle have agreed to negotiate in good faith for the manufacture of phase 3 control units, ADPs and related components. We are also assessing other potential partners to assure continued availability of ADS for our clinical and development activities through our phase 3 clinical program, and, if approved, initial commercial distribution. *See,* "– Business Operations – Strategic Alliances and Collaboration Arrangements – Battelle Collaboration Agreement."

Our AFECTAIR aerosol-conducting airway connector has been manufactured by Lacey Manufacturing Company, a division of Precision Products, LLC (Lacey), which also provided labeling and packaging services. We hold sufficient quantities of this device to support our AEROSURF phase 2b clinical trial.

Distribution

We currently receive labeling, packaging and distribution services to support our AEROSURF clinical activities in the U.S., European Union and Latin America from Almac Group Limited under an agreement that expires October 15, 2016.

We received warehousing, distribution and related services for SURFAXIN from ASD Specialty Healthcare Inc. (ASD) and Integrated Commercialization Solutions, Inc. (ICS), affiliates of AmerisourceBergen Specialty Group. ICS provided third-party logistics and assisted us with inventory tracking, customer service, order management, distribution, returned goods, contract and accounts receivable management, certain financial management services and other similar services for SURFAXIN and AFECTAIR. ASD acted as our exclusive specialty distributor for SURFAXIN in the U.S. and provided related services. Following the cessation of commercial activities for SURFAXIN, we terminated the arrangement with ASD. ICS continues to provide limited inventory services for AFECTAIR in support of our clinical activities under an agreement that will expire in October 2016.

Our collaboration with Laboratorios del Dr. Esteve, S.A. (Esteve) provides that Esteve has responsibility for distribution of specified KL_4 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 expect to contract for third-party distribution services 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 ADS 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. In August 2015, we agreed to amend the Collaboration Agreement to adjust the anticipated Project Plan Cost (as defined in the Agreement) and change the date for completion of Stage 3 ("Milestone Date") as defined in the Collaboration Agreement from May 31, 2016 to July 15, 2016. As of December 31, 2015, if this development project is successfully completed, we expect to fund development activities of approximately $6.6 million through 2016, subject to certain rights of termination outlined in the Collaboration Agreement.

Pursuant to the Collaboration Agreement, we and Battelle (i) have defined the requirements of the phase 3 ADS and agreed upon a detailed project plan for the next two stages of the project (Stage 1), (ii) are developing the ADS in accordance with the project plan (Stage 2), and (iii) plan to complete all required testing, verification and documentation to be in a position to manufacture a sufficient supply of ADSs (Stage 3) to support our phase 3 clinical program. Upon completion of the three-stage project plan, we and Battelle intend to negotiate in good faith potentially to enter into an agreement for the manufacture of a sufficient number of ADS to support the planned AEROSURF phase 3 clinical program, and, if AEROSURF is approved, to negotiate in good faith potentially to enter into a supply agreement providing for an initial commercial supply of ADSs.

A Steering Committee, comprised of an equal number of members appointed by each party, 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 ADSs. We and Battelle shared equally in the costs of Stage 1 activities. Following completion of Stage 1, we and Battelle agreed 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 $70 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 71,429 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 35,714 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 July 15, 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 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 to support our AEROSURF development activities and resources and expertise to support the registration and commercialization of AEROSURF and potentially support the development and, if approved, commercialization of our other 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, ADS and aerosol-conducting airway connector technologies through patents and patent term restorations, (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 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 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. Thereafter, royalties shall be paid in respect of a given licensed product until the expiration of the last licensed patent containing a valid claim covering the licensed product in such country. For countries in the EU in which royalties are paid only by virtue of licensed know-how, royalties shall be payable commencing from the date of first commercial sale of the first licensed product in such country and 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 country of the EU. 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 surfactant technology that have been issued worldwide include composition of matter, formulation, and uses and include the following issued U.S. 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, South Korea, and Singapore. In the U.S., 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, European patent 2723323B1 issued on September 23, 2015 and another U.S. patent application (US 14/387707) along with multiple foreign counterparts are pending. U.S. Patents Nos. 8,748,396 and 8,748,397 and European patent 2723323B1will 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 its ex-U.S. rights to Philip Morris Products S.A. (PMPSA), we entered into a license agreement with PMPSA with respect to rights outside of the U.S., effective on the same date and on substantially the same terms and conditions as the U.S. License Agreement. These agreements licensed to us all rights in and to PMUSA and PMPSA proprietary aerosol technology. 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 (*see,* "– Aerosol Technology Patents and Patent Rights.") in the territories. In connection with exclusive undertakings of PMUSA and PMPSA not to exploit the aerosol 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 licensed aerosol 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 have been required to pay minimum royalties quarterly beginning in 2014, but are entitled to reduce future quarterly royalties above the quarterly minimums in the amount of the true-up payments we make to satisfy minimum royalties for prior quarters. Our license rights extend to innovations to the aerosol technology that are made under the License Agreements. We believe that our AEROSURF aerosolized KL_4 surfactant can be developed to potentially address a broad range of serious respiratory conditions. We are developing AEROSURF to treat premature infants with RDS using the proprietary aerosol technology.

Aerosol Technology Patents and Patent Rights

We currently hold exclusive licenses to the aerosol technology, which is the core technology in our ADS. This technology is based on a capillary aerosol generator and is licensed 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 aerosol technology includes certain non-surfactant drugs to treat certain designated pediatric and adult respiratory indications in hospitals and other health care institutions. The aerosol 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, European patent No. 2265309 was issued on December 16, 2015 and several foreign patents have issued during 2011 through 2015. 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

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 determines whether to designate a drug as an Orphan Drug. If a drug is designated as an Orphan Drug, it is eligible to obtain certain benefits, 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 KL_4 surfactant for the treatment of RDS in premature infants. 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 KL_4 surfactant for the prevention and treatment of BPD in premature infants, (ii) our KL_4 surfactant for the treatment of acute respiratory distress syndrome (ARDS) in adults, and (iii) our KL_4 surfactant for the treatment of CF.

The European Commission grants "Orphan Medicinal Product" designation for pharmaceutical products for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than 5 in 10,000 people which provides for exclusive marketing rights for indications in Europe for 10 years (subject to revision after six years) following marketing approval by the European Medicines Agency (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 32 weeks gestational age, (ii) our KL4 surfactant for the treatment of RDS in premature infants of less than 37 weeks gestational age, (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. In submitting our request to the EMA for Orphan Medicinal Product designations, instead of listing the drug product under the USAN name (lucinactant) as we have in the U.S., we were required to submit our request under the names of the four APIs in our KL4 surfactant (lucinactant) as follows: sinapultide (KL4), dipalmitoylphosphatidylcholine, palmitoyl-oleoyl phosphatidylglycerol and palmitic acid.

Fast Track Designations and Priority Review

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, and rolling review, 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 in adults. We believe that other of our products may qualify for Fast Track or other designations, including potentially breakthrough therapy, accelerated approval and priority review. These designations and programs are intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life-threatening conditions.

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. 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, we believe that efforts to aerosolize animal-derived surfactants have not been satisfactory due to 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). In addition, aerosol particle size and output consistency is important throughout the aerosolized surfactant dosing period. In particular, for clinical registration trials, a surfactant aerosol delivery system needs to deliver a consistent dose to the patient throughout the individual dosing period as well as consistent dose from device to device. 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 products for several companies. Chiesi has recently investigated the use of nebulized Curosurf using a PARI eFlow® Neonatal Nebulizer System (CureNeb study; PAS 2013 abstract). 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. A further potential competitor to our aerosolized surfactant drug technology may be administration of surfactant via laryngeal mask airway (LMA).

GOVERNMENT REGULATION

In the U.S., 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. Drug products, medical devices, and drug-device combination products must receive all relevant regulatory approvals or clearances before it may be marketed in the U.S. 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 Products

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

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.

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, or 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.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases 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.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA 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 $2,374,000 for fiscal year 2016, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding $114,000 per product and $585,000 per establishment for fiscal year 2016. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. If the NDA submission is filed, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use. 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, or 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, or 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, or 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.

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 moiety 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 by means of greater effectiveness, greater safety, or providing a major contribution to patient care. 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 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.

Under the fast track program, sponsors have the opportunity to engage in more frequent interactions with FDA. In addition, 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.

The Hatch-Waxman Act

Orange Book Listing: In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the 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, or 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 to be bioequivalent 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 labeling 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 received 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.

An applicant submitting an NDA under Section 505(b)(2) of the FDC Act, which permits the filing of an NDA where at least some of the information required from approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference, is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

Market Exclusivity: Market exclusivity provisions under the FDC Act also can delay the submission or the approval of certain applications. The FDC Act provides a five-year period of non-patent exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. A drug is entitled to NCE exclusivity if it contains a drug substance no active moiety of which has been previously approved by the FDA. During the exclusivity period, the FDA may not receive for review an ANDA or file a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. The FDC Act also provides three years of market exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions for use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs for the original conditions of use, such as the originally approved indication. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension: After NDA approval, the owner of a relevant drug patent may apply for up to a five-year patent extension. Only one patent may be extended for each regulatory review period, which is composed of two parts: a testing phase, and an approval phase. The allowable patent term extension is calculated as half of the drug's testing phase - the time between the day the IND becomes effective 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.

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 U.S. 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.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, or REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or 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. In addition, prescription drug manufacturers in the U.S. must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate products.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Medical Device Products

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory which is: (i) recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them; (ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (iii) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by FDA before they are marketed.

Generally, establishments that manufacture and/or distribute devices, including manufacturers, contract manufacturers, sterilizers, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers, initial importers, manufacturers of accessories and components sold directly to the end user, and U.S. manufacturers of export-only devices, are required to register their establishments with the FDA and provide FDA a list of the devices that they handle at their facilities.

Pre-market Authorization and Notification

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 premarket approval application, or 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 I and II devices. Some devices that have been classified as Class III are regulated pursuant to the 510(k) requirements because FDA has not yet called for PMAs for these devices. Other less common regulatory pathways to market for Class III devices include the humanitarian device exception, or HDE, or a product development protocol or PDP.

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. Manufacturers of such 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 Quality System Regulation, or 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 Products

A combination product is a product comprised of (i) two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; (ii) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (iii) a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (iv) any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

FDA is divided into various branches, or Centers, by product type. Different Centers typically review drug, biologic, or device applications. 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 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. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which Center to assign the product based on consistency with other combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product. 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, although the agency has the discretion to require separate applications to more than one Center. One reason to submit multiple evaluations is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each may be evaluated by a different lead Center.

International Approvals

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. 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. In addition, international regulators may require different manufacturing practices than the FDA's cGMPs.

Anti-Kickback, False Claims Laws

In addition to FDA restrictions on marketing of pharmaceutical products, medical devices, and combination products, several other types of state and federal laws have been applied to restrict certain marketing practices in the medical product industry in recent years. These laws include anti-kickback statutes, false claims statutes, and other statutes pertaining to health care fraud and abuse. 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. The Patient Protection and Affordable Care Act, or PPACA, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, PPACA amended the healthcare program anti-kickback statute such that a violation can serve as a basis for liability under the federal false claims law. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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 offeror/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.

EMPLOYEES

As of March 11, 2016, we have 58 employees, including 5 part-time employees. 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.

***Note**: Information concerning the shares of our common stock and related share prices in these risk factors has been adjusted to reflect a 1-for-14 reverse split of our common stock and a change in the number of shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation, as amended (Certificate of Incorporation), that were made effective on January 22, 2016.*

To be able to secure the additional capital that we will require, we are substantially dependent upon our ability to successfully complete enrollment in our ongoing phase 2b clinical trial before the end of 2016 and release top line data in the first quarter of 2017, in accordance with our plan. If we are unable to successfully complete enrollment and release top line data in accordance with our plan, or if the results of our clinical trial are inconclusive, or present an unacceptable benefit / risk profile due to suboptimal efficacy and / or safety profile, we may be unable to secure the additional capital that we will require to support our research and development activities and operations and have sufficient cash resources to service and repay debt, which could have a material adverse effect on our business and our ability to continue as a going concern.

Our business and our ability to secure the significant additional capital that we will require to support our research and development activities and operations and have sufficient cash resources to service and repay debt, is highly dependent upon our ability to successfully develop, manufacture, secure regulatory approval for, and commercialize our AEROSURF combination drug/device product candidate for the treatment of respiratory distress syndrome (RDS) in premature infants. At the present time, we are conducting a phase 2b clinical trial, the enrollment for which is expected to be completed before the end of 2016, with top line results expected in the first quarter of 2017. At December 31, 2015, we had cash and cash equivalents of approximately $38.7 million, which we expect to be sufficient to fund our phase 2b clinical trial and our operations through the first quarter of 2017. If for any reason, we should experience delays in successfully completing this clinical trial, whether due to slower rates of enrollment or of initiation of clinical sites, or failure to timely supply aerosol delivery system (ADS) and disposable AEROSURF delivery packs as needed, or otherwise, and any such delay extends beyond the period for which we have sufficient funding, we may have difficulty securing the additional capital that we require to complete the trial and continue our development program on acceptable terms, if at all. Moreover, even if we are able to complete our phase 2b clinical trial on time, but obtain results that are inconclusive, fail to achieve our stated endpoints, or otherwise present an inappropriate benefit / risk profile, or if we suffer regulatory setbacks or delays that jeopardize or ability to successfully commercialize our product, if approved, we may be unable to secure the additional capital that we require before we exhaust our cash resources. Accordingly, failure to obtain acceptable and promising results within the required time could have a material adverse effect on our ability to secure the additional capital that we will require, through strategic transactions or otherwise, and likely adversely affect our ability to continue as a going concern.

We will require significant additional capital to support our research and development activities and operations and have sufficient cash resources to service and repay debt, but our ability to raise such capital may be adversely impacted by a number of factors may represent significant challenges to accessing the capital markets at a time when we would like or require, and at an increased cost of capital. 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.

As of December 31, 2015, we had cash and cash equivalents of approximately $38.7 million, current accounts payable and accrued expenses of $10.8 million, and $25 million of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield). The principal portion of the debt is payable in two equal installments in February 2018 (subject to potential deferral in certain circumstances) and February 2019. Before any additional financings, we anticipate that we will have sufficient cash available to support our operations and debt service obligations through the first quarter of 2017.

Our operations have consumed substantial amounts of cash since inception. As of December 31, 2015, we have an accumulated deficit of approximately $579 million and we expect to continue to incur significant, increasing operating losses over the next several years. Following the approval of SURFAXIN® in 2012, we initiated commercial activities in late 2013. However, with revenue growth slower than expected and more of our capital and resources being allocated to SURFAXIN than expected, we reassessed and initiated a plan to focus our limited capital and resources to the development of AEROSURF. Our plan was to (i) enter into a strategic alliance or collaboration arrangement to support the manufacture and commercialization of SURFAXIN, or (ii) cease our manufacturing and commercial activities for SURFAXIN. After considering potential alternatives, we began winding down commercial activities in April 2015. In 2014, cash outflows for manufacturing, marketing, medical and commercial activities for SURFAXIN were approximately $19 million. We also reduced our work force by approximately 50%, predominantly in commercial infrastructure and manufacturing. In addition, we allowed our real property lease for our Totowa, NJ manufacturing operations to expire in June 2015. Since that time, we have focused our capital and resources primarily on the AEROSURF clinical development program and further development of our lyophilized KL4 surfactant drug product and our aerosol delivery system (ADS), which is based on our capillary aerosol generator technology.

