The information in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell nor do they seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Filed pursuant to Rule 424(b)(5) Registration No. 333-174786

# **SUBJECT TO COMPLETION, DATED OCTOBER 30, 2013**

PRELIMINARY PROSPECTUS SUPPLEMENT (To Prospectus dated June 21, 2011)



We are offering shares of our common stock in this offering. Each share will be sold at a public offering price of \$ per share. Our common stock is listed on The NASDAQ Capital Market under the symbol "DSCO." On October , 2013, the last reported sale price of our common stock on The NASDAQ Capital Market was \$ per share.

Investing in our common stock involves significant risks. See "Risk Factors" beginning on page S-7 of this prospectus supplement and page 2 of the accompanying prospectus.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities, or passed upon the accuracy or adequacy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

	Per	
	Share	Total
Public offering price	\$ \$	
Underwriting discount (1)	\$ \$	
Proceeds to us (before expenses)	\$ \$	

(1) Excludes underwriter out-of-pocket expenses we have agreed to reimburse. See the section entitled "Underwriting" in this prospectus supplement for additional information. We have granted the underwriters an option for a period of 30 days to purchase up to an additional shares at the public offering price, less the underwriting discount, solely to cover over-allotments, if any. If the underwriters exercise the option in full, the total underwriting discount payable by us will be \$ and the total proceeds to us, before expenses, will be \$

We anticipate that delivery of the shares will be made through the facilities of the Depository Trust Company on or about November , 2013, subject to customary closing conditions.

Stifel

Piper Jaffray

**Lazard Capital Markets** 

**Roth Capital Partners** 

Prospectus Supplement dated October , 2013

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#### ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is the prospectus supplement, which describes the specific terms of the securities we are offering, including the price, the amount of common stock being offered and the risks of investing in our common stock, and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part, the accompanying prospectus, including the documents incorporated by reference, provides more general information, some of which may not apply to our common stock. This prospectus supplement and the accompanying prospectus are part of a "shelf" registration statement on Form S-3 that we filed with the Securities and Exchange Commission on June 8, 2011. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. You should read both this prospectus supplement and the accompanying prospectus together with the additional information about us described in the section entitled "Where You Can Find More Information" and "Incorporation by Reference." To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the SEC before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in the accompanying prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein or therein. We have not, and the underwriters have not, authorized anyone to provide you with information different from that contained in any of these documents. If anyone provides you with different or inconsistent information, you should not rely on it. The information contained in these documents is accurate only as of the date of each document, as the case may be, regardless of the time of delivery of this prospectus supplement and accompanying prospectus or of any sale of common stock. Our business, financial condition, results of operations and prospects may change after the date set forth in each document in which the information is presented.

We are making offers to sell and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus outside the United States. You should not consider this prospectus supplement and the accompanying prospectus to be an offer to sell, or a solicitation of an offer to buy, shares of common stock if the person making the offer or solicitation is not qualified to do so or if it is unlawful for you to receive the offer or solicitation.

References in the prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein to "we," "our," "us" and the "company" refer to Discovery Laboratories, Inc. and its subsidiary, unless the context requires otherwise.

#### PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and information appearing elsewhere in this prospectus supplement and in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our securities. The following summary is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial statements and notes thereto appearing elsewhere in this prospectus supplement and the accompanying prospectus. Before you decide to invest in our securities, to fully understand this offering and its consequences to you, you should carefully read the entire prospectus supplement and the accompanying prospectus carefully, including the risk factors beginning on page S-7 of this prospectus supplement and beginning on page 2 of the accompanying prospectus, and the consolidated financial statements and related notes included or incorporated by reference in this prospectus supplement, the accompanying prospectus and the other documents incorporated by reference herein and therein.

## **Our Business**

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

## Our Initial Focus – Respiratory Distress Syndrome (RDS)

We are developing our KL4 surfactant and drug delivery technologies initially to improve the management of RDS in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants, and the most prevalent respiratory disease in the neonatal intensive care unit (NICU). RDS can result in long-term respiratory problems, developmental delay and death. Mortality and morbidity rates associated with RDS have not meaningfully improved over the last decade. We believe that the RDS market is presently underserved, and that our RDS programs have the potential to greatly improve the management of RDS and, over time, to become a new standard of care for premature infants with RDS.

Premature infants with RDS currently are treated with surfactants that can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may result in serious respiratory conditions and complications. To avoid such adverse results, neonatologists generally provide surfactants as initial therapy only to premature infants with severe RDS where the potential benefits of surfactant therapy outweigh the risks associated with endotracheal intubation and mechanical ventilation. For infants with less severe RDS, neonatologists will first attempt to provide respiratory support using a less invasive means, such as nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of these infants do not respond adequately to nCPAP, an outcome referred to as nCPAP failure, and require subsequent surfactant administration via intubation and mechanical ventilation. As it is not possible to ascertain in advance which patients will experience nCPAP failure, neonatologists are faced with a dilemma, because the outcome for those infants who experience nCPAP failure and receive delayed surfactant therapy may not be as favorable as the outcome for those infants who receive surfactant therapy as initial therapy.

In the United States, approximately 360,000 premature births occur each year, of which we estimate that approximately 160,000 premature infants could potentially benefit from early surfactant therapy to address surfactant deficiency or insufficiency. However, only approximately 45,000 will receive surfactants administered using intubation and mechanical ventilation as the first line of therapy, and more than 70% of surfactant deficient infants (approximately 115,000) will not receive first-line surfactant therapy and instead receive nCPAP alone. Of those infants that are treated with nCPAP alone, approximately 45,000 will experience nCPAP failure and require subsequent endotracheal intubation and surfactant therapy.

We believe that the neonatal medical community increasingly recognizes the potential benefits of (i) a synthetic, peptide-containing surfactant such as SURFAXIN®, and more importantly, (ii) a less-invasive method of delivering surfactant, such as AEROSURF®, to treat premature infants at risk of suffering from respiratory disorders.

# SURFAXIN®

In 2012, the U.S. Food and Drug Administration (FDA) approved our first KL4 surfactant drug product, SURFAXIN (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the U.S. On October 4, 2013, we announced that the FDA has agreed to updated product specifications for SURFAXIN, and that we have initiated manufacturing of SURFAXIN drug product for commercial sale. We expect that SURFAXIN will be commercially available in the fourth quarter 2013.

## AEROSURF®

AEROSURF is an investigational combination drug-device product that combines our KL<sub>4</sub> surfactant with our proprietary capillary aerosol generator (CAG). We are developing AEROSURF to deliver our KL<sub>4</sub> surfactant in aerosolized form to premature infants with RDS. AEROSURF potentially will provide neonatologists with the ability to avoid invasive procedures and deliver our KL<sub>4</sub> surfactant in aerosolized form to premature infants supported with nCPAP. For this reason, we believe that AEROSURF, if approved, may enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

Based on the expected number of infants that do not receive first-line surfactant therapy and the perceived potential pharmacoeconomic benefits that might be derived from delivering surfactants without endotracheal intubation and mechanical ventilation, we anticipate that the market potential for AEROSURF in the U.S. is in the range of \$600 million to over \$1 billion. We believe that the opportunity in markets outside the U.S. is potentially comparable to the U.S. However, there can be no assurance that we will succeed in gaining approval to market AEROSURF in the U.S. market or in markets outside the U.S., nor can there be assurance that our revenues estimates will be achieved.

## AEROSURF Development Plan Update

We are developing a lyophilized (freeze-dried) dosage form of our KL4 surfactant that can be stored as a powder and resuspended to liquid form prior to use, with the objective of improving ease of use for healthcare practitioners, as well as potentially prolonging shelf life and eliminating the need for cold-chain storage. This lyophilized dosage form is intended initially to be used in our AEROSURF development program. We completed a technology transfer of our lyophilized surfactant manufacturing process to DSM Pharmaceuticals, Inc. (DSM), our contract manufacturer with expertise in lyophilized products. DSM has manufactured an supply of clinical drug product needed for the initial phase of our phase 2 program and will manufacture the clinical drug supply needed to complete our phase 2 clinical program. We also recently entered into a development agreement with DSM for the further development of this lyophilized KL4 surfactant, potentially for our AEROSURF phase 3 program and, if approved, commercial supply.

With the assistance of Battelle Memorial Institute (Battelle), we completed development of a clinic-ready CAG device, which has passed a rigorous design verification testing program, and have manufactured a sufficient number of clinic-ready CAGs to support the initial phase of our AEROSURF phase 2 clinical program. We plan to continue development of our CAG and expect to manufacture additional devices to support completion of our phase 2 and potentially our phase 3 clinical program. The CAG has been designed to produce aerosolized KL4 surfactant in volumes up to ten times the output produced by currently available aerosol devices.

# AEROSURF Proposed Phase 2 Clinical Program

On October 17, 2013, we announced that we have submitted an Investigational New Drug (IND) Application to the FDA for our initial AEROSURF phase 2 clinical trial. The FDA has confirmed receipt of the IND and has indicated that, unless otherwise notified during its review, we may initiate our phase 2 clinical program for AEROSURF after a 30-day period. We anticipate patient enrollment could begin in the fourth quarter of 2013.

The primary goal of the initial phase of the proposed AEROSURF phase 2 program, phase 2a, is to evaluate the safety and tolerability of a single exposure of aerosolized KL4 surfactant drug product. This phase is planned as an escalating dose study evaluating three dose levels of aerosolized KL4 surfactant. The comparator is nCPAP alone. The study will be conducted in three centers in the U.S. and is expected to be completed by mid-2014. The design of the second phase of the study, phase 2b, will be informed by the results of phase 2a. The primary objective will be to determine the optimal dose and expected efficacy margin. This phase is expected to be conducted in multiple centers and completed by mid-2015.

# **Beyond RDS**

We expect that we will be able to leverage the information, data and know-how that we gain from our development efforts with AEROSURF for RDS to support development of a product pipeline intended to address serious critical care respiratory conditions of larger children and adults in pediatric intensive care units (PICUs) and intensive care units (ICUs). However, we are delaying these efforts as we focus our resources on advancing the development of AEROSURF to phase 2 clinical trials and the commercial introduction of SURFAXIN. If we are able to achieve our objectives, we believe we will be in a better position to assess the potential of developing products based on our CAG and other drug delivery technologies to address the critical care needs of patients in the PICU and ICU.

# Commercial and Medical Affairs Organizations

In the U.S., we have established our own specialty respiratory critical care commercial and medical affairs organizations that are experienced in neonatal/pediatric respiratory critical care, and will focus on neonatal indications, beginning with SURFAXIN and the AFECTAIR® device for infants. These organizations will be responsible for the commercial introduction of SURFAXIN. With our established relationships and contacts in the neonatal community, we believe that we also will be able to use our commercial and medical affairs organizations in the future to efficiently support the introduction of AEROSURF. In addition, with their expertise in respiratory critical care and in launching new products that address neonatal/pediatric conditions, we expect that these teams may potentially support introductions of other synergistic products in the NICU/PICU.

*Note:* The RDS population estimates and estimates and data included in the discussion above have been derived from the following sources, among others: IMS MIDAS data (MAT Sept 2008); CDC National Vital Statistics, 2005, Births by birth weight (CDC Website); "Annual Summary of Vital Statistics: 2006", Pediatrics, Martin et al.; Vermont Oxford Network (VON) data, 2006; UNICEF data, 2005 (website); and our primary market research (2010). Our estimate of the number of premature infants that could potentially benefit from early surfactant therapy is derived from data from the foregoing sources, taking into account several factors, including without limitation, gestational age of premature infants, treatment rates for nCPAP, rates of nCPAP failure, and incidence of RDS.

# **Financial Update**

As of September 30, 2013, we had cash and cash equivalents of \$21.2 million. Net cash outflows for the quarter ended September 30, 2013 were approximately \$10.1 million.

Beginning on October 4, 2013, we initiated an offering under our At-the-Market Equity Offering Sales Agreement dated February 11, 2013 ("ATM Program") with Stifel, Nicolaus & Company, Incorporated ("Stifel"). We issued 713,920 shares of our common stock at various prices, resulting in net proceeds to us of approximately \$1.9 million, after deducting commissions due to Stifel, as the sales agent.

Pursuant to the terms of a Facility Agreement dated February 13, 2013 (the "Deerfield Facility") with affiliates of Deerfield Management Company, L.P. ("Deerfield"), Deerfield agreed to loan us up to \$30 million on a secured basis on the terms outlined in the Deerfield Facility. Deerfield advanced \$10 million upon execution of the Deerfield Facility and agreed to advance an additional \$20 million, subject to certain conditions, following the first commercial sale of SURFAXIN, provided that the first sale occurs not later than December 31, 2013. With the recent FDA approval of updated product specifications for SURFAXIN, we have manufactured commercial product and, upon completion of final release testing, expect to initiate the commercial launch of SURFAXIN in the fourth quarter of 2013. We anticipate that we will meet the requirements and become eligible to receive the \$20 million advance from Deerfield, although there can be no assurance that we will be successful.

For a further discussion of the Deerfield Facility, including the terms of the facility, and the fees and common stock warrants issuable in connection therewith, see our Annual Report on Form 10-K for the year ended December 31, 2012, "Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources."

There can be no assurance that we will be successful in securing the additional capital required to support our operations, execute our research and development activities, and successfully complete the commercial introduction of SURFAXIN, AFECTAIR and, if approved, our KL4 surfactant pipeline products, beginning with AEROSURF. In addition to capital, if any, that we may raise through debt facilities and financial transactions, we seek strategic alliances to assist us in markets outside the United States, with a current focus predominantly on the European Union. To date, our discussions with potential partners have centered on AEROSURF. We prefer strategic partners that have broad experience in the designated markets, including regulatory and product development expertise as well as an ability to commercialize our products. In addition to development and commercial support, such alliances typically also would provide us with financial resources to support our activities, potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses. However, there can be no assurance that we will be successful in securing the necessary capital, or concluding any strategic alliance, or other similar transaction.

# **Trademark Notice**

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

# **Corporate Information**

We maintain our principal offices and research laboratories at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania. Our telephone number is 215-488-9300. Our company maintains websites at www.discoverylabs.com, www.surfaxin.com and www.afectair.com. Information contained in, or accessible through, our website does not constitute a part of this prospectus supplement or the accompanying prospectus.

#### THE OFFERING

Common stock offered	shares
Common stock to be outstanding after this offering (1)	shares
Risk factors	See "Risk Factors" beginning on page S-7 of this prospectus supplement and page 2 of the accompanying prospectus for a discussion of factors you should consider carefully when making an investment decision.
Use of proceeds	The net proceeds from this offering will be used primarily (i) to support the commercial introduction of SURFAXIN® drug product, (ii) to advance our AEROSURF® development program, including our planned phase 2 clinical program and (iii) for general corporate purposes. See "Use of Proceeds" on page S-9 of this prospectus supplement.
The NASDAQ Capital Market symbol	DSCO

If the underwriters' over-allotment option is exercised in full, we will issue and sell an additional shares and will have approximately shares outstanding after the offering (without giving effect to any exercise of outstanding warrants or options to purchase shares of our common stock or any other issuance of common stock after October 25, 2013 other than in connection with this offering). Except as otherwise noted, all information in this prospectus supplement assumes no exercise of the underwriters' over-allotment option.

<sup>(</sup>i) The number of shares of common stock to be outstanding immediately after this offering as shown above is based on 55,747,355 shares of common stock actually outstanding as of October 25, 2013. This number excludes: (i) 5,486,893 shares of our common stock subject to options outstanding as of October 25, 2013, which have a weighted average exercise price of \$7.82 per share; (ii) 10,182,335 shares of common stock issuable upon exercise of warrants outstanding as of October 25, 2013, at a weighted average exercise price of approximately \$4.54 per share; (iii) 18,936 shares of common stock issuable upon vesting of restricted stock units; (iv) 274,890 shares of common reserved for potential future issuance pursuant to our 401(k) Plan as of October 25, 2013; (v) 2,907,607 shares of common stock available for future grant under our 2011 Long-Term Incentive Plan, as amended; and (v) an indeterminate number of shares of common stock issuable under our effective shelf registration statements on Form S-3, including shares of common stock that may be issued under an the ATM Program with Stifel, under which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell until February 11, 2016 up to a maximum of \$23,038,092 of shares of our common stock.

#### FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein and therein, contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans and our expectations and timing related to commercialization of SURFAXIN®, the development and potential regulatory plan to secure marketing authorization for AEROSURF® and our other potential pipeline products, if approved; our research and development programs, including planning for development activities, anticipated timing of clinical trials and potential development milestones; plans for the manufacture of drug products, active pharmaceutical ingredients (APIs) and materials and medical devices; and plans regarding potential strategic alliances and other collaborative arrangements to develop, manufacture and market our products.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of the risks and uncertainties include, but are not limited to:

- the risks that, even if we succeed with the commercial introduction of SURFAXIN in the fourth quarter of 2013 and secure an additional \$20 million under the Deerfield Facility, we nevertheless will require, but may be unable to secure, significant additional capital to continue our operations, fund our debt service and support our research and development activities, including our planned clinical programs, until such time, if ever, that our revenues from all sources are sufficient to offset our cash outflows. To the extent that we raise such capital through additional financings, such additional financings could result in equity dilution. Moreover, we have pledged substantially all of our assets to secure our obligations under the Deerfield Facility, 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 investments;
- the risk that, if the delay in commercial availability of SURFAXIN extends beyond December 31, 2013, we may be unable to access \$20 million under the Deerfield Facility, which could adversely impact our plans and our ability to meet our objectives, and that any further delay could have a material adverse effect on our ability business, operations and financial condition;
- the risk that, although we have slowed, and plan to continue to slow, the pace of certain investments that we otherwise would make during this period, our plan to maintain our commercial and medical affairs capabilities and continue to invest in the AEROSURF development program has limited and will limit our ability to significantly reduce our cash outflows;
- the risk that, if we fail to successfully commercialize SURFAXIN as planned, or if SURFAXIN does not gain market acceptance for any reason and we do not achieve revenues consistent with our expectations, our revenues would be limited, and we may be unable to secure additional capital when needed, whether from strategic alliances or other sources, to continue our commercial and medical affairs activities, as well as our research and development programs and our operations would be impaired, which ultimately could have a material adverse effect on our business, financial condition and results of operations;
- risks relating to the ability of our sales and marketing organization to effectively market SURFAXIN in the U.S. and, if approved, our other product candidates in a timely manner, if at all; and that we may not succeed in developing a sufficient market awareness of our products or that our product candidates may not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;
- the risks that, although we have filed an IND for our AEROSURF phase 2 clinical program and expect to initiate our phase 2 clinical program in the fourth quarter of 2013, the FDA may not agree with our proposed plans, may request additional information or may require us to conduct additional studies, which could delay or preclude commencement of the clinical program within the anticipated time, if at all;

- risks related to our efforts to gain regulatory approval, in the U.S. and elsewhere, for our drug product and medical device candidates, including AEROSURF, a drug-device combination product that we are developing to address RDS in premature infants, and our lyophilized KL4 surfactant that we expect will be the drug component of AEROSURF and potentially be developed as a life cycle extension of SURFAXIN under the name SURFAXIN LS;
- risks relating to our research and development activities, which among other things involve time-consuming and expensive preclinical studies and potentially multiple clinical trials that may be subject to potentially significant delays or regulatory holds or fail;
- risks relating to the transfer of our manufacturing technology to contract manufacturing organizations (CMOs) and assemblers;
- risks relating to our and our CMOs' ability to manufacture our KL4 surfactant, in liquid and lyophilized dosage forms, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for both commercial and research and development activities;
- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems or
  delays in manufacturing our KL4 surfactant drug products and the APIs used in the manufacture of our drug product, CAG devices and other
  materials on a timely basis or in an amount sufficient to support the commercial introduction of SURFAXIN and the AFECTAIR device for
  infants, our aerosol-conducting airway connector, as well as our research and development activities for AEROSURF and our other product
  candidates;
- the risk that we may be unable to enter into strategic alliances and/or collaboration agreements that would assist and support us in markets outside the U.S. with the development of our KL4 surfactant pipeline products, beginning with AEROSURF (our combination drug-device product based on our aerosolized KL4 surfactant and our CAG technology that we are developing to address RDS in premature infants) and the development of our lyophilized KL4 surfactant, and, if approved, commercialization of AEROSURF in markets outside the U.S.; and potentially support the commercialization of SURFAXIN in countries where regulatory approval is facilitated by the information contained in the SURFAXIN new drug application (NDA) approved by the FDA; and potentially support the development and, if approved, commercialization, of our other pipeline products;
- other risks and uncertainties as detailed in "Risk Factors" in our most recent Annual Report on Form 10 K filed with the Securities and Exchange Commission on March 15, 2013, our most recent Quarterly Reports on Form 10 Q for the quarter ended March 31, 2013, filed on May 7, 2013, and for the quarter ended June 30, 2013, filed on August 8, 2013, and any amendments thereto, and in the documents incorporated by reference in this prospectus supplement.

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

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

#### RISK FACTORS

An investment in our common stock involves significant risks. You should carefully consider the risks described below or in any applicable prospectus supplement and other information, including our financial statements and related notes previously included in our periodic reports filed with the SEC, and in the documents incorporated therein by reference before deciding to invest in our securities, including without limitation, our Annual Report on Form 10-K for the year ended December 31, 2012 and our Quarterly and Current Reports filed thereafter, each of which is incorporated herein by reference. The risks described below are not the only ones that we face. Additional risks 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 securities would likely decline and you could lose all or part of your investment.

