

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

**FORM S-3**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

**DISCOVERY LABORATORIES, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**94-3171943**

(I.R.S. Employer Identification Number)

**2600 Kelly Road, Suite 100  
Warrington, Pennsylvania 18976**

(Address, Including Zip Code and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

**Mary B. Templeton, Esq.  
Senior Vice President, General Counsel and Corporate Secretary**

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

**(215) 488-9300**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

**Ira L. Kotel, Esq.  
Dentons US LLP  
1221 Avenue of the Americas  
New York, New York 10020  
(212) 768-6700**

**Approximate date of commencement of proposed sale to public:** From time to time or at one time after this registration statement becomes effective in light of market conditions and other factors.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (Securities Act), other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the U.S. Securities and Exchange Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (Exchange Act).

Large accelerated filer   
 Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer   
 Smaller reporting company

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered <sup>(1)(2)</sup>	Proposed Maximum Offering Price Per Unit <sup>(1)(2)</sup>	Proposed Maximum Aggregate Offering Price <sup>(2)(3)</sup>	Amount of Registration Fee <sup>(4)</sup>
<b>Debt Securities</b>				
Preferred Stock, par value \$.001 per share				
Common Stock, par value \$.001 per share				
<b>Warrants</b>				
<b>Total</b>	<b>\$ 250,000,000</b>	<b>100%</b>	<b>\$ 250,000,000</b>	<b>\$ 32,200</b>

- (1) There are being registered under this registration statement such indeterminate number of shares of common stock and preferred stock of the registrant, such indeterminate number of warrants of the registrant and such indeterminate principal amount of debt securities of the registrant, as shall have an aggregate initial offering price not to exceed \$250,000,000. There are being registered under this registration statement such indeterminate number of each identified class of the identified securities as may be issued upon conversion, exchange, or exercise of any other securities that provide for such conversion, exchange or exercise, up to a proposed maximum offering price of \$250,000,000. In addition, pursuant to Rule 416 under the Securities Act, the shares of common stock and preferred stock being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions. The common stock to be issued pursuant to this registration statement may include the issuance of shares of common stock issuable pursuant to currently outstanding warrants as follows: (a) up to 4,552,600 shares issuable upon exercise of warrants at an exercise price of \$1.50 per share through February 22, 2016, (b) up to 79,365 shares issuable upon exercise of warrants at an exercise price of \$4.10 per share through October 13, 2015, (c) up to 1,190,474 shares issuable upon exercise of a warrant at an exercise price of \$6.00 per share through June 22, 2015, (d) up to 83,333 shares issuable upon exercise of warrants at an exercise price of \$6.69 through December 11, 2015, (e) up to 135,077 shares issuable upon exercise of warrants at an exercise price of \$10.59 through April 30, 2015, and (f) up to 916,669 shares issuable upon exercise of warrants at an exercise price of \$12.75 per share through February 23, 2015. If any debt securities are issued at an original issue discount, then the debt securities registered pursuant to this registration statement shall include such greater principal amount as shall result in an amount to be registered hereunder that equals the aggregate initial offering price, but in no event shall the initial public offering price of securities registered hereunder exceed \$250,000,000 less the aggregate dollar amount of all securities previously issued hereunder, or the equivalent thereof in one or more foreign currencies. Any securities registered under this registration statement may be sold separately or as units with other securities registered under this registration statement. The proposed maximum initial offering prices per unit will be determined, from time to time, by the registrant in connection with the issuance by the registrant of the securities registered under this registration statement.
- (2) Not specified with respect to each class of securities being registered under this registration statement pursuant to General Instruction II.D. of Form S-3 under the Securities Act.
- (3) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act. No additional consideration will be received for common stock, preferred stock or debt securities that are issued upon conversion into or exchange for or exercise of preferred stock or debt securities. The proposed maximum aggregate offering price per class of security will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act.