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, and other sources, are sufficient to offset our cash flow requirements. For the next several years, we do not expect to receive revenues from the sale of approved products, and our cash outflows for development programs, operations and debt service are likely to far outpace the rate at which we may generate revenues and other cash inflows from all available 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 our research and development programs, or, if approved, commercialization of our products.

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 need to seek additional capital in the equity 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. However, a number of factors, including our status as a smaller reporting company under the SEC regulations, conditions in the global financial markets, and the timing and outcomes of our clinical activities, may present significant challenges to 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 (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel), 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 status under SEC regulations as a smaller reporting company and the related limitation on primary offerings under our universal shelf registration statement, which was filed with the SEC on Form S-3 (File No. 333-196420) and declared effective on June 13, 2014 (2014 Universal Shelf), may make it more difficult to raise additional capital in the public markets when needed, if at all, including under our ATM Program or pursuant to a public offering.

Our ability to use our ATM Program with Stifel or to raise additional capital from time to time through a public offering under our 2014 Universal Shelf may be constrained by restrictions under the Form S-3, which limits the value of primary securities offerings in any 12-month period by companies whose equity securities held by nonaffiliated persons and entities (public float) is less than $75 million to no more than one-third of their public float. To raise needed capital, we may be required to seek other forms of transactions, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time consuming and costly, or privately placed, potentially with registration rights or priced at a discount to the market value of our stock, or contain other terms and conditions, or other transactions, any of which could result in substantial equity dilution of stockholders' interests. 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.

If we fail to adhere to the strict listing requirements of The Nasdaq Capital Market (Nasdaq), we may be subject to delisting. As a result, our stock price may decline and our common stock eventually 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.

On June 29, 2015, we received a letter from The Nasdaq Stock Market indicating that for 30 consecutive trading days our common stock had not maintained a minimum closing per share bid price of $1.00 (Minimum Bid Price Requirement) as required by Nasdaq Listing Rule 5550(a)(2). Under Nasdaq's Listing Rules, we initially had 180 calendar days from the date of the notification (the Compliance Period), or until December 28, 2015, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the closing bid price of our common stock must close above $1.00 for a minimum of 10 consecutive business days; thereafter, our common stock would continue to be eligible for listing on Nasdaq. At the end of the initial Compliance Period, Nasdaq notified that us we qualified for an extension of the Compliance Period to June 2016. On January 21, 2016, at a Special Meeting of Stockholders, our stockholders approved a 1-for-14 reverse split, which was effective on January 22, 2016 and brought us into compliance with the Minimum Bid Price Requirement.

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

Our clinical development program for AEROSURF involves significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes. Our clinical trials may be delayed, or fail, which will harm our business prospects.

We are currently conducting a phase 2a clinical program evaluating the safety and tolerability of aerosolized KL_4 surfactant drug product administered to premature infants 26 to 28 week gestational age who are receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to infants receiving nCPAP alone. We are also conducting a phase 2b clinical trial in premature infants 26 to 32 weeks gestational age receiving nCPAP for RDS, which is designed to evaluate the safety and tolerability of aerosolized KL_4 surfactant compared to infants receiving nCPAP alone and evaluate certain endpoints, including time to nCPAP failure (defined as the need for intubation and delayed surfactant therapy), incidence of nCPAP failure and physiological parameters indicating the effectiveness of lung function. These clinical trials are two of a series of clinical trials that will be needed to gain marketing authorization for AEROSURF, if at all. 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.

We have opened a number of clinical sites outside the U.S. where our experience is more limited. We use the services of third party clinical trial providers and third party contract research organizations (CROs) to carry out most of our clinical trial related activities and accurately report their results, which may impact our ability to control the timing, conduct, expense and quality of our clinical trials. One CRO has responsibility for substantially all of our clinical trial related activities and reporting. If our CROs do not successfully carry out their activities or meet expected deadlines, our trials may be delayed. We may also need to replace our CROs. Although we believe that there are a number of other third-party CROs we could engage to continue these activities, the replacement of an existing CRO may result in delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our drug candidates. If we fail to adequately manage the design, execution and regulatory aspects of our complex and diverse clinical trials, our studies and any potential regulatory approvals may be delayed, or we may fail to gain approvals for our product candidates.

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 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.

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, file or approve a new drug application (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 2 clinical program for AEROSURF. There can be no assurance that issues requiring protracted and time-consuming preclinical studies will not arise or that our clinical program trials will be concluded successfully. 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 ADS used. In addition, if the ADS to be used in our 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. There can be no assurance that we will be successful in gaining regulatory approval for AEROSURF.

Clinical trials may indicate that our product candidates lack efficacy, have harmful side effects or raise safety or other concerns that may significantly reduce the likelihood of regulatory approval, result in significant restrictions on use and safety warnings in the approved label, adversely affect placement within the treatment paradigm, or otherwise significantly diminish the commercial potential of the product candidate. Also, positive results in a registration trial may not be replicated in subsequent confirmatory trials. Even if later stage clinical trials are successful, regulatory authorities may disagree with our view of the data or require additional studies, may disagree with trial design or the endpoints employed in the trials, may fail to approve the processes used to manufacture a product candidate, may find the cGMP compliance status of a facility that manufactures a product candidate unsatisfactory, may fail to approve or delay approval of our product candidates, dosing or delivery methods, companion devices or may otherwise grant marketing approval that is more restricted than anticipated, including indications covering narrow patient populations and the imposition of safety monitoring or educational requirements or risk evaluation and mitigation strategies. The occurrence of any such events could result in the incurrence of significant costs and expenses, have an adverse effect on our business, including our financial condition and results of operations, or cause our stock price to decline or experience periods of volatility. Even if we are able to successfully develop new products or indications, we may make a strategic decision to discontinue development of such product or indication if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline.

For AEROSURF, we currently plan to pursue clinical development in the U.S., the European Union, Latin America and Canada, 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. While we would prefer to design a single, global clinical program that would satisfy the regulators in all of our target markets, 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;
- 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. There may be situations in which demonstrating the efficacy and safety of a product candidate may not be sufficient to gain regulatory approval unless superiority to comparative products can be shown. Also, legislative bodies or regulatory agencies could enact new laws or regulations or change existing laws or regulations at any time, which could affect our ability to obtain or maintain approval of our products or product candidates. For example, the EU recently finalized legislation, which will apply as early as mid-2016, related to the conduct of clinical trials. While the aim of the new legislation is to improve in operational efficiency and streamline the overall clinical trial authorization process, the new requirements also provide for increased transparency of clinical trial results and submission of quality data relating to the products and product candidates used for such trials. Starting in 2015, the EMA will make certain clinical trial reports publicly available, which may limit our ability to protect competitively-sensitive information contained in our clinical trial reports. Failure to comply with new laws or regulations could result in significant monetary penalties as well as reputational and other harms. We are unable to predict when and whether any further changes to laws or regulatory policies affecting our business could occur, such as efforts to reform medical device regulation or the pedigree requirements for medical products or to implement new requirements for combination products, and whether such changes could have a material adverse effect on our business and results of operations. Regulatory authorities may also question the sufficiency for approval of the endpoints we select for our clinical trials. Regulatory authorities could also add new requirements, such as the completion of additional studies, as conditions for obtaining approval or obtaining an indication. The imposition of additional requirements may delay our clinical development and regulatory filing efforts, and delay or prevent us from obtaining regulatory approval for new product candidates, new indications for existing products or maintenance of our current labels

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.

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, CROs, drug substances and materials suppliers and contract manufacturing organizations (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 with CMOs, to produce sufficient drug product and ADSs 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 ADS 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 ADS that is suitable for use in our ongoing phase 2 clinical program and currently are working with Battelle Memorial Institute (Battelle) to further develop the ADS 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 an ADS 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 program.

- We will require access to sophisticated engineering capabilities. We have our own medical device engineering staff and we are currently working with Battelle, which has expertise in medical device development and medical device design and a successful track record in developing aerosolization systems for the medical and pharmaceutical industries. If for any reason we are unable to retain our own engineering capabilities, the agreement with Battelle is terminated, and we are unable to identify design engineers and medical device experts to support our development efforts, including for a clinic-ready ADS for use in our planned phase 3 clinical program and, potentially, for commercial use and later versions of the ADS, 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.

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

In 2015, we modified our business strategy to focus primarily on the development of aerosolized KL4 surfactants, beginning with AEROSURF. We plan to continually evaluate our business strategy and will modify our plans as necessary to achieve our objectives. The execution of a clinical program is complex and involves the cooperation of many individuals 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 delays or 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, when we experienced slower enrollment in our phase 2a clinical trials than we expected, we reassessed the number of sites that would be needed and expanded our activities ex-U.S. In the future, if we determine that an alternative approach would better enable us to achieve our objectives, 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 we will secure regulatory approval for our products and execute any product launches effectively and 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 our KL4 surfactant 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 alliances, collaboration arrangements and other strategic transactions. However, there can be no assurance that our efforts will be successful or that, even if we identify and enter into any strategic transaction, that such transactions will be successfully implemented, if at all, within our expected time frames.

We plan to continue evaluating our business strategy and may modify our strategy in the future. To respond to changing circumstances, we may expand or alter our research and development activities from time to time, and allocate resources to work on development of different products or may pace, delay or halt the development of potential product programs. As a result of changes in our strategy, we may also change or refocus our existing drug development and manufacturing activities or our plans for commercialization of our products, if approved. This decisions 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. Our development program for AEROSURF has progressed into phase 2b and we are planning for a potential phase 3 clinical program. Our planned clinical trials are expected to enroll more patients, be conducted in a larger number of sites both in the U.S. and abroad, and will require more of our management resources to be successful. In addition to working on the AEROSURF development program, from time to time, we support studies of other potential KL_4 surfactant pipeline products. 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 our manufacturing and commercial activities.

If we are successful in identifying potential strategic or collaboration partners, we will be required to dedicate management resources and implement controls to establish alliance structures, and potentially add a layer of complexity to our operations. We plan to distribute our products, if approved, in the U.S. on our own. For other major markets, we plan to identify potential strategic alliances and collaboration arrangements that would have the resources and capabilities to distribute our products. 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 require us to recruit, train and integrate skilled management, scientific, medical and operations personnel; establish and effectively manage strategic partnerships and collaboration arrangements to support our development and commercialization activities; and 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.

We may enter into strategic alliances 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 financial resources for our AEROSURF development program, and development, regulatory and commercial market expertise to support the commercial introduction of AEROSURF in selected markets outside the U.S. We seek to identify potential strategic partners who could provide local 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), although there can be no assurance that we will ultimately secure such an alliance, if at all, on acceptable terms.

If we succeed in entering into one or more strategic alliances 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 partner rights 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 capabilities to develop and 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 certain 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 opportunities for strategic alliances and collaboration arrangements. 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.

We plan to consider strategic alliances or collaboration agreements to potentially provide for the marketing and sale of our products, if approved, including AEROSURF, which expose us to additional risks.

To secure the additional capital that we require to advance the development of our product candidates, we seek one or more strategic alliances, distribution or collaboration arrangements that could support the commercialization of AEROSURF, if approved. The terms of any such arrangements may not be favorable to us.

If we enter into alliances, distribution or collaboration arrangements to commercialize our products, such arrangements will subject us to a number of risks, including:

- our alliance partners, distributors or collaborators may require that we transfer to them important rights to our products and/or product candidates;
- we may not be able to control the amount and timing of resources that our distributors or collaborators devote to the commercialization of our products;

- if our alliance partners, distributors or collaborators fail to perform their obligations under our distribution or commercialization arrangements to our satisfaction, we may not achieve our goals within the desired time, if at all, and 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, distributors or collaborators may experience financial difficulties; and

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

If we fail to enter into arrangements with third parties in a timely manner or if such parties fail to perform, it could adversely affect our activities. We and our third-party alliance partners, distributors and collaborators must also perform our respective activities in compliance with applicable federal, state and local or foreign laws.

In addition, if we establish alliance, distribution or collaboration arrangements for the commercialization of our approved products, our third-party collaborators and we 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 plan to rely on third parties to manufacture our lyophilized KL4 surfactant and medical devices, which exposes us to risks that may affect our ability to maintain supplies of our clinical materials and ADSs and could potentially delay our research and development activities, regulatory approval and commercialization of our drug product candidates.

Our manufacturing strategy includes manufacturing our lyophilized KL4 surfactant and our ADS for AEROSURF, using third-party contract manufacturing organizations (CMOs). Technology transfers 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, after a product candidate is approved, 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 clinical or commercial 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, lyophilized KL4 surfactant drug products, medical devices, and 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 manufacture our lyophilized KL4 surfactant product candidate and our ADS and aerosol-conducting airway connector using CMOs. We have in the past experienced manufacturing or quality control problems 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, including cGMP or QSR, or other FDA or similar foreign regulatory requirements could adversely affect our ability to manufacture our product candidates, which could have a material adverse effect on our ability to produce our product candidates under development or obtain approval of our product candidates, and potentially adversely affect our research activities and our business and financial condition. We currently do not have back-up facilities for 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. However, we do not have fully-redundant systems and equipment to respond promptly in the event of a significant loss at a CMO's manufacturing operations. Under certain conditions, we may be unable to produce our drug product and medical devices 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 and QSRs, it will adversely affect our development activities and clinical programs.

For the development and, if approved, commercialization of AEROSURF, we will depend upon third parties to manufacture and assemble our ADS. 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 dosage form, we plan to rely on CMOs to manufacture and assemble the ADS and all subcomponents of the ADS to support any preclinical experiments, our ongoing and planned clinical trials and, if approved, commercial device. The ADS 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 ADP 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 Memorial Institute (Battelle) to develop a clinic-ready ADS to support our phase 2 clinical program and currently are collaborating to develop a phase 3/commercial ADS device. As with many device development initiatives, there is a risk that, even if we are able to finalize specifications for an ADS that is suitable for use in a phase 3 clinical trial and, if approved, commercial applications, we may have difficulty identifying manufacturers that are able to consistently manufacture and assemble the subcomponents of our ADS 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 the ADS and, if developed, later versions of the ADS, 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 ADS 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 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 execute our development plans for our current and potential pipeline products. Such delays could adversely impact our operations and financial condition.

We rely on suppliers for our active drug substances, materials and excipients, and third parties for 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. 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 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 supply agreements relating to continued access to active drug substances with only two of the four providers of our drug substances. If we do not maintain manufacturing and service relationships that are important to us and are not able to identify a replacement supplier or vendor or develop our own manufacturing capabilities, our ability to obtain regulatory approval for our products could be impaired or delayed and our costs could substantially increase. Even if we are able to find replacement manufacturers, suppliers and vendors when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. 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.