# Risks Related to this Offering and Our Common Stock

# The market price of our stock may be adversely affected by market volatility.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- 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;
- announcements of the results of clinical trials by us or our competitors;
- patient adverse reactions to drug products;
- changes in the United States or foreign regulatory policy during the period of product development;
- changes in the United States or foreign political environment and the passage of laws, including tax, environmental or other laws, affecting the product development business;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- 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 in our Annual Report on Form 10-K for the year ended December 31, 2012, our most recent Quarterly Reports on Form 10 Q for the quarter ended March 31, 2013, filed on May 7, 2013, and for the quarter ended June 30, 2013, filed on August 8, 2013, and our other public filings.

In addition, the price of our common stock could also be affected by market factors, including rebalancing of portfolios by institutional investors and resetting of indexes. Our common stock is listed for quotation on The NASDAQ Capital Market. During the twelve month period ended September 30, 2013, the price of our common stock ranged from \$1.50 to \$3.29. 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 September 30, 2013, the average daily trading volume in our common stock was approximately 374,555 shares and the average number of transactions per day was approximately 1,081. 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 we may face in the future are ultimately determined to be meritless or unsuccessful, they involve substantial costs and a diversion of management attention and resources, which could negatively impact our business.

# If we raise additional capital in the future, your ownership in us could be diluted.

Any issuance of equity we may undertake in the future to raise additional capital could cause the price of our common stock to decline, or require us to issue shares at a price that is lower than that paid by holders of our common stock in the past, which would result in those newly issued shares being dilutive. If we obtain funds through a credit facility or through the issuance of debt or preferred securities, these securities would likely have rights senior to your rights as a common shareholder, which could impair the value of our common stock.

## A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and all of the shares sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act unless these shares are purchased by affiliates. In addition, as of October 25, 2013, 15,669,228 shares of our common stock are issuable upon exercise of outstanding options and warrants granted by us, which also have been registered or registered for resale on registration statements filed with the Securities and Exchange Commission. The outstanding options have a weighted average exercise price of \$7.82 per share and expire through October 2023. The outstanding warrants have a weighted average exercise price of \$4.54 per share and expire between November 2013 and March 2016. If our stock price increases, the holders of such options, warrants and convertible securities may exercise such securities and could sell a large number of these shares into the market. These additional issuances and sales could cause the market price of our common stock to decline. We also have entered into an ATM Program with Stifel, under which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell until February 11, 2016 up to a maximum of \$23,038,092 of shares of our common stock. Use of these equity programs would increase our outstanding shares, which could cause the market price of our common stock to decline.

We cannot predict whether future issuances of shares of our common stock or the availability of shares for resale in the open market will decrease the market price per share of our common stock. Sales of substantial amounts of our shares of common stock in the public market, or even the perception that such sales might occur, could adversely affect the market price of the shares of our common stock.

## Our management will have broad discretion with respect to the use of the proceeds of this offering.

Although we have highlighted the intended use of proceeds for this offering, our management will have broad discretion as to the application of these net proceeds and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds.

## You will experience immediate dilution in the book value per share of the common stock you purchase.

Investors who purchase our common stock in this offering will experience immediate dilution in their net tangible book value per share of \$ . See "Dilution" on page S-10 for a more detailed discussion of the dilution you will incur in this offering.

## USE OF PROCEEDS

The net proceeds from the sale of the common stock offered hereby are estimated to be approximately \$ million, based on an offering price of \$ per share (or approximately \$ million if the underwriters exercise in full its over-allotment option to purchase additional shares of common stock), after deduction of estimated offering expenses and the underwriters' discounts and commissions. We will retain broad discretion over the use of the net proceeds from the sale of our securities offered hereby and the net proceeds from the sales of securities offered by this prospectus supplement and the accompanying prospectus will be used primarily (i) to support the commercial introduction of SURFAXIN® drug product, (ii) to advance our AEROSURF® development program, including our planned phase 2 clinical program and (iii) for general corporate purposes.

The amounts and timing of the expenditures may vary significantly depending on numerous factors, including but not limited to (a) the timing of the FDA's review of the Company's recently-submitted IND for AEROSURF and (i) whether the FDA will agree with the Company's proposed clinical program or require additional preclinical or other development activities prior to initiating a clinical program activities, and (ii) whether the FDA will require changes in the clinical program as proposed, which could result in an increase in the time or investment needed to complete the clinical program as finally approved and (b) the timing of completion of (i) the Company's contract manufacturing organization (CMO), DSM Pharmaceuticals, Inc. ("DSM") efforts to manufacture additional lyophilized KL4 surfactant for use in its AEROSURF phase 2b clinical program, to further develop and scale up manufacture additional lyophilized KL4 surfactant for use in the Planned AEROSURF phase 3 clinical program and, if approved, for commercial supply, and to manufacture additional lyophilized KL4 surfactant for use in the Company's other research and development activities; and (ii) development work to further develop and manufacture additional clinic-ready CAGs for use in the AEROSURF phase 2b and phase 3 clinical programs. Pending the application of the net proceeds, we intend to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

#### DILUTION

The net tangible book value of our common stock on June 30, 2013 was approximately \$16.7 million, or approximately \$0.30 per share. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the aggregate number of shares of common stock outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

After giving effect to the assumed sale of shares of our common stock in this offering at an assumed public offering price equal to \$ per share, and after deducting the underwriting discount and the estimated offering expenses, our pro forma as adjusted net tangible book value on June 30, 2013 would have been approximately \$ million, or approximately \$ per share. This represents an immediate increase in the net tangible book value of \$ per share to existing shareholders and an immediate dilution of \$ per share to new investors purchasing shares of common stock in this offering. The following table illustrates this dilution:

0.30
0.30

If the underwriters exercise in full their option to purchase additional shares at the assumed public offering price of \$ per share, which is the closing price of our common stock on October 25, 2013, the as adjusted net tangible book value after this offering would be \$ per share, representing an increase in net tangible book value of \$ per share to existing shareholders and immediate dilution in net tangible book value of \$ per share to investors participating in this offering at the assumed offering price.

This table does not take into account further dilution to new investors that could occur upon the exercise of outstanding options and warrants having a per share exercise price less than the per share offering price to the public in this offering. As of June 30, 2013, there were 54,788,094 shares of common stock outstanding, which does not include:

- 5,466,783 shares of common stock issuable upon exercise of options outstanding as of June 30, 2013, at a weighted average exercise price of \$8.40 per share;
- 10,290,335 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2013, at a weighted average exercise price of \$4.51 per share;
- 18,936 shares of common stock issuable upon vesting of restricted stock units;
- 153,481 shares of common stock reserved for potential future issuance pursuant to our 401(k) Plan as of June 30, 2013;
- 2,952,808 shares of common stock available for future grant under our 2011 Long-Term Incentive Plan, as amended, as of June 30, 2013; and
- an indeterminate number of shares of common stock issuable under our effective shelf registration statements on Form S-3, including shares of common stock that may be issued under our ATM Program, under which Stifel, as our exclusive agent, at our discretion and at such times that we determine from time to time, may sell until February 11, 2016 up to a maximum of \$23,038,092 of shares of our common stock.

See, "The Offering" at page S-4 for additional information concerning our outstanding shares of common stock and related reserves.

## UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus supplement, the underwriters named below have agreed to purchase, and we have agreed to sell to them, the number of shares at the public offering price, less the underwriting discount, as set forth on the cover page of this prospectus supplement, as indicated below:

Number of Underwriters Shares

Stifel, Nicolaus & Company, Incorporated Piper Jaffray & Co. Lazard Capital Markets LLC Roth Capital Partners, LLC Total:

The underwriters are offering the shares subject to their acceptance of the securities from us and subject to prior sale. The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the shares offered by this prospectus supplement are subject to the approval of certain legal matters by its counsel and to other conditions. The underwriters are obligated to take and pay for all of the shares offered by this prospectus supplement if any such shares are taken.

The underwriters have an option to buy up to additional shares from us to cover sales by the underwriters which exceed the number of shares specified in the table above. The underwriters may exercise this option at any time and from time to time during the 30-day period from the date of this prospectus supplement. If any additional shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriters initially propose to offer the shares directly to the public at the public offering price listed on the cover page of this prospectus supplement. After the initial offering of the shares, the offering price and other selling terms may from time to time be varied by the underwriters.

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent, including the absence of any material adverse change in our business and the receipt of customary legal opinions, letters and certificates.

# **Discount and Expenses**

The following table summarizes the public offering price, underwriting discount and proceeds before expenses to us assuming both no exercise and full exercise of the underwriters' option to purchase additional shares:

		Total	
		Without Over-	With Over-
	Per Share	Allotment	Allotment
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds to us (before expenses)	\$	\$	\$

The expenses of the offering, not including the underwriting discount, payable by us are estimated to be \$185,000, which includes up to \$50,000 that we have agreed to reimburse the underwriters for their out-of-pocket expenses incurred in connection with this offering.

Lazard Frères & Co. LLC referred this transaction to Lazard Capital Markets LLC and will receive a referral fee from Lazard Capital Markets LLC in connection therewith.

## Listing on The NASDAQ Capital Market

Our shares of common stock are listed on The NASDAQ Capital Market under the symbol "DSCO." Our registrar and transfer agent for our common stock is Continental Stock Transfer & Trust Company.

## **No Sales of Similar Securities**

We and each of our executive officers and directors, subject to certain exceptions, have agreed with the underwriters not to dispose of or hedge any of our shares of common stock or securities convertible into or exercisable or exchangeable for common stock for 90 days after the date of this prospectus supplement without first obtaining the written consent of the representatives of the underwriters. However, we may issue securities (i) pursuant to our employee benefit and compensation plans, (ii) pursuant to outstanding options, warrants and rights, (iii) pursuant to the Deerfield Facility, (iv) in connection with strategic alliances involving us and (v) in other cases as specified in the underwriting agreement. In addition, we may sell common stock under the ATM Program commencing 30 days after the date of this prospectus supplement. The 90-day "lock-up" period is subject to extension such that, in the event that either (i) during the last 17 days of the "lock-up" period, we issue an earnings or financial results release or material news or a material event relating to us occurs, or (ii) prior to the expiration of the "lock-up" period, we announce that we will release earnings or financial results during the 16-day period beginning on the last day of the "lock-up" period, then in either case the expiration of the "lock-up" period will be extended until the expiration of the 18-day period beginning on the issuance of the earnings or financial results release or the occurrence of the material news or material event, as applicable, unless the representatives of the underwriters waive, in writing, such an extension. The restrictions described above do not apply to certain transactions by our officers and directors pursuant to any trading plan established pursuant to Rule 10b-5 of the Securities and Exchange Act of 1934.

## **Price Stabilization, Short Positions**

In order to facilitate the offering of the shares, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. The underwriters must close out any short position by purchasing shares of common stock in the open market. A short position may be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchased in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of our common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of our common stock above independent market levels or prevent or slow a decline in the market price of our common stock. The underwriters are not required to engage in these activities, and may end any of these activities at any time.

# **Passive Market Making**

In connection with this offering, the underwriters may engage in passive market-making transactions in our common stock on the NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

# Indemnification

We and the underwriters have agreed to indemnify each other, and we have also agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and liabilities arising from breaches of representations and warranties contained in the underwriting agreement. We have also agreed to contribute to payments the underwriters may be required to make in respect of such liabilities.

# **Electronic Distribution**

A prospectus in electronic format may be made available on websites maintained by the underwriters. The underwriters may agree to allocate a number of shares to other underwriters for sale to its online brokerage account holders. Internet distributions will be allocated by the underwriters on the same basis as other allocations.

# **Certain Relationships**

The underwriters are their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses. Stifel acts as our sales agent under the ATM Program.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve our securities and/or instruments. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

# **United Kingdom**

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (e) of the Order (all such persons together being referred to as "relevant persons"). The shares are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such shares will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

The underwriters have represented and agreed that:

- (a) they have only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 or FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to us, and
- (b) they have complied with, and will comply with all applicable provisions of FSMA with respect to anything done by them in relation to the shares in, from or otherwise involving the United Kingdom.

#### **European Economic Area**

To the extent that the offer of the shares is made in any Member State of the European Economic Area (EEA) that has implemented the Prospectus Directive before the date of publication of a prospectus in relation to the shares which has been approved by the competent authority in the Member State in accordance with the Prospectus Directive (or, where appropriate, published in accordance with the Prospectus Directive and notified to the competent authority in the Member State in accordance with the Prospectus Directive), the offer (including any offer pursuant to this document) is only addressed to qualified investors in that Member State within the meaning of the Prospectus Directive or has been or will be made otherwise in circumstances that do not require us to publish a prospectus pursuant to the Prospectus Directive.

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), the underwriters have represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the "Relevant Implementation Date") they have not made and will not make an offer of shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that they may, with effect from and including the Relevant Implementation Date, make an offer of shares to the public in that Relevant Member State at any time:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities,
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts, or
- (c) in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive. For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC, (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State. The expression "2010 PD Amending Directive" means Directive 2010/73/EU.

The EEA selling restriction is in addition to any other selling restrictions set out below. In relation to each Relevant Member State, each purchaser of shares (other than the underwriters) will be deemed to have represented, acknowledged and agreed that it will not make an offer of shares to the public in any Relevant Member State, except that it may, with effect from and including the date on which the Prospectus Directive is implemented in the Relevant Member State, make an offer of shares to the public in that Relevant Member State at any time in any circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive, provided that such purchaser agrees that it has not and will not make an offer of any shares in reliance or purported reliance on Article 3(2)(b) of the Prospectus Directive. For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Relevant Member State has the same meaning as in the preceding paragraph.

## **LEGAL MATTERS**

The validity of the issuance of the securities offered hereby will be passed upon by Dentons US LLP, New York, New York. LeClairRyan, A Professional Corporation, Newark, New Jersey, is acting as counsel for the underwriters in connection with this offering.

## **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2012, and the effectiveness of our internal control over financial reporting as of December 31, 2012, as set forth in their reports which are incorporated by reference in this prospectus and elsewhere in the registration statement. The report on our consolidated financial statements for the year ended December 31, 2012 contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 2 to the consolidated financial statements. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's reports, given on their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and periodic reports, proxy statements and other information with the SEC. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of our SEC filings are also available to the public from the SEC's Website at "http://www.sec.gov." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to ir@DiscoveryLabs.com or contact John Tattory, our Vice President, Finance, at the following address or telephone number: Discovery Laboratories, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, Attention: John Tattory; (215) 488-9300. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

Our company maintains websites at www.discoverylabs.com, www.surfaxin.com and www.afectair.com. Information contained in, or accessible through, our website does not constitute a part of this prospectus supplement or the accompanying prospectus.

# INCORPORATION BY REFERENCE

We have filed with the Securities and Exchange Commission a registration statement on Form S-3 under the Securities Act relating to the common stock we are offering by this prospectus supplement. The SEC allows us to "incorporate by reference" the information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement, and information that we file later with the SEC will automatically update and supersede information in this prospectus supplement. We incorporate by reference the documents listed below and any future filings we make with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, until this offering is completed:

- 1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed on March 15, 2013;
- 2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, filed on May 7, 2013;

- 3. Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed on August 8, 2013;
- 4. Our Current Reports on Form 8-K filed with the SEC on February 13, 2013 (as amended by our Current Report on Form 8-K/A filed with the SEC on June 14, 2013), April 2, 2013, April 15, 2013, May 7, 2013 (excluding the matters in Item 2.02 and any information pertaining to such Item in Exhibit 99.1 therein, which are not incorporated by reference herein), May 10, 2013 (excluding Exhibits 5.1 and 23.1 therein, which are not incorporated by reference herein), May 31, 2013, June 10, 2013, June 11, 2013 (as amended by our Current Report on Form 8-K/A filed with the SEC on October 25, 2013), August 8, 2013 (excluding the matters in Item 2.02 and any information pertaining to such Item in Exhibit 99.1 therein, which are not incorporated by reference herein), October 4, 2013 and October 17, 2013 (excluding the matters in Item 7.01 and any information pertaining to such Item in Exhibit 99.1 therein, which is not incorporated by reference herein); and
  - 5. The description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on July 13, 1995.

Furthermore, all reports and other documents subsequently filed (but not furnished) by us with the SEC pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 prior to the termination of this offering shall be deemed to be incorporated by reference in this prospectus supplement and to be a part of this prospectus supplement from the date of filing of such reports and documents. We are not incorporating by reference any documents or portions thereof that are not deemed "filed" with the SEC, including information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K. Any statement contained in any document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus supplement modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

This prospectus supplement and the accompanying prospectus are only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus supplement and the accompanying prospectus. Statements contained in this prospectus supplement as to the contents of any contract or other document are qualified by reference to the copy of that contract or document filed as an exhibit to the registration statement or that will be filed as an exhibit to the current report on Form 8-K upon completion of this offering.

Each person to whom a copy of this prospectus supplement is delivered may request a copy of any or all of the information incorporated by reference in this prospectus supplement, including the exhibits to any filings incorporated by reference herein, from us, at no charge, or from the Securities and Exchange Commission in the above described manner.

## \$200,000,000



Debt Securities, Preferred Stock, Common Stock, Debt Warrants and Equity Warrants

We may sell from time to time in one or more offerings up to \$200,000,000 in the aggregate of:

- · our secured or unsecured debt securities, in one or more series, which may be either senior, senior subordinated or subordinated debt securities;
- · shares of our preferred stock in one or more series;
- · shares of our common stock;
- debt warrants:
- · equity warrants; and
- · any combination of the foregoing.

When we decide to sell particular securities, we will provide you with the specific terms and the public offering price of the securities we are then offering in one or more prospectus supplements to this prospectus. The prospectus supplement may add to, change or update information contained in this prospectus. The prospectus supplement may also contain important information about U.S. federal income tax consequences. You should carefully read this prospectus, together with any prospectus supplements and information incorporated by reference in this prospectus and any prospectus supplements, before you decide to invest. This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

Our common stock is quoted on The Nasdaq Capital Market® under the trading symbol "DSCO." Any common stock sold pursuant to this prospectus or any prospectus supplement will be listed on that exchange, subject to official notice of issuance. Each prospectus supplement to this prospectus will contain information, where applicable, as to any other listing on any national securities exchange of the securities covered by the prospectus supplement.

The aggregate market value of our outstanding common stock held by non-affiliates is  $\{\cdot\}$  based on  $[\cdot]$  shares of outstanding common stock, of which  $[\cdot]$  are held by non-affiliates, and a per share price of \$2.45 based on the closing sale price of our common stock on May 31, 2011. We have not offered any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on and includes the date of this prospectus.

Investing in our securities involves significant risks. See "Risk Factors" beginning on page 2.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 21, 2011.

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This prospectus is part of a registration statement we filed with the Securities and Exchange Commission. You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with additional or different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the prospectus.

## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the "SEC") utilizing a "shelf" registration process or continuous offering process, which allows us to offer and sell any combination of the securities described in this prospectus in one or more offerings. Using this prospectus, we may offer up to a total dollar amount of \$200,000,000 of these securities.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities pursuant to this registration statement and the prospectus contained herein, we will provide a prospectus supplement that will contain specific information about the terms of that offering. That prospectus supplement may include additional risk factors about us and the terms of that particular offering. Prospectus supplements may also add to, update or change the information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in such prospectus supplement. In addition, as we describe in the section entitled "Where You Can Find More Information," we have filed and plan to continue to file other documents with the SEC that contain information about us and the business conducted by us and our subsidiaries. Before you decide whether to invest in any of these securities, you should read this prospectus, the prospectus supplement that further describes the offering of these securities and the information we file with the SEC.

In this prospectus and any prospectus supplement, unless otherwise indicated, the terms "Discovery", "the Company", "we", "us" and "our" refer and relate to Discovery Laboratories, Inc., and its consolidated subsidiaries.

#### ABOUT DISCOVERY

Discovery Laboratories, Inc. is a specialty biotechnology company developing surfactant therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Our novel proprietary KL<sub>4</sub> surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol and lyophilized formulations. We are also developing our proprietary capillary aerosolization technology and novel patient interfaces to enable efficient, targeted upper respiratory or alveolar delivery of aerosolized KL<sub>4</sub> surfactant. We believe that our proprietary technologies make it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

We are developing our lead products, Surfaxin® (lucinactant), Surfaxin LS<sup>TM</sup> and Aerosurf®, to address the most significant respiratory conditions affecting neonatal populations. Our research and development efforts are currently focused on the management of respiratory distress syndrome (RDS) in premature infants. We have filed a New Drug Application (NDA) for Surfaxin for the prevention of RDS in premature infants, and received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in April 2009 (2009 Complete Response Letter). The safety and efficacy of Surfaxin for the prevention of RDS in premature infants has previously been demonstrated in a large, multinational Phase 3 clinical program. We believe that a key remaining step to potentially gain U.S. marketing approval is to satisfy the FDA as to the final validation of an important quality control release and stability test for Surfaxin, the fetal rabbit Biological Activity Test (BAT). We have been conducting a comprehensive preclinical program intended to satisfy the FDA's requirements with respect to the BAT. If successful, we believe that we could be in a position to file a Complete Response in the third quarter of 2011, which could lead to approval of Surfaxin for the prevention of RDS in premature infants in the first quarter 2012.