(4) Pursuant to Rule 457(o) under the Securities Act, the registration fee is calculated on the maximum offering price of all securities listed, and the table does not specify information by each class about the amount to be registered. Pursuant to Rule 415(a)(6) under the Securities Act, this registration statement includes a total of \$70,026,788 of unsold securities that had previously been registered under the Registrant's registration statement on Form S-3, initially filed with the U.S. Securities and Exchange Commission (Commission) on June 8, 2011 (No. 333-174786) (2011 Registration Statement). The 2011 Registration Statement initially registered securities for a maximum aggregate offering price of \$200,000,000 and of that amount the Registrant has previously sold common stock and warrants for an aggregate offering price of \$129,973,212, leaving a balance of unsold securities with an aggregate offering price of \$70,026,788. In connection with the registration of such unsold securities on the 2011 Registration Statement, the Registrant paid a registration fee of \$8,130 for such unsold securities, which registration fee will continue to be applied to such unsold securities. Pursuant to Rule 415(a)(6), the offering of the unsold securities registered under the 2011 Registration Statement will be deemed terminated as of the date of effectiveness of this registration statement. If the Registrant sells any of such unsold securities pursuant to the 2011 Registration Statement after the date of the initial filing, and prior to the date of effectiveness, of this registration statement, the registrant will file a pre-effective amendment to this registration statement which will reduce the number of such unsold securities included on this registration statement and increase the additional securities registered hereon so that the total amount of securities registered hereon will equal \$250,000,000, and will pay the additional registration fee resulting therefrom.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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## EXPLANATORY NOTE

This registration statement contains two prospectuses:

- a base prospectus which covers the offering, issuance and sale by us of up to \$250,000,000 of our debt securities, preferred stock, common stock, debt warrants and equity warrants; and
- a sales agreement prospectus covering the offering, issuance and sale by the Registrant of up to \$23,038,092 of our common stock that may be issued and sold under an at-the-market equity offering sales agreement dated February 11, 2013 (ATM Program) with Stifel, Nicolaus & Company, Incorporated.

The base prospectus immediately follows this explanatory note. The sales agreement prospectus immediately follows the base prospectus. The \$23,038,092 of common stock that may be offered, issued and sold by us under the sales agreement prospectus is included in the \$250,000,000 of securities that may be offered, issued and sold by us under the base prospectus.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the U.S. Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where an offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED MAY 30, 2014**

**PROSPECTUS**

**\$250,000,000**



**Discovery Laboratories, Inc.**

**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 \$250,000,000 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® (Nasdaq) 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.

**Investing in our securities involves significant risks. See “Risk Factors” beginning on page 6.**

**Neither the U.S. Securities and Exchange Commission (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      , 2014.

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Commission 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. 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. Using this prospectus, we may offer up to a total dollar amount of \$250,000,000 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 Commission 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 Commission.

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.

## PROSPECTUS SUMMARY

### 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 (KL<sub>4</sub> surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL<sub>4</sub> surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of our aerosolized KL<sub>4</sub> surfactant using less invasive administration procedures than presently required. We believe that our proprietary technologies may make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

### Initial Focus – Respiratory Distress Syndrome in Premature Infants

We are initially focused on improving the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants. RDS is the most prevalent respiratory disease in the neonatal intensive care unit (NICU) and can result in long-term respiratory problems, developmental delay and death.

Our first KL<sub>4</sub> surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the U.S. Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL<sub>4</sub> surfactant in liquid form and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States. SURFAXIN has been commercially available in the United States since November 2013.

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

AEROSURF® is our investigational combination drug/device product that combines our KL<sub>4</sub> surfactant with our proprietary capillary aerosol generator (CAG). With AEROSURF, if approved, neonatologists potentially will be able to administer aerosolized KL<sub>4</sub> surfactant to premature infants supported by nCPAP alone, without invasive intubation and mechanical ventilation. By enabling delivery of our KL<sub>4</sub> surfactant using less invasive procedures, we believe that AEROSURF may address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

We are also developing a lyophilized (freeze-dried) dosage form of our KL<sub>4</sub> surfactant that is stored as a powder and reconstituted to liquid form prior to use with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are initially developing this dosage form for use in our AEROSURF development program. We also plan to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and, if successful, expect to commercially introduce this dosage form as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the United States and potentially in other markets.

To support the commercial introduction of SURFAXIN in the United States and our other KL<sub>4</sub> surfactant pipeline products, if approved, we have established our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL<sub>4</sub> surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL<sub>4</sub> surfactant.



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

### **Beyond Respiratory Distress Syndrome**

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

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

### **Trademark Notice**

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

### **Corporate Information**

We maintain our principal offices and research facilities at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976. Our telephone number is 215-488-9300. We maintain our corporate website at <http://www.DiscoveryLabs.com>. Our website and the information contained therein or connected thereto are not incorporated into this prospectus.

## SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time during which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans, and our expectations related to the commercialization of SURFAXIN and our development and potential regulatory plans to secure marketing authorization for our products under development, starting with AEROSURF, if approved; our expectations, timing and anticipated outcomes of submitting regulatory filings for our products under development; our research and development programs, including planning for development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant pipeline, our CAG for delivery of aerosolized medications; plans for the manufacture of drug products, active pharmaceutical ingredients and materials and medical devices; and plans regarding potential strategic alliances and other collaborative arrangements to develop, manufacture and market our products.

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

- the risk that we will require in the near term, but may be unable to secure, significant additional capital to continue our operations, fund our debt service and support our research and development activities, including expensive and time-consuming clinical trials, until such time, if ever, that our revenues from all sources are sufficient to offset our cash outflows. To the extent that we raise such capital through additional financings, such additional financings could result in equity dilution;
- the risk that, if we fail to successfully commercialize SURFAXIN, and if we do not achieve revenues consistent with our expectations, it may be more difficult to secure the additional capital we will require when needed, if at all, whether from strategic alliances or other sources, to continue our commercial and medical affairs activities, as well as our research and development programs and our operations would be impaired, which ultimately could have a material adverse effect on our business, financial condition and results of operations;
- risks relating to the ability of our sales and marketing organization to effectively introduce SURFAXIN in the United States and, if approved, our other product candidates, in a timely manner, if at all; and that we may not succeed in developing sufficient market awareness of our products or that our product candidates may not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;
- risks relating to our ability to timely modify our business strategy to respond to changing circumstances, assumptions and forecasts, and otherwise as needed to manage growth effectively and respond to developments in our commercial operations and research and development activities, as well as our business, our industry and other factors;
- the risk that our AEROSURF phase 2 clinical program may be interrupted, delayed, or fail, which will harm our business;
- the risk that we and the FDA or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;
- risks relating to the transfer of our manufacturing technology to CMOs and assemblers;
- risks relating to our and our CMOs' ability to manufacture our KL4 surfactant, in liquid and lyophilized dosage forms, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for both commercial and research and development activities;
- risks relating to our and our CMOs' ability to develop and manufacture combination drug/device products based on our CAG technology, for preclinical and clinical studies of our product candidates and, if approved, for commercialization;

- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems in manufacturing our KL<sub>4</sub> surfactant drug products and the active pharmaceutical ingredients used in the manufacture of our drug products, CAG devices and other materials on a timely basis or in an amount sufficient to support our needs;
- the risk that we may not succeed in implementing our long-term manufacturing strategy to assure continuity of SURFAXIN commercial drug product supply, which could expose us to risks that may affect our ability to maintain sufficient supplies of SURFAXIN commercial drug product;
- 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 United States with the development of our KL<sub>4</sub> surfactant pipeline products, beginning with AEROSURF, including development of our lyophilized KL<sub>4</sub> surfactant, and, if approved, commercialization of AEROSURF in markets outside the United States; 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;
- risks relating to our plans potentially to secure marketing and distribution capabilities in certain markets through third-party strategic alliances and/or marketing alliances and/or distribution arrangements, that could require us to give up rights to our drug products, drug product candidates and drug delivery technologies;
- risks relating to our pledge of substantially all of our assets to secure our obligations under the Deerfield Loan, which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investment;
- the risk that market conditions, the competitive landscape or other factors may make it difficult to launch and profitably sell our products;
- risks relating generally to our research and development activities, which among other things may involve time-consuming and expensive preclinical studies and potentially multiple clinical trials that may be subject to potentially significant delays or regulatory holds or fail;
- risks related to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug products, medical device and combination drug/device product candidates, including AEROSURF, and our lyophilized KL<sub>4</sub> surfactant that we expect will be the drug component of AEROSURF and potentially be developed as a life cycle extension of SURFAXIN under the name SURFAXIN LS;
- risks relating to the rigorous regulatory approval processes, including pre-filing activities, required for approval of any drug, combination drug-device product or medical device that we may develop, whether independently, with strategic development partners or pursuant to collaboration arrangements;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;
- risks that unfavorable credit and financial markets may adversely affect our ability to fund our activities, through our “at the market offering” program (ATM Program) or otherwise, and that our ATM Program may expire unutilized or be exhausted; and that additional equity financings could result in substantial equity dilution or result in a downward adjustment to the exercise price of five-year warrants that we issued in February 2011 (which contain price-based anti-dilution adjustments);
- risks that reimbursement and health care reform may adversely affect us or that our products will not be accepted by physicians and others in the medical community;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug products and medical device candidates;
- the risk that if we fail to maintain compliance with continued listing requirements of Nasdaq, our common stock may be delisted and the value of our common stock decrease;
- the risks that we may be unable to maintain and protect the patents and licenses related to our products and that other companies may develop competing therapies and/or technologies;
- the risks that we may become involved in securities, product liability and other litigation and that our insurance may be insufficient to cover costs of damages and defense;
- the risk that we, our strategic partners or collaborators will be unable to attract and retain key employees, including qualified scientific, professional and other personnel, in a competitive market for skilled personnel, which could have a material adverse effect on our commercial and development activities and our operations; and
- other risks and uncertainties detailed in “Risk Factors” and elsewhere in this prospectus, and in the documents incorporated by reference in this prospectus.