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 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 patients receiving our drug products and 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, potential future product sales and stock price.

Adverse safety events involving our products under development and 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.

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 identify strategic opportunities, including potential strategic alliances, joint development opportunities, acquisitions, technology licensing arrangements and other similar opportunities. Such opportunities may result in substantial investments in our business. 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 secure needed capital and expertise to support our development programs and our financial condition could be adversely affected.

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 and management's expectations 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 have a secured loan from Deerfield, currently in the amount of $25 million, which is secured by a security interest on substantially all of our assets. The principal amount is payable in two equal installments of $12.5 million in each of February 2018, subject to a one-year potential deferral if we have achieved a specified market capitalization, and February 2019. 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 or untitled 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.

If AEROSURF is approved for commercial sale, we 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.

In addition, failure to comply with domestic and international privacy and security laws can result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws, including protecting electronically stored information from cyber attacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or collectively, HIPAA. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. We are continually evaluating our compliance programs, including policies, training and various forms of monitoring, designed to address the outlined 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.

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. 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. We believe that other potential products in our KL4 surfactant technology pipeline may also qualify for Fast Track or other designations, including potentially breakthrough therapy, accelerated approval and priority review. These designations and programs are intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life-threatening conditions. Our product candidates may cease to qualify for Fast Track designation and our other product candidates may fail to qualify for any such designation or program. Moreover, even if we are successful in gaining a designation that is intended to facilitate or expedite development or review of a product candidate, 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 a drug 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 affects 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. If we develop AEROSURF for the treatment of RDS, we believe that this Orphan Drug designation is likely to apply, although the FDA may determine that our Orphan Drug designation does not apply to this product candidate. Then, the only option for obtaining an Orphan Drug designation is to submit a new Orphan Drug designation request, 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.

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.

Our development program for AEROSURF is in phase 2 clinical trials. 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 corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations affecting our activities, including 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 others. 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.

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

For our 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.

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 AEROSURF is 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, or if we are placed in a "second line" position compared to our competition, 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.
- the perception of the value-added provided by our products compared to the price of our products and the willingness of physicians and hospitals to pay
- the willingness of hospitals in the various markets, including those ex-U.S., to adopt continuous positive airway pressure (nCPAP) as a means of providing non-invasive respiratory support and for the administration of our aerosolized KL4 surfactant

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

If we receive marketing authorization in the United States for AEROSURF, our approved labeling will contain, among other things, limitations that affect the manner in which we may promote, market and sell our approved product. Any promotion, marketing and sales efforts will have to 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 promptly implemented a plan and responded to the concerns raised in the letter 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.

A catastrophic event at our Warrington, Pennsylvania 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.

All of our facilities are located our headquarters in Warrington, Pennsylvania. We maintain our analytical testing and device development laboratories in Warrington, Pennsylvania. We depend upon third-party manufacturers to manufacture our lyophilized KL4 surfactant, our AFECTAIR device and our ADS. All of these products are or will be manufactured at a single source facility. If a catastrophic event occurred at our headquarters facility 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 headquarters 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. Applicable manufacturers are to report data to the U.S. Centers for Medicare and Medicaid Services (CMS) on an annual basis, and the data are made publicly available via a CMS website. 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. In December 2015, legislation was enacted that imposed a two-year moratorium on the medical device excise tax, which means that the tax will not apply to sales during the period from January 1, 2016 through December 31, 2017. However, we cannot predict the effect that subsequent legislation, if any, may have on the length of the moratorium or on the excise tax itself. 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.

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 is accorded 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 proprietary rights to products or processes that appear to be patentable.

The parties who licensed 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 KL4 surfactant composition of matter claims, KL4 peptide method of manufacture claims and relevant European patents, began to expire in November 2009, and will expire on various dates ending in 2017. For our aerosolized KL4 surfactant, we hold worldwide exclusive licenses from Philip Morris USA Inc. (PMUSA) and Philip Morris Products S.S. (PMPSA) to the proprietary aerosol 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 proprietary aerosol 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 Europe 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 proprietary aerosol technology, and our novel aerosol-conducting airway connector.

Our technology platform is based on the scientific rationale of using our KL4 surfactant technology, our proprietary aerosol 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, PMUSA, PMPSA and The Scripps Institute. These agreements require us to make payments and satisfy performance obligations to maintain our rights under these licensing agreements. All of these agreements last either throughout the life of the related patents or for a number of years after the first commercial sale of the relevant product. In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology. Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We rely on agreements containing obligations regarding intellectual property, confidentiality and noncompetition provisions that could be breached and may be difficult to enforce.

Although we take what we believe to be reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of our confidential and proprietary information and trade secrets to third parties, as well as agreements that provide for disclosure and assignment to us of all rights to the ideas, developments, improvements, discoveries and inventions of our employees, consultants, advisors and research collaborators while we employ them, such agreements can be difficult and costly to enforce. We generally seek to enter into these types of agreements with consultants, advisors and research collaborators; however, to the extent that such parties apply or independently develop intellectual property in connection with any of our projects, disputes may arise concerning allocation of the related proprietary rights. Such disputes often involve significant expense and yield unpredictable results.

Moreover, although all employees enter into agreements with us that include non-compete covenants, and our five senior executive officers have agreements that include broader non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, such non-compete provisions can be difficult and costly to monitor and enforce, such that, if any should resign, we may not be successful in enforcing our noncompetition agreements with them.

Despite the protective measures we employ, we still face the risk that:

- agreements may be breached;
- agreements may not provide adequate remedies for the applicable type of breach;
- our trade secrets or proprietary know-how may otherwise become known;
- our competitors may independently develop similar technology; or
- our competitors may independently discover our proprietary information and trade secrets.

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.

Over the past few years, we implemented a plan to hire additional qualified personnel to support the advancement of AEROSURF development, as well as our other KL4 surfactant products under development programs. In particular, we enhanced our clinical operations, regulatory affairs, quality control and assurance and administrative capabilities. 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 five executive officers, including, in February 2016, our President and Chief Executive Officer; in March 2013, the Senior Vice President, General Counsel and Corporate Secretary; and the Senior Vice President, Human Resources; in March 2014, the Senior Vice President and Chief Financial Officer; and in December 2014, the Senior Vice President and Chief Development Officer. The agreements of executive officers other than that of our President and Chief Executive Officer will expire on March 31, 2017. In addition, we have agreements with three other officers that if not renewed will expire on March 31, 2017. 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.

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, 2015, the price of our common stock ranged between $2.69 and $25.48. 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, 2015, the average daily trading volume in our common stock was approximately 41,481 shares, and the average number of transactions per day was approximately 953. 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.

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 15, 2016, there were 8,191,289 shares of common stock issued and outstanding. In addition, as of December 31, 2015, approximately (i) 8.5 million shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, (ii) 0.9 million shares of our common stock were reserved for issuance pursuant to our equity incentive plans, and (iii) 4,567 shares of our common stock were reserved for issuance pursuant to our 401(k) Plan. The exercise of stock options and other securities could cause our stockholders to experience substantial dilution. Moreover, holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

The 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 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 development, 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 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 Certificate of Incorporation, our Amended and Restated By-Laws (By-Laws) and Delaware law could defer a change of our management and thereby discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation, our 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 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. In January 2013, we amended the lease (Amendment) to extend the term for an additional five years until February 2018; reduce the balance of a security deposit we maintain for the benefit of the landlord over a two year period beginning in 2013, from $400,000 to $225,000; reduce the base rent effective as of October 1, 2012; eliminate our obligation to remove certain improvements and restore the premises upon expiration of the lease; and adjust our option to extend the lease to an additional period of five years through February 2023. 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), and supporting our research and development work for our lyophilized and aerosolized KL4 surfactant dosage forms as well as efforts to identify and protect our intellectual property. We also maintain a controlled medical device development laboratory 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.

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 15, 2016, we had 104 holders of record of shares of our common stock. As of March 15, 2016, there were 8,191,289 shares of our common stock issued and outstanding.

The following table sets forth the quarterly sales price ranges of our common stock for the periods indicated, as reported by Nasdaq (adjusted for the 1-for-14 reverse stock split that was effective January 22, 2016).

	2015		2014	
	High	Low	High	Low
Period:				
First Quarter	$ 25.48	$ 15.89	$ 38.78	$ 29.40
Second Quarter	$ 20.72	$ 8.96	$ 32.76	$ 21.14
Third Quarter	$ 10.50	$ 3.50	$ 28.42	$ 21.14
Fourth Quarter	$ 7.53	$ 2.69	$ 28.14	$ 13.86

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.

Not applicable.

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

INTRODUCTION

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

Management's discussion and analysis of financial condition and results of operations (MD&A) is provided as a supplement to the accompanying consolidated financial statements and footnotes to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. This item should be read in connection with our Consolidated Financial Statements for the year ending December 31, 2015 and notes thereto (Notes) included in this Annual Report of Form 10-K. *See,* "Item 8 – Financial Statements and Supplementary Data."

***Note**: Information concerning the shares of our common stock and related share prices in this MD&A has been adjusted to reflect a 1-for-14 reverse split of our common stock and a change in the number of shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation, as amended (Certificate of Incorporation), that were made effective on January 22, 2016. (See, "Item 8 – Notes to consolidated financial statements – Note 2 – Basis of Presentation").*

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, 2015 and 2014.
- **Liquidity and Capital Resources**: this section provides a discussion of our capital resources, future capital requirements, cash flows, committed equity financing facilities, historical financing transactions, outstanding debt arrangements and commitments.

OVERVIEW

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a biotechnology company focused on developing novel KL4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies being developed to enable noninvasive administration of aerosolized KL4 surfactant. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our core development program, AEROSURF® (lucinactant for inhalation), is focused on improving the management of respiratory distress syndrome (RDS) in premature infants, a serious respiratory condition that can result in long-term respiratory problems, developmental delay and death. Premature infants born prior to 37 weeks gestational age may not have fully developed natural lung surfactant and therefore may need surfactant therapy to sustain life. Higher incidence and severity of RDS are correlated with younger gestational ages; however, RDS can occur at any premature gestational age. RDS is the most prevalent respiratory disease in the neonatal intensive care unit (NICU). We estimate that 120,000 to 150,000 premature infants are given respiratory support after birth each year in the United States because they have or are at risk for RDS.

Surfactant therapy is a life-saving treatment for RDS and the primary therapy to address an underlying surfactant deficiency. Surfactants currently available in the U.S. are animal-derived and must be administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. Intubation is associated with airway trauma and clinical instability that can extend beyond the respiratory system such as increased intracranial pressure and risk for brain injury. Mechanical ventilation is associated with ventilator-associated lung injury, chronic lung disease and increased risk of infection. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support, such as nasal continuous positive airway pressure (nCPAP). Unfortunately, since nCPAP does not address the underlying surfactant deficiency, many premature infants respond poorly to nCPAP (typically within the first 72 hours of life) and may require intubation and delayed surfactant therapy (an outcome referred to as nCPAP failure).

In addition, many premature infants with RDS who receive surfactant therapy as initial therapy are capable of breathing without mechanical ventilation, but require surfactant therapy for RDS. Because surfactant therapy requires intubation, these infants generally are supported with mechanical ventilation for either a limited or extended period of time. If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to these premature infants without exposing them to the risks associated with intubation and mechanical ventilation.

AEROSURF is an investigational combination drug/device product that combines our proprietary KL4 surfactant with our novel aerosol delivery system (ADS), which is based primarily on our capillary aerosol generator technology. We are developing AEROSURF to enable administration of aerosolized KL4 surfactant to premature infants receiving nCPAP, without invasive intubation and mechanical ventilation. We believe that, if approved, AEROSURF will have the potential to transform the treatment of RDS, allow for earlier treatment of those premature infants who currently receive surfactants later in their course of treatment, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy as a result of nCPAP failure.

The current surfactant market for RDS 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 and lack of medical innovation. Treatment options for RDS have not improved significantly, nor have mortality and morbidity rates for RDS meaningfully improved over the last few decades. We believe that the neonatal medical community would respond favorably to the introduction of a synthetic, peptide-containing (KL4) surfactant and a less-invasive method of surfactant administration. By enabling delivery of our aerosolized KL4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits. We believe that AEROSURF has the potential to create a worldwide annual market opportunity of $600 million to a $1 billion per year. *See,* "Item 1 – Business – Surfactant Therapy – The RDS Market."

The drug product component of our AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL4 surfactant liquid instillate drug product that was approved by the U.S. Food and Drug Administration (FDA) in 2012 under the name SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. In the second quarter of 2015, we determined to cease commercial and manufacturing activities for SURFAXIN to focus our limited resources on advancing the AEROSURF clinical development program and our aerosolized KL4 surfactant pipeline. We believe that gaining the approval of SURFAXIN provided us valuable experience to support the further development of our KL4 surfactant product candidates, beginning with AEROSURF.

In the future, we believe that we may be able to leverage the data and know-how that we gain from our development activities for our KL4 surfactant, in liquid, lyophilized and aerosolized dosage forms, to support a potential product pipeline of KL4 surfactant products to address serious critical care respiratory and other conditions in children and adults in pediatric and adult intensive care units. While we remain focused on AEROSURF, we have supported and plan in the future to support potential opportunities to explore the utility of our KL4 surfactant to address a variety of respiratory conditions. Although there can be no assurance, we would consider supporting such efforts in the future if we are able to secure separate funding, including through potential government-supported and other grant programs that are dedicated to advancing research and development initiatives.

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). There can be no assurance however, that we will secure the additional capital needed to undertake such explorations, that we will undertake such explorations or that, even if we do, that we will be successful.

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 4 – Accounting Policies and Recent Accounting Pronouncements."

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.

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, 2015 and 2014 was $55.2 million (or $7.98 basic net loss per share) and $44.1 million (or $7.28 basic net loss per share), respectively. Included in the net loss is (i) the change in fair value of certain common stock warrants classified as derivative liabilities, resulting in non-cash income of $0.9 million and $3.8 million for 2015 and 2014, respectively; (ii) interest expense of $4.5 million and $4.6 million for 2015 and 2014, respectively, associated with the Deerfield Loan; and (iii) for 2015, an $11.8 million non-cash loss on debt extinguishment.

The operating loss for the years ended December 31, 2015 and 2014 was $39.8 million and $43.3 million, respectively. The decrease in operating loss from 2014 to 2015 was due to a $5.3 million decrease in operating expenses partially offset by a $1.5 million decrease in grant revenues and a $0.3 million decrease in SURFAXIN product sales.

Grant Revenue

We recognized grant revenue of $1.0 million and $2.5 million for the years ended December 31, 2015 and 2014, respectively, 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 provided support for the initial AEROSURF phase 2a clinical trial in premature infants 29 to 34 week gestational age with RDS. We received and expended $1.8 million in 2014 under this award and received and expended the remaining award amount in the first quarter of 2015.