We are developing Surfaxin LS, our initial lyophilized KL4 surfactant, and Aerosurf, our initial aerosolized KL4 surfactant, for the prevention and/or treatment of RDS in premature infants in both the United States and in other major markets worldwide. In addition to our lead products, we plan over time to develop our KL4 surfactant technology into a broad product pipeline that potentially will address a variety of debilitating respiratory conditions for which there currently are no or few approved therapies, in patient populations ranging from premature infants to adults. We are conducting research and preclinical development with our KL4 surfactant potentially to address Acute Lung Injury (ALI), and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and Chronic Obstructive Pulmonary Disease (COPD). We have conducted and are planning in the future to conduct additional exploratory preclinical studies to assess the feasibility of using our KL4 surfactant in combination with small and large molecule therapeutics to deliver therapies to the lung to treat a range of pulmonary conditions and disease.

We are also developing our aerosol delivery technology platform, including our proprietary capillary aerosolization technology and novel patient interfaces. Our capillary aerosolization device has the potential to enable targeted upper respiratory or alveolar delivery of therapies for pulmonary applications and has been initially designed to produce high quality, low-velocity aerosolized KL4 surfactant for intra-pulmonary delivery. Our proprietary patient interface technology has the potential to increase the efficiency of aerosol delivery to the patient, reduce drug wastage, and result in more precise aerosol dosing.

An important priority continues to be to secure strategic and financial resources to potentially maximize the inherent value of our KL4 surfactant technology. We prefer to accomplish our objectives through strategic alliances, including potential business alliances, and commercial and development partnerships. Although we are actively engaged in discussions with potential strategic and/or financial partners, there can be no assurance that any strategic alliance or other financing transaction will be successfully concluded. Until such time as we secure sufficient strategic and financial resources to support the continuing development of our KL4 surfactant technology and support our operations, we will continue to focus on our RDS programs, primarily Surfaxin, and conserve our resources, predominantly by curtailing and pacing investments in our other pipeline programs.

## **Corporate Information**

Surfaxin<sup>®</sup>, Surfaxin LS<sup>TM</sup> and Aerosurf<sup>®</sup> are our trademarks. This prospectus also includes product names, trademarks and trade names of other companies, which names are the exclusive property of the holders thereof.

We maintain our principal offices and research at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976. Our telephone number is 215-488-9300. Our website address is <a href="https://www.discoverylabs.com">www.discoverylabs.com</a>. Information contained in our website is not a part of this prospectus. Our common stock is listed on The Nasdaq Capital Market, where our symbol is "DSCO."

#### RISK FACTORS

An investment in our common stock involves significant risks. You should carefully consider the risks described below or in any applicable prospectus supplement and other information, including our financial statements and related notes previously included in our periodic reports filed with the SEC, and in the documents incorporated therein by reference before deciding to invest in our securities. The risks described below are not the only ones that we face. Additional risks 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 securities would likely decline and you could lose all or part of your investment.

If we do not secure FDA approval of Surfaxin for the prevention of RDS in premature infants during the next review cycle, or if other delays associated with the FDA's review process occur, it could have a material adverse effect on our business, financial condition and results of operations, and make it more difficult to secure required additional capital. Moreover, if Surfaxin is approved, we will need additional capital and/or commercialization resources to support the launch of Surfaxin.

Our ability to execute our business plans is dependent in large part upon our ability to complete the comprehensive preclinical program, file the Complete Response to the 2009 Complete Response Letter and satisfy the FDA as to the anticipated review activities that we expect will occur during the six-month review period. There can be no assurance that the FDA will conclude its review within the anticipated time frame. There can be no assurance that we will secure U.S. marketing approval of Surfaxin as a result of this review, if at all. If we are not successful in gaining approval of Surfaxin, it could have a material adverse effect on our business, financial condition and results of operations.

We believe that we have sufficient capital to fund our planned research and development activities to the end of the second quarter of 2012. Our plans include activities to potentially advance Surfaxin LS and Aerosurf towards planned Phase 3 and Phase 2 clinical trials, filing the Complete Response in the third quarter of 2011 and the potential approval of Surfaxin, which we anticipate could occur in the first quarter of 2012. If we are unable to secure the approval of Surfaxin within this time frame, we will have to seek new capital to continue our operations. Such capital could take the form of strategic partnerships, alliances or financings and other similar transactions. However, if we do not secure FDA marketing approval for Surfaxin, we believe that it may be more difficult to identify strategic partnerships, alliances or financings on terms that are favorable to us, if at all, than it would be if we were to secure FDA approval for Surfaxin. If we are unable to secure additional capital on terms that are acceptable to us, our business would be harmed. See, "— The 2009 Complete Response Letter and the resulting delay in our gaining approval of Surfaxin has caused us to make fundamental changes in our business strategy and to take steps to conserve our financial resources, which may expose us to unanticipated risks and uncertainties. We plan to continue assessing our regulatory position and available resources and may implement at any time additional and potentially significant changes to our business strategy, development programs and our operations, which, if adopted, could prove to be disruptive and detrimental to our development programs."

Moreover, as we conserve our resources pending the potential approval of Surfaxin, we have made only limited investments in preparing for the potential commercialization of Surfaxin. Therefore, if we succeed in gaining U.S. marketing approval for Surfaxin, we will need additional capital and or commercialization resources, through strategic partnerships, marketing alliances or other transactions, to fund the commercialization activities associated with the launch of our drug product. If we are unable to secure a strategic partnership, marketing alliance or other similar transaction that would provide for the commercialization of Surfaxin, or if we are unable to secure additional capital to build our own commercial organization, even if we succeed in gaining approval of Surfaxin, we may be unable to launch our product and therefore, could be unable to generate revenues from our approved product to support our business. *See*, "— We currently have limited expertise in marketing or selling pharmaceutical products and limited marketing capabilities, which may restrict our success in commercializing our product candidates. To launch our drug product candidates, if approved, we plan to seek third-party distribution arrangements and marketing alliances, which could require us to give up rights to our drug product candidates. As we continue to assess our business and regulatory position, we may also choose to develop our own sales and marketing capability to launch our products in the United States, which could increase the cost to commercialize our products."

## We may not successfully develop and market our products, and even if we do, we may not become profitable.

We currently have no products approved for marketing and sale and are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products. Our long-term viability will be impaired if we are unable to obtain regulatory approval for, or successfully market, our product candidates. Even if we successfully develop and gain regulatory approval for our products, we still may not generate sufficient or sustainable revenues or we may not become profitable. In addition, even after making significant investments, preclinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products.

As of December 31, 2010, we have an accumulated deficit of approximately \$376.5 million and we expect to continue to incur significant, increasing operating losses over the next several years. To date, we have generated capital to support our activities primarily from equity financings, research grants, collaboration agreements, and investments. Our ability to operate our business and continue our activities is dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, through strategic alliances and other financing alternatives, we will likely not have sufficient cash flow and liquidity to fund our business operations, forcing us to curtail our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the market price of our common stock may decline.

In addition, depending on conditions in the global financial markets, we may face significant challengers accessing the capital markets when we would like or require, and an increased cost of capital. Except for our Committed Equity Financing Facilities (CEFFs) (which are subject to certain limitations), we currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. In any such event, the market price of our common stock may decline. In addition, failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan, financial performance and stock price and could delay new product development and clinical trial plans.

The regulatory approval process for our products is expensive and time-consuming and the outcome is uncertain. We may not obtain required regulatory approvals to commercialize our products.

To test, make and sell our products under development, including Surfaxin, we must receive regulatory approvals for each product. The FDA and foreign regulators, such as the European Medicines Agency (EMA), extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products. This approval process includes (i) preclinical studies and clinical trials of each drug product candidate and active pharmaceutical ingredient to establish its safety and effectiveness, and (ii) confirmation by the FDA and foreign regulators that we maintain good laboratory and manufacturing practices during testing and manufacturing. Even if favorable data are generated by clinical trials, the FDA or foreign regulator may not accept or approve an NDA or MAA filed for a drug product on a timely basis or at all.

In particular, we filed with the FDA an NDA for Surfaxin for the prevention of RDS in premature infants. In April 2009, we received a Complete Response Letter for this NDA. We have interacted with the FDA on multiple occasions to discuss and clarify proposals to resolve a key remaining issue that relates to the ability of our optimized BAT to adequately reflect the biological activity of Surfaxin throughout its shelf life and to discriminate biologically active from inactive Surfaxin drug product. We are currently conducting a comprehensive preclinical program that consists of a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and the well-established preterm lamb model of RDS. The FDA indicated that to gain approval of Surfaxin, data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. These studies are intended to demonstrate comparability of drug product used in the Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use, and will also be used to gain the FDA's agreement on final acceptance criteria, with respect to biological activity as assessed by the BAT, for release and ongoing stability of Surfaxin drug product. Even if we believe that our side-by-side studies are successful, the FDA may not accept the results or may interpret the data in a different manner. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to secure FDA approval or further delay associated with the FDA's review process with respect to Surfaxin could potentially delay or prevent the approval of our other products and would have a material adverse effect on our business.

Even assuming that we gain regulatory approval to market our drugs, if the FDA and foreign regulators later withdraw their approval or otherwise restrict marketing, our business would be materially harmed.

The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. Without regulatory approval, we will not be able to market our products. Even if we were to succeed in gaining regulatory approvals for any of our products, the FDA or a foreign regulator could at any time withdraw any approvals granted if there is a later discovery of previously unidentified problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, or the FDA or a foreign regulator may restrict or delay our marketing of a product, including by requiring us to include warnings and other restrictions in the package inserts for our products, or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. Any withdrawal of our regulatory approval or significant restriction on our ability to market our products after approval would have a material adverse effect on our business.

The 2009 Complete Response Letter and the resulting delay in our gaining approval of Surfaxin has caused us to make fundamental changes in our business strategy and to take steps to conserve our financial resources, which may expose us to unanticipated risks and uncertainties. We plan to continue assessing our regulatory position and available resources and may implement at any time additional and potentially significant changes to our business strategy, development programs and our operations, which, if adopted, could prove to be disruptive and detrimental to our development programs.

Prior to receipt of the 2009 Complete Response Letter, we planned to establish our own commercialization organization. To conserve cash resources following receipt of the 2009 Complete Response Letter, we implemented cost-containment measures and reduced our workforce, which primarily affected our commercial organization.

The delay in gaining approval of Surfaxin also caused us to evaluate our business strategy and implement fundamental changes. To secure capital and to develop and, if approved, commercialize our KL4 surfactant drug products, we have since focused on identifying potential strategic alliances, development agreements or other collaboration arrangements to develop and commercialize our products in all markets. We have also considered various other financial alternatives that could potentially provide infusions of capital and other resources needed to advance our KL4 respiratory pipeline programs, meet our capital requirements and continue our operations. Although we continue to consider potential opportunities, there can be no assurance that any strategic alliance or other financing alternatives will be successfully concluded. We plan to continue assessing our regulatory position and available resources with a view to maintaining and strengthening our financial and operational position and, as a result, may implement at any time additional and potentially significant changes to our business strategy, development programs and our operations. Such changes, if adopted, could prove to be disruptive and detrimental to our development programs. Moreover, consideration and planning of such strategic changes diverts management's attention and other resources from day-to-day operations, which may subject us to further risks and uncertainties.

If we succeed in entering into one or more strategic alliances, our ability to execute our current operating plan will depend upon numerous factors, including, the performance of the strategic partners and collaborators with whom we may contract. Under these arrangements, our partners may control key decisions relating to the development, and assuming approval, commercialization, of our products. Such rights of our partners would limit our flexibility in considering development strategies and in commercializing our products. In addition, if we breach or terminate our strategic alliance agreements or if our strategic partners otherwise fail to conduct their activities in a timely manner, or if there is a dispute about our respective obligations, we may need to seek other partners or, in the alternative and after a potentially unacceptable delay, develop our own internal sales and marketing capabilities to commercialize our products in the United States. If we fail to successfully develop these relationships, or if we or our partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of our products.

For example, our collaboration arrangement with Laboratorios del Dr. Esteve, S.A. (Esteve) for Surfaxin and certain other of our drug product candidates is focused on key southern European markets. If we or Esteve should fail to conduct our respective collaboration-related activities in a timely manner, or otherwise breach or terminate the agreements that make up our collaboration arrangements, or if a dispute should arise under our collaboration arrangements, such events could impair our ability to commercialize or develop our products for the Esteve territory in Europe. In that event, we may need to seek other partners and collaboration arrangement, or we may have to develop our own internal capabilities to market the covered products in the Esteve territory without a collaboration arrangement.

As we continue to manage our cash resources and work to secure additional capital while we continue our efforts to potentially gain approval of Surfaxin the United States, we have limited our level of investment in, and have slowed the pace of, our research and development programs to address RDS, including for Surfaxin LS and Aerosurf. Such reductions in investment will cause us to experience delays in the progress of our programs and will lengthen the time to potentially gain approval of our product candidates.

Even though some of our product candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other product candidates that do not qualify for expedited review.

The FDA has notified us that two indications of our KL4 surfactant technology pipeline, Bronchopulmonary Dysplasia (BPD) in premature infants and Acute Respiratory Distress Syndrome (ARDS) in adults, have been granted designation as "Fast Track" products under provisions of the Food and Drug Administration Modernization Act of 1997. We believe that other potential products in our KL4 surfactant technology pipeline may also qualify for Fast Track designation. Fast Track designation does not accelerate clinical trials nor does it mean that the regulatory requirements are less stringent. Our products may cease to qualify for expedited review and our other product candidates may fail to qualify for Fast Track designation or expedited review. Moreover, even if we are successful in gaining Fast Track designation, other factors could result in significant delays in our development activities with respect to our Fast Track products.

Our research and development activities involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes.

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

- complete our preclinical and clinical trials of our KL4 surfactant product candidates with scientific results that are sufficient to support further development and regulatory approval;
- receive the necessary regulatory approvals;
- obtain adequate supplies of surfactant active drug substances, manufactured to our specifications and on commercially reasonable terms;
- perform under agreements to supply drug substances, medical device components and related services necessary to manufacture our KL4 surfactant product candidates, including Surfaxin, Surfaxin LS and Aerosurf;
- resolve to the FDA's satisfaction the matters identified in the 2009 Complete Response Letter for Surfaxin for the prevention of RDS in premature infants;
- provide for sufficient manufacturing capabilities, at our manufacturing operations in Totowa and with third-party contract manufacturers, to produce sufficient drug product, including Surfaxin and Surfaxin LS, and our proprietary capillary aerosolization systems and novel patient interfaces and related materials to meet our preclinical and clinical development requirements;
- obtain the capital necessary to fund our research and development efforts, including our business administration, preclinical and clinical organizations, and our quality and manufacturing operations.

Because these factors, many of which are outside our control, could have a potentially significant impact on our development activities, the success, timing of completion and ultimate cost of development of any of our product candidates is highly uncertain and cannot be estimated with any degree of certainty. The timing and cost to complete drug trials alone may be impacted by, among other things:

- slow patient enrollment;
- long treatment time required to demonstrate effectiveness;
- lack of sufficient clinical supplies and material;
- adverse medical events or side effects in treated patients;
- lack of compatibility with complementary technologies;
- failure of a drug product candidate to demonstrate effectiveness; and
- lack of sufficient funds.

If we do not successfully complete clinical trials, we will not receive regulatory approval to market our KL4 surfactant products. Failure to obtain and maintain regulatory approval and generate revenues from the sale of our products would have a material adverse effect on our financial condition and results of operations and likely reduce the market value of our common stock.

#### Our clinical trials may be delayed, or fail, which will harm our business.

We have completed our Phase 3 clinical trials for Surfaxin for the prevention of RDS in premature infants and certain Phase 2 trials for other drug product candidates for other indications. If we successfully advance our other KL4 surfactant development programs through the initial preclinical phase of development, we plan to conduct Phase 2 and/or Phase 3 clinical trials after we have secured adequate capital to support that activity. Such clinical trials generally take two to five years or more to complete and may be delayed by a number of factors. We may not reach agreement with the FDA or a foreign regulator on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and foreign regulators on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Like many biotechnology companies, even after obtaining promising results in earlier trials or in preliminary findings for such clinical trials, we may suffer significant setbacks in late-stage clinical trials. Data obtained from clinical trials are susceptible to varying interpretations that may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials. The timing and completion of current and planned clinical trials of our product candidates depend on many factors, including the rate at which patients are enrolled. Delays in patient enrollment in clinical trials may occur, which would be likely to result in increased costs, program delays, or both.

Patient enrollment is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility and enrollment criteria for the study;
- the willingness of patients or their parents or guardians to participate in the clinical trial;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

If we succeed in achieving our patient enrollment targets, patients that enroll in our clinical trials could suffer adverse medical events or side effects that are known, such as a decrease in the oxygen level of the blood upon administration, or currently unknown to us. It is also possible that we, our Scientific Advisory Board (SAB), the trial Safety Monitoring Committee (SMC), the FDA or foreign regulators could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If we, our SAB, the SMC or any regulator believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. In addition, clinical trials may be interrupted, delayed or halted, in whole or in part, for reasons other than health and safety concerns, including, among other things, matters related to the design of the study, drug availability, SAB and/or SMC recommendation, or business reasons.

In addition to our efforts to gain approval of Surfaxin for the prevention of RDS in premature infants, we have completed a Phase 2 clinical trial to evaluate the use of Surfaxin in children up to two years of age suffering from Acute Respiratory Failure and our aerosolized KL4 surfactant was the subject of an investigator-initiated Phase 2a trial assessing the safety, tolerability and short-term effectiveness of aerosolized KL4 surfactant in patients with CF. We are also planning to initiate clinical studies in support of other products in our KL4 surfactant technology pipeline. 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.

Manufacturing problems potentially could cause us to delay preclinical or clinical programs, or, if our products are approved, product launch, or cause us to experience shortages of product inventories, which could have a material adverse effect on our business.

The manufacture of pharmaceutical products requires significant expertise and compliance with strictly enforced federal, state and foreign regulations. We, our contract manufacturers or our materials and drug substances suppliers may experience manufacturing or quality control problems that could result in a failure to maintain compliance with the FDA's current good manufacturing practices (cGMP) requirements, or those of foreign regulators, which is necessary to continue manufacturing our drug products, materials or drug substances. Other problems that may be encountered include:

- the need to make necessary modifications to qualify and validate a facility;
- difficulties with production and yields, including manufacturing and completing all required release testing on a timely basis to meet demand;
- availability of raw materials and supplies;
- quality control and assurance;
- casualty damage to a facility; and
- shortages of qualified personnel.

Such a failure could result in production and shipment delays of our products or an inability to obtain materials or drug substance supplies.

For example, we manufacture our Surfaxin drug product at our facility in Totowa, New Jersey. In December 2010, we began manufacturing additional Surfaxin batches for use in the comprehensive preclinical program. We routinely employ an array of quality control and release tests to assess each of the batches we produce. In January 2011, quality control testing performed by us indicated that two newly-manufactured Surfaxin batches did not meet one of the pre-specified release specifications and, therefore, cannot be used in the comprehensive preclinical program. We are continuing to manufacture additional Surfaxin batches to support the Complete Response and, at the same time, in accordance with our quality assurance procedures and pharmaceutical manufacturing practices, we are conducting an investigation into the manufacture of the Surfaxin batches that did not meet specification to determine the probable cause. We have manufactured eight additional Surfaxin batches that continue to meet specifications and can be used for the comprehensive preclinical program. We currently plan to manufacture two additional Surfaxin batches and, if successful, we believe that we could file a Complete Response to the 2009 Complete Response Letter in the third quarter of 2011. After an anticipated six-month FDA review cycle, which is expected to include, among other things, pre-approval inspections of our manufacturing facility, quality assurance / quality control facilities, third-party raw material suppliers and testing laboratories, we anticipate the potential marketing approval of Surfaxin for the prevention of RDS in premature infants in the United States as early as the first quarter of 2012. However, there can be no assurance, however, that we will be able to complete the manufacture of the requisite number of batches as planned or that other batches that we manufacture will not fail to meet all release or stability specifications. There can also be no assurance that our ongoing investigation will establish a probable cause

Furthermore, to manufacture the requisite number of Surfaxin batches needed to complete the comprehensive preclinical program, we have had, and may again need, to purchase additional supplies of drug product substances and excipients, which could involve order lead times and acceptance testing activities and result in further delays. If any of the current or additional batches that we plan to manufacture for use in the comprehensive preclinical program do not meet all release and stability specifications, we will have to initiate additional investigations to determine the probable cause of any such failures, which could have a material, adverse effect on our ability to gain regulatory approval of Surfaxin. Failure to complete the manufacture of a sufficient number of batches to potentially satisfy the FDA could result in further delays of the filing of our Complete Response, which would have a material adverse effect on our business.

Manufacturing or quality control problems have occurred in the past and may again occur at our facility in Totowa, New Jersey, or may occur at the facilities of a contract manufacturer of our drug substances and materials suppliers. Such problems may require potentially complex, time-consuming and costly comprehensive investigations to determine the root causes of such problems and may also require detailed and time-consuming remediation efforts, which can further delay a return to normal manufacturing and production activities. Any failure by our own manufacturing operations or by the manufacturing operations of any of our suppliers to comply with cGMP requirements or other FDA or similar foreign regulatory requirements could adversely affect our ability to manufacture our drug products, which in turn would adversely affect our clinical research activities and our ability to develop and gain regulatory approval to market our drug products.