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

The forward-looking statements contained in this prospectus 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 Commission, 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.*

**We will require in the near term, but may be unable to secure when needed, significant additional capital to support our operations, pay our debt service, commercialize our approved products and continue our other research and development programs, beginning with AEROSURF. Moreover, any financings could result in substantial dilution to our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.**

Our operations have consumed substantial amounts of cash since inception. As of March 31, 2014, we have an accumulated deficit of approximately \$491 million and we expect to continue to incur significant, increasing operating losses over the next several years. As of March 31, 2014, we had cash and cash equivalents of approximately \$76 million and \$30 million (\$18.8 million net of discount) of long-term debt under a secured loan (Deerfield Loan) with affiliates of Deerfield Management Company, L.P. (Deerfield). Before any additional financings, including under our ATM Program, we anticipate that we will have sufficient cash available to support our operations and debt service obligations through the third quarter of 2015.

We expect to continue to require significant additional infusions of capital to execute our business strategy until such time as the net revenues from SURFAXIN and, potentially, AEROSURF, and from potential strategic alliance and collaboration arrangements and other sources, are sufficient to offset our cash flow requirements. SURFAXIN drug product has been available commercially since November 2013. Our early experience suggests that the time required to obtain hospital formulary acceptance and receive a hospital's purchase request is longer than we expected. While we continue to believe that we will ultimately be successful with the commercial introduction of SURFAXIN, we expect our revenues from SURFAXIN will be modest in the next several years and then increase slowly over time. Accordingly, for the next several years, we expect that our cash outflows for development programs, operations and debt service will outpace our revenues from product sales.

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

- seek collaborators for one or more of our development programs for territories that we had planned to retain or on terms that are less favorable than might otherwise be available; and/or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

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

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

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

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

We are currently conducting a phase 2a clinical trial, which is an open label, single-dose study with the primary goal of evaluating the safety and tolerability of aerosolized KL4 surfactant drug product administered in escalating inhaled doses in premature infants 29 to 32 weeks gestational age who are receiving nCPAP for RDS, compared to infants receiving nCPAP alone. This clinical trial is the first in a series of clinical trials that will be needed to gain marketing authorization for AEROSURF. Such programs generally take two to five years or more to complete and may be delayed by a number of factors. We may not reach agreement with the FDA or a foreign regulator on the design of any one or more of the clinical trials necessary for approval, or we may be unable to reach agreement on a single design that would permit us to conduct a single clinical program. Conditions imposed by the FDA and foreign regulators on our clinical program could significantly increase the time required to complete and the costs of conducting clinical trials. For example, we may not be successful in achieving a study design that is acceptable to both the FDA and regulators in other countries, which would cause us to limit the scope of our activities or greatly increase our investment. Like many biotechnology companies, even after obtaining promising preliminary findings or results in earlier preclinical studies and clinical trials, we may suffer significant setbacks in any stage of our clinical trials. Clinical data is susceptible to varying interpretations that may delay, limit or prevent regulatory approval. In addition, we may be unable to enroll patients quickly enough to meet our expectations for completing any or all of these trials.