During the second quarter of 2015, we were awarded an additional $1.0 million under a previously awarded Phase II SBIR grant from the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH valued at up to $3.0 million over three years to support continued development of the company's aerosolized KL4 surfactant as a potential medical countermeasure to mitigate acute and chronic/late-phase radiation-induced lung injury. We were awarded an initial $1.0 million under this grant during the third quarter of 2014. For the initial award, we received and expended $0.7 million in 2014 and $0.3 million through the third quarter of 2015. During the fourth quarter, we received and expended $0.7 million under the additional $1.0 million awarded in the second quarter of 2015, and we anticipate receiving the balance of this award through the third quarter of 2016. Additionally, next year we may be eligible for a third award of up to an additional $1.0 million following completion of certain research activities.

Cost of Product Sales

(in thousands)	Years Ended December 31,	
	2015	**2014**
Cost of product sales	$ 929	$ 2,671

Cost of product sales for 2015 and 2014 includes $0.7 million and $2.4 million, respectively, of inventory reserves for costs of SURFAXIN finished goods inventory that was not expected to be recoverable through commercial sale of the product during the initial launch period due to product expiration. The decrease in cost of product sales from 2014 to 2015 is due to our decision in the second quarter of 2015 to cease our manufacturing and commercial activities for SURFAXIN and focus our limited resources on AEROSURF.

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, 2015 and 2014 are as follows:

(in thousands)	Years Ended December 31,	
	2015	**2014**
Product development and manufacturing	$ 14,446	$ 14,920
Medical and regulatory operations	7,125	8,126
Direct preclinical and clinical programs	7,317	3,644
Total Research and Development Expenses	$ 28,888	$ 26,690

Research and development expenses include non-cash charges associated with stock-based compensation and depreciation of $1.1 million and $1.8 million for 2015 and 2014, respectively.

For a description of the clinical programs included in research and development expenses, *See,* "Item 1 – Business – Surfactant Therapy."

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 ADS, (ii) design and development activities related to our ADS 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 $0.5 million from 2014 to 2015, due to a decrease of $3.6 million in manufacturing costs due to the closure of our manufacturing facility for SURFAXIN in Totowa, New Jersey (Totowa Facility) in June 2015, partially offset by an investment of $3.1 million in 2015 for development activities under our collaboration agreement with Battelle for the further development of our ADS for use in our planned AEROSURF phase 3 clinical program and, if approved, initial commercial activities.

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 for our 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 decreased $1.0 million from 2014 to 2015 due to a $1.5 million decrease in medical affairs activities resulting from the cessation of manufacturing and commercial activities and the related reduction in work force that occurred beginning in April 2015, partially offset by a $0.7 million increase in preclinical and clinical capabilities to support our AEROSURF development program.

Direct Preclinical and Clinical Programs

Direct preclinical and clinical programs include: (i) development activities, toxicology studies and other preclinical studies; and (ii) activities 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 $3.7 million from 2014 to 2015 due to a $4.0 million increase in AEROSURF clinical trial activities, including patient enrollment in the ongoing Phase 2a clinical trial in premature infants 26 to 28 week gestational age and manufacture of additional clinic-ready ADS to support further clinical activities, including the recently initiated AEROSURF Phase 2b clinical trial, partially offset by a $0.3 million decrease in preclinical studies.

If our early clinical results are encouraging, we anticipate that our direct clinical program costs will increase significantly over the next two years as we execute the remainder of the AEROSURF phase 2 clinical development program and prepare for a potential phase 3 clinical program. If successful, we estimate that direct clinical program costs for 2016 for the AEROSURF Phase 2 program will be approximately $13 to $15 million.

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,	
	2015	2014
Salaries & benefits	$ 10,320	$ 12,755
Contracted services	11,943	7,064
Raw materials, aerosol devices and supplies	2,010	3,969
Rents and utilities	1,225	1,431
Depreciation	476	755
Contract manufacturing	1,568	87
Travel	616	749
Stock-based compensation	642	1,014
Other	863	1,315
Allocation to batch production	(775)	(2,449)
Total	$ 28,888	$ 26,690

The decrease in salaries and benefits from 2014 to 2015 is due to our decision to cease manufacturing and commercial activities for SURFAXIN and to close our Totowa Facility upon expiration of the lease on June 30, 2015.

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 increase from 2014 to 2015 is due to AEROSURF clinical trial activities, including patient enrollment in the ongoing Phase 2a clinical trial in premature infants 26 to 28 week gestational age and manufacture of additional clinic-ready ADS to support further clinical activities, including the recently initiated AEROSURF Phase 2b clinical trial as well as development activities under our collaboration agreement with Battelle for the further development of our ADS for use in our planned AEROSURF phase 3 clinical program and, if approved, initial commercial activities.

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 decreased from 2014 to 2015 primarily due to a decrease in purchases of raw materials and supplies and a decrease in aerosol devices for use in our AEROSURF phase 2 clinical trials.

Rents and utilities are costs related to our leased manufacturing, laboratory, and corporate facilities. The decrease from 2014 to 2015 is primarily due to the expiration of the lease for our Totowa Facility on June 30, 2015.

Contract manufacturing represents costs related to the technology transfer of our liquid and lyophilized KL4 surfactant manufacturing processes to a CMO and manufacture of a sufficient supply of lyophilized KL4 surfactant to support the planned AEROSURF phase 2 clinical program. The costs in 2015 related to activities to complete a technology transfer of our lyophilized surfactant manufacturing process to our CMO as well as a second technology transfer to a new facility at our CMO.

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

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 $55.6 million in expenses for the two-year period ended December 31, 2015. 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 (see, "Item 1A – Risk Factors"), other risks could arise that we may not foresee that could affect our ability to estimate projections and timelines.

Our research and development programs have been focused initially on the management of RDS in premature infants. Our lead program, AEROSURF for the treatment of RDS in premature infants, involves the following projects (i) lyophilized KL_4 surfactant, which we are developing initially for use in our AEROSURF development program; (ii) aerosol delivery technologies, in particular the development and manufacture of a clinic-ready ADS to support our AEROSURF phase 2 clinical program and further development of the ADS for use in a potential Phase 3 clinical program and, if approved initial commercial supply; and (iii) AEROSURF phase 2 clinical trial activities and preparatory work for the planned AEROSURF phase 3 clinical program. We also developed SURFAXIN liquid instillate for the prevention of RDS in premature infants at high risk for RDS, which was approved by the FDA in 2012, but after initiating commercial activities in 2013, we determined to cease our manufacturing and commercial activities in 2015 to focus our limited resources on AEROSURF.

For our AEROSURF clinical program, we are enrolling a phase 2a clinical trial and have initiated our AEROSURF phase 2b clinical trial. We are focused on advancing the AEROSURF phase 2 clinical program. Our lead projects, including the potential timing and milestones, are also discussed in "Item 1 – Business – Business Strategy." We are also planning for our potential phase 3 clinical program. We expect to make additional investments in our development capabilities, including for manufacturing development of our lyophilized KL_4 surfactant, further development of our ADS under our collaboration agreement with Battelle, and the conduct of the ongoing and 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 2 clinical program, assess the results and execute the later stages of the planned AEROSURF clinical development program.

In the future, we believe that, if we are successful with AEROSURF, 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, in the future we may explore other 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. However, there can be no assurance that we will secure the additional capital needed, through government-funded grant programs or otherwise, to undertake such explorations, that we will undertake such explorations or that, even if we do, that we will be successful.

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, 2015	2014
Selling, General and Administrative Expenses	$ 11,004	$ 16,732

Selling, general and administrative expenses consist 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 include non-cash charges associated with stock-based compensation and depreciation of $1.1 million and $2.0 million for the years ended December 31, 2015 and 2014, respectively.

Selling, general and administrative expenses decreased $5.7 million from 2014 to 2015 due to our decision in April 2015 to cease manufacturing and commercial activities for SURFAXIN and focus our limited resources on the development of our aerosolized KL4 surfactant, beginning with AEROSURF.

We plan to continue investments in protecting our existing intellectual property, and in pursuing potential additional intellectual property rights, including patents, trademarks, and trade secrets, and regulatory exclusivity designations, such as potential orphan drug, new drug product exclusivities, Fast Track, breakthrough therapy, accelerated approval and priority review. *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, 2015	2014
Change in fair value of common stock warrant liability	$ 851	$ 3,791

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. 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 five-year warrants that we issued in the February 2011 public offering (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 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, they 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, 2015	2014
Loss on debt extinguishment	$ (11,758)	$ –
Interest income	4	6
Interest expense	(4,583)	(4,597)
Other income / (expense)	150	–
Other income / (expense), net	$ (16,187)	$ (4,591)

The restructuring of the Deerfield Loan (*see,* Note 9, "Deerfield Loan") qualifies as an extinguishment of debt in accordance with ASC 470, *Debt-Modifications and Extinguishments*, and as a result, we have incurred an $11.8 million non-cash loss on debt extinguishment consisting of the difference between the reacquisition price of the Deerfield Loan and the net carrying amount of the extinguished Deerfield Loan, which includes $4.1 million in fair value of the Series A and Series B warrants issued to Deerfield as part of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes.

Interest expense primarily consists of interest expense associated with the Deerfield Loan (*see,* "– Liquidity and Capital Resources – Deerfield Loan").

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

(in thousands)	December 31, 2015	2014
Cash interest expense	$ 1,451	$ 2,625
Non-cash amortization of debt discounts	1,287	1,948
Debt discount write-off	707	–
Amortization of prepaid interest expense	971	–
Amortization of debt costs	12	19
Write-off of debt costs	66	–
Total Deerfield Loan interest expenses	4,494	$ 4,592

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 Deerfield Warrants. Debt discount write-off represents the proportional write-off of unamortized debt discount at the time of a $2.5 million pre-payment of principal amount outstanding under the Deerfield Loan. Amortization of prepaid interest expense represents non-cash amortization of the $5 million of Series A and Series B units Deerfield agreed to purchase in our July 2015 public offering and accept in satisfaction of $5 million of future interest payments due under the Deerfield Notes. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan, and the write-off of debt costs represents the write-off of the remaining costs at the time of the debt restructuring.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2015, we had cash and cash equivalents of approximately $38.7 million, current accounts payable and accrued expenses of $10.8 million, and $25 million of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield). The principal portion of the debt is payable in two equal installments in February 2018 (subject to potential deferral in certain circumstances) and February 2019. Before any additional financings or other transactions, we anticipate that we will have sufficient cash available to support our development programs, business operations and debt service obligations through the first quarter of 2017.

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, the commercialization of SURFAXIN, including marketing, commercial and medical affairs activities, and we expect to continue to incur substantial losses over the next four to five years. To secure the significant additional capital that we will need, we expect to utilize all or a combination of potential strategic alliances, collaboration agreements and other strategic transactions, public or private equity offerings (including our ATM Program), or through debt arrangements. We also believe that our success in these efforts will be largely dependent upon our ability to successfully and timely complete the AEROSURF phase 2b clinical trial. Failure to complete the clinical trial within the expected time line in the fourth quarter of 2016 and obtain acceptable and promising results could have a material adverse effect on our ability to secure the additional capital that we will require, through strategic transactions or otherwise, and our ability to continue as a going concern.

Our ability to secure capital under our ATM Program or pursuant to public offerings under our 2014 Universal Shelf will be constrained by the value of our equity securities held by nonaffiliated persons and entities (public float), which as of March 18, 2016 is approximately $13.4 million. Our 2014 Universal Shelf was filed on Form S-3, which limits the size of primary securities offerings conducted by companies that have a public float of less than $75 million in any 12-month period to no more than one-third of their public float. Based on the closing market price of our common stock on March 18, 2016 ($1.65) we could raise up to approximately $4.5 million under our 2014 Universal Shelf. To raise capital, we may be required to seek other forms of transactions, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time consuming and costly, or private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests. In addition, although we gave regained compliance with the Minimum Bid Price Requirement of the Nasdaq Listing Rules, there can be no assurance that we will be able to maintain continued compliance, including with certain other Nasdaq listing requirements that require us to maintain a market capitalization of at least $35 million or stockholders' equity of at least $2.5 million. If we fail to meet both of these requirements, we would receive another delisting notice from Nasdaq, which could further depress the value of our stock. In addition, to be able to raise sufficient capital to support our activities in the near term through public or private equity offerings, given our current per share market price, we may have to seek approval from our stockholders to increase the number of shares of common stock authorized for issuance under our Certificate of Incorporation. Moreover, if any such offering were to involve the issuance of common stock in excess of 20% of our outstanding common stock, we may be required under Nasdaq Listing Rules to seek stockholder approval before we can proceed. There can be no assurance that we would be successful in obtaining such approvals. Failure to secure the additional capital that we will need, whether from non-dilutive sources or from equity offerings, would have a material adverse impact on our business and our ability to continue as a going concern.

We have in the past collaborated with research organizations and universities to assess the potential utility of our KL4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical program and medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological, and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. Although there can be no assurance, we continue to pursue such funding opportunities and expect that we may qualify for similar programs in the future.

An important priority for us is to identify potential strategic transactions, including without limitation strategic alliances and collaboration arrangements that would potentially provide additional capital to support our AEROSURF development activities and strategic resources to support the registration and commercial introduction of AEROSURF. We seek a significant strategic alliance partner that has broad experience, including local 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. We have engaged in discussions with potential counterparties and a number of these entities have expressed interest in AEROSURF and our KL4 surfactant and drug delivery technologies.

Our future capital requirements will depend upon many factors, including our efforts to (i) advance the AEROSURF development program to completion of the phase 2b clinical trials as planned; (ii) assure near- and long-term continuity of supply for our lyophilized KL4 surfactant and ADS and related components with CMOs to support our clinical activities, (iv) develop our ADS 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, which likely will be designed to enroll significantly more premature infants than our phase 2 clinical trials, 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. There can be no assurance that our AEROSURF development program will be successful within our anticipated time frame, if at all; that we will be able to secure regulatory approval for AEROSURF and our other potential KL4 surfactant product candidates in the U.S. and other markets; or that we will be successful in securing the capital we will require when needed. Failure to secure the necessary additional capital when needed could have a material adverse effect on our business, financial condition and results of operations and could compel us to pace, delay or cease our new product development and clinical trial activities and ultimately cease 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, 2015, we had outstanding warrants to purchase approximately 8.5 million shares of our common stock that are exercisable at various prices on different dates into 2024. This includes 4.8 million warrants issued in a July 2015 public offering with an exercise price of $9.80 per share, and 2.9 million pre-funded warrants, of which the entire purchase price was pre-paid upon issuance. Upon exercise of the pre-funded warrants, we would issue the shares to the holders and receive no additional proceeds.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. In the future, our ability to continue as a going concern is dependent on our ability to raise additional capital to fund our research and development programs and meet our obligations on a timely basis. If we are unable to secure the required additional capital, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to limit our development programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to secure additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Moreover, if we fail in the future to make any required payment under our Deerfield Loan or fail to comply with any commitments contained in the loan documents, Deerfield would be able to declare us in default regarding that indebtedness, which could result in the acceleration of the payment obligations under all or a portion of our 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 our assets securing the debt and could significantly diminish the market value and marketability of our common stock. Our December 31, 2015 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

As of December 31, 2015, 36 million shares of common stock and 5 million shares of preferred stock were authorized under our Certificate of Incorporation and approximately 18.3 million shares of common stock and 5 million shares of preferred stock were available for issuance and not otherwise reserved.