We currently do not have a back-up facility. Any interruption of our manufacturing operations at Totowa, NJ, could result in a shortage of drug supply for use in preclinical and clinical activities and, if approved, to satisfy commercial requirements for Surfaxin. A number of factors could cause interruptions, including:

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

In connection with our manufacturing activities, we own certain specialized manufacturing equipment, employ experienced manufacturing senior executive and managerial personnel, and continue to invest in enhanced quality systems and manufacturing capabilities. However, we do not have fully-redundant systems and equipment to respond promptly in the event of a significant loss at our manufacturing operations. We may under certain conditions be unable to produce Surfaxin and our other KL<sub>4</sub> surfactant product candidates at the required volumes or to appropriate standards, if at all. If we are unable to successfully develop and maintain our manufacturing capabilities and at all times comply with cGMP, it will adversely affect our clinical development activities and, potentially, the sales of our products, if approved.

If the parties we depend on for supplying our active drug substances, materials and excipients as well as manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.

We rely on suppliers for our active drug substances, materials and excipients, and third parties for certain manufacturing-related services to manufacture drug product that meets appropriate content, quality and stability standards for use in preclinical programs and clinical trials and, if approved, for commercial distribution. Our ability to manufacture depends upon receiving adequate supplies and related services, which may be difficult or uneconomical to procure. The manufacturing process for Aerosurf, a combination drug-device product, includes the integration of a number of component parts, many of which are comprised of a large number of subcomponent parts that we expect we will purchase from a potentially large number of manufacturers. We and our suppliers may not be able to (i) produce our drug substances, or manufacture materials and excipients or our drug product, or capillary aerosolization systems subcomponent parts or integrated devices, including our novel patient interfaces, to appropriate standards for use in our preclinical programs or clinical studies, (ii) comply with manufacturing specifications under any definitive manufacturing, supply or services agreements with us, or (iii) maintain relationships with our suppliers and service providers for a sufficient time to successfully produce and market our product candidates.

In some cases, we are dependent upon a single supplier to provide all of our requirements for one or more of our drug substances, materials and excipients or one or more of our drug product device subcomponents, components and subassemblies. To assure compliance with cGMP requirements, we have entered into Quality Agreements with all of our suppliers of active drug substances and related materials. However, we have a requirements contract relating to continued access to active drug substances with only one of three providers of our drug substances. If we do not maintain manufacturing and service relationships that are important to us and are not able to identify a replacement supplier or vendor or develop our own manufacturing capabilities, our ability to obtain regulatory approval for our products could be impaired or delayed and our costs could substantially increase. Even if we are able to find replacement manufacturers, suppliers and vendors when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. Such delays could have a material adverse effect on our development activities and our business.

Failure to develop our capillary aerosolization technology, patient interface technology and related componentry in a timely manner, if at all, would have a material adverse effect on our efforts to develop aerosolized KL4 surfactant and our business strategy.

Since early 2008, we have been responsible for development of our proprietary capillary aerosolization technology, including finalizing the design of an optimized capillary aerosolization device and disposable dose packets that are suitable for use in our planned Phase 2 and Phase 3 clinical trials. Our development activities are subject to certain risks and uncertainties, including, without limitation:

- We may not successfully develop an optimized prototype capillary aerosolization system that is suitable for use in a clinical environment, if at all, on a timely basis and such inability may delay or prevent initiation of our planned clinical trials.
- We will require access to sophisticated engineering capabilities. Our plans include our medical device engineering staff working with leading medical device development engineers and medical device design experts that have a successful track record of developing innovative devices for the medical and pharmaceutical industries. If we are unable to identify design engineers and medical device experts to support our development efforts, including for the optimized prototype capillary aerosolization system and novel patient interfaces for use in our planned clinical trials and, potentially, for later development versions of the capillary aerosolization systems, it would impair our ability to commercialize or develop our 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 the necessary medical device development expertise. There can be no assurance, however, that we will successfully identify or be able to enter into agreements with such potential partners or collaborators on terms and conditions that are favorable to us. If we are unable to secure the necessary medical device development expertise to support our development program, this could impair our ability to commercialize or develop our aerosolized KL4 surfactant.

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

If we fail to identify or maintain relationships with manufacturers, assemblers and integrators of our capillary aerosolization systems or subcomponents, the timeline of our plans for the development and, if approved, commercialization of our aerosolized KL<sub>4</sub> surfactant, including Aerosurf, could suffer.

In connection with the development of our aerosolized KL4 surfactant, including Aerosurf, which is a drug/device combination product, we currently plan to rely on third-party contract manufacturers to manufacture and assemble the subcomponents of our capillary aerosolization technology and to assemble and integrate the component parts to support our preclinical experiments, planned clinical studies and potential commercialization of Aerosurf. Certain of these components must be manufactured in an environmentally-controlled area and, when assembled, the critical drug product-contact components and patient interface systems must be packaged and sterilized. Each of the aerosolization system devices must be quality-control tested prior to release and monitored for conformance to designated product specification.

We have worked with selected component manufacturers and an integrator to manufacture and integrate our initial prototype capillary aerosolization system. We are currently focused on developing an optimized capillary aerosolization device and patient interfaces to meet regulatory and ease-of-use design requirements for Aerosurf and prepare for potential Phase 2 clinical trials. However, as with many device development initiatives, there is a risk that we will not be successful in our development efforts and that the manufacturers and integrator that we identify may not be able to consistently manufacture and integrate, if at all, the subcomponents of our capillary aerosolization systems to our specified standards. In addition, we may not be able to identify qualified additional or replacement manufacturers and integrators to manufacture subcomponents and integrate our optimized capillary aerosolization system and, if developed, later versions of our capillary aerosolization systems, or we may not be able to enter into agreements with them on terms and conditions favorable and acceptable to us. In addition, the manufacturers and assemblers and integrators 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, assemblers and integrators that have the required expertise to produce our capillary aerosolization systems as and when needed, it will adversely affect our timeline for the development and, if approved, commercialization of our aerosolized KL4 surfactant, including Aerosurf.

We currently have limited expertise in marketing or selling pharmaceutical products and limited marketing capabilities, which may restrict our success in commercializing our product candidates. To launch our drug product candidates, if approved, we plan to seek third-party distribution arrangements and marketing alliances, which could require us to give up rights to our drug product candidates. As we continue to assess our business and regulatory position, we may also choose to develop our own sales and marketing capability to launch our products in the United States, which could increase the cost to commercialize our products.

We have limited experience in marketing or selling pharmaceutical products and have limited marketing capabilities. Following receipt of the 2009 Complete Response Letter, we assessed our regulatory and financial position and determined that it would be in our best interest to seek to commercialize our drug product candidates, if approved, through one or more strategic alliances rather than through our own commercial organization. Such alliances could take a number of forms. We may rely on third-party distributors to distribute, or enter into marketing alliances to sell, our products internationally and potentially also in the United States. We may not be successful in identifying such third parties or finalizing such arrangements on terms and conditions that are favorable to us and, as a result, we may not be able to commercialize our drug product candidates on a timely basis. If we enter into distribution arrangements and marketing alliances to commercialize our drug product candidates, such arrangements will subject us to a number of risks, including:

- our distributors or collaborators may require that we transfer to them important rights to our products and/or drug product candidates;
- we may not be able to control the amount and timing of resources that our distributors or collaborators devote to the commercialization of our drug product candidates;
- if our distributors or collaborators fail to perform their obligations under our arrangements to our satisfaction, we may not achieve our projected sales and our revenues would suffer. We also may incur additional expense to terminate such arrangements and to identify and enter into arrangements with replacement distributors or collaborators;
- our distributors or collaborators may experience financial difficulties; and
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to perform its obligations under any arrangement, which would adversely affect our business.

If we fail to enter into arrangements with third parties in a timely manner or if such parties fail to perform, it could adversely affect sales of our products. We and our third-party distributors and collaborators must also market our products in compliance with federal, state and local laws related to providing incentives and inducements. Violation of these laws can result in substantial penalties.

If we do not identify third-party distributors, marketing alliances or other arrangements that have terms that are acceptable to us, or if we determine that our business would be better served by retaining the marketing rights to our products and drug product candidates, we may commercialize our drug product candidates ourselves. This approach would likely cause our commercialization costs to increase, but would potentially avoid the transfer of rights to our products or drug product candidates. Developing an internal marketing and sales capability is potentially a difficult, expensive and time-consuming process and requires a substantial capital investment. Recruiting, training and retaining qualified personnel would be critical to our success. Competition for such personnel is intense, and we may be unable to attract and retain a sufficient number of qualified individuals to successfully support the launch and continued distribution of our products. We also may be unable to provide competitive incentive to retain our sales force. If we are unable to successfully attract and motivate a commercial team to support the launch and sale of our products, we would have difficulty selling, maintaining and increasing the sales of our products, which would have a material adverse effect on our business.

Even if we develop an internal commercial organization to support the launch of Surfaxin in the United States, we may also need to enter into co-promotion arrangements with third parties where our own personnel are neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements may not be favorable to us. In addition, if we enter into co-promotion arrangements or market and sell additional products directly, we may need to further expand our commercial staff and incur additional expense.

We plan to market and sell Surfaxin, if approved, in international markets and potentially in the United States through one or more strategic partners or other collaborators. We currently have such an alliance with Esteve for distribution of our KL4 surfactant products in Andorra, Greece, Italy, Portugal and Spain. We have limited influence over the decisions made by Esteve or its sublicensees or the resources that they may devote to the marketing and distribution of Surfaxin 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. Also, we may not be able to enter into marketing and sales agreements for Surfaxin on acceptable terms, if at all, in territories not covered by the Esteve agreement, or for any of our other drug product candidates.

If we fail to establish or secure marketing and sales capabilities or fail to enter into arrangements with third parties in a timely manner or if such third parties fail to perform, it could adversely affect sales of our products. In addition, even if we establish or secure such capabilities, we and any of our third-party collaborators must also market our products in compliance with federal, state and local laws relating to the restrictions on incentives and inducements. Violation of these laws can result in substantial penalties. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, or if our distributors fail to promote our products, we will have difficulty maintaining and increasing the sales of our products.

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

Any potential products that we bring to market may not gain or maintain market acceptance by governmental purchasers, group purchasing organizations, physicians, patients, healthcare payers and others in the medical community. If any products that we develop do not achieve an adequate level of acceptance, we may not generate sufficient revenues to support continued commercialization of these products. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the perceived safety and efficacy of our products;
- the potential advantages over alternative treatments;
- the prevalence and severity of any side effects;
- the relative convenience and ease of administration;
- cost effectiveness;
- the willingness of the target patient population to try new products and of physicians to prescribe our products;
- the effectiveness of our marketing strategy and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

# If we do not adequately forecast customer demand for our product candidates, including Surfaxin, if approved, our business could suffer.

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

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

Until such time as we are able to commercialize any of our lead products, if approved, and generate revenues, we will need substantial additional funding to support our ongoing research and development activities and continue to operate as a going concern. In addition to focusing our resources on potentially gaining approval of Surfaxin, our current plans require that we make prudent investments in our lead drug product and device development programs, Surfaxin LS and Aerosurf, and focus our resources on being in a position to initiate key clinical programs after we have secured the necessary capital to advance these programs to potential approval. We would prefer to accomplish our objectives through strategic alliances and collaboration arrangements. If we are unable to raise substantial additional funds through strategic alliances or other alternatives, including potentially future debt and equity financings, we may be forced to further limit investments in our development programs, which could have a material adverse effect on our business. In the meantime, as we continue to conserve our financial resources, we will likely experience additional delays in our development programs.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, which will likely result in significant legal and accounting expense and diversion of management resources, and current and potential stockholders may lose confidence in our financial reporting and the market price of our stock will likely decline.

We are required by the SEC to establish and maintain adequate internal control over financial reporting that provides reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We are likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses in those internal controls.

In our internal control report for our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, management was unable to conclude that we had maintained effective internal control over financial reporting as of September 30, 2010, and identified a material weakness regarding our process and procedures related to the initial classification and subsequent accounting of registered warrants as liabilities or equity instruments. Upon a reassessment of those financial instruments, in light of generally accepted accounting principles (GAAP) as currently interpreted, we determined that we should have accounted for registered warrants that we issued in May 2009 and February 2010 as derivative liabilities instead of equity. As a result, to reclassify the affected warrants as derivative liabilities, in November 2010, we restated our consolidated financial statements for the periods ended beginning June 30, 2009 through June 30, 2010. The process to restate our financial statements was highly time-consuming, resource-intensive and involved substantial attention from management and significant legal and accounting expense.

To remediate the identified material weakness in our internal controls, we have enhanced our process to identify and correctly apply developments in accounting and to improve our understanding of the nuances of increasingly complex accounting standards. We have improved access to the accounting literature, research materials and documents and increased communication among our legal and finance personnel and third party professionals with whom we consult regarding complex accounting applications.

Any failure to maintain internal controls could adversely affect our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and Nasdaq, we could face severe consequences from those authorities. In either case, there could result a material adverse effect on our business. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. We can give no assurance that additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, although we believe that we have remediated the material weakness that we identified in November 2010, in the future our controls and procedures may no longer be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements. Responding to inquiries from the SEC or Nasdaq in the future will, regardless of the outcome, likely consume a significant amount of our management resources and cause us to incur significant legal and accounting expense. Further, many companies that have restated their historical financial statements have experienced a decline in stock price and related stockholder lawsuits.

# Our Committed Equity Financing Facilities may become unavailable to us if we do not comply with their conditions.

Except for our CEFFs (which are subject to certain limitations), we currently do not have arrangements to obtain additional financing. If we are unable to meet the conditions provided under the CEFFs, we will not be able to issue any portion of the shares potentially available for issuance under the CEFFs to fund our activities and the CEFFs may expire. For example, as of December 31, 2010, we had three CEFFs that were potentially available to us. However, the December 2008 CEFF expired in February 2011 without having been fully utilized and the May 2008 CEFF will expire on June 18, 2011. Moreover, Kingsbridge has the right under certain circumstances to terminate the CEFFs, including in the event of a material adverse event. In addition, even if we meet all the conditions provided under the CEFFs, we are dependent upon the financial ability of Kingsbridge to perform its obligations and purchase shares of our common stock under the CEFFs. Any inability on our part to use at least one of the CEFFs or any failure by Kingsbridge to perform its obligations under the CEFFs could have a material adverse effect on our ability to finance our activities.

In addition, our ability to draw down under any new CEFF in the future may be impaired. In February 2011, we issued five-year warrants that contain anti-dilution provisions that potentially adjust the exercise price of these warrants upon the issuance of securities at prices lower than the warrant exercise price. The warrant anti-dilution provisions are not triggered by draw downs under our existing CEFFs but would be triggered by draw downs under any new CEFF. In that event, the potential dilutive effect of a draw down under a future CEFF could be increased if the discounted purchase price of such draw down is less than the exercise price of the warrants, which could result in a decline in the market price of our stock.

If our current CEFFs should become unavailable, due to expiration or for any reason, if we are unable to successfully raise sufficient additional capital through a new CEFF, strategic alliances and other financing alternatives, we will likely not have sufficient cash flow and liquidity to fund our business operations, forcing us to curtail our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in that event, the market price of our common stock may decline further.

## The market price of our stock may be adversely affected by market volatility.

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- patient adverse reactions to drug products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the United States or foreign regulatory policy during the period of product development;
- changes in the United States or foreign political environment and the passage of laws, including tax, environmental or other laws, affecting the
  product development business;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards; and
- the occurrence of any of the risks described in these "Risk Factors" or elsewhere in this Registration Statement, our Annual Report on Form 10-K or our other public filings with the SEC, and any amendments thereto.

Our common stock is listed for quotation on The Nasdaq Capital Market. During the twelve month period ended December 31, 2010, the price of our common stock, adjusted for the 1-for-15 reverse stock split that was made effective on December 28, 2010, ranged between \$2.52 and \$12.58. 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, 2010, the average daily trading volume in our common stock, adjusted for the 1-for-15 reverse stock split, was approximately 175,455 shares, and the average number of transactions per day, adjusted for the 1-for-15 reverse stock split, was approximately 2,465. 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 are ultimately determined to be meritless or unsuccessful, they would involve substantial costs and a diversion of management attention and resources, which could negatively impact our business.

If we fail to adhere to the strict listing requirements of The Nasdaq Capital Market, we may be subject to delisting. As a result, our stock price may decline and, following a hearing, our common stock may be delisted. If our stock were no longer listed on the Nasdaq Capital Market, the liquidity of our securities likely would be impaired.

Our common stock currently trades on the Nasdaq Capital Market under the symbol DSCO. If we fail to adhere to the market's strict listing criteria, our stock may be delisted. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our common stock. We believe that current and prospective investors would view an investment in our common stock more favorably if it continues to be listed on the Nasdaq Capital Market.

In December 2009, we received a letter from The Nasdaq Global Market® (Global Market) indicating that we had failed to comply with Nasdaq Listing Rule 5450(a)(1) (Minimum Bid Price Rule), which requires that we maintain a minimum closing bid price of \$1.00 per share. Under the Nasdaq Listing Rules, to avoid delisting, the closing bid price of our stock had to rise above \$1.00 for a minimum of 10 consecutive business days during the 180 calendar days following the date of the notification, or prior to June 1, 2010. Anticipating that we would not regain compliance with the Minimum Bid Price Rule on or before June 1, 2010, in May 2010, we applied to transfer our common stock to the Nasdaq Capital Market, which was effective on June 4, 2010. Based on our ability to comply with all listing requirements of the Nasdaq Capital Market other than the Minimum Bid Price Rule, Nasdaq also granted us an additional 180 days, or until November 29, 2010, to regain compliance with the Minimum Bid Price Rule.

On November 30, 2010, we received written notification from Nasdaq that our common stock was subject to delisting because we had not regained compliance with the Minimum Bid Price Rule within the 180-day period previously granted. We requested a hearing with a Nasdaq Hearing Panel, which stayed the delisting of our stock pending the Panel's review. On December 28, 2010, we implemented a 1-for-15 reverse stock split, after which the closing market price of our stock was above \$1.00. On January 11, 2011, following our hearing, the Nasdaq Hearing Panel determined that we had regained compliance with the Minimum Bid Price Rule because our common stock had maintained a minimum closing bid price of \$1.00 per share over a period of 10 consecutive business. Currently, our common stock continues to comply with all Nasdaq Listing Requirements for the Nasdaq Capital Market.

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

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our CEFFs, 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 require significant 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 (either pursuant to this registration statement or otherwise) and through the exercise of outstanding warrants, our stockholders may experience substantial dilution. We may sell shares of our common stock in one or more transactions at prices that may be at a discount to the then-current market value of our common stock and on such other terms and conditions as we may determine from time to time. Any such transaction could result in substantial dilution of our existing stockholders. If we sell shares of our common stock in more than one transaction, stockholders who purchase our common stock may be materially diluted by subsequent sales. Such sales could also cause a drop in the market price of our common stock. The issuance of shares of our common stock under the CEFFs has, and the issuance of shares upon exercise of the related warrants we issued to Kingsbridge will have, a dilutive impact on our other stockholders and the issuance, or even potential issuance, of such shares could have a negative effect on the market price of our common stock. In addition, if we access the CEFFs, we will issue shares of our common stock to Kingsbridge at a discount (from 4.38% to 17.5%, depending upon the market price) to the daily volume-weighted average price of our common stock on each trading day, which will further dilute the interests of other stockholders. Furthermore, to the extent that Kingsbridge sells to third parties the shares of our common stock that we sell to Kingsbridge under the CEFFs, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Kingsbridge may cause holders of our common stock to sell their shares, or it may encourage short sales of our common stock or other similar transactions. T

As of May 31, 2011, we had 24,178,502 shares of common stock issued and outstanding. In addition, as of May 31, 2011, approximately (i) 13,188,573 million shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, (ii) 941,126 million shares of our common stock were reserved for issuance pursuant to our equity incentive plans, and (iii) 244,667 million shares of our common stock were reserved for issuance pursuant to our 401(k) Plan. The exercise of stock options and other securities could cause our stockholders to experience substantial dilution. Moreover, holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

If, during the term of certain of our warrants, we declare or make any dividend or other distribution of our assets to holders of shares of our common stock, by way of return of capital or otherwise (including any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement or other similar transaction), then the exercise price of such warrants may adjust downward and the number of shares of common stock issuable upon exercise of such warrants would increase. In addition, in February 2011, we issued five-year warrants that contain an anti-dilution provision that, subject to certain exclusions, would adjust the exercise price of these warrants upon the issuance of securities at prices lower than the warrant exercise price. For the purpose of valuing securities that we may issue in the future in unit offerings, this anti-dilution provision values the warrant portion of a unit offering based on a Black Scholes pricing model. Such Black Scholes value is subtracted from the actual per-unit price of the offering to determine the per-share value of the shares issued in such unit offering for the purposes of the anti-dilution provision. If we issue shares or units or warrants in a financing that triggers the anti-dilution provision of our February 2011 five-year warrants, the exercise price of the February 2011 five-year warrants will be lowered thereby, increasing the likelihood that such warrants would be exercised. As a result of such warrant adjustments, we may be required to issue more shares of common stock, or shares at lower prices, than previously anticipated, which could result in further dilution of our existing stockholders.