The timing and completion of current and planned clinical trials of our product candidates depend on many factors, including the rate at which patients are enrolled. Delays in patient enrollment in clinical trials may occur, which would be likely to result in increased costs, program delays, or both. Patient enrollment is a function of many factors, including:

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

If we are able to achieve our patient enrollment targets in our clinical trials, our patients could suffer adverse medical events or side effects that are known to be associated with surfactant administration, such as a decrease in the oxygen level of the blood, or currently unknown to us. It is also possible that we, our AEROSURF Clinical Trial Steering Committee, the Safety Review Committee, or the FDA could interrupt, delay or halt any one or more of our clinical trials for AEROSURF or any of our product candidates. If our AEROSURF Clinical Trial Steering Committee, the Safety Review Committee, any regulator or we believe that study participants face unacceptable health risks, any one or more of our clinical trials could be suspended or terminated. In addition, clinical trials may be interrupted, delayed or halted, in whole or in part, for reasons other than health and safety concerns, including, among other things, matters related to the design of the study, drug availability, AEROSURF Clinical Trial Steering Committee and/or Safety Review Committee recommendation, or business reasons.

In addition to our planned clinical program to support AEROSURF, in the future, we also may initiate or support clinical trials evaluating other KL4 surfactant pipeline products. All of these clinical trials will be time-consuming and potentially costly. Should we fail to complete our clinical development programs or should such programs yield unacceptable results, such failures would have a material adverse effect on our business.

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

We initiated the commercial introduction of SURFAXIN in late 2013. SURFAXIN product sales are expected to constitute most, if not all, of our total revenue from product sales over the next several years. Our efforts to successfully execute the commercial introduction of SURFAXIN are subject to a variety of risks and uncertainties that could cause actual results to be materially different. The commercial success of SURFAXIN and our ability to generate and increase revenues will depend on a number of factors, including the following:

- the number of hospitals and critical-care centers that agree to place SURFAXIN drug product on their formulary lists and the length of time required to achieve broad formulary acceptance;
- the willingness of hospitals to accept and employ WARMING CRADLE® dry-block heater, a device that warms drug vials at the temperature and for the time period designated in the SURFAXIN prescribing information;
- the effectiveness of our marketing, sales and medical affairs organizations and their ability to (a) accurately describe SURFAXIN consistent with its approved labeling, and (b) educate and provide critical care providers and hospitals with medical and scientific education and information;
- our ability to gain access to the entire market with our commercial organization;
- our ability to provide hospitals acceptable evidence of the safety and efficacy of SURFAXIN and the perceived advantages of SURFAXIN, a synthetic, peptide-containing surfactant, over alternative animal-derived surfactants;
- the pharmacoeconomic benefits (which are determined by comparing, among other things, the cost and effects of a product when compared to different treatment options) and cost-effectiveness of our products;
- the impact of adding SURFAXIN and WARMING CRADLE heater to formulary and medical device hospital lists and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs and other competitive products;
- the availability of different size drug vials and medical devices to meet the specific needs of healthcare practitioners;
- the claims, limitations, warnings and other information that appear in the package insert and labeling of SURFAXIN drug product;
- the willingness of third-party payers, including government payers, to provide coverage and reimbursements to patients, physicians and other providers who wish to prescribe and use our products;
- our ability to secure and maintain regulatory marketing approvals from the United States and foreign regulatory authorities;
- the rate of preterm births;
- the number of infants who are diagnosed with RDS and the number treated with SURFAXIN;
- the growth of commercial sales;
- our ability to meet commercial demand for SURFAXIN, including through maintenance of commercial supplies of our active drug substances and other excipients, and manufacturing capabilities, by ourselves and through contract manufacturing organizations (CMOs); and commercial inventory supplies of our medical device products; and
- the sufficiency of coverage or reimbursement by third parties.

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

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

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

Even if we are successful in achieving formulary acceptance of SURFAXIN and, if approved, AEROSURE, and adoption of AFECTAIR device, in our target hospitals, if we do not achieve broad market acceptance of our products by physicians, respiratory therapists, nurses and other personnel in the NICU and PICU and elsewhere in the hospital, as well as patients, healthcare payers and others in the medical community in general, we may not generate sufficient revenues to support continued commercialization of these and our other products, if approved for commercial sale. The degree of market acceptance of our approved products will depend on a number of factors, including:

- the willingness of physicians and hospitals to utilize our products and the willingness of hospitals' P&T committees to place our products on formulary or on the list of medical devices the hospital will purchase;
- the safety and efficacy of our products, both in fact and as perceived by the medical community, regulatory agencies and insurers and other payers, on both a short and long-term basis;
- the potential advantages of our products over alternative treatments;
- the relative convenience and ease of use;
- the prevalence and severity of any adverse events, including any unexpected adverse events of which we become aware; and
- the degree to which the market believes that we are able to manufacture our products and produce supply sufficient to meet market demand.