Cash Flows

As of December 31, 2015 and 2014, we had cash and cash equivalents of $38.7 million and $44.7 million. Cash outflows for 2015 consisted of $33.5 million used for ongoing operating activities and $0.2 million for investing activities. Cash provided by financing activities consisted of $32.6 million of proceeds from the July 2015 registered public offering and $0.1 million of proceeds from the exercise of warrants, partially offset by $5.0 million in principal payments on the Deerfield Loan and $0.1 million in repayment of equipment loans.

Operating Activities

Net cash used in operating activities was $33.5 million and $41.2 million for the years ended December 31, 2015 and 2014, 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.

Investing Activities

Net cash used in investing activities was $0.2 million and $0.8 million for the years ended December 31, 2015 and 2014, respectively, and represents capital expenditures, partially offset by proceeds from sale of property and equipment during 2015.

Financing Activities

Net cash provided by financing activities was $27.7 million and $0.4 million for the years ended December 31, 2015 and 2014, respectively, summarized as follows:

(in thousands)	Years Ended December 31,	
	2015	**2014**
Issuance of securities, net of expenses	$ 32,629	$ –
Exercise of common stock warrants and options	136	457
Principal payments on long-term debt	(5,000)	–
Repayment of equipment loans	(62)	(80)
Cash flows from financing activities, net	$ 27,703	$ 377

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, 2015, after reserves for outstanding unexercised warrants and amounts remaining available under our ATM Program, approximately $139.0 million remained available under the 2014 Universal Shelf. The 2014 Universal Shelf will expire in June 2017.

Registered Public Offerings

On July 22, 2015, we completed a registered public offering of 1,791,667 Series A units and 3,000,000 Series B units each at a price per unit of $8.40, resulting in gross proceeds of $40.25 million ($37.6 million net after underwriting discount and expenses), including the exercise in full by the underwriters of their option to purchase up to an additional 625,000 Series A units at a price per unit of $8.40 to cover over-allotments. The proceeds included $5.0 million in non-cash consideration from Deerfield in the form of a reduction in future interest payments due under the Deerfield Loan (*see,* Note 9, “Deerfield Loan”). Each Series A unit consists of one share of common stock and a Series A warrant to purchase one share of common stock at an exercise price of $9.80 per share. Each Series B unit consists of a fully paid pre-funded Series B warrant to purchase one share of common stock at an exercise price of $8.40 per share, and a Series B warrant to purchase one share of common stock at an exercise price of $9.80 per share. The shares of common stock and warrants were immediately separable such that no units were issued. The warrants are exercisable immediately at the election of the holder for cash or through a net cashless exercise, provided that a holder may not exercise a warrant to the extent that after giving effect to such exercise, such holder would beneficially own in excess of 9.99% (or 4.99% as may be elected by such holder) of the shares of our common stock outstanding immediately after such exercise. All warrants will expire on the seventh anniversary of the issue date. The net proceeds will be used primarily (i) to advance the AEROSURF development program, and (ii) for general corporate purposes. The offering was made pursuant to a preliminary prospectus supplement dated July 16, 2015 to the 2014 Universal Shelf.

Warrants

During the year ended December 31, 2015, holders of the 2011 Warrants exercised warrants to purchase 51,193 shares of our common stock at an exercise price of $2.66 per share, resulting in proceeds to us of $0.1 million.

During the year ended December 31, 2014, holders of the 2011 Warrants exercised warrants to purchase 20,346 shares of our common stock at an exercise price of $21.00 per share, resulting in proceeds to us of $0.4 million.

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, as amended on February 11, 2016, will terminate upon the earliest of: (1) the sale of all shares subject to the ATM Agreement, (2) February 11, 2019 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.

Deerfield Loan

Long-term debt consists solely of amounts due under a $25 million loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for the periods presented:

(in thousands)	December 31, 2015	December 31, 2014
Note payable	$ 25,000	$ 30,000
Unamortized discount	–	(9,698)
Long-term debt, net of discount	$ 25,000	$ 20,302

Under the terms of the Deerfield loan agreement, Deerfield made two advances, the first upon execution of the agreement in February 2013 in the amount of $10 million, and the second upon the first commercial sale of SURFAXIN in December 2013 in the amount of $20 million. In connection with each advance, we paid Deerfield a transaction fee equal to 1.5% of the amount disbursed. The outstanding principal accrued interest at a rate of 8.75%, payable quarterly in cash. The Deerfield Loan agreement also contains customary terms and conditions, representations and warranties and affirmative and negative covenants, including restrictions on our ability to incur additional indebtedness and grant additional liens on our assets, but it does not require us to meet minimum financial and revenue performance covenants. 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, 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).

Upon execution of the Deerfield Loan, we issued to Deerfield warrants to purchase approximately 0.2 million shares of our common stock at an exercise price of $39.34 per share. Upon receipt of the second advance in December 2013, we issued to Deerfield warrants to purchase an additional 0.3 million shares of our common stock at an exercise price of $39.34 per share (together with the warrants issued in connection with the execution of the agreement, the Deerfield Warrants). The number of shares of common stock into which the Deerfield Warrants are exercisable and the exercise price will be, and have been, 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 Deerfield Loan agreement, February 13, 2019, and contain limitations on the ability of a holder to exercise the Deerfield Warrants if after such exercise, the holder would beneficially own more than 9.985% of the total number of shares of our common stock then issued and outstanding. The Deerfield Warrants may be exercised in whole or in part 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 Warrants 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 initially 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 (0.5 million warrants in total), and (ii) a $450,000 transaction fee. The discount was 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.

On July 9, 2015, we entered into an amendment to our Deerfield Loan agreement and related notes (Deerfield Notes) to better align our Deerfield Loan principal repayment obligations with anticipated milestones under our clinical development program for AEROSURF. Under the terms of the amendment, (i) upon execution, we prepaid in cash $2.5 million of the principal amounts outstanding, (ii) on July 22, 2015, upon the occurrence of the July 2015 public offering, we prepaid in cash an additional $2.5 million of the principal amounts outstanding, (iii) the principal installment originally due in February 2017 was eliminated and (iv) each of the principal payments due in February 2018 and February 2019 was increased to $12.5 million. We also paid Deerfield's expenses (including reasonable counsel fees and expenses) incurred in connection with the amendment. Under the Deerfield Loan agreement, the $12.5 million principal installment due in February 2018 may be deferred one year if we achieve the market capitalization milestone set forth in the Deerfield Loan agreement.

On July 22, 2015, we entered into a second amendment to our Deerfield Loan agreement and Deerfield Notes, pursuant to which (a) upon closing the July 2015 public offering on July 22, 2015, we prepaid in cash $2.5 million of the principal amounts outstanding, as contemplated by the first amendment, and (b) Deerfield purchased and accepted $5 million Series A and Series B units offered in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes. In addition, (i) we paid in cash when due on September 30, 2015, all accrued and unpaid interest under the Deerfield Notes for the period from June 30, 2015 to July 22, 2015 at the original rate of 8.75%; (ii) Deerfield agreed to apply the $5 million prepaid interest accruing from and after July 23, 2015, as and when such payments are due and payable, as follows; first, to interest accruing on the $12.5 million principal installment due on February 13, 2019, and second, to interest accruing on the $12.5 million principal installment due on February 13, 2018, until fully allocated, which is scheduled to occur at the end of the second quarter of 2016; (iii) after the full allocation of the $5 million interest prepayment, any remaining interest due on the principal amount of the Deerfield Notes will accrue at a rate of 8.25% per annum; and (iv) no credit will be given with respect to prepaid interest on principal under the Deerfield Notes that is prepaid, in whole or in part, except for a prepayment at our election or a prepayment required under the Deerfield Loan agreement in connection with a Major Transaction that qualifies as a "Qualified Major Transaction." A "Qualified Major Transaction" means a change of control transaction (as defined in the Deerfield Warrants), in which (i) we are not the surviving entity and (ii) our common stock valuation (as defined in the Deerfield Warrants) immediately prior to the change of control transaction equals or exceeds $100 million. In addition, we paid Deerfield's expenses (including reasonable counsel fees and expenses) incurred in connection with the second amendment.

The restructuring of the Deerfield Loan was accounted for as an extinguishment of debt in accordance with ASC Topic 470, *Debt – Modifications and Extinguishments*, and as a result, we have incurred an $11.8 million non-cash loss on debt extinguishment consisting of the difference between the reacquisition price of the Deerfield Loan and the net carrying amount of the extinguished Deerfield Loan, which includes $4.1 million in fair value of the Series A and Series B warrants issued to Deerfield as part of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes.

Contractual Obligations and Commitments

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 remaining under the extended portion of the lease are approximately $2.0 million.

Until June 30, 2015, we leased approximately 21,000 square feet of space for our manufacturing operations in Totowa, New Jersey (Totowa Facility), at an annual rent of $525,000. The lease for this facility, which was used to manufacture SURFAXIN drug product, expired on June 30, 2015.

Rent expense under these leases was $1.0 million and $1.2 million for the years ended December 31, 2015 and 2014, respectively.

Battelle Collaboration

In October 2014, we entered into a collaboration agreement with Battelle providing for the further development of our ADS 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 $6.6 million through 2016. *See,* "Item 8 – Notes to consolidated financial statements – Note 12 – Corporate Partnership, Licensing and Research Funding Agreements."

Severance Arrangements

Effective February 1, 2016, we terminated the Employment Agreement of our President and Chief Executive Officer (the Former CEO). In connection therewith, upon execution by the Former CEO of a plenary release in form satisfactory to us, he became entitled under his Employment Agreement to the following severance and other benefits, in addition to any vested benefits under our company plans or policies: (i) a pro rata bonus equal to a percentage of his Annual Bonus Amount determined by dividing the aggregate bonuses paid to other contract executives for the year 2016 by the aggregate target bonuses of such other contract executives for 2016, and further prorated for the number of days the Former CEO was employed during 2016, payable at the time that other contract executives are paid bonuses with respect to 2016; (ii) a severance amount equal to the sum of the Former CEO's base salary then in effect and his Annual Bonus Amount, payable in equal installments through August 1, 2017 (the Severance Period); and (iii) all stock options held by the Former CEO will continue to vest during the Severance Period, and continue to be exercisable for up to 36 months after the date of termination. From and after the end of the Severance Period, the Former CEO will forfeit all of his unvested stock options in accordance with the terms of the 2011 Plan. The Former CEO 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 Former CEO 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.

In April 2015, we implemented a restructuring plan to voluntarily cease manufacturing and commercial activities for SURFAXIN and focus our resources on the development of our aerosolized KL_4 surfactant pipeline for respiratory diseases, beginning with AEROSURF. As part of a restructuring plan, we closed our Totowa Facility upon expiration of the lease on June 30, 2015. The total severance cost for all impacted employees is $2.9 million, of which $1.0 million was accrued as of December 31, 2014 for Totowa employees. The remaining $1.9 million was charged to expense during 2015 ($1.0 million to research and development expenses and $0.9 million to selling, general and administrative expenses). We paid $2.6 million of the severance and retention benefits during 2015. The remaining $0.3 million will be paid through June 30, 2016.

In April 2015, we terminated the Employment Agreement of our Senior Vice President and Chief Operating Officer (the Former COO). In connection therewith, upon execution by the Former COO of a plenary release in form satisfactory to us, he became entitled under his Employment Agreement to the following severance and other benefits, in addition to any vested benefits under our company plans or policies: (i) a pro rata bonus in the amount of $31,000, paid in January 2016 at the time that current executives were paid bonuses for 2015; (ii) a severance amount equal to the sum of the Former COO's base salary then in effect and his Annual Bonus Amount, payable in equal installments through April 17, 2016 (the Severance Period); and (iii) all vested stock options held by the Former COO have continued to be exercisable during the Severance Period. The Former COO's unvested stock options were forfeited in accordance with the terms of our 2011 Long-Term Incentive Plan. In addition, the Former COO 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 Former COO 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.

Effective November 30, 2014 we and our Senior Vice President, Research and Development (the Former Development Officer) agreed to terminate his employment under his existing Employment Agreement dated April 1, 2013 (Employment Agreement). In connection therewith, upon execution by the Former Development Officer of a plenary release in form satisfactory to us, he became entitled under his Employment Agreement to the following severance and other benefits, in addition to any vested benefits under our company plans or policies: a severance amount equal to the sum of the Former Development Officer'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 vested stock options held by the Former Development Officer continued to be exercisable through the end of a consultancy ending on May 31, 2016. The Former Development Officer's unvested stock options were forfeited in accordance with the terms of our 2011 Long-Term Incentive Plan. In addition, the Former Development Officer was made 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.

Off-Balance Sheet Arrangements

We did not have any material off-balance sheet arrangements at December 31, 2015 or 2014, 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, 2015. 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, 2015.

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

(c) Changes in internal controls

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, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Not applicable.

PART III

Except as set forth below, the information required by Items 10 through 14 of Part III is incorporated herein by reference to our definitive proxy statement or an amendment to this annual report on Form 10-K, in either case, to be filed with the Securities and Exchange Commission within 120 days after the end of our 2015 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 our website 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 28, 2016

By: /s/ Craig Fraser
Craig Fraser, 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/ Craig Fraser	Craig Fraser Director, President, and Chief Executive Officer (Principal Executive)	March 28, 2016
/s/ John Tattory	John Tattory Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2016
/s/ John R. Leone	John R. Leone Director (Chairman of the Board)	March 28, 2016
/s/ Joseph M. Mahady	Joseph M. Mahady Director	March 28, 2016
/s/ Bruce A. Peacock	Bruce A. Peacock Director	March 28, 2016
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 28, 2016

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	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 Amendment to Amended and Restated Certificate of Incorporation, as amended, filed on January 21, 2016	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 21, 2016.
3.4	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.
3.5	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 dated February 13, 2013, issued to affiliates of Deerfield Management Co., LLP (Deerfield) under a Facility Agreement dated as of February 13, 2012 between Discovery and Deerfield	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on June 14, 2013.
4.2	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.
4.3	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.
4.4	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.
4.5	Form of Series A Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.
4.6	Form of Pre-Funded Series B Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.

Exhibit No.	Description	Method of Filing
4.7	Form of Series B Warrant dated July 22, 2015	Incorporated by reference to Exhibit 4.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 17, 2015.
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.
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.