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interest.

As of May 31, 2011, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately thirteen percent (13%) of the issued and outstanding shares of our common stock. For the purpose of computing this amount, an affiliated entity includes any entity that is known to us to be the beneficial owner of more than five percent (5%) of our issued and outstanding common stock. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

Our technology platform is based solely on our proprietary KL<sub>4</sub> surfactant technology, our novel capillary aerosolization technology, and our novel patient interface and related componentry.

Our technology platform is based on the scientific rationale of using our KL4 surfactant technology, our capillary aerosolization technology and our novel patient interface and related componentry to treat life-threatening respiratory disorders and to serve as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our drug product candidates and our drug-device combination products based on these technologies. Any material problems with our technology platforms could have a material adverse effect on our business.

If we cannot protect our intellectual property, other companies could use our technology in competitive products. Even if we obtain patents to protect our products, those patents may not be sufficiently broad or they may expire and others could then compete with us.

We seek patent protection for our drug product candidates to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to successfully obtain patents, defend our patents and otherwise prevent others from infringing our proprietary rights, including our trade secrets.

The patent position of companies relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office (USPTO) has not adopted a consistent policy regarding the breadth of claims that it will allow in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not secure rights to products or processes that appear to be patentable.

We and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the USPTO and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the USPTO or foreign patent office issuing patents. In addition, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, even if the USPTO or foreign patent offices were to issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide us any protection against competitors.

The patents that we hold also have a limited term. We have licensed a series of patents for our KL4 surfactant technology from Johnson & Johnson and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation (Ortho Pharmaceutical), which are important, both individually and collectively, to our strategy of commercializing our KL4 surfactant products. These patents, which include important KL4 surfactant composition of matter claims and relevant foreign patents, began to expire in November 2009, and will expire on various dates ending in 2017 or, in some cases, possibly later. Of the patents that have expired, we have obtained two extensions of the patent term for a total of two years for our most important patent, with further extensions possible into 2014. For our aerosolized KL4 surfactant, we hold exclusive licenses in the United States from Philip Morris USA Inc. (PMUSA) and outside the United States from Philip Morris Products S.A. (PMPSA) to our capillary aerosolization technology for use with pulmonary surfactants for all respiratory diseases. Our exclusive license in the United States also extends to other (non-surfactant) drugs to treat a wide range of pediatric and adult respiratory indications in hospitals and other health care institutions. The capillary aerosolization technology patents expire on various dates beginning in May 2016 and ending in 2023, or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop enhanced or additional products or processes that will be patentable under patent law and, if we do enhance or develop additional products that we believe are patentable, additional patents may not be issued to us. See also, "– If we cannot meet requirements under our license agreements, we could lose the rights to our products."

# Intellectual property rights of third parties could limit our ability to develop and market our products.

Our commercial success also depends upon our ability to operate our business without infringing the patents or violating the proprietary rights of others. In certain cases, the USPTO keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine in advance what inventions third parties may claim in their pending patent applications. We may need to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others through legal proceedings, which would be costly, unpredictable and time consuming. Even in proceedings where the outcome is favorable to us, they would likely divert substantial resources, including management time, from our other activities. Moreover, any adverse determination could subject us to significant liability or require us to seek licenses that third parties might not grant to us or might only grant at rates that diminish or deplete the profitability of our products. An adverse determination could also require us to alter our products or processes or cease altogether any product sales or related research and development activities.

# If we cannot meet requirements under our license agreements, we could lose the rights to our products.

We depend on licensing agreements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Johnson & Johnson, Ortho Pharmaceutical, PMUSA and PMPSA. These agreements require us to make payments and satisfy performance obligations to maintain our rights under these licensing agreements. All of these agreements last either throughout the life of the patents or for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

# We rely on confidentiality agreements that could be breached and may be difficult to enforce.

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

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

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

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We 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.

W. Thomas Amick, our Chairman of the Board and Chief Executive Officer joined our company on a full-time basis as Chief Executive Officer in October 2010. As of October 18, 2010, we entered into an executive employment agreement with Mr. Amick, which expires in October 2011 and contains an automatic one-year renewal at the end of each term, unless otherwise terminated by either party.

As of December 31, 2010, we had employment agreements with four executive officers in addition to Mr. Amick, including: President and Chief Financial Officer and Treasurer; Executive Vice President, General Counsel and Secretary; Chief Operating Officer; and Senior Vice President, Human Resources. These agreements provide for automatic one-year renewal at the end of each term, unless otherwise terminated by either party, and will expire in May 2012. In addition, in May 2010, we entered into retention agreements with five other officers under which each officer is provided certain severance benefits, based on title. 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.

We expect that, once we have secured sufficient strategic and financial resources to support our operations, including the continuing development of our KL4 surfactant technology, we will seek to attract candidates to join our management and development teams, although there can be no assurances that we will be successful in that endeavor. Moreover, although our five senior executive officers have agreements that include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, such noncompete provisions can be difficult and costly to monitor and enforce, such that we may not be successful in retaining these individuals and, if any should resign, in enforcing our noncompetition agreements with them.

We may be unable to attract and retain necessary executive talent. Our industry generally seeks to attract and retain executive talent with compensation packages that include a significant equity component. At this time, however, we have only limited equity incentives available. Moreover, the equity incentives, including options and restricted stock, that we have issued are, for the most part, significantly devalued or out of the money and less likely to be exercisable in the future. We plan on seeking stockholder approval for additional equity incentives that we believe would enhance our ability to retain our current key employees and attract the necessary additional executive talent. However, there can be no assurance that our stockholders will approve such incentives and, even if our stockholders approve new equity incentives, that we will be able to attract and retain key executive talent in the interim period, if ever.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel. While we attempt to provide competitive compensation packages to attract and retain key personnel at all levels in our organization, many of our competitors have greater resources and more experience than we do, making it difficult for us to compete successfully for key personnel. We may experience intense competition for qualified personnel and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to lawsuits brought by their former employers.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies intensely in many ways. We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

- developing products;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals or products; and
- manufacturing and marketing products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or foreign regulatory approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities that may successfully develop and commercialize products that are more effective or less expensive than our products. As none of our products are approved, we currently have limited or no experience in these areas. In addition, developments by our competitors may render our drug product candidates obsolete or noncompetitive.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors frequently aggressively seek patent protection and licensing arrangements to collect royalties for use of technology that they have developed. Some of these technologies may compete directly with the technologies that we are developing. These institutions will also compete with us in recruiting highly qualified scientific personnel. We expect that therapeutic developments in the areas in which we are active may occur at a rapid rate and that competition will intensify as advances in this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

Our business activities expose us to liability claims and the use of our products in clinical trials exposes us to product liability claims. If any such claims are brought against us, we may experience reduced demand for our products or damages that exceed our insurance coverage and we may incur substantial costs.

Our business activities, including testing, manufacturing and, if approved, marketing our drug products and medical devices exposes us to liability risks. Using our drug product candidates or medical devices in clinical trials also may expose us to product liability claims. If any of our products are approved for commercial sale, the risk of product liability claims will be increased. Even if approved, our products may be subject to claims resulting from unintended effects that result in injury or death. In addition, we are subject to product liability claims involving our capillary aerosolization and other medical devices and alleged mechanical failures, design defects, or other safety issues that result in an unsafe condition leading to injury or death. Product liability claims alleging inadequate disclosure and warnings in our package inserts and medical device disclosures may also arise.

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. We may need to obtain additional product liability insurance coverage, including withy locally-authorized insurers licensed in countries where we conduct our clinical trials, before initiating clinical trials. We also expect to review and obtain additional product liability insurance coverage, if warranted, before commercializing any of our drug product candidates; 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.

Our corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations affecting our activities in the jurisdictions in which we may sell our products, if approved, and a failure to comply with such regulations or prevail in litigation related to noncompliance could harm our business.

Many of our activities, including the research, development, manufacture, sale and marketing of our products, are subject to extensive laws and regulation, including without limitation, health care "fraud and abuse" laws, such as the federal false claims act, the federal anti-kickback statute, and other state and federal laws and regulations. We have developed and implemented a corporate compliance policy and oversight program based upon what we understand to be current industry best practices, but we cannot assure you that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such investigations, actions or lawsuits are instituted against us, and if we are not successful in defending or disposing of them without liability, such investigations, actions or lawsuits could result in the imposition of significant fines or other sanctions and could otherwise have a significant impact on our business.

# We expect to face uncertainty over reimbursement and healthcare reform.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payers, which include governmental health administration authorities, managed care providers and private health insurers. Third party payers increasingly challenge the price and examine the cost effectiveness of medical products and services. Moreover, the current political environment in the United States and abroad may result in the passage of significant legislation that could, among other things, restructure the markets in which we operate and restrict pricing strategies of drug development companies. If, for example, price restrictions were placed on the distribution of our drugs, we may be forced to curtail development of our pipeline products and this could have a material adverse effect on our business, results of operations and financial condition. Even if we succeed in commercializing our drug products, uncertainties regarding health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in quantities or at prices that will enable us to achieve profitability.

To obtain reimbursement from a third party payer, it must determine that our drug product is a covered benefit under its health plan, which is likely to require a determination that our product is:

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining a determination that a product is a covered benefit may be a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data about our products to each payer. We may not be able to provide sufficient data to gain coverage.

Even when a payer determines that a product is covered, the payer may impose limitations that preclude payment for some uses that are approved by the FDA or other regulatory authorities. Cost-containment measures, if implemented to affect the coverage or reimbursement of our products could have a material adverse effect on our ability to market our products profitably. Moreover, coverage does not imply that any product will be covered in all cases or that reimbursement will be available at a rate that would permit a health care provider to cover its costs of using our product.

Provisions of our Restated Certificate of Incorporation, as amended, our Amended and Restated By-Laws, our Shareholder Rights Agreement and Delaware law could defer a change of our management and thereby discourage or delay offers to acquire us.

Provisions of our Amended and Restated Certificate of Incorporation, as amended, our Amended and Restated By-Laws, our Shareholder Rights Agreement and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Restated Certificate of Incorporation, as amended, allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, before the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock. We have adopted a Shareholder Rights Agreement, which under certain circumstances would significantly impair the ability of third parties to acquire control of us without prior approval of our Board of Directors thereby discouraging unsolicited takeover proposals. The rights issued under the Shareholder Rights Agreement would cause substantial dilution to a person or group that attempts to acquire us on terms not approved in advance by our Board of Directors.

The failure to prevail in litigation or the costs of litigation, including securities class action and patent claims, could harm our financial performance and business operations.

We are potentially susceptible to litigation. For example, as a public company, we may be subject to claims asserting violations of securities laws. Even if such actions are found to be without merit, the potential impact of such actions, which generally seek unquantified damages and attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in any future proceeding would not have a potentially material adverse effect on our business, results of operations and financial condition.

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 clinical trials. Such claims, with or without merit, if not resolved, could be time-consuming and result in costly litigation. Although we believe such claims are unlikely to have a material adverse effect on our financial condition or results of operations, it is impossible to predict with certainty the eventual outcome of such claims and there can be no assurance that we will be successful in any proceeding to which we may be a party.

In addition, as the USPTO keeps United States patent applications confidential in certain cases while the applications are pending, we cannot ensure that our products or methods do not infringe upon the patents or other intellectual property rights of third parties. As the biotechnology and pharmaceutical industries expand and more patents are applied for and issued, the risk increases that our patents or patent applications for our KL4 surfactant product candidates may give rise to a declaration of interference by the USPTO, or to administrative proceedings in foreign patent offices, or that our activities lead to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal proceedings against us seeking to invalidate our patents, obtain substantial damages or enjoin us from conducting research and development activities.

# FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1934 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations; plans regarding our efforts to gain U.S. regulatory approval for our lead product, Surfaxin® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants; the possibility, timing and outcome of submitting regulatory filings for our products under development; our research and development programs for our KL4 surfactant technology, our capillary aerosolization technology platform and our novel patient interfaces, including planning for and timing of any clinical trials and potential development milestones; the development of financial, clinical, manufacturing and distribution plans related to the potential commercialization of our drug products, if approved; and plans regarding potential strategic alliances and other collaborative arrangements with pharmaceutical companies and others to develop, manufacture and market our products.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of the risks and uncertainties include, but are not limited to:

- risks related generally to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug product candidates, including our lead products that we are developing to address respiratory distress syndrome (RDS) in premature infants: Surfaxin for the prevention of RDS, Surfaxin LS (our initial lyophilized KL4 surfactant) and Aerosurf (our initial aerosolized KL4 surfactant);
- the risk that we and the FDA or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;
- the risk that the FDA will not be satisfied with the results of our efforts to (i) finally validate our optimized BAT, (ii) demonstrate that the BAT has the ability to adequately reflect the biological activity of Surfaxin throughout its shelf life and to discriminate biologically active from inactive Surfaxin drug product, and (iii) demonstrate the comparability of drug product used in the Surfaxin Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use through prospectively-designed, side-by-side preclinical studies (i.e., concordance studies) using the optimized BAT and the well-established preterm lamb model of RDS;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;
- risks relating to the rigorous regulatory approval processes, including pre-filing activities, required for approval of any drug or combination drug-device products that we may develop, whether independently, with strategic development partners or pursuant to collaboration arrangements;
- the risk that the FDA may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities;
- the risk that we may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin;
- risks relating to our efforts to manufacture within our planned timeframe the additional batches of Surfaxin for use in our comprehensive preclinical
  program and to complete the investigation into the manufacture of the two batches manufactured in January 2011 that did not meet specification;
- risks, if we succeed in gaining approval of Surfaxin and our other drug products, relating to our lack of marketing and distribution capabilities, which we will have to develop internally or secure through third-party strategic alliances and/or marketing alliances and/or distribution arrangements, that could require us to give up rights to our drug products and drug product candidates;
- risks, if we succeed in gaining approval of Surfaxin and our other drug products, that reimbursement and health care reform may adversely affect us or that our products will not be accepted by physicians, patients and others in the medical community;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- risks relating to our research and development activities, which involve time-consuming and expensive preclinical studies and other efforts, and
  potentially multiple clinical trials, which may be subject to potentially significant delays or regulatory holds, or may fail, and which must be
  conducted using sophisticated and extensive analytical methodologies, including an acceptable BAT, if required, as well as other quality control
  release and stability tests to satisfy the requirements of the regulatory authorities;
- risks relating to our ability to develop and manufacture drug products and drug-device combination products based on our capillary aerosolization technology for clinical studies and, if approved, for commercialization of our products;

- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers and assemblers;
- the risk that we, our contract manufacturers or any of our third-party suppliers may encounter problems or delays in manufacturing or assembling drug products, drug product substances, capillary aerosolization devices and related components and other materials on a timely basis or in an amount sufficient to support our development efforts and, if our products are approved, commercialization;
- the risk that we may be unable to identify potential strategic partners or collaborators with whom we can develop and, if approved, commercialize our products in a timely manner, if at all;
- the risk that we or our strategic partners or collaborators will not be able to attract or maintain qualified personnel;
- the risk that, if approved, market conditions, the competitive landscape or other factors may make it difficult to launch and profitably sell our products;
- the risk that we may not be able to raise additional capital or enter into strategic alliances or collaboration agreements (including strategic alliances for development or commercialization of our drug products and combination drug-device products);
- risks that the unfavorable credit environment will adversely affect our ability to fund our activities, that our share price will not reach or remain at the price level necessary for us to access capital under our CEFFs, that the CEFFs may expire before we are able to access the full dollar amount potentially available thereunder, and that additional equity financings could result in substantial equity dilution;
- the risk that, although we have regained compliance with the Minimum Bid Price Requirement of The Nasdaq Capital Market by implementing a reverse split, we will be unable to maintain compliance with the listing requirements of Nasdaq, including without limitation those relating to market capitalization and stockholders equity, which could increase the probability that our stock will be delisted from Nasdaq, which could cause our stock price to decline;
- risks related to our need for significant additional capital to continue our planned research and development activities and continue operating as a going concern, which if derived from additional financings, could result in equity dilution;
- the risks that we may be unable to maintain and protect the patents and licenses related to our products and that other companies may develop competing therapies and/or technologies;
- the risks that we may become involved in securities, product liability and other litigation and that our insurance may be insufficient to cover costs of damages and defense;
- the risks that we will be unable to attract and retain key employees in a competitive market for skilled personnel, which could affect our ability to develop and market our products; and
- other risks and uncertainties detailed in our most recent Annual Report on Form 10-K and other filings with the SEC, and any amendments thereto, and in any documents incorporated by reference in this prospectus.

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

The forward-looking statements contained in this prospectus or the documents incorporated by reference herein speak only 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.

### **USE OF PROCEEDS**

Except as described in any prospectus supplement or post-effective amendment, we will retain broad discretion over the use of the net proceeds from the sale of our securities offered hereby and the net proceeds from the sales of securities offered by this prospectus will be used to meet working capital requirements for: (i) efforts intended to gain regulatory approval to market and sell, and prepare for the potential commercial launch in the United States of Surfaxin for the prevention of RDS in premature infants; (ii) development of our other lead KL4 surfactant pipeline programs, Surfaxin LS<sup>TM</sup> (our initial lyophilized KL4 surfactant) and Aerosurf (our initial aerosolized KL4 surfactant) to address the most significant respiratory conditions affecting neonatal populations, initially RDS in premature infants; (iii) investments in life cycle development of our KL4 surfactant technology for other respiratory conditions to address respiratory conditions such as ALI and, potentially in the future, other diseases associated with inflammation of the lung, such as Asthma and COPD; (iv) development of our capillary aerosolization technology and novel patient interfaces, initially to support delivery of our aerosolized KL4 surfactant to patients in the neonatal intensive care unit (NICU), beginning with Aerosurf; (v) continued investment in manufacturing capabilities and quality systems to meet the anticipated preclinical, clinical and potential future commercial requirements of Surfaxin, Surfaxin LS, Aerosurf and our other KL4 surfactant products; and (vi) seeking strategic partnerships and/or collaboration arrangements in the international and domestic markets for the development and potential commercialization of our KL4 for respiratory conditions and disorders affecting adult patients.

We expect, from time to time, to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used. The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our research and development efforts, technological advances and the competitive environment for Surfaxin and our other product candidates and their intended uses. Pending the application of the net proceeds, we intend to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

### RATIO OF EARNINGS TO FIXED CHARGES

Our earnings were insufficient to cover fixed charges in each of the years in the five-year period ended December 31, 2010 and in the three-month period ended March 31, 2011. Our fixed charges do not include any dividend requirements with respect to preferred stock because, as of the date of this prospectus and for the five preceding fiscal years, we have had no preferred stock outstanding.

We compute the ratio of earnings to fixed charges by dividing (i) earnings (loss), which consists of net income from continuing operations before income taxes plus fixed charges and amortization of capitalized interest less interest capitalized during the period and adjusted for undistributed earnings in equity investments, by (ii) fixed charges, which consist of interest expense, capitalized interest and the interest portion of rental expense under operating leases estimated to be representative of the interest factor.

											Three Months Ended				
	Fiscal Year Ended December 31,										N	March 31,			
		2006		2007		2008		2009 2010		2010	2011				
			(in thousands)												
Ratio of earnings to fixed charges (1)															
Coverage deficiency	\$	(46,333)	\$	(40,005)	\$	(39,106)	\$	(29,871)	\$	(19,175)	\$	(3,837)			

(1) Adjusted earnings, as described above, were insufficient to cover fixed charges in each period. We have not included a ratio of earnings to combined fixed charges and preferred stock dividends because we do not have any preferred stock outstanding.

# DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we offer under a prospectus supplement may differ from the terms we describe below. However, no prospectus supplement shall fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. As of March 31, 2011, we had \$0.4 million in outstanding indebtedness, including accrued interest.

We will issue the senior debt securities under the senior indenture that we will enter into with the trustee named in the senior indenture. We will issue the subordinated debt securities under the subordinated indenture that we will enter into with the trustee named in the subordinated indenture. We have filed forms of these documents as exhibits to the registration statement which includes this prospectus. We use the term "indentures" in this prospectus to refer to both the senior indenture and the subordinated indenture.

The indentures will be qualified under the Trust Indenture Act of 1939. We use the term "trustee" to refer to either the senior trustee or the subordinated trustee, as applicable.

The following summaries of material provisions of the senior debt securities, the subordinated debt securities and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities. Except as we may otherwise indicate, the terms of the senior indenture and the subordinated indenture are identical.

#### General

Debt securities may be issued in separate series without limitation as to aggregate principal amount. We may specify a maximum aggregate principal amount for the debt securities of any series.