**As a company, we have limited experience in the field of marketing or selling pharmaceutical and medical device products and limited marketing capabilities, which may restrict our success in commercializing our products. We have established our own commercial and medical affairs organization to launch our products in the United States. While we believe that this strategy greatly improves our ability to introduce our products in the United States, it may also increase the cost to commercialize our products.**

We have limited experience in marketing or selling pharmaceutical and medical device products, although we have endeavored to hire individuals that have significant experience in neonatal indications and/or hospital-based products. We plan to rely solely on our own specialty respiratory critical care commercial and medical affairs organization to market and support SURFAXIN, and our products under development, AEROSURE and potentially SURFAXIN LS, if approved, in the United States. We also plan to rely on our own commercial and medical affairs organization to introduce AFECTAIR device in the United States. Commercializing our products in the United States on our own may cause our commercialization costs to increase, but will potentially avoid the transfer of rights to our products or drug product candidates and thereby potentially increase the revenue opportunity. Building our own commercial and medical affairs capabilities is potentially expensive and time-consuming and requires a substantial capital investment. Recruiting, training and retaining qualified personnel will be critical to our success. Competition for such personnel can be intense, and we may be unable to attract and retain a sufficient number of qualified individuals to successfully support the launch and continued distribution of our products. We also may be unable to provide competitive incentives to retain our sales force. If we are unable to successfully retain, motivate and attract experienced individuals for our commercial and medical affairs organization to support the introduction, marketing and sale of our products, we will have difficulty selling, maintaining and increasing the sales of our products, which could have a material adverse effect on our business.

We may also seek strategic alliances and/or collaboration arrangements to support the potential commercial introduction of SURFAXIN and, if approved, SURFAXIN LS in countries where regulatory marketing authorization is facilitated by the information contained in the SURFAXIN NDA approved by the FDA. We may not be successful in entering into any such arrangements, and the terms of any such arrangements may not be favorable to us. In addition, if we enter into co-marketing arrangements to market and sell additional products directly, we may need to further expand our commercial staff and incur additional expense.

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

- our collaborators may require that we transfer to them important rights to our products and/or product candidates;

- we may not be able to control the amount and timing of resources that our collaborators devote to the commercialization of our products;
- if our 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 collaborators;
- our 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 collaborators must also market our products in compliance with applicable federal, state and local laws, or foreign equivalents, related to providing incentives and inducements. Violation of these laws can result in substantial penalties.

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

**If we do not adequately forecast customer demand for our approved products, including SURFAXIN and, if approved, AEROSURE, our business could suffer. If we are successful, we also potentially are subject to risks associated with doing business globally.**

Our business planning requires us to forecast demand and revenues despite numerous uncertainties. Actual results of operations may deviate materially from projected results. The timing and amount of customer demand and the commercial requirements to meet changing customer demand are difficult to predict. We may not be able to accurately forecast customer demand for our products and product candidates, starting with SURFAXIN, or to respond effectively to unanticipated increases in demand. This could have an adverse effect on our business. If we overestimate customer demand, or attempt to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity.

In addition, economic conditions at any time may result in reduced demand for our products, increased pricing pressure, longer sales cycles, and slower adoption rates for our products. Conditions in the healthcare industry, including lower healthcare utilization, cost containment efforts by governments and other payers for healthcare services and other factors may result in weaker overall customer demand and increased pricing pressure for our products. Such economic conditions may also adversely affect our suppliers, which could affect our ability to manufacture and sell our products.

We expect in the future to offer certain of our products in the European Union (EU) and other markets internationally, which would subject us to risks associated with doing business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, increasingly complex labor environments, expropriation and other governmental actions, availability of raw materials, changes in taxation, importation limitations, export/import control restrictions, changes in or violations of U.S. or local laws, including the United States Foreign Corrupt Practices Act, pricing restrictions, economic and political instability, diminished or insufficient protection of intellectual property, and disruption in a significant geographic region regardless of cause, including war, terrorism, riot, civil insurrection or social unrest. Failure to comply with, or material changes to, the laws and regulations that affect our business could have an adverse effect on our business, financial condition or results of operations.