Exhibit No.	Description	Method of Filing
10.11*	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under Discovery's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.11 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 16, 2015.
10.12*	Discovery's Amended and Restated 2011 Long-Term Incentive Plan effective as of January 22, 2016	Incorporated by reference to Exhibit 10.12 in the Original Filing.
10.13*	Employment Agreement by and between the Company and Craig Fraser dated as of February 1, 2016.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 3, 2016
10.14*	Inducement Stock Option Award Agreement dated February 1, 2016 between Craig Fraser and Discovery under Discovery's 2011 Long-Term Incentive Plan	Incorporated by reference to Exhibit 10.3 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 3, 2016.
10.15*	Employment Agreement dated as of December 19, 2014, by and between Discovery and Steven G. Simonson, M.D.	Incorporated by reference to Exhibit 10.4 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 2015.
10.16*	Amendment dated December 29, 2014 to Employment Agreement dated as of December 19, 2014, effective as of April 1, 2015, by and between Discovery and Steven G. Simonson, M.D.	Incorporated by reference to Exhibit 10.5 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on May 11, 2015.
10.17*	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.
10.18*	Amendment dated December 29, 2014 to Employment Agreement dated as of March 21, 2014, by and between Discovery and John A. Tattory	Incorporated by reference to Exhibit 10.19 to Discovery's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the SEC on March 16, 2015.
10.19	Form of Indemnification Agreement between the Company and its named executive officers, including Craig Fraser, and directors.	Incorporated by reference to Exhibit 10.4 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 3, 2016
10.20	Lease Agreement dated May 26, 2004, and First Amendment to Lease Agreement, dated April 2, 2007, by and between TR Stone Manor Corp. and Discovery	Incorporated by reference to Exhibits 10.1 and 10.2 to Discovery's Current Report on Form 8-K, as filed with the SEC on April 6, 2007.
10.21	Second Amendment to Lease Agreement, dated January 3, 2013 by and between TR Stone Manor Corp. and Discovery	Incorporated by reference to Exhibits 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on January 8, 2013.

Exhibit No.	Description	Method of Filing
10.22+	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.
10.23+	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.
10.24+	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.
10.25	Amendment dated as of August 4, 2015 to Collaboration Agreement dated as of October 14, 2014 between Discovery and Battelle Memorial Institute.	Incorporated by reference to Exhibit 10.3 to Discovery's Quarterly Report on Form 10-Q, as filed with the SEC on August 10, 2015.
10.30+	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.
10.31	Amendment dated July 9, 2015 to Facility Agreement dated February 13, 2013 by and between the Company and Deerfield	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 9, 2015.
10.32	Second Amendment dated July 22, 2015 to Facility Agreement dated February 13, 2013 by and between the Company and Deerfield	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on July 24, 2015.
10.33	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.
10.34	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.
10.35	At-the-Market Equity Offering Sales Agreement dated February 11, 2013 between Discovery and Stifel Nicolaus & Company, Incorporated	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the SEC on February 13, 2013.
10.36	Amendment No. 1 dated February 11, 2016, to the 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 16, 2016.
21.1	Subsidiaries of Discovery	Filed herewith.

Exhibit No.	Description	Method of Filing
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm	Incorporated by reference to Exhibit 23 in the Original Filing.
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, 2015, formatted in Extensive Business Reporting Language ("XBRL"): (i) Balance Sheets as of December 31, 2015 and December 31, 2014, (ii) Statements of Operations for the years ended December 31, 2015 and December 31, 2014, (iii) Statements of Changes in Equity for the years ended December 31, 2015 and December 31, 2014, (iv) Statements of Cash Flows for the years ended December 31, 2015 and December 31, 2014, 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

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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. (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc. at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst and Young LLP

Philadelphia, Pennsylvania
March 28, 2016

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY

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

	December 31, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 38,722	$ 44,711
Inventory, net	–	27
Prepaid interest, current portion	1,710	–
Prepaid expenses and other current assets	362	821
Total current assets	40,794	45,559
Property and equipment, net	1,039	1,637
Restricted cash	225	225
Prepaid interest, non-current portion	2,319	–
Other assets	–	78
Total assets	$ 44,377	$ 47,499
LIABILITIES & STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,263	$ 350
Accrued expenses	7,582	6,116
Deferred revenue	–	43
Common stock warrant liability	223	1,258
Equipment loans, current portion	–	62
Total current liabilities	11,068	7,829
Long-term Debt:		
Long-term debt, gross	25,000	30,000
Discount on long-term debt	–	(9,698)
Long-term debt, net	25,000	20,302
Other liabilities	43	169
Total liabilities	36,111	28,300
Stockholders' Equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	–	–
Common stock, $0.001 par value; 36,000,000 shares authorized; 8,196,011 and 6,114,843 shares issued at December 31, 2015 and 2014, respectively; 8,194,519 and 6,113,351 shares outstanding at December 31, 2015 and 2014, respectively	8	6
Additional paid-in capital	590,490	546,255
Accumulated deficit	(579,178)	(524,008)
Treasury stock (at cost); 1,492 shares	(3,054)	(3,054)
Total stockholders' equity	8,266	19,199
Total liabilities & stockholders' equity	$ 44,377	$ 47,499

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, 2015	2014
Revenues:		
Product sales	$ 7	$ 312
Grant revenue	980	2,523
	987	2,835
Expenses:		
Cost of product sales	929	2,671
Research and development	28,888	26,690
Selling, general, and administrative	11,004	16,732
	40,821	46,093
Operating loss	(39,834)	(43,258)
Change in fair value of common stock warrant liability	851	3,791
Other income / (expense):		
Loss on debt extinguishment	(11,758)	–
Interest and other income	237	6
Interest and other expense	(4,666)	(4,597)
Other income / (expense), net	(16,187)	(4,591)
Net loss	$ (55,170)	$ (44,058)
Net loss per common share		
Basic	$ (7.98)	$ (7.28)
Diluted	$ (7.98)	$ (7.84)
Weighted average number of common shares outstanding		
Basic	6,967	6,078
Diluted	6,967	6,145

See notes to consolidated financial statements

Consolidated Statements of Changes in Stockholders' Equity

(In thousands)	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount			Shares	Amount	
Balance – January 1, 2014	**6,047**	**$ 6**	**$ 541,499**	**$ (479,950)**	**(1)**	**$ (3,054)**	**$ 58,501**
Net Loss	–	–	–	(44,058)	–	–	(44,058)
Issuance of common stock, 401(k) Plan employer match	43	–	944	–	–	–	944
Exercise of common stock warrants	20	–	803	–	–	–	803
Exercise of stock options for cash	1	–	30	–	–	–	30
Issuance of common stock, consultants	1	–	38	–	–	–	38
Stock-based compensation expense	3	–	2,941	–	–	–	2,941
Balance – December 31, 2014	**6,115**	**$ 6**	**$ 546,255**	**$ (524,008)**	**(1)**	**$ (3,054)**	**$ 19,199**
Net Loss	–	–	–	(55,170)	–	–	(55,170)
Issuance of common stock, July 2015 financing	1,792	2	37,626	–			37,628
Issuance of common stock, 401(k) Plan employer match	94	–	539	–	–	–	539
Issuance of common stock warrants	–	–	4,053	–	–	–	4,053
Exercise of common stock warrants	194	–	320	–	–	–	320
Stock-based compensation expense	1	–	1,697	–	–	–	1,697
Balance – December 31, 2015	**8,196**	**$ 8**	**$ 590,490**	**$ (579,178)**	**(1)**	**$ (3,054)**	**$ 8,266**

See notes to consolidated financial statements

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (55,170)	$ (44,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	712	818
Change in provision for excess inventory	(174)	1,873
Stock–based compensation and 401(k) plan employer match	2,235	3,923
Fair value adjustment of common stock warrants	(851)	(3,791)
Amortization of discount of long-term debt	1,287	1,948
Loss on debt extinguishment	11,758	–
Debt discount write-off	707	–
Loss on sale of equipment	84	–
Reduction in required restricted cash under lease agreement	–	100
Amortization of prepaid interest	971	–
Changes in:		
Inventory	201	(1,788)
Accounts receivables	–	67
Prepaid expenses and other current assets	459	(44)
Accounts payable	2,913	(1,083)
Accrued expenses	1,466	1,331
Deferred revenue	(43)	(96)
Other assets	67	–
Other liabilities	(126)	(369)
Net cash used in operating activities	(33,504)	(41,169)
Cash flows from investing activities:		
Purchase of property and equipment	(458)	(780)
Proceeds from sale of property and equipment	270	–
Net cash used in investing activities	(188)	(780)
Cash flows from financing activities:		
Proceeds from issuance of securities, net of expenses	32,629	–
Proceeds from exercise of common stock warrants and options	136	457
Principal payments on long-term debt	(5,000)	–
Repayment of equipment loans	(62)	(80)
Net cash provided by financing activities	27,703	377
Net decrease in cash and cash equivalents	(5,989)	(41,572)
Cash and cash equivalents – beginning of year	44,711	86,283
Cash and cash equivalents – end of year	$ 38,722	$ 44,711
Supplementary disclosure of cash flows information:		
Interest paid	$ 1,468	$ 2,630

See notes to consolidated financial statements

Note 1 – The Company and Description of Business

Discovery Laboratories, Inc. (referred to as "we," "us," or the "Company") is a biotechnology company focused on developing novel KL4 surfactant therapies for respiratory diseases and other potential applications. Surfactants are produced naturally in the lung and are essential for normal respiratory function and survival. Our proprietary technology platform includes a synthetic, peptide-containing surfactant (KL4 surfactant) that is structurally similar to endogenous pulmonary surfactant, and novel drug delivery technologies being developed to enable noninvasive administration of aerosolized KL4 surfactant. We believe that our proprietary technology platform may make it possible to develop a pipeline of surfactant products to address a variety of respiratory diseases for which there are few or no approved therapies.

Our core development program, AEROSURF® (lucinactant for inhalation), is focused on improving the management of respiratory distress syndrome (RDS) in premature infants, a serious respiratory condition that can result in long-term respiratory problems, developmental delay and death. Premature infants born prior to 37 weeks gestational age may not have fully developed natural lung surfactant and therefore may need surfactant therapy to sustain life. Higher incidence and severity of RDS are correlated with younger gestational ages; however, RDS can occur at any premature gestational age. RDS is the most prevalent respiratory disease in the neonatal intensive care unit (NICU). Surfactant therapy is a life-saving treatment for RDS and the primary therapy to address an underlying surfactant deficiency. Surfactants currently available in the U.S. are animal-derived and must be administered using invasive endotracheal intubation and mechanical ventilation, each of which may result in serious respiratory conditions and other complications. Intubation is associated with airway trauma and clinical instability that can extend beyond the respiratory system such as increased intracranial pressure and risk for brain injury. Mechanical ventilation is associated with ventilator-associated lung injury, chronic lung disease and increased risk of infection. To avoid these risks, many premature infants are initially treated with noninvasive respiratory support, such as nasal continuous positive airway pressure (nCPAP). Unfortunately, since nCPAP does not address the underlying surfactant deficiency, many premature infants respond poorly to nCPAP (typically within the first 72 hours of life) and may require intubation and delayed surfactant therapy (an outcome referred to as nCPAP failure). In addition, many premature infants with RDS who receive surfactant therapy as initial therapy are capable of breathing without mechanical ventilation, but require surfactant therapy for RDS. Because surfactant therapy requires intubation, these infants generally are supported with mechanical ventilation for either a limited or extended period of time. If surfactant therapy could be administered noninvasively, neonatologists would be able to provide surfactant therapy to these premature infants without exposing them to the risks associated with intubation and mechanical ventilation.

AEROSURF is an investigational combination drug/device product that combines our proprietary KL4 surfactant with our novel aerosol delivery system (ADS), which is based primarily on our capillary aerosol generator technology. We are developing AEROSURF to enable administration of aerosolized KL4 surfactant to premature infants receiving nCPAP, without invasive intubation and mechanical ventilation. We believe that, if approved, AEROSURF will have the potential to transform the treatment of RDS, allow for earlier treatment of those premature infants who currently receive surfactants later in their course of treatment, decrease the morbidities and complications currently associated with surfactant administration, and reduce the number of premature infants who are subjected to invasive intubation and delayed surfactant therapy as a result of nCPAP failure. By enabling delivery of our aerosolized KL4 surfactant using noninvasive methods, we believe that AEROSURF, if approved, will address a serious unmet medical need and potentially provide transformative clinical and pharmacoeconomic benefits.

The drug product component of our AEROSURF product candidate is a lyophilized (freeze-dried) dosage form of our KL4 surfactant liquid instillate drug product that was approved by the U.S. Food and Drug Administration (FDA) in 2012 under the name SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. In the second quarter of 2015, we determined to cease commercial and manufacturing activities for SURFAXIN to focus our limited resources on advancing the AEROSURF clinical development program and our aerosolized KL4 surfactant pipeline. We believe that gaining the approval of SURFAXIN provided us valuable experience to support the further development of our KL4 surfactant product candidates, beginning with AEROSURF.

Note 2 – Basis of Presentation

The accompanying consolidated financial statements reflect a 1-for-14 reverse split of our common stock and a change in the number of shares of common stock authorized for issuance under our Amended and Restated Certificate of Incorporation, as amended (Certificate of Incorporation), that was approved by our Board of Directors and stockholders and made effective on January 22, 2016. All share and per share information herein that relates to our common stock has been retroactively restated to reflect the reverse stock split and reduction in authorized shares.

Note 3 – Liquidity Risks and Management's Plans

As of December 31, 2015, we had cash and cash equivalents of approximately $38.7 million, current accounts payable and accrued expenses of $10.8 million, and $25 million of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management, L.P. (Deerfield). The principal portion of the debt is payable in two equal installments in February 2018 (subject to potential deferral in certain circumstances) and February 2019. Before any additional financings or other transactions, we anticipate that we will have sufficient cash available to support our development programs, business operations and debt service obligations through the first quarter of 2017.

We have incurred substantial losses since inception, due to investments in research and development, manufacturing, the commercialization of SURFAXIN, including marketing, commercial and medical affairs activities, and we expect to continue to incur substantial losses over the next four to five years. To secure the significant additional capital that we will need, we expect to utilize all or a combination of potential strategic alliances, collaboration agreements and other strategic transactions, public or private equity offerings (including our ATM Program), or through debt arrangements. We also believe that our success in these efforts will be largely dependent upon our ability to successfully and timely complete the AEROSURF phase 2b clinical trial. Failure to complete the clinical trial within the expected time line in the fourth quarter of 2016 and obtain acceptable and promising results could have a material adverse effect on our ability to secure the additional capital that we will require, through strategic transactions or otherwise, and our ability to continue as a going concern.

Our ability to secure capital under our ATM Program or pursuant to public offerings under our 2014 Universal Shelf will be constrained by the value of our equity securities held by nonaffiliated persons and entities (public float), which as of March 18, 2016 is approximately $13.4 million. Our 2014 Universal Shelf was filed on Form S-3, which limits the size of primary securities offerings conducted by companies that have a public float of less than $75 million in any 12-month period to no more than one-third of their public float. Based on the closing market price of our common stock on March 18, 2016 ($1.65) we could raise up to approximately $4.5 million under our 2014 Universal Shelf. To raise capital, we may be required to seek other forms of transactions, including, for example, under a registration statement on Form S-1, the preparation and maintenance of which would be more time consuming and costly, or private placements, potentially with registration rights or priced at a discount to the market value of our stock, or other transactions, any of which could result in substantial equity dilution of stockholders' interests. In addition, although we have regained compliance with the Minimum Bid Price Requirement of the Nasdaq Listing Rules, there can be no assurance that we will be able to maintain continued compliance, including with certain other Nasdaq listing requirements that require us to maintain a market capitalization of at least $35 million or stockholders' equity of at least $2.5 million. If we fail to meet both of these requirements, we would receive another delisting notice from the Nasdaq Capital Market, which could further depress the value of our stock. In addition, to be able to raise sufficient capital to support our activities in the near term through public or private equity offerings, given our current per share market price, we may have to seek approval from our stockholders to increase the number of shares of common stock authorized for issuance under our Certificate of Incorporation. Moreover, if any such offering were to involve the issuance of common stock in excess of 20% of our outstanding common stock, we may be required under Nasdaq Listing Rules to seek stockholder approval before we can proceed. There can be no assurance that we would be successful in obtaining such approvals. Failure to secure the additional capital that we will need, whether from non-dilutive sources or from equity offerings, would have a material adverse impact on our business and our ability to continue as a going concern.