We are not limited as to the amount of debt securities we may issue under the indentures. The prospectus supplement will set forth:

- whether the debt securities will be senior or subordinated;
- the offering price;
- the title;
- any limit on the aggregate principal amount;
- the person who shall be entitled to receive interest, if other than the record holder on the record date;
- the date the principal will be payable;
- the interest rate, if any, the date interest will accrue, the interest payment dates and the regular record dates;
- the place where payments may be made;
- any mandatory or optional redemption provisions;
- if applicable, the method for determining how the principal, premium, if any, or interest will be calculated by reference to an index or formula;
- if other than U.S. currency, the currency or currency units in which principal, premium, if any, or interest will be payable and whether we or the holder may elect payment to be made in a different currency;
- the portion of the principal amount that will be payable upon acceleration of stated maturity, if other than the entire principal amount;
- if the principal amount payable at stated maturity will not be determinable as of any date prior to stated maturity, the amount which will be deemed to be the principal amount;
- any defeasance provisions if different from those described below under "Satisfaction and Discharge; Defeasance;"
- any conversion or exchange provisions;
- any obligation to redeem or purchase the debt securities pursuant to a sinking fund;
- whether the debt securities will be issuable in the form of a global security;
- any subordination provisions, if different from those described below under "Subordinated Debt Securities;"
- any deletions of, or changes or additions to, the events of default or covenants; and
- any other specific terms of such debt securities.

Unless otherwise specified in the prospectus supplement:

- the debt securities will be registered debt securities; and
- registered debt securities denominated in U.S. dollars will be issued in denominations of \$1,000 or an integral multiple of \$1,000.

Debt securities may be sold at a substantial discount below their stated principal amount, bearing no interest or interest at a rate which at the time of issuance is below market rates.

### **Exchange and Transfer**

Debt securities may be transferred or exchanged at the office of the security registrar or at the office of any transfer agent designated by us.

We will not impose a service charge for any transfer or exchange, but we may require holders to pay any tax or other governmental charges associated with any transfer or exchange.

In the event of any potential redemption of debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange, any debt security of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt security of that series selected for redemption, in whole or in part, except the unredeemed portion being redeemed in part.

We may initially appoint the trustee as the security registrar. Any transfer agent, in addition to the security registrar, initially designated by us will be named in the prospectus supplement. We may designate additional transfer agents or change transfer agents or change the office of the transfer agent. However, we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

### **Global Securities**

The debt securities of any series may be represented, in whole or in part, by one or more global securities. Each global security will:

- be registered in the name of a depositary that we will identify in a prospectus supplement;
- be deposited with the depositary or nominee or custodian; and
- bear any required legends.

No global security may be exchanged in whole or in part for debt securities registered in the name of any person other than the depositary or any nominee unless:

- the depositary has notified us that it is unwilling or unable to continue as depositary or has ceased to be qualified to act as depositary;
- an event of default is continuing; or
- any other circumstances described in a prospectus supplement.

As long as the depositary, or its nominee, is the registered owner of a global security, the depositary or nominee will be considered the sole owner and holder of the debt securities represented by the global security for all purposes under the indenture. Except in the above limited circumstances, owners of beneficial interests in a global security:

- will not be entitled to have the debt securities registered in their names,
- will not be entitled to physical delivery of certificated debt securities, and
- will not be considered to be holders of those debt securities under the indentures.

Payments on a global security will be made to the depositary or its nominee as the holder of the global security. Some jurisdictions have laws that require that certain purchasers of securities take physical delivery of such securities in definitive form. These laws may impair the ability to transfer beneficial interests in a global security.

Institutions that have accounts with the depositary or its nominee are referred to as "participants." Ownership of beneficial interests in a global security will be limited to participants and to persons that may hold beneficial interests through participants. The depositary will credit, on its book-entry registration and transfer system, the respective principal amounts of debt securities represented by the global security to the accounts of its participants.

Ownership of beneficial interests in a global security will be shown on and effected through records maintained by the depositary, with respect to participants' interests, or any participant, with respect to interests of persons held by participants on their behalf.

Payments, transfers and exchanges relating to beneficial interests in a global security will be subject to policies and procedures of the depositary.

The depositary policies and procedures may change from time to time. Neither we nor the trustee will have any responsibility or liability for the depositary's or any participant's records with respect to beneficial interests in a global security.

# **Payment and Paying Agent**

The provisions of this paragraph will apply to debt securities unless otherwise indicated in the prospectus supplement. Payment of interest on a debt security on any interest payment date will be made to the person in whose name the debt security is registered at the close of business on the regular record date. Payment on debt securities of a particular series will be payable at the office of a paying agent or paying agents designated by us. However, at our option, we may pay interest by mailing a check to the record holder. The corporate trust office initially will be designated as our sole paying agent.

We may also name any other paying agents in the prospectus supplement. We may designate additional paying agents, change paying agents or change the office of any paying agent. However, we will be required to maintain a paying agent in each place of payment for the debt securities of a particular series.

All moneys paid by us to a paying agent for payment on any debt security which remain unclaimed at the end of two years after such payment was due will be repaid to us. Thereafter, the holder may look only to us for such payment.

# Consolidation, Merger and Sale of Assets

We may not consolidate with or merge into any other person, in a transaction in which we are not the surviving corporation, or convey, transfer or lease our properties and assets substantially as an entirety to, any person, unless:

- the successor, if any, is a U.S. corporation, limited liability company, partnership, trust or other entity;
- the successor assumes our obligations on the debt securities and under the indenture;
- immediately after giving effect to the transaction, no default or event of default shall have occurred and be continuing; and
- certain other conditions are met.

If the debt securities are convertible for our other securities or securities of other entities, the person with whom we consolidate or merge or to whom we sell all of our property must make provisions for the conversion of the debt securities into securities which the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

# **Events of Default**

Unless we inform you otherwise in the prospectus supplement, the indenture will define an event of default with respect to any series of debt securities as one or more of the following events:

- (1) failure to pay principal of or any premium on any debt security of that series when due and payable;
- (2) failure to pay any interest on any debt security of that series when it becomes due and payable, and continuation of that failure for a period of 90 days (unless the entire amount of such payment is deposited by us with the trustee or paying agent prior to the expiration of the 90-day period);
- (3) failure to deposit any sinking fund payment, when and as due in respect of any debt security of that series;
- (4) failure to perform or breach of any other covenant or warranty by us in the indenture (other than a covenant or warranty that has been included in the indenture solely for the benefit of a series of debt securities other than the series), which failure continues uncured for a period of 90 days after we receive the notice required in the indenture;

- (5) our bankruptcy, insolvency or reorganization; and
- (6) any other event of default with respect to debt securities of that series that is described in the applicable prospectus supplement accompanying this prospectus.

An event of default of one series of debt securities is not necessarily an event of default for any other series of debt securities.

If an event of default, other than an event of default described in clause (5) above, shall occur and be continuing, either the trustee or the holders of at least 25% in aggregate principal amount of the outstanding securities of that series may declare the principal amount of the debt securities of that series to be due and payable immediately.

If an event of default described in clause (5) above shall occur, the principal amount of all the debt securities of that series will automatically become immediately due and payable. Any payment by us on the subordinated debt securities following any such acceleration will be subject to the subordination provisions described below under "Subordinated Debt Securities."

After acceleration the holders of a majority in aggregate principal amount of the outstanding securities of that series may, under certain circumstances, rescind and annul such acceleration if all events of default, other than the non-payment of accelerated principal, or other specified amount, have been cured or waived.

Other than the duty to act with the required care during an event of default, the trustee will not be obligated to exercise any of its rights or powers at the request of the holders unless the holders shall have offered to the trustee security and indemnity satisfactory to it against the costs, expenses and liabilities to be incurred in compliance with such request.

Generally, the holders of a majority in aggregate principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee.

A holder will not have any right to institute any proceeding under the indentures, or for the appointment of a receiver or a trustee, or for any other remedy under the indentures, unless:

- (1) the holder has previously given to the trustee written notice of a continuing event of default with respect to the debt securities of that series;
- (2) the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made a written request and have offered reasonable indemnity to the trustee to institute the proceeding; and
- (3) the trustee has failed to institute the proceeding and has not received direction inconsistent with the original request from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series within 90 days after the original request.

A holder may not use the indenture to prejudice the rights of any holder, or to obtain or to seek to obtain priority or preference over another holder or to enforce any right under the indenture, except in the manner provided in the indenture and for the equal and ratable benefit of all holders (it being understood that the trustee does not have an affirmative duty to ascertain whether or not such actions or forbearances are unduly prejudicial to such holders).

Holders may, however, sue to enforce the payment of principal, premium or interest on any debt security on or after the due date or to enforce the right, if any, to convert any debt security without following the procedures listed in (1) through (3) above.

We will furnish the trustee an annual statement by our officers as to whether or not we are in default in the performance of the indenture and, if so, specifying all known defaults.

# **Modification and Waiver**

We and the trustee may make modifications and amendments to the indentures with the consent of the holders of a majority in aggregate principal amount of the outstanding securities of each series affected by the modification or amendment.

However, neither we nor the trustee may make any modification or amendment without the consent of the holder of each outstanding security of that series affected by the modification or amendment if such modification or amendment would:

change the stated maturity of any debt security;

- reduce the principal, premium, if any, or interest on any debt security;
- reduce the principal of an original issue discount security or any other debt security payable on acceleration of maturity;
- reduce the rate of interest on any debt security;
- change the currency in which any debt security is payable;
- impair the right to enforce any payment after the stated maturity or redemption date;
- waive any default or event of default in payment of the principal of, premium or interest on any debt security;
- waive a redemption payment or modify any of the redemption provisions of any debt security;
- adversely affect the right to convert any debt security in any material respect; or
- change the provisions in the indenture that relate to modifying or amending the indenture.

### Satisfaction and Discharge; Defeasance

We may be discharged from our obligations on the debt securities of any series that have matured or will mature or be redeemed within one year if we deposit with the trustee enough cash to pay all the principal, interest and any premium due to the stated maturity date or redemption date of the debt securities.

Each indenture will contain a provision that permits us to elect:

- to be discharged from all of our obligations, subject to limited exceptions, with respect to any series of debt securities then outstanding; and/or
- to be released from our obligations under the following covenants and from the consequences of an event of default resulting from a breach of these
  covenants: (1) the subordination provisions under a subordinated indenture; and (2) covenants as to payment of taxes and maintenance of corporate
  existence.

To make either of the above elections, we must deposit in trust with the trustee enough money to pay in full the principal, interest and premium on the debt securities. This amount may be made in cash and/or U.S. government obligations. As a condition to either of the above elections, we must deliver to the trustee an opinion of counsel that the holders of the debt securities will not recognize income, gain or loss for Federal income tax purposes as a result of the action.

If any of the above events occurs, the holders of the debt securities of the series will not be entitled to the benefits of the indenture, except for the rights of holders to receive payments on debt securities or the registration of transfer and exchange of debt securities and replacement of lost, stolen or mutilated debt securities

# Notices

Notices to holders will be given by mail to the addresses of the holders in the security register.

# **Governing Law**

The indentures and the debt securities will be governed by, and construed under, the law of the State of New York.

# Regarding the Trustee

The indentures will limit the right of the trustee, should it become a creditor of us, to obtain payment of claims or secure its claims.

The trustee will be permitted to engage in certain other transactions. However, if the trustee, acquires any conflicting interest, and there is a default under the debt securities of any series for which they are trustee, the trustee must eliminate the conflict or resign.

# **Subordinated Debt Securities**

Payment on subordinated debt securities will, to the extent provided in the indenture, be subordinated in right of payment to the prior payment in full of all of our senior indebtedness. Subordinated debt securities also are effectively subordinated to all debt and other liabilities, including trade payables and lease obligations, if any, of our subsidiaries.

Upon any distribution of our assets upon any dissolution, winding up, liquidation or reorganization, the payment of the principal of and interest on subordinated debt securities will be subordinated in right of payment to the prior payment in full in cash or other payment satisfactory to the holders of senior indebtedness of all senior indebtedness. In the event of any acceleration of the subordinated debt securities because of an event of default, the holders of any senior indebtedness would be entitled to payment in full in cash or other payment satisfactory to such holders of all senior indebtedness obligations before the holders of subordinated debt securities are entitled to receive any payment or distribution. The indentures will require us to promptly notify holders of designated senior indebtedness if payment of subordinated debt securities is accelerated because of an event of default.

We may not make any payment on subordinated debt securities, including upon redemption at the option of the holder of any subordinated debt securities or at our option, if:

- a default in the payment of the principal, premium, if any, interest, rent or other obligations in respect of designated senior indebtedness occurs and is continuing beyond any applicable period of grace, which is called a "payment default"; or
- a default other than a payment default on any designated senior indebtedness occurs and is continuing that permits holders of designated senior indebtedness to accelerate its maturity, and the trustee receives notice of such default, which is called a "payment blockage notice" from us or any other person permitted to give such notice under the indenture, which is called a "non-payment default".

We may resume payments and distributions on subordinated debt securities:

- in the case of a payment default, upon the date on which such default is cured or waived or ceases to exist; and
- in the case of a non-payment default, the earlier of the date on which such nonpayment default is cured or waived or ceases to exist and 179 days after
  the date on which the payment blockage notice is received by the trustee, if the maturity of the designated senior indebtedness has not been
  accelerated.

No new period of payment blockage may be commenced pursuant to a payment blockage notice unless 365 days have elapsed since the initial effectiveness of the immediately prior payment blockage notice and all scheduled payments of principal, premium and interest, including any liquidated damages, on the notes that have come due have been paid in full in cash. No non-payment default that existed or was continuing on the date of delivery of any payment blockage notice shall be the basis for any later payment blockage notice unless the non-payment default is based upon facts or events arising after the date of delivery of such payment blockage notice.

If the trustee or any holder of the notes receives any payment or distribution of our assets in contravention of the subordination provisions on subordinated debt securities before all senior indebtedness is paid in full in cash, property or securities, including by way of set-off, or other payment satisfactory to holders of senior indebtedness, then such payment or distribution will be held in trust for the benefit of holders of senior indebtedness or their representatives to the extent necessary to make payment in full in cash or payment satisfactory to the holders of senior indebtedness of all unpaid senior indebtedness.

In the event of our bankruptcy, dissolution or reorganization, holders of senior indebtedness may receive more, ratably, and holders of subordinated debt securities may receive less, ratably, than our other creditors (including our trade creditors). This subordination will not prevent the occurrence of any event of default under the indenture.

Unless we inform you otherwise in the prospectus supplement, we will not be prohibited from incurring debt, including senior indebtedness, under any indenture relating to subordinated debt securities. We may from time to time incur additional debt, including senior indebtedness.

We are obligated to pay reasonable compensation to the trustee and to indemnify the trustee against certain losses, liabilities or expenses incurred by the trustee in connection with its duties relating to subordinated debt securities. The trustee's claims for these payments will generally be senior to those of noteholders in respect of all funds collected or held by the trustee.

### **Certain Definitions**

"indebtedness" means:

- (1) all indebtedness, obligations and other liabilities for borrowed money, including overdrafts, foreign exchange contracts, currency exchange agreements, interest rate protection agreements, and any loans or advances from banks, or evidenced by bonds, debentures, notes or similar instruments, other than any account payable or other accrued current liability or obligation incurred in the ordinary course of business in connection with the obtaining of materials or services;
- (2) all reimbursement obligations and other liabilities with respect to letters of credit, bank guarantees or bankers' acceptances;

- (3) all obligations and liabilities in respect of leases required in conformity with generally accepted accounting principles to be accounted for as capitalized lease obligations on our balance sheet;
- (4) all obligations and liabilities, contingent or otherwise, as lessee under leases for facility equipment (and related assets leased together with such equipment) and under any lease or related document (including a purchase agreement, conditional sale or other title retention or synthetic lease agreement) in connection with the lease of real property or improvement thereon (or any personal property included as part of any such lease) which provides that such Person is contractually obligated to purchase or cause a third party to purchase the leased property or pay an agreed upon residual value of the leased property, including the obligations under such lease or related document to purchase or cause a third party to purchase such leased property (whether or not such lease transaction is characterized as an operating lease or a capitalized lease in accordance with GAAP) or pay an agreed upon residual value of the leased property to the lessor:
- (5) all obligations with respect to an interest rate or other swap, cap or collar agreement or other similar instrument or agreement or foreign currency hedge, exchange, purchase agreement or other similar instrument or agreement;
- (6) all direct or indirect guaranties or similar agreements in respect of, and our obligations or liabilities to purchase, acquire or otherwise assure a creditor against loss in respect of, indebtedness, obligations or liabilities of others of the type described in (1) through (5) above;
- (7) any indebtedness or other obligations described in (1) through (6) above secured by any mortgage, pledge, lien or other encumbrance existing on property which is owned or held by us; and
- (8) any and all refinancings, replacements, deferrals, renewals, extensions and refundings of, or amendments, modifications or supplements to, any indebtedness, obligation or liability of the kind described in clauses (1) through (7) above.

"senior indebtedness" means the principal, premium, if any, interest, including any interest accruing after bankruptcy, and rent or termination payment on or other amounts due on our current or future indebtedness, whether created, incurred, assumed, guaranteed or in effect guaranteed by us, including any deferrals, renewals, extensions, refundings, amendments, modifications or supplements to the above. However, senior indebtedness does not include:

- indebtedness that expressly provides that it shall not be senior in right of payment to subordinated debt securities or expressly provides that it is on the same basis or junior to subordinated debt securities;
- our indebtedness to any of our majority-owned subsidiaries; and
- subordinated debt securities.

### DESCRIPTION OF PREFERRED STOCK

We currently have authorized 5,000,000 shares of preferred stock, par value \$.001 per share. As of the date of this prospectus, we do not have any shares of preferred stock outstanding. Under our Restated Certificate of Incorporation, our Board of Directors is authorized to issue shares of our preferred stock from time to time, in one or more classes or series, without stockholder approval. Prior to the issuance of shares of each series, the Board of Directors is required by the General Corporation Law of the State of Delaware and our Restated Certificate of Incorporation to adopt resolutions and file a Certificate of Designation with the Secretary of State of the State of Delaware, fixing for each such series the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series. Any exercise of our Board of Directors of its rights to do so may affect the rights and entitlements of the holders of our common stock as set forth below.

Our Board of Directors could authorize the issuance of shares of preferred stock with terms and conditions which could have the effect of discouraging a takeover or other transaction which holders of some, or a majority, of such shares might believe to be in their best interests or in which holders of some, or a majority, of such shares might receive a premium for their shares over the then-market price of such shares.

# General

Subject to limitations prescribed by the General Corporation Law of the State of Delaware, our Restated Certificate of Incorporation and our Amended and Restated By-Laws ("By-Laws"), our Board of Directors is authorized to fix the number of shares constituting each series of preferred stock and the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series, including such provisions as may be desired concerning voting, redemption, dividends, dissolution or the distribution of assets, conversion or exchange, and such other subjects or matters as may be fixed by resolution of the Board of Directors. Each series of preferred stock that we offer under this prospectus will, when issued, be fully paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

The applicable prospectus supplement(s) will describe the following terms of the series of preferred stock in respect of which this prospectus is being delivered:

- the title and stated value of the preferred stock;
- the number of shares of the preferred stock offered, the liquidation preference per share and the purchase price of the preferred stock;
- the dividend rate(s), period(s) and/or payment date(s) or the method(s) of calculation for dividends;
- whether dividends shall be cumulative or non-cumulative and, if cumulative, the date from which dividends on the preferred stock shall accumulate;
- the procedures for any auction and remarketing, if any, for the preferred stock;
- the provisions for a sinking fund, if any, for the preferred stock;
- the provisions for redemption, if applicable, of the preferred stock;
- any listing of the preferred stock on any securities exchange or market;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock or another series of our preferred stock, including the conversion price (or its manner of calculation) and conversion period;
- the terms and conditions, if applicable, upon which preferred stock will be exchangeable into our debt securities, including the exchange price, or its manner of calculation, and exchange period;
- voting rights, if any, of the preferred stock; a discussion of any material and/or special United States federal income tax considerations applicable to the preferred stock;
- whether interests in the preferred stock will be represented by depositary shares;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs;
- any limitations on issuance of any series of preferred stock ranking senior to or on a parity with the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions on the preferred stock.

Unless otherwise specified in the prospectus supplement, the preferred stock will, with respect to dividend rights and rights upon liquidation, dissolution or winding up of Discovery rank:

- senior to all classes or series of our common stock, and to all equity securities issued by us the terms of which specifically provide that such equity
  securities rank junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of us;
- on a parity with all equity securities issued by us that do not rank senior or junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of us; and
- junior to all equity securities issued by us the terms of which do not specifically provide that such equity securities rank on a parity with or junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of us (including any entity with which we may be merged or consolidated or to which all or substantially all of our assets may be transferred or which transfers all or substantially all of our assets).

As used for these purposes, the term "equity securities" does not include convertible debt securities.

# **Transfer Agent and Registrar**

The transfer agent and registrar for any series of preferred stock will be set forth in the applicable prospectus supplement.

### DESCRIPTION OF COMMON STOCK

This description of our common stock is a summary. You should keep in mind, however, that it is our Restated Certificate of Incorporation and our By-Laws, and not this summary, which define any rights you may acquire as a stockholder. There may be other provisions in such documents which are also important to you. You should read such documents for a full description of the terms of our capital stock, along with the applicable provisions of Delaware law.