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

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



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

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. With respect to our research and development activities, to respond to changing circumstances, we may, from time to time, refocus our product development efforts on different products or may pace, delay or halt the development of various products. As a result of changes in our strategy, we may also change or refocus our existing drug discovery, development, commercialization and manufacturing activities. This could require changes in our facilities and personnel and restructuring various financial arrangements. There can be no assurances that any product development or other changes that we implement will be successful or that, after implementation of any such changes, that we will not refocus our efforts on new or different objectives.

**Our manufacturing strategy includes relying, at least in part, on third parties to manufacture our approved products as well as our drug product and medical device candidates, which exposes us to risks that may affect our ability to maintain supplies of our commercial products and/or delay our research and development activities, regulatory approval and commercialization of our drug product and medical device candidates.**

We currently manufacture SURFAXIN at our manufacturing operations in Totowa, New Jersey (Totowa Facility). Our lease for the Totowa Facility expires in June 2015. Our long-term strategy includes potentially extending the term of our lease, although there can be no assurance that we will be successful, and/or manufacturing SURFAXIN with CMOs. We also expect to manufacture our lyophilized KL<sub>4</sub> surfactant, our CAG and AFECTAIR device, with CMOs. Our efforts to conduct a technology transfer of our manufacturing process and our planned future reliance on CMOs exposes us, among other things, to the following risks:

- we may be unable to identify manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all, because the number of potential CMOs is limited and the FDA must approve any replacement CMO. This approval could require one or more pre-approval inspections as well as a potentially lengthy qualification process. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our approved products after receipt of FDA approval. This could take as long as 2 years to qualify and receive regulatory approval;
- we may implement a plan to execute a technology transfer of our manufacturing process to a CMO and, after investing significant time and resources, learn that the CMO we chose is unable to successfully complete the technology transfer and manufacture our products in accordance with our plan;
- CMOs might be unable to manufacture our products in the volume and to our specifications to meet our commercial, preclinical and clinical needs, or we may have difficulty scheduling the production of drug product and devices in a timely manner to meet our timing requirements;
- CMOs may not perform as agreed, or may not remain in the CMO business for a lengthy time, or may refuse to renew an expiring agreement as expected, or may fail to produce a sufficient supply to meet our commercial and/or clinical needs;
- CMOs are subject to ongoing periodic unannounced inspection by the FDA, international health authorities, registered Notified Bodies, the U.S. Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with current good manufacturing practices (cGMP) and/or quality system regulations (QSR) and other government regulations and corresponding foreign standards. We do not have control over a CMO's compliance with these regulations and standards;
- if we desire to make our drug products and/or devices available outside the United States for commercial or clinical purposes, our CMOs would become subject to, and may not be able to comply with, corresponding manufacturing and QSR of the various foreign regulators having jurisdiction over our activities abroad. Such failures could restrict our ability to execute our business strategies; and
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not have rights to, or may have to share, the intellectual property rights to any such innovation. We may be required to pay fees or other costs for access to such improvements.

Each of the foregoing risks and others could create uncertainty concerning our ability to maintain continuous supply of our products and product candidates, delay our commercial manufacturing plans and our development programs, as well as the approval, if any, of our product candidates, by the FDA or foreign regulator, or result in higher costs or deprive us of potential product revenues.

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

The manufacture of pharmaceutical and medical device products requires significant expertise and compliance with strictly enforced federal, state and foreign regulations. We, our CMOs or our materials and drug substances suppliers may experience manufacturing or quality control and assurance problems that could result in a failure to maintain compliance with cGMP and quality system requirements, or those of foreign regulators or notified bodies, which is necessary to continue manufacturing of our drug products, materials or drug substances. Other problems that may be encountered include:

- the need to make necessary modifications to maintain a qualified facility;
- difficulties with production and yields, including manufacturing and completing all required release testing on a timely basis to meet demand;
- quality control and assurance problems related to, among other things, in-process monitoring and controls, and release and stability testing of our drug product, or materials and drug substances;
- casualty damage to a facility; and
- shortages of qualified personnel.

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

We currently manufacture our SURFAXIN drug product at our Totowa Facility. We manufacture our lyophilized KL4 surfactant, WARMING CRADLE dry-block heaters and AFECTAIR aerosol-conducting airway connectors with CMOs. In the past, we have experienced manufacturing or quality control problems and such problems may again occur, at our Totowa Facility or at the facilities of a CMO or a manufacturer of our drug substances and materials suppliers. Such problems may in the particular circumstance require potentially complex, time-consuming and costly comprehensive investigations