We have in the past collaborated with research organizations and universities to assess the potential utility of our KL4 surfactant in studies funded in part through non-dilutive grants issued by U.S. Government-sponsored drug development programs, including grants in support of initiatives related to our AEROSURF clinical program and medical and biodefense-related initiatives under programs that encourage private sector development of medical countermeasures against chemical, biological, radiological, and nuclear terrorism threat agents, and pandemic influenza, and provide a mechanism for federal acquisition of such countermeasures. Although there can be no assurance, we continue to pursue such funding opportunities and expect that we may qualify for similar programs in the future.

An important priority for us is to identify potential strategic transactions, including without limitation strategic alliances and collaboration arrangements that would potentially provide additional capital to support our AEROSURF development activities and strategic resources to support the registration and commercial introduction of AEROSURF. We seek a significant strategic alliance partner that has broad experience, including local 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. We have engaged in discussions with potential counterparties and a number of these entities have expressed interest in AEROSURF and our KL4 surfactant and drug delivery technologies.

Our future capital requirements will depend upon many factors, including our efforts to (i) advance the AEROSURF development program to completion of the phase 2b clinical trials as planned; (ii) assure near- and long-term continuity of supply for our lyophilized KL4 surfactant and ADS and related components with CMOs to support our clinical activities, (iv) develop our ADS 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, which likely will be designed to enroll significantly more premature infants than our phase 2 clinical trials, 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. There can be no assurance that our AEROSURF development program will be successful within our anticipated time frame, if at all; that we will be able to secure regulatory approval for AEROSURF and our other potential KL4 surfactant product candidates in the U.S. and other markets; or that we will be successful in securing the capital we will require when needed. Failure to secure the necessary additional capital when needed could have a material adverse effect on our business, financial condition and results of operations and could compel us to pace, delay or cease our new product development and clinical trial activities and ultimately cease 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, 2015, we had outstanding warrants to purchase approximately 8.5 million shares of our common stock that are exercisable at various prices on different dates into 2024. This includes 4.8 million warrants issued in a July 2015 public offering with an exercise price of $9.80 per share, and 2.9 million pre-funded warrants, of which the entire purchase price was pre-paid upon issuance. Upon exercise of the pre-funded warrants, we would issue the shares to the holders and receive no additional proceeds.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. In the future, our ability to continue as a going concern is dependent on our ability to raise additional capital to fund our research and development programs and meet our obligations on a timely basis. If we are unable to secure the required additional capital, we will likely not have sufficient cash flows and liquidity to fund our business operations, which could significantly limit our ability to continue as a going concern. In that event, we may be forced to limit our development programs and consider other means of creating value for our stockholders, such as licensing the development and/or commercialization of products that we consider valuable and might otherwise plan to develop ourselves. If we are unable to raise the necessary capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to secure additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline. Moreover, if we fail in the future to make any required payment under our Deerfield Loan or fail to comply with any commitments contained in the loan documents, Deerfield would be able to declare us in default regarding that indebtedness, which could result in the acceleration of the payment obligations under all or a portion of our 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 our assets securing the debt and could significantly diminish the market value and marketability of our common stock. Our December 31, 2015 financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

As of December 31, 2015, 36 million shares of common stock and 5 million shares of preferred stock were authorized under our Certificate of Incorporation and approximately 18.3 million shares of common stock and 5 million shares of preferred stock were available for issuance and not otherwise reserved.

Note 4 – 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, 2015 and 2014, respectively. Warrants classified as liabilities are recorded at their fair market value. Other financial instruments, including long-term debt, accounts payable and accrued expenses, are carried at cost, which we believe approximates fair value.

Property and equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to ten years). Leasehold improvements are amortized over the shorter of the estimated useful lives or the remaining term of the lease. Repairs and maintenance costs are charged to expense as incurred.

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).

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, 2015 and 2014 as management believes there are no circumstances that indicate the carrying amount of the assets will not be recoverable. In the second quarter of 2015, we closed the Totowa Facility and sold manufacturing equipment for total cash proceeds of $0.3 million, resulting in a $0.1 million loss from the sale and disposal of these assets.

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 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.

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, 2015 and 2014, the number of shares of common stock potentially issuable upon the exercise of certain stock options and warrants was 9.1 million and 1.6 million shares, respectively. As of December 31, 2015, all potentially dilutive securities were anti-dilutive and therefore have been excluded from the computation of diluted net loss per share. As of December 31, 2014, there were 1.2 million shares 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, 2015, the effect of the adjustments for warrants classified as derivative liabilities was anti-dilutive. For the year ended December 31, 2014, the effect of the adjustments for warrants classified as derivative liabilities was dilutive.

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

(in thousands)	December 31, 2015	December 31, 2014
Numerator:		
Net loss as reported	$ (55,170)	$ (44,058)
Less: income from change in fair value of warrant liability	(851)	(3,791)
Numerator for diluted net loss per common share	$ (56,021)	$ (47,849)
Denominator:		
Basic weighted average common shares outstanding	6,967	6,078
Dilutive common shares from assumed warrant exercises	–	67
Diluted weighted average common shares outstanding	6,967	6,145

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.

Business segments

We currently operate in one business segment, which is the research and development of products focused on surfactant 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.

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*, which requires an entity to present debt issuance costs in the balance sheet as a direct deduction from the carrying amount of the corresponding debt liability, consistent with debt discounts. The guidance would not address situations in which debt issuance costs do not have an associated debt liability or exceed the carrying amount of the associated debt liability (e.g., an undrawn or partially drawn line of credit). The new standard is effective for us in the annual period ending December 31, 2016, including interim periods within that annual period. Early adoption is permitted and the standard is to be applied retrospectively. We are evaluating the effect that ASU 2015-03 will have on our consolidated financial statements and related disclosures.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes*, which requires an entity to classify all deferred tax assets and liabilities as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. Also, companies will no longer allocate valuation allowances between current and noncurrent deferred tax assets because those allowances also will be classified as noncurrent. The new standard is effective for fiscal years beginning after December 15, 2016, with early adoption permitted. We have adopted ASU 2015-17 as of December 31, 2015, and the adoption of this update is not expected to have a material effect on our consolidated financial statements and related disclosures.

Note 5 – 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, 2015 and 2014:

	Fair Value	Fair value measurement using		
(in thousands)	December 31, 2015	Level 1	Level 2	Level 3
Assets:				
Cash and cash equivalents	$ 38,722	$ 38,722	$ –	$ –
Certificate of deposit	225	225	–	–
Total Assets	$ 38,947	$ 38,947	$ –	$ –
Liabilities:				
Common stock warrants	$ 223	$ –	$ –	$ 223

	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

The following table summarizes changes in the fair value of the common stock warrants measured on a recurring basis using Level 3 inputs for 2015 and 2014:

(in thousands)	
Balance at January 1, 2014	**$ 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**
Exercise of warrants [1]	(184)
Change in fair value of common stock warrant liability	(851)
Balance at December 31, 2015	**$ 223**

[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, 2015	2014
Historical volatility	159%	55% – 84%
Expected term (in years)	0.2	0.1 – 1.1
Risk-free interest rate	0.15%	0.03% – 0.31%

Fair Value of Long-Term Debt

At December 31, 2015, the estimated fair value of the Deerfield Loan (*see,* Note 9 – Deerfield Loan) approximated the carrying value of $25.0 million. At December 31, 2014, the estimated fair value of the Deerfield Loan was $22.2 million compared to a carrying value, net of discounts, of $20.3 million. At December 31, 2014, the estimated fair value of the Deerfield Loan was 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.

Note 6 – Property and Equipment

Property and equipment comprises the following:

(in thousands)	December 31, 2015	2014
Manufacturing, laboratory & office equipment	$ 6,290	$ 9,154
Furniture & fixtures	778	817
Leasehold improvements	2,437	2,718
Subtotal	9,505	12,689
Accumulated depreciation and amortization	(8,466)	(11,052)
Property and equipment, net	$ 1,039	$ 1,637

Depreciation expense on property and equipment for the years ended December 31, 2015 and 2014 was $0.7 million and $0.8 million, respectively.

Note 7 – Accrued Expenses

Accrued expenses are comprised of the following:

(in thousands)	December 31, 2015	2014
Salaries, bonus & benefits	$ 2,387	$ 2,332
Research and development	3,254	1,641
Manufacturing operations	1,097	876
Professional fees	326	376
Sales and marketing	–	318
Other	518	573
Total accrued expenses	$ 7,582	$ 6,116

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.

On February 22, 2011, we issued registered warrants (2011 Warrants) that expired on February 22, 2016 and had a fair value at issuance of $8.0 million. As of December 31, 2015, there were 0.3 million warrant shares potentially issuable upon exercise of these warrants, with a fair value of $0.2 million. These warrants contained anti-dilution provisions that in certain circumstances would adjust the exercise price if we issued 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. Although by their express terms, these warrants were not subject to potential cash settlement, due to the nature of the anti-dilution provisions, they were 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 was adjusted downward to $2.66 per share at the time of the July 2015 public offering.

During the year ended December 31, 2015, holders of the 2011 Warrants exercised warrants to purchase 51,193 shares of our common stock at an exercise price of $2.66 per share, resulting in proceeds to us of $0.1 million. During the year ended December 31, 2014, holders of the 2011 Warrants exercised warrants to purchase 20,346 shares of our common stock at an exercise price of $21.00 per share, resulting in proceeds to us of $0.4 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 loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield) for the periods presented:

(in thousands)	December 31, 2015	2014
Note payable	$ 25,000	$ 30,000
Unamortized discount	–	(9,698)
Long-term debt, net of discount	$ 25,000	$ 20,302

Under the terms of the Deerfield loan agreement, Deerfield made two advances, the first upon execution of the agreement in February 2013 in the amount of $10 million, and the second upon the first commercial sale of SURFAXIN in December 2013 in the amount of $20 million. In connection with each advance, we paid Deerfield a transaction fee equal to 1.5% of the amount disbursed. The outstanding principal accrued interest at a rate of 8.75%, payable quarterly in cash. The Deerfield Loan agreement also contains customary terms and conditions, representations and warranties and affirmative and negative covenants, including restrictions on our ability to incur additional indebtedness and grant additional liens on our assets, but it does not require us to meet minimum financial and revenue performance covenants. 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, 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).

Upon execution of the Deerfield Loan, we issued to Deerfield warrants to purchase approximately 0.2 million shares of our common stock at an exercise price of $39.34 per share. Upon receipt of the second advance in December 2013, we issued to Deerfield warrants to purchase an additional 0.3 million shares of our common stock at an exercise price of $39.34 per share (together with the warrants issued in connection with the execution of the agreement, the Deerfield Warrants). The number of shares of common stock into which the Deerfield Warrants are exercisable and the exercise price will be, and have been, 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 Deerfield Loan agreement, February 13, 2019, and contain limitations on the ability of a holder to exercise the Deerfield Warrants if after such exercise, the holder would beneficially own more than 9.985% of the total number of shares of our common stock then issued and outstanding. The Deerfield Warrants may be exercised in whole or in part 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 Warrants 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 initially 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 advance and the second advance (0.5 million warrants in total), and (ii) a $450,000 transaction fee. The discount was 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.

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%

On July 9, 2015, we entered into an amendment to our Deerfield Loan agreement and related notes (Deerfield Notes) to better align our Deerfield Loan principal repayment obligations with anticipated milestones under our clinical development program for AEROSURF. Under the terms of the amendment, (i) upon execution, we prepaid in cash $2.5 million of the principal amounts outstanding, (ii) on July 22, 2015, upon the occurrence of the July 2015 public offering, we prepaid in cash an additional $2.5 million of the principal amounts outstanding, (iii) the principal installment originally due in February 2017 was eliminated and (iv) each of the principal payments due in February 2018 and February 2019 was increased to $12.5 million. We also paid Deerfield's expenses (including reasonable counsel fees and expenses) incurred in connection with the amendment. Under the Deerfield Loan agreement, the $12.5 million principal installment due in February 2018 may be deferred one year if we achieve the market capitalization milestone set forth in the Deerfield Loan agreement.

On July 22, 2015, we entered into a second amendment to our Deerfield Loan agreement and Deerfield Notes, pursuant to which (a) upon closing the July 2015 public offering on July 22, 2015, we prepaid in cash $2.5 million of the principal amounts outstanding, as contemplated by the first amendment, and (b) Deerfield purchased and accepted $5 million Series A and Series B units offered in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes. In addition, (i) we paid in cash when due on September 30, 2015, all accrued and unpaid interest under the Deerfield Notes for the period from June 30, 2015 to July 22, 2015 at the original rate of 8.75%; (ii) Deerfield agreed to apply the $5 million prepaid interest accruing from and after July 23, 2015, as and when such payments are due and payable, as follows; first, to interest accruing on the $12.5 million principal installment due on February 13, 2019, and second, to interest accruing on the $12.5 million principal installment due on February 13, 2018, until fully allocated, which is scheduled to occur at the end of the second quarter of 2016; (iii) after the full allocation of the $5 million interest prepayment, any remaining interest due on the principal amount of the Deerfield Notes will accrue at a rate of 8.25% per annum; and (iv) no credit will be given with respect to prepaid interest on principal under the Deerfield Notes that is prepaid, in whole or in part, except for a prepayment at our election or a prepayment required under the Deerfield Loan agreement in connection with a Major Transaction that qualifies as a "Qualified Major Transaction." A "Qualified Major Transaction" means a change of control transaction (as defined in the Deerfield Warrants), in which (i) we are not the surviving entity and (ii) our common stock valuation (as defined in the Deerfield Warrants) immediately prior to the change of control transaction equals or exceeds $100 million. In addition, we paid Deerfield's expenses (including reasonable counsel fees and expenses) incurred in connection with the second amendment.

The restructuring of the Deerfield Loan was accounted for as an extinguishment of debt in accordance with ASC Topic 470, *Debt – Modifications and Extinguishments*, and as a result, we have incurred an $11.8 million non-cash loss on debt extinguishment consisting of the difference between the reacquisition price of the Deerfield Loan and the net carrying amount of the extinguished Deerfield Loan, which includes $4.1 million in fair value of the Series A and Series B warrants issued to Deerfield as part of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes.