We currently have authorized 50 million shares of common stock, par value \$0.001 per share. As of May 31, 2011, there were 24,178,502 shares of common stock outstanding, which does not include:

- 815,088 shares of common stock issuable upon exercise of options outstanding as of May 31, 2011, at a weighted average exercise price of \$58.91 per share;
- 13,188,573 shares of common stock issuable upon exercise of warrants outstanding as of May 31, 2011, at a weighted average exercise price of \$5.55:
- 851,170 shares of common stock reserved for potential future issuance pursuant to the May 2008 CEFF;
- 1,274,925 shares of common stock reserved for potential future issuance pursuant to the June 2010 CEFF;
- 126,038 shares of common stock available for future grant under our 2007 Long-Term Incentive Plan; and
- 244,667 shares of common stock reserved for potential future issuance pursuant to a 401(k) Plan, as of May 31, 2011; and
- an indeterminate number of shares of common stock issuable under our effective shelf registration statements on Form S-3;

Subject to any preferential rights of any preferred stock created by our Board of Directors, as a holder of our common stock you are entitled to such dividends as our Board of Directors may declare from time to time out of funds that we can legally use to pay dividends. The holders of common stock possess exclusive voting rights, except to the extent our Board of Directors specifies voting power for any preferred stock that, in the future, may be issued.

As a holder of our common stock, you are entitled to one vote for each share of common stock and do not have any right to cumulate votes in the election of directors. Upon our liquidation, dissolution or winding-up, you will be entitled to receive on a proportionate basis any assets remaining after provision for payment of creditors and after payment of any liquidation preferences to holders of preferred stock. Holders of our common stock have no preemptive rights and no conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. All the outstanding shares of common stock are, and the shares offered by this prospectus, when issued and paid for, will be, validly issued, fully paid and nonassessable. Our common stock is quoted on The NASDAQ Capital Market under the symbol "DSCO.

### Stockholder Rights Plan

The summary description of the Rights set out herein does not purport to be complete, and is qualified in its entirety by reference to the terms and provisions of our Shareholder Rights Agreement, dated as of February 6, 2004 (Certain values in the following discussion gave been adjusted to give effect to a 1-for-15 reverse stock split that was effected in December 2010).

On February 6, 2004, our Board of Directors adopted a shareholder rights agreement (the Rights Agreement). Pursuant to the Rights Agreement our Board of Directors (i) declared that each stockholder of record as of the close of business on February 6, 2004, would be issued a dividend of one preferred stock purchase right (a Right) for each share of our common stock held by such stockholder and (ii) determined that each share of common stock issued by us after such date through the Final Expiration Date (as defined below) shall be issued with a tandem Right. Each Right represents the right to purchase fifteen tenthousandths (0.0015) of a share of our Series A Junior Participating Cumulative Preferred Stock (Series A Preferred) at an exercise price equal to \$50 per one ten-thousandths of a share (as the same may be adjusted, the Exercise Price). The Rights shall be evidenced by certificates for our common stock until the earlier to occur of:

- 10 days following a public announcement that a person or group of affiliated or associated persons (with certain exceptions, an Acquiring Person) have acquired beneficial ownership of 15% or more of the outstanding shares of our common stock; and
- 10 business days (or such later date as may be determined by action of the Board of Directors before such time as any person or group of affiliated persons becomes an Acquiring Person) following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the outstanding shares of Common Stock (the earlier of such dates being called the Distribution Date).

The Rights are not exercisable until the Distribution Date. Until a Right is exercised, the holder thereof, as such, will have no rights as a Discovery stockholder, including, without limitation, the right to vote or to receive dividends.

The Rights will expire upon the close of business on February 6, 2014 (the "Final Expiration Date"), unless the Rights are earlier redeemed or exchanged by us, in each case as described below.

The shares of Series A Preferred purchasable upon exercise of the Rights will be entitled, when, as and if declared, to a minimum preferential quarterly dividend payment of 10,000 times the per share amount of dividends declared on our common stock. If no common stock dividend is declared in a quarter, a preferred stock quarterly dividend of \$1.00 per share will be required. Upon our liquidation, holders of Series A Preferred will be entitled to a preferential distribution payment of at least 10,000 times the payment made per share of common stock. Each share of Series A Preferred will entitle the holder to 10,000 votes, voting together with our common stock. Upon any merger, consolidation or other transaction in which shares of our common stock are converted or exchanged, the holders of Series A Preferred will be entitled to receive 10,000 times the amount of consideration received per share of our common stock in respect of such transaction. The Rights are protected by customary anti-dilution provisions.

Because of the nature of the Series A Preferred dividend and liquidation rights, the fair market value of each one ten-thousandths of a share of Series A Preferred purchasable upon exercise of each Right should approximate the fair market value of one share of our common stock. If any person or group of affiliated or associated persons becomes an Acquiring Person, each holder of a Right, (other than Rights beneficially owned by the Acquiring Person, which become void), will have the right to receive upon exercise and payment of the then current Exercise Price, that number of shares of our common stock having a market value of two times the Exercise Price.

If, after a person or group has become an Acquiring Person, we are acquired in a merger or other business combination transaction, or 50% or more of our consolidated assets or earning power are sold, proper provision will be made so that each holder of a Right (other than Rights beneficially owned by an Acquiring Person, which become void) will thereafter have the right to receive, upon exercise at the then current Exercise Price, that number of shares of common stock of the person with whom we engaged in the foregoing transaction (or its parent), which at the time of such transaction will have a market value of two times the Exercise Price. In lieu of exercise, our Board of Directors may exchange the Rights (other than Rights owned by an Acquiring Person, which become void), in whole or in part, for such securities or other property or rights as the Board may determine, including any class or series of our common stock or preferred stock.

At any time before the time an Acquiring Person becomes such, our Board of Directors may redeem the Rights in whole, but not in part, at a price of \$.015 per Right, subject to adjustment.

We may amend the Rights to the extent and on the conditions set out in the Rights Agreement.

### **Anti-Takeover Provisions**

As a corporation organized under the laws of the State of Delaware, we are subject to Section 203 of the General Corporation Law of the State of Delaware, which restricts our ability to enter into business combinations with an interested stockholder or a stockholder owning 15% or more of our outstanding voting stock, or that stockholder's affiliates or associates, for a period of three years. These restrictions do not apply if:

- before becoming an interested stockholder, our Board of Directors approves either the business combination or the transaction in which the stockholder becomes an interested stockholder;
- upon consummation of the transaction in which the stockholder becomes an interested stockholder, the interested stockholder owns at least 85% of our voting stock outstanding at the time the transaction commenced, subject to exceptions; or
- on or after the date a stockholder becomes an interested stockholder, the business combination is both approved by our Board of Directors and authorized at an annual or special meeting of our stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

# **Number of Directors; Removal**

Our By-Laws provide that our Board of Directors shall consist of at least three directors and may consist of such larger number as may be determined, from time-to-time, by the Board of Directors. Our By-laws provide that directors may be removed with or without cause by the affirmative vote of holders of a majority of the total voting power of all outstanding securities.

This provision and the Board of Directors' right to issue shares of our preferred stock from time to time, in one or more classes or series without stockholder approval are intended to enhance the likelihood of continuity and stability in the composition of the policies formulated by our Board of Directors. These provisions are also intended to discourage some tactics that may be used in proxy fights.

### **Transfer Agent and Registrar**

The Transfer Agent and Registrar for our common stock is Continental Stock Transfer & Trust Company.

#### DESCRIPTION OF WARRANTS

# **Outstanding Warrants**

As of May 31, 2011, 13,188,573 shares of common stock were issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$5.55.

We may issue, in one or more series, debt warrants to purchase debt securities, as well as equity warrants to purchase preferred stock or common stock. The warrants may be issued independently or together with any securities and may be attached to or separate from the securities. If the warrants are issued pursuant to warrant agreements, we will so specify in the prospectus supplement relating to the warrants being offered pursuant to the prospectus supplement. While the following the terms described below will apply generally to any warrants we may offer, we will describe the particular terms of any series of warrants in the applicable prospectus supplement. The terms of any warrants offered under a prospectus supplement for a particular series of warrants may specify different or additional terms than those specified below.

### **Debt Warrants**

The applicable prospectus supplement will describe the terms of debt warrants offered, the warrant agreement relating to the debt warrants and the debt warrant certificates representing the debt warrants, including the following:

- the title of the debt warrants;
- the aggregate number of the debt warrants;
- the price or prices at which the debt warrants will be issued;
- the designation, aggregate principal amount and terms of the debt securities purchasable upon exercise of the debt warrants, and the procedures and conditions relating to the exercise of the debt warrants;
- the designation and terms of any related debt securities with which the debt warrants are issued, and the number of the debt warrants issued with each debt security;
- the principal amount of debt securities purchasable upon exercise of each debt warrant;
- the date on which the right to exercise the debt warrants will commence, and the date on which this right will expire;
- the maximum or minimum number of debt warrants which may be exercised at any time;
- a discussion of any material federal income tax considerations; and
- any other terms of the debt warrants and terms, procedures and limitations relating to the exercise of debt warrants.

Debt warrant certificates will be exchangeable for new debt warrant certificates of different denominations, and debt warrants may be exercised at the corporate trust office of the warrant agent or any other office indicated in the prospectus supplement, by delivering the properly completed and duly executed warrant certificate and paying the required amount to the warrant agent in immediately available funds. Prior to the exercise of their debt warrants, holders of debt warrants will not have any of the rights of holders of the debt securities purchasable upon exercise and will not be entitled to payment of principal of or any premium, if any, or interest on the debt securities purchasable upon exercise.

# **Equity Warrants**

The applicable prospectus supplement will describe the following terms of equity warrants offered:

- the title of the equity warrants;
- the securities (i.e., preferred stock or common stock) for which the equity warrants are exercisable;
- the price or prices at which the equity warrants will be issued;
- if applicable, the designation and terms of the preferred stock or common stock with which the equity warrants are issued, and the number of equity warrants issued with each share of preferred stock or common stock; and
- any other terms of the equity warrants, including terms, procedures and limitations relating to the exchange and exercise of equity warrants.

Holders of equity warrants will not be entitled, by virtue of being such holders, to vote, consent, receive dividends, receive notice as stockholders with respect to any meeting of stockholders for the election of our directors or any other matter, or to exercise any rights whatsoever as our stockholders.

The exercise price payable and the number of shares of common stock or preferred stock purchasable upon the exercise of each equity warrant will be subject to adjustment in certain events, including the issuance of a stock dividend to holders of common stock or preferred stock or a stock split, reverse stock split, combination, subdivision or reclassification of common stock or preferred stock. In lieu of adjusting the number of shares of common stock or preferred stock purchasable upon exercise of each equity warrant, we may elect to adjust the number of equity warrants. No adjustments in the number of shares purchasable upon exercise of the equity warrants will be required until cumulative adjustments require an adjustment of at least 1% thereof. We may, at our option, reduce the exercise price at any time. No fractional shares will be issued upon exercise of equity warrants, but we will pay the cash value of any fractional shares otherwise issuable. Notwithstanding the foregoing, in case of any consolidation, merger, or sale or conveyance of our property as an entirety or substantially as an entirety, the holder of each outstanding equity warrant shall have the right to the kind and amount of shares of stock and other securities and property, including cash, receivable by a holder of the number of shares of common stock or preferred stock into which the equity warrant was exercisable immediately prior to the transaction.

### **Exercise of Warrants**

Each warrant will entitle the holder to purchase for cash such principal amount of securities or shares of stock at such exercise price as shall in each case be set forth in, or be determinable as set forth in, the prospectus supplement relating to the warrants offered thereby. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the prospectus supplement relating to the warrants offered thereby. After the close of business on the expiration date, unexercised warrants will become void.

The warrants may be exercised as set forth in the prospectus supplement relating to the warrants offered. Upon receipt of payment and the taking of other action specified in the applicable prospectus supplement, we will, as soon as practicable, forward the securities purchasable upon exercise. If less than all of the warrants represented by such warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

# **Outstanding Warrants Under This Prospectus**

None of the warrants described in this section have been listed for trading on any securities exchange. The number of shares issuable upon exercise of any of the warrants issued prior to December 28, 2010, as well as the exercise prices and any trading thresholds triggering optional redemption and redemption prices for such warrants, have been adjusted for the 1-for-15 reverse stock split that was made effective December 28, 2010.

# Warrants Issued on February 22, 2011

Pursuant to the Prior Registration Statement, on February 22, 2011 we issued five-year warrants to purchase an aggregate of up to 5,000,000 shares of common stock and fifteen-month warrants to purchase an aggregate of up to 5,000,000 shares of common stock.

### Terms Applicable to Five-Year Warrants

The five-year warrants are exercisable at any time up to the date that is five years after such date at an exercise price of \$3.20 per share of common stock. The five-year warrants contain anti-dilution protection upon the issuance of any common stock, securities convertible into common stock, or certain other issuances at a price below the then-existing exercise price of the warrants, with certain exceptions. The terms of the five-year warrants, including the full-ratchet anti-dilution provisions, may make it difficult for us to raise additional capital consistent with prevailing market terms, if at all.

# Terms Applicable to Fifteen-Month Warrants

The fifteen-month warrants are exercisable beginning on the date of original issuance and at any time up to the date that is fifteen months after such date, at an exercise price of \$2.94 per share of common stock.

### Terms Applicable to Five-Year Warrants and Fifteen-Month Warrants

Exercisability. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. If a registration statement covering the issuance of the shares of common stock underlying the warrants is not effective and an exemption from registration for the issuance and resale of such shares would only be available if the exercise of the warrants is effected pursuant to a cashless exercise, then the holder may exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. There is no circumstance that requires us to effect a net cash settlement of the warrants.

Adjustment of Exercise Price. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. In addition, the exercise price of the five-year warrants is subject to adjustment as described above in "Terms Applicable to Five-Year Warrants."

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions. We will not enter into or be party to a fundamental transaction, which is a merger or other change of control transaction, as described in the warrants, unless the successor entity, as described in the warrants, assumes the warrants and delivers new warrants that are substantially similar. If we enter into, or are a party to, a fundamental transaction pursuant to which our stockholders are entitled or required to receive securities issued by another company or cash or other assets in exchange for shares of our common stock, which we refer to as a corporate event, a holder of a warrant will have the right to receive, upon an exercise of the warrant, consideration as if the holder had exercised its warrant immediately prior to such corporate event.

*Rights as a Stockholder*. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Waivers and Amendments. Any term of the warrants may be amended or waived with our written consent and the written consent of the holders of warrants.

# Warrants Issued on October 14, 2010

Pursuant to the Prior Registration Statement, on October 14, 2010 we issued warrants to purchase an aggregate of up to 79,365 shares of common stock.

Exercisability. The warrants are exercisable at any time up to the date that is five years after the date of original issuance at an exercise price of \$4.10 per share of common stock. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering the issuance of the shares of common stock underlying the warrants is not effective and an exemption from registration for the issuance and resale of such shares of common stock would only be available in case of a cashless exercise, the holder may exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated in payment of the aggregate exercise price, elect instead to receive the net number of shares of common stock determined according to the formula set forth in the warrant. There is no circumstance that requires us to effect a net cash settlement of the warrants.

Adjustment of Exercise Price. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Optional Redemption. The Company may redeem any or all outstanding warrants at any time within 20 days following the occurrence of a trading threshold at a per warrant redemption price of \$0.001, upon 20 days' written notice to the holder of the warrant. A trading threshold will be deemed to have occurred on any date that the reported VWAP for any five (5) out of seven (7) consecutive trading days immediately prior to such date, exceeds \$6.75, with a minimum average daily trading volume for such seven (7) day period of at least 33,333 shares of common stock (with such price and volume criteria being appropriately adjusted for any share dividend, share split or other similar transaction that may occur on or after the issuance). Upon the expiration of the 20-day notice period (as it may be extended if the registration statement is not effective) all warrants noticed for redemption that have not been exercised by the holder will, upon payment of the aggregate redemption price, cease to represent the right to purchase any shares of Common Stock and will be deemed cancelled and void and of no further force or effect without any further act or deed on our part.

Transferability. Subject to applicable securities laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions. We will not enter into or be party to a fundamental transaction, which is a merger or other change of control transaction, as described in the warrants, unless the successor entity, as described in the warrants, assumes the warrants and agrees to deliver new warrants that are substantially similar. If we enter into, or are a party to, a fundamental transaction pursuant to which our stockholders are entitled or required to receive securities issued by another company or cash or other assets in exchange for shares of our common stock, which we refer to as a corporate event, a holder of a warrant will have the right to receive, upon an exercise of the warrant, consideration as if the holder had exercised its warrant immediately prior to such corporate event.

*Rights as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Waivers and Amendments. Any term of the warrants may be amended or waived with our written consent and the written consent of the holders of warrants.

### Warrants Issued June 22, 2010

Pursuant to the Prior Registration Statement, on June 22, 2010 we issued warrants to purchase an aggregate of up to 1,190,474 shares of common stock.

Exercisability. The warrants are at any time up to the date that is five years after such date, at an exercise price of \$6.00 per share of common stock being purchased. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants is not available and an exemption from registration is otherwise not available for the resale of such shares of common stock underlying the warrants, the holder may exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. There is no circumstance that requires us to effect a net cash settlement of the warrants.

Adjustment of Exercise Price. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions. We will not enter into or be party to a fundamental transaction, which is a merger or other change of control transaction, as described in the warrants, unless the successor entity, as described in the warrants, assumes the warrants and delivers new warrants that are substantially similar. If we enter into, or are a party to, a fundamental transaction pursuant to which our stockholders are entitled or required to receive securities issued by another company or cash or other assets in exchange for shares of our common stock, which we refer to as a corporate event, a holder of a warrant will have the right to receive, upon an exercise of the warrant, consideration as if the holder had exercised its warrant immediately prior to such corporate event.

*Rights as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Waivers and Amendments. Any term of the warrants may be amended or waived with our written consent and the written consent of the holders of warrants.

### Warrant Issued on June 11, 2010

As consideration for the execution and delivery of the Common Stock Purchase Agreement with Kingsbridge (described under "Plan of Distribution - Committed Equity Financing Facility (CEFF)"), we also issued to Kingsbridge on June 11, 2010, pursuant to the Prior Registration Statement, a warrant to purchase up to 83,333 shares of our common stock, which is fully exercisable (in whole or in part) beginning December 11, 2010 and for a period of five years thereafter.

The warrant is generally exercisable at an exercise price of \$6.69 per share of common stock for cash except, in certain circumstances the warrant may be exercised on a cashless basis. In addition, the holder of the warrant may not exercise the warrant to the extent that the shares to be received pursuant to the exercise, when aggregated with all other shares beneficially owned by such holder, would result in the holder owning more than 9.9% of the common stock outstanding on the exercise date or our being required to file any notification or report under the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended.

The exercise price of the warrant is subject to anti-dilution adjustments, including upon reclassification, consolidation, merger, mandatory share exchange, sale of substantially all assets, subdivision or combination of shares, issuance of stock dividends, issuance of liquidating dividends and spin-offs.

In case of a failure by Kingsbridge, reasonably within the control of Kingsbridge, to accept a properly made draw down notice under the CEFF, the warrant permits us to demand surrender of the warrant or any remaining portion of the warrant, shares underlying the warrant or cash from the holder under certain circumstances as described in the warrant.

# Warrants Issued on April 30, 2010

Pursuant to the Prior Registration Statement, on April 30, 2010 we issued warrants to purchase an aggregate of up to 135,077 shares of common stock.

Exercisability. The warrants became exercisable 181 days after the date of original issuance until five years after the date of original issuance at an exercise price of \$10.59 per share of common stock. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants, and an exemption from registration are not available for the resale of such shares of common stock underlying the warrants, the holder may, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

Adjustment of Exercise Price. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions. We will not enter into or be party to a fundamental transaction, which is a merger or other change of control transaction, as described in the warrants, unless the successor entity, as described in the warrants, assumes the warrants and delivers new warrants that are substantially similar. If we enter into, or are a party to, a fundamental transaction pursuant to which our stockholders are entitled or required to receive securities issued by another company or cash or other assets in exchange for shares of our common stock, which we refer to as a corporate event, a holder of a warrant will have the right to receive, upon an exercise of the warrant, consideration as if the holder had exercised its warrant immediately prior to such corporate event.

*Rights as a Stockholder*. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Waivers and Amendments. Any term of the warrants may be amended or waived with our written consent and the written consent of the holders of warrants.

# Warrants Issued on February 23, 2010

Pursuant to the Prior Registration Statement, on February 23, 2010 we issued warrants to purchase an aggregate of up to 916,669 shares of common stock.

Exercisability. The warrants are exercisable beginning on the date of original issuance and at any time up to the date that is five years after such date at an exercise price of \$12.75 per share of common stock. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

Adjustment of Exercise Price. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions. We will not enter into or be party to a fundamental transaction, which is a merger or other change of control transaction, as described in the warrants, unless the successor entity, as described in the warrants, assumes the warrants and delivers new warrants that are substantially similar. If we enter into, or are a party to, a fundamental transaction pursuant to which our stockholders are entitled or required to receive securities issued by another company or cash or other assets in exchange for shares of our common stock, which we refer to as a corporate event, a holder of a warrant will have the right to receive, upon an exercise of the warrant, consideration as if the holder had exercised its warrant immediately prior to such corporate event.

*Rights as a Stockholder*. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Waivers and Amendments. Any term of the warrants may be amended or waived with our written consent and the written consent of the holders of warrants.

### Warrants Issued on May 13, 2009

Pursuant to the Prior Registration Statement, on May 13, 2009, we issued warrants to purchase an aggregate of up to 466,667 shares of common stock.