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

(in thousands)	December 31, 2015	2014
Cash interest expense	$ 1,451	$ 2,625
Non-cash amortization of debt discounts	1,287	1,948
Debt discount write-off	707	–
Amortization of prepaid interest expense	971	–
Amortization of debt costs	12	19
Write-off of debt costs	66	–
Total Deerfield Loan interest expenses	4,494	$ 4,592

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 Deerfield Warrants. Debt discount write-off represents the proportional write-off of unamortized debt discount at the time of a $2.5 million pre-payment of principal amount outstanding under the Deerfield Loan. Amortization of prepaid interest expense represents non-cash amortization of the $5 million of Series A and Series B units Deerfield agreed to purchase and accept in our July 2015 public offering in satisfaction of $5 million of future interest payments due under the Deerfield Notes. The amortization of debt costs represents professional fees incurred in connection with the Deerfield Loan, and the write-off of debt costs represents the write-off of the remaining costs at the time of the debt restructuring.

Note 10 – Stockholders' Equity

Registered Public Offerings

On July 22, 2015, we completed a registered public offering of 1,791,667 Series A units and 3,000,000 Series B units each at a price per unit of $8.40, resulting in gross proceeds of $40.25 million ($37.6 million net after underwriting discount and expenses), including the exercise in full by the underwriters of their option to purchase up to an additional 625,000 Series A units at a price per unit of $8.40 to cover over-allotments. The proceeds included $5.0 million in non-cash consideration from Deerfield in the form of a reduction in future interest payments due under the Deerfield Loan (*see,* Note 9, "Deerfield Loan"). Each Series A unit consists of one share of common stock and a Series A warrant to purchase one share of common stock at an exercise price of $9.80 per share. Each Series B unit consists of a fully paid pre-funded Series B warrant to purchase one share of common stock at an exercise price of $8.40 per share, and a Series B warrant to purchase one share of common stock at an exercise price of $9.80 per share. The shares of common stock and warrants were immediately separable such that no units were issued. The warrants are exercisable immediately at the election of the holder for cash or through a net cashless exercise, provided that a holder may not exercise a warrant to the extent that after giving effect to such exercise, such holder would beneficially own in excess of 9.99% (or 4.99% as may be elected by such holder) of the shares of our common stock outstanding immediately after such exercise. All warrants will expire on the seventh anniversary of the issue date. The net proceeds will be used primarily (i) to advance the AEROSURF development program, and (ii) for general corporate purposes. The offering was made pursuant to a preliminary prospectus supplement dated July 16, 2015 to the 2014 Universal Shelf.

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.

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, as amended on February 11, 2016, will terminate upon the earliest of: (1) the sale of all shares subject to the ATM Agreement, (2) February 11, 2019 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.

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, 2015 and 2014, the match resulted in the issuance of 94,114 and 42,371 shares of common stock, respectively. Expenses associated with the 401(k) match for the years ended December 31, 2015 and 2014 were $0.5 million and $1.0 million, respectively.

Common Shares Reserved for Future Issuance

Common shares reserved for potential future issuance upon exercise of warrants

The chart below summarizes shares of our common stock reserved for future issuance upon the exercise of warrants:

(in thousands, except price per share data)	December 31, 2015	December 31, 2014	Exercise Price	Expiration Date
Battelle – 2014 collaboration agreement[1]	107	107	$ 70.00	10/10/2024
Investors – July 2015 financing	4,792	–	$ 9.80	07/22/2022
Investors – July 2015 financing (prefunded)	2,857	–	–	07/22/2022
Deerfield – 2013 loan	500	500	$ 39.34	2/13/2019
Former employee	2	2	$ 44.80	3/18/2016
Investors – February 2011 financing	274	325	$ 2.66	2/22/2016
PharmaBio – October 2010 financing	–	6	$ 57.40	10/13/2015
Investors – June 2010 financing	–	85	$ 84.00	6/22/2015
Kingsbridge – June 2010 CEFF	–	6	$ 93.66	12/11/2015
PharmaBio – April 2010 financing	–	10	$ 148.26	4/30/2015
Investors – February 2010 financing	–	66	$ 178.50	2/23/2015
Total	8,532	1,107		

(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, 2015 and 2014, we had 0.4 million and 0.5 million shares, respectively, available for potential future issuance under the 2011 Long-Term Incentive Plan (the 2011 Plan). On January 21, 2016, at a Special Meeting of Stockholders, our stockholders authorized the issuance of an additional 1.1 million shares under the 2011 Long-Term Incentive Plan, which shares were registered on Form S-8 on January 27, 2016.

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

As of December 31, 2015 and 2014, we had 4,567 and 438, respectively, reserved for potential future issuance under the 401(k) Plan. On October 27, 2015 the Board of Directors approved the issuance of 78,571 shares of common stock that may be issued pursuant to our 401(k) Plan. These shares were registered on Form S-8 on January 6, 2016.

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 2.0 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.

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

	December 31,	
	2015	**2014**
Stock Options and RSUs Outstanding		
2011 Plan	493	437
2007 Plan	17	18
1998 Plan	12	13
Total Outstanding	522	468
Available for Future Grants under 2011 Plan	420	476

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 two 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, 2015	467	$ 63.04	
Granted	185	15.64	
Forfeited or expired	(135)	42.81	
Outstanding at December 31, 2015	517	$ 51.35	6.6
Vested and exercisable at December 31, 2015	294	$ 74.84	4.9

(in thousands, except for weighted-average data)

Restricted Stock Units	Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2015	1	$ 23.94
Awarded	5	$ 6.72
Vested	(1)	$ 23.94
Unvested at December 31, 2015	5	$ 6.72

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, 2015 and 2014 was $10.48 and $25.48, respectively. The weighted-average grant-date fair value of RSUs granted during the years ended December 31, 2015 and 2014 was $6.72 and $23.94, respectively. The total intrinsic value of options outstanding, vested, and exercisable as of December 31, 2015 are each $0.

Stock-Based Compensation

We recognized stock-based compensation expense in accordance ASC Topic 718 for the years ended December 31, 2015 and 2014 of $1.7 million and $2.9 million, respectively.

Stock-based compensation expense was classified as follows:

(in thousands)	December 31, 2015	2014
Research and development	$ 642	$ 1,014
Selling, general and administrative	1,054	1,927
Total	$ 1,696	$ 2,941

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, 2015	2014
Weighted average expected volatility	83%	100%
Weighted average expected term	5.5 years	5.4 years
Weighted average risk-free interest rate	1.50%	1.65%
Expected dividends	–	–

The total fair value of the underlying shares of the options vested during 2015 and 2014 equals $2.7 million and $3.1 million, respectively. As of December 31, 2015, there was $1.9 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 1.8 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 ADS 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 $3.1 million and $0.3 million for the years ended December 31, 2015 and 2014, respectively.

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 $70.00 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 71,429 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 35,714 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 July 15, 2016, which date was adjusted, and may be further 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 ADS 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 $400,000 and $300,000 in 2015 and 2014, respectively, 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.

Note 13 – Commitments

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 remaining under the extended portion of the lease are approximately $2.0 million.

Until June 30, 2015, we leased approximately 21,000 square feet of space for our manufacturing operations in Totowa, New Jersey (Totowa Facility), at an annual rent of $525,000. The lease for this facility, which was used to manufacture SURFAXIN drug product, expired on June 30, 2015

Rent expense under these leases was $1.0 million and $1.2 million for the years ended December 31, 2015 and 2014, respectively.

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 $6.6 million through 2016.

Restructuring Plan

In April 2015, we implemented a restructuring plan to voluntarily cease the commercialization of SURFAXIN and focus our resources on the development of our aerosolized KL4 surfactant pipeline for respiratory diseases, beginning with AEROSURF. As part of the restructuring plan, we ceased manufacturing activities at our Totowa Facility, which we closed upon the expiration of our lease on June 30, 2015.

The total severance cost for all impacted employees is $2.9 million, of which $1.0 million was accrued as of December 31, 2014 for Totowa employees. The remaining $1.9 million was charged to expense during 2015 ($1.0 million to research and development expenses and $0.9 million to selling, general and administrative expenses). We paid $2.6 million of the severance and retention benefits during 2015. The remaining $0.3 million will be paid through June 30, 2016.

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, 2015 and 2014 is as follows:

(in thousands)	December 31, 2015	2014
Income tax benefit, statutory rates	$ 18,758	$ 14,980
State taxes on income, net of Federal benefit	3,760	2,871
Research and development tax credit	1,047	1,472
Employee related	(340)	(2,131)
Warrant valuation related	289	1,289
Income tax benefit	23,514	18,481
Valuation allowance	(23,514)	(18,481)
Income tax benefit	$ –	$ –

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2015 and 2014, are as follows:

(in thousands)	December 31, 2015	2014
Long-term deferred tax assets:		
Net operating loss carryforwards (Federal and state)	$ 218,203	$ 191,643
Research and development tax credits	13,917	12,927
Compensation expense on stock	2,776	2,588
Charitable contribution carryforward	6	7
Inventory reserve	–	907
Deferred revenue	–	16
Other accrued	469	1,088
Depreciation	482	2,630
Capitalized research and development	–	1,123
Total long-term deferred tax assets	235,853	212,929
Less: valuation allowance	(235,853)	(212,929)
Deferred tax assets, net of valuation allowance	$ –	$ –

We are in a net deferred tax asset position at December 31, 2015 and 2014 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, 2015 or 2014, nor were any incurred in 2015 or 2014.

At December 31, 2015 and 2014, we had available carryforward net operating losses for Federal tax purposes of $540.2 million and $473.3 million, respectively, and a research and development tax credit carryforward of $13.9 million and $12.9 million, respectively. The Federal net operating loss and research and development tax credit carryforwards will continue to expire through 2035.

At December 31, 2015, 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, 2015 and 2014, we had available carryforward losses of approximately $527.1 million and $470.4 million, respectively, for state tax purposes. Of the $527.1 million state tax carryforward losses, $503.7 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.

Note 16 – Selected Quarterly Financial Data (Unaudited)

The following tables contain unaudited statement of operations information for each quarter of 2015 and 2014. The operating results for any quarter are not necessarily indicative of results for any future period.

2015 Quarters Ended:

(in thousands, except per share data)	Mar. 31	June 30	Sept. 30	Dec. 31	Total Year
Revenues:					
Product sales	$ 7	$ –	$ –	$ –	$ 7
Grant revenues	184	75	66	655	980
Total revenues	191	75	66	655	987
Expenses:					
Cost of sales	929	–	–	–	929
Research and development	7,082	7,129	6,452	8,225	28,888
Selling, General and administrative	3,353	3,383	2,057	2,211	11,004
Total expenses	11,364	10,512	8,509	10,436	40,821
Operating loss	(11,173)	(10,437)	(8,443)	(9,781)	(39,834)
Change in fair value of common stock warrant liability	(31)	469	139	274	851
Other expense, net	(975)	(1,358)	(13,252)	(602)	(16,187)
Net loss	$ (12,179)	$ (11,326)	$ (21,556)	$ (10,109)	$ (55,170)
Net loss per common share - basic	$ (1.96)	$ (1.82)	$ (2.80)	$ (1.26)	$ (7.98)
Net loss per common share - diluted	$ (1.96)	$ (1.82)	$ (2.80)	$ (1.26)	$ (7.98)
Weighted average number of common shares outstanding - basic	6,114	6,125	7,550	8,050	6,967
Weighted average number of common shares outstanding - diluted	6,114	6,125	7,550	8,050	6,967

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	$ (1.96)	$ (1.68)	$ (1.82)	$ (1.68)	$ (7.28)
Net loss per common share - diluted	$ (1.96)	$ (1.96)	$ (1.82)	$ (2.10)	$ (7.84)
Weighted average number of common shares outstanding - basic	6,052	6,076	6,086	6,097	6,078
Weighted average number of common shares outstanding - diluted	6,052	6,134	6,086	6,111	6,145

Note 17 Subsequent Events

We evaluated all events or transactions that occurred after December 31, 2015 through the date we issued these financial statements. During this period, we noted two subsequent events as described below:

Share Consolidation

On January 21, 2016, at a Special Meeting of Stockholders, our stockholders approved proposals authorizing the Board of Directors, in its discretion, to implement a reverse split based on an exchange ratio in a designated range and to reduce the number of authorized shares of common stock at one half the exchange ratio implemented for the reverse split.

We filed a Certificate of Amendment to our Certificate of Incorporation to (i) effect a share consolidation, or reverse split, of the common stock, par value $0.001 per share, at a ratio of 1-for-14, effective at 12:01 a.m. on January 22, 2016, and (ii) reduce the number of authorized shares of common stock under our Certificate of Incorporation from 250 million to 36 million. Because the Amendment did not reduce the number of authorized shares of common stock in the same proportion as the reverse split, the Amendment had the effect of increasing the amount of common stock available for issuance relative to the amount of common stock available for issuance prior to the Amendment. Further, any warrants, options, restricted stock units and rights outstanding as of the effective date that were subject to adjustment were adjusted in accordance with the terms thereof. Those adjustments may have included, without limitation, changes to the number of shares of common stock that may be obtained upon exercise or conversion of these securities, and changes to the applicable exercise or purchase price. The stockholders also approved the issuance of an additional 1.1 million shares under the 2011 Long-Term Incentive Plan.

Executive Severance

On February 1, 2016, the Company announced the appointment of Craig Fraser to serve as our President and Chief Executive Officer, effective February 1, 2016. Upon recommendation of the Nomination and Governance Committee of our Board of Directors also appointed Mr. Fraser to serve as a member of the Board, effective immediately.

In connection with the foregoing, effective February 1, 2016, we terminated the Employment Agreement of our then President and Chief Executive Officer (the Former CEO). In connection therewith, upon execution by the Former CEO of a plenary release in form satisfactory to us, he became entitled under his Employment Agreement to the following severance and other benefits, in addition to any vested benefits under our company plans or policies: (i) a pro rata bonus equal to a percentage of his Annual Bonus Amount determined by dividing the aggregate bonuses paid to other contract executives for the year 2016 by the aggregate target bonuses of such other contract executives for 2016, and further prorated for the number of days the Former CEO was employed during 2016, payable at the time that other contract executives are paid bonuses with respect to 2016; (ii) a severance amount equal to the sum of the Former CEO's base salary then in effect and his Annual Bonus Amount, payable in equal installments through August 1, 2017 (the Severance Period); and (iii) all stock options held by the Former CEO will continue to vest during the Severance Period, and continue to be exercisable for up to 36 months after the date of termination. From and after the end of the Severance Period, the Former CEO will forfeit all of his unvested stock options in accordance with the terms of the 2011 Plan. The Former CEO 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 Former CEO 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.

Exhibit 21.1

Subsidiaries of Registrant: 1. Acute Therapeutics, Inc.

Exhibit 31.1

CERTIFICATIONS

I, Craig Fraser, certify that:

1. I have reviewed this Annual Report on Form 10-K/A 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 29, 2016

/s/ Craig Fraser
Craig Fraser
President and Chief Executive Officer

CERTIFICATIONS

I, John Tattory, certify that:

1. I have reviewed this Annual Report on Form 10-K/A 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 29, 2016

/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/A for the fiscal year ended December 31, 2015 ("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 29, 2016

/s/ Craig Fraser
Craig Fraser
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.