Exercisability. The warrants are exercisable at any time up to the date that is five years after such date at an exercise price of \$17.25 per share of common stock. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, except upon at least 61 days' prior notice from the holder to us, the holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

Adjustment of Exercise Price. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions. We will not enter into or be party to a fundamental transaction, which is a merger or other change of control transaction, as described in the warrants, unless the successor entity, as described in the warrants, assumes the warrants and delivers new warrants that are substantially similar. If we enter into, or are a party to, a fundamental transaction pursuant to which our stockholders are entitled or required to receive securities issued by another company or cash or other assets in exchange for shares of our common stock, which we refer to as a corporate event, a holder of a warrant will have the right to receive, upon an exercise of the warrant, consideration as if the holder had exercised its warrant immediately prior to such corporate event.

*Rights as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Waivers and Amendments. Any term of the warrants may be amended or waived with our written consent and the written consent of the holders of warrants.

# PLAN OF DISTRIBUTION

We may sell the securities being offered by us in this prospectus pursuant to underwritten public offerings, negotiated transactions, block trades or any combination of such methods. We may sell the securities to or through underwriters, dealers, agents or directly to one or more purchasers. We and our agents reserve the right to accept and to reject in whole or in part any proposed purchase of securities. A prospectus supplement or post-effective amendment, which we will file each time we effect an offering of any securities, will provide the names of any underwriters, dealers or agents, if any, involved in the sale of such securities, and any applicable fees, commissions, or discounts to which such persons shall be entitled to in connection with such offering.

We and our agents, dealers and underwriters, as applicable, may sell the securities being offered by us in this prospectus from time to time in one or more transactions at:

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale;
- prices related to such prevailing market prices;
- varying prices determined at the time of sale; or

negotiated prices.

We may determine the price or other terms of the securities offered under this prospectus by use of an electronic auction. We will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the underwriters' obligations in the applicable prospectus supplement or amendment.

We may solicit directly offers to purchase securities. We may also designate agents from time to time to solicit offers to purchase securities. Any agent that we designate, who may be deemed to be an underwriter as that term is defined in the Securities Act, may then resell such securities to the public at varying prices to be determined by such agent at the time of resale.

We may engage in at the market offerings of our common stock. An at the market offering is an offering of our common stock at other than a fixed price to or through a market maker. We shall name any underwriter that we engage for an at the market offering in a post-effective amendment to the registration statement containing this prospectus. We shall also describe any additional details of our arrangement with such underwriter, including commissions or fees paid, or discounts offered, by us and whether such underwriter is acting as principal or agent, in the related prospectus supplement.

If we use underwriters to sell securities, we will enter into an underwriting agreement with the underwriters at the time of the sale to them, which agreement shall be filed as an exhibit to the related prospectus supplement. Underwriters may also receive commissions from purchasers of the securities. Underwriters may also use dealers to sell securities. In such an event, the dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents.

Underwriters, dealers, agents and other persons may be entitled, under agreements that may be entered into with us, to indemnification by us against certain civil liabilities, including liabilities under the Securities Act or to contribution with respect to payments which they may be required to make in respect of such liabilities. Underwriters and agents may engage in transactions with, or perform services for, us in the ordinary course of business.

If so indicated in the applicable prospectus supplement, we may authorize underwriters, dealers or other persons to solicit offers by certain institutions to purchase the securities offered by us under this prospectus pursuant to contracts providing for payment and delivery on a future date or dates. The obligations of any purchaser under these contracts will be subject only to those conditions described in the applicable prospectus supplement, and the prospectus supplement will set forth the price to be paid for securities pursuant to those contracts and the commissions payable for solicitation of the contracts.

Any underwriter may engage in over-allotment, stabilizing and syndicate short covering transactions and penalty bids in accordance with Regulation M of the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions involve bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate short covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the underwriters to reclaim selling concessions from dealers when the securities originally sold by such dealers are purchased in covering transactions to cover syndicate short positions. These transactions may cause the price of the securities sold in an offering to be higher than it would otherwise be. These transactions, if commenced, may be discontinued by the underwriters at any time.

Our common stock is quoted on Nasdaq Capital Market under the symbol "DSCO." The other securities are not listed on any securities exchange or other stock market and, unless we state otherwise in the applicable prospectus supplement, we do not intend to apply for listing of the other securities on any securities exchange or other stock market. Any underwriters to whom we sell securities for public offering and sale may make a market in the securities that they purchase, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. Accordingly, we give you no assurance as to the development or liquidity of any trading market for the securities.

The anticipated date of delivery of the securities offered hereby will be set forth in the applicable prospectus supplement relating to each offering.

In order to comply with certain state securities laws, if applicable, the securities may be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the securities may not be sold unless the securities have been registered or qualified for sale in such state or an exemption from regulation or qualification is available and is complied with. Sales of securities must also be made by us in compliance with all other applicable state securities laws and regulations.

We shall pay all expenses of the registration of the securities.

### **Committed Equity Financing Facility (CEFF)**

On June 11, 2010, we entered into our fifth Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge), a private investment firm. Specifically, we entered into a Common Stock Purchase Agreement, which entitles us to sell, and obligates Kingsbridge to purchase, from time to time over a period of three years, subject to certain conditions and restrictions, shares of our common stock for cash consideration of up to an aggregate of the lesser of \$35 million or 2,106,476 shares (adjusted for the 1-for-15 reverse stock split), representing 19.99% of the shares of our common stock outstanding as of such date (but in no event more than the number of shares that we may issue under the CEFF without breaching our obligations under the rules and regulations of The NASDAQ Capital Market and the principal trading market at the time, including those relating to stockholder approval).

As consideration for the execution and delivery of the Common Stock Purchase Agreement, we also issued to Kingsbridge, pursuant to the Prior Registration Statement, a warrant to purchase up to 83,333 shares of our common stock at a price of \$6.69 per share (adjusted for the 1-for-15 reverse stock split) (the "Kingsbridge Warrant"), which is further described under "Description of the Warrants - Warrant issued June 11, 2011."

The shares of common stock that may be issued to Kingsbridge under the Common Stock Purchase Agreement and upon exercise of the Kingsbridge Warrant were initially registered under the Prior Registration Statement. Of such shares, 831,551 shares (adjusted for the 1-for-15 reverse stock split) have been issued under the Prior Registration Statement for an aggregate offering price of \$2.4 million and up to the lesser of 1,274,925 shares or \$32.6 million in aggregate offering price may be issued under the registration statement to which this prospectus relates, in addition to up to 83,333 shares that may be issued upon exercise of the Kingsbridge Warrant. Kingsbridge may offer to the public for sale the shares of our common stock that we may issue to it pursuant to the Common Stock Purchase Agreement, or that Kingsbridge may acquire upon exercise of the Kingsbridge Warrant.

Under the CEFF, for a period of 36 months from the date of execution of the Common Stock Purchase Agreement, we may, from time to time, at our discretion and subject to certain conditions that we must satisfy, "draw down" funds under the CEFF by selling shares of our common stock to Kingsbridge. To initiate a draw down, we will issue to Kingsbridge a "draw down notice" containing among other information the total draw down amount, the first day of the draw down pricing period, which will consist of eight consecutive trading days, and the "threshold price," or the minimum price at which a purchase may be completed on any trading day. The threshold price may be either (i) 90% of the closing price of our common stock on the trading day immediately preceding the first trading day of the draw down pricing period or (ii) a price that we determine, in our sole discretion, but not less than \$0.20 per share. The purchase price of the shares to be purchased in a draw down will be at a discount ranging from 4.375% to 17.5% of the volume-weighted average price (VWAP) of our common stock for each of the eight consecutive trading days in the draw down pricing period. The discount on each trading day will be determined as follows:

VWAP*	% of VWAP (Applicable Discount)
Equal to or exceeds \$6.00	4.375
Equal to or exceeds \$5.00 but is less than \$6.00	4.750
Equal to or exceeds \$4.00 but is less than \$5.00	5.250
Equal to or exceeds \$3.00 but is less than \$4.00	5.750
Equal to or exceeds \$2.00 but is less than \$3.00	6.000
Equal to or exceeds \$1.25 but is less than \$2.00	7.500
Equal to or exceeds \$0.75 but is less than \$1.25	8.500
Equal to or exceeds \$0.50 but is less than \$0.75	9.500
Equal to or exceeds \$0.25 but is less than \$0.50	15.000
Equal to or exceeds \$0.20 but is less than \$0.25	17.500

<sup>\*</sup> As defined in the Common Stock Purchase Agreement, "VWAP" means the volume-weighted average price per share (the aggregate sales price of all trades of our common stock during each trading day divided by the total number of shares of common stock traded during that trading day) of our common stock during any trading day as reported by Bloomberg, L.P. using the AQR function or another mutually agreed recognized trading platform.

If the daily VWAP of our common stock falls below a threshold price on any trading day during a draw down pricing period, the Common Stock Purchase Agreement provides that any such trading day will be disregarded in calculating the number of shares of common stock to be issued in respect of the draw down pricing period and the total draw down amount shall be reduced by one eighth for each such day. However, at its election, Kingsbridge may buy up to the pro-rata portion of shares allocated to any day that is disregarded at a purchase price determined by reference to the threshold price instead of the VWAP, less the discount specified in the table above.

In addition, if trading in our common stock is suspended for any reason for more than three consecutive or non-consecutive hours during any trading day during a draw down pricing period, Kingsbridge will not be required, but may elect, to purchase the pro-rata portion of shares of common stock allocated to that day.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. Each draw down is limited to the lesser of \$15 million or 3.5% of our market capitalization as of the date on which the draw down notice is delivered. Unless Kingsbridge agrees otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next draw down pricing period. Kingsbridge is not obligated to purchase shares at a purchase price that is below \$0.20 per share (before applicable discount). Accordingly, there is no assurance that we will be able to access the CEFF, if ever, at such times and in amounts that are necessary to fund our activities.

The Common Stock Purchase Agreement also provides that, in connection with each draw down, we may in our discretion include in our draw down notice a request that Kingsbridge purchase an amount that is in addition to the amount that Kingsbridge is otherwise obligated under the Common Stock Purchase Agreement to purchase in connection with such draw down pricing period (a supplemental amount). If we designate a supplemental amount, we may also designate a separate threshold price with respect to such supplemental amount, subject to a minimum price per share of \$0.20. The supplemental amount in each draw down pricing period is not subject to a dollar limitation, except that, when aggregated with all other amounts drawn by us under the Common Stock Purchase Agreement, the supplemental amount may not exceed the total commitment amount available under the agreement. If Kingsbridge agrees to purchase any supplemental amount, in whole or in part, we will sell to Kingsbridge that number of shares of our common stock that equals the supplemental amount, or portion thereof designated by Kingsbridge, at a price equal to the greater of (i) the daily VWAP of our common stock on the trading day with respect to which Kingsbridge notifies us of its election to exercise its option or (ii) the supplemental amount threshold price designated by us, in either case less a discount calculated in the same manner specified in the table above.

During the term of the CEFF, without the written consent of Kingsbridge, we may not enter into any equity line or other financing that is substantially similar to the CEFF or agree to issue any shares of common stock or securities of any type that are, or may become, convertible or exchangeable into shares of common stock where the purchase, conversion or exchange price for such common stock is determined using any floating discount or other post-issuance adjustable discount to the market price of common stock. Any future issuance by us of a convertible security that (i) contains provisions that adjust the conversion price of such convertible security solely for stock splits, dividends, distributions or similar events or pursuant to anti-dilution provisions or (ii) is issued in connection with debt financing to support research and development activities and conditioned upon us meeting certain developmental milestones and of any security issued in a secured debt financing is permitted.

Kingsbridge agreed in the Common Stock Purchase Agreement that, during the term of the CEFF, neither Kingsbridge nor any of its affiliates, nor any entity managed or controlled by it, will, or will cause or assist any person to, enter into any short sale of any of our securities, as "short sale" is defined in Regulation SHO promulgated under the Securities Exchange Act of 1934, as amended.

Before Kingsbridge is obligated to buy any shares of our common stock pursuant to a draw down, the following conditions, none of which is in Kingsbridge's control, must be met or waived:

- Each of our representations and warranties in the Common Stock Purchase Agreement must be true and correct in all material respects as of the date when made and as of the date of the applicable draw down notice as though made at that time, except for representations and warranties that are expressly made as of a particular date.
- We must have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required to be performed, satisfied or complied with by us under the Common Stock Purchase Agreement and the Kingsbridge Warrant.
- We must have complied in all respects with all applicable federal, state and local governmental laws, rules, regulations and ordinances in connection with the execution, delivery and performance of the Common Stock Purchase Agreement and the consummation of the transactions it contemplates except for any failures to so comply that would not reasonably be expected to have a material adverse effect on us.
- The registration statement that includes this prospectus must be effective under the Securities Act and neither we nor Kingsbridge shall have received notice that the SEC has issued or intends to issue a stop order with respect to the registration statement or that the SEC otherwise has suspended or withdrawn the effectiveness of the registration statement, or intends or has threatened to do so and no other suspension of the use or withdrawal of the effectiveness of the registration statement shall exist.
- We must not have knowledge of any event that could reasonably be expected to have the effect of causing the registration statement to be suspended or otherwise ineffective as of the settlement date for the purchase of shares under the CEFF.

- Trading in our common stock shall not have been suspended by the SEC, The NASDAQ Capital Market (or other principal market on which our common stock is traded) or the Financial Industry Regulatory Authority and trading in securities generally on The NASDAQ Capital Market (or other principal market on which our common stock is traded) shall not have been suspended or limited.
- No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed or, to our knowledge, threatened by any court or governmental authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by the Common Stock Purchase Agreement.
- No action, suit or proceeding before any arbitrator or any governmental authority shall be pending or, to our knowledge, threatened, and, to our
  knowledge, no inquiry or investigation by any governmental authority shall have been threatened against us or any of our officers, directors or
  affiliates seeking to enjoin, prevent or change the transactions contemplated by the Common Stock Purchase Agreement, or seeking material damages
  in connection with such transactions, except for any action, suit or proceeding which could not reasonably be expected to have a material adverse
  effect.
- We must have sufficient shares of common stock, calculated using the closing trade price of the common stock as of the trading day immediately preceding a draw down, registered under the registration statement to issue and sell such shares in accordance with such draw down.
- We must generally be current on any and all invoices submitted to us regarding fees and expenses of Kingsbridge, except for such fees, or portion thereof, that we dispute in good faith.
- Prior to delivery of the first draw down notice, Kingsbridge must have received an opinion from our outside legal counsel.

There is no guarantee that we will be able to meet the foregoing conditions or any other conditions under the Common Stock Purchase Agreement or that we will be able to draw down any portion of the amounts available under the CEFF.

We are entitled in certain circumstances, including the existence of certain kinds of nonpublic information, to deliver a blackout notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus, for not more than 30 days. If we deliver a blackout notice in the five trading days following the settlement of a draw down, then we must pay amounts to Kingsbridge, or issue Kingsbridge additional shares in lieu of payment, calculated by means of a varying percentage of an amount based on the number of shares held by Kingsbridge that were purchased pursuant to the draw down and the change in the market price of our common stock between the date the blackout notice is delivered and the date the prospectus again becomes available.

Kingsbridge may terminate the CEFF upon one business day's notice to us if we enter into a transaction prohibited by the Common Stock Purchase Agreement without Kingsbridge's prior written consent or if a material adverse effect relating to our business continues for ten trading days after we receive notice from Kingsbridge of the material adverse effect. We may terminate the CEFF upon one business day's notice to Kingsbridge, except that we may not terminate the CEFF during any draw down pricing period. In addition, either we or Kingsbridge may terminate the CEFF upon one business day's notice if the other party has breached a material representation, warranty or covenant to the Common Stock Purchase Agreement and such breach is not remedied within 10 trading days after notice of such breach is delivered to the breaching party.

The foregoing summary of the CEFF does not purport to be complete and is qualified by reference to the Common Stock Purchase Agreement and the Kingsbridge Warrant, copies of which have been filed or incorporated by reference as exhibits to the registration statement of which this prospectus is a part.

In addition to our issuance of shares of common stock to Kingsbridge pursuant to the Common Stock Purchase Agreement and of the Kingsbridge Warrant issued to Kingsbridge as consideration for the execution of the Common Stock Purchase Agreement, the registration statement to which this prospectus relates also covers the sale of those shares and the shares issuable upon exercise of the Kingsbridge Warrant, from time to time by Kingsbridge to the public.

As described above, the number of shares to be issued by us in connection with any draw down pricing period, and the aggregate purchase price for these shares, will not be known until the draw down pricing period is complete.

The shares of common stock issued under the Common Stock Purchase Agreement may be sold in one or more of the following manners:

- ordinary brokerage transactions and transactions in which the broker solicits purchasers; or
- a block trade in which the broker or dealer so engaged will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction.

In addition, Kingsbridge and any unaffiliated broker-dealer will be subject to liability under the federal securities laws and must comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock by Kingsbridge or any unaffiliated broker-dealer. Under these rules and regulations, Kingsbridge and any unaffiliated broker-dealer:

- may not engage in any stabilization activity in connection with our common stock;
- must furnish each broker which offers shares of our common stock covered by the prospectus that is a part of our registration statement with the number of copies of such prospectus and any prospectus supplement which are required by each broker; and
- may not bid for or purchase any of our common stock or attempt to induce any person to purchase any of our common stock other than as permitted
  under the Exchange Act.

These restrictions may affect the marketability of the shares of common stock purchased and sold by Kingsbridge and any unaffiliated broker-dealer.

We and Kingsbridge have agreed to indemnify and hold each other and each person who controls us and Kingsbridge, respectively, harmless against certain liabilities, including certain liabilities under the Securities Act. We have agreed to pay up to \$45,000 of Kingsbridge's reasonable attorneys' fees and expenses (exclusive of disbursements and out-of-pocket expenses) incurred by Kingsbridge in connection with the preparation, negotiation, execution and delivery of the Common Stock Purchase Agreement and related transaction documentation. We have also agreed to pay (i) certain fees and expenses incurred by Kingsbridge in connection with any amendments, modifications or waivers of the Common Stock Purchase Agreement and (ii) as compensation for all other ongoing due diligence of our company, legal and transaction expenses of Kingsbridge, a fee equal to 1.85% of the gross proceeds of each individual draw down. Further, if we issue a draw down notice and fail to cause delivery of the shares to Kingsbridge within two trading days of the applicable settlement date, we have agreed to pay Kingsbridge as liquidated damages (prorated over the initial 30 days following the settlement date) equal to 2% of the payment required to be made by Kingsbridge with respect to such shares and an amount that when taken together with the liquidated damages, compensates Kingsbridge for any actual loss incurred as a result of failure to deliver.

#### **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2010, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

#### **LEGAL MATTERS**

If and when the securities being registered hereunder are issued, the validity of such issuance will be passed upon for us by SNR Denton US LLP, New York, New York.

# WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and periodic reports, proxy statements and other information with the SEC. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of our SEC filings are also available to the public from the SEC's Website at "http://www.sec.gov." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to ir@DiscoveryLabs.com or contact John G. Cooper, our President and Chief Financial Officer, at the following address or telephone number: Discovery Laboratories, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, Attention: John G. Cooper; (215) 488-9300. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

We maintain a Website at "http://www.DiscoveryLabs.com". Our Website and the information contained therein or connected thereto are not incorporated into this Registration Statement.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act relating to the securities we are offering by this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further information with respect to us and our securities. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the registration statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

### INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents filed with SEC listed below:

- 1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed on March 31, 2011, as amended by our Annual Report on Form 10-K/A, filed on April 29, 2011;
- 2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed on May 13, 2011;
- 3. Our Current Reports on Form 8-K filed with the SEC on January 10, 2011, January 12, 2011, February 2, 2011, February 9, 2011, February 16, 2011, March 22, 2011 (excluding the matters in Item 2.02 and Exhibit 99.1 therein, which are not incorporated by reference herein), May 11, 2011 (excluding the matters in Item 2.02 and Exhibit 99.1 therein, which are not incorporated by reference herein), and June 1, 2011; and
- 4. The description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on July 13, 1995.

All reports and other documents subsequently filed by us with the SEC pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 after the date of this prospectus and before the termination of the offering shall be deemed to be incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of such reports and documents. This prospectus also incorporates by reference any documents that we file with the SEC after the date that the initial registration statement is filed with the SEC and before the effectiveness of the registration statement. Any statement contained in any document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a copy of these filings, at no cost, by sending an e-mail to ir@DiscoveryLabs.com and requesting any one or more of such filings or by contacting John G. Cooper, our President and Chief Financial Officer, at the following address or telephone number: Discovery Laboratories, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622, Attention: John G. Cooper; (215) 488-9300. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

\$200,000,000



Discovery Laboratories, Inc.

Debt Securities, Preferred Stock and Common Stock, Debt Warrants and Equity Warrants

No dealer, salesperson or other person is authorized to provide you with information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. We are offering to sell, and seeking offers to buy, only the securities of Discovery Laboratories, Inc. covered by this prospectus, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or of any sale of the shares.

June 21, 2011



# PROSPECTUS SUPPLEMENT

Stifel Piper Jaffray

Lazard Capital Markets Roth Capital Partners

October , 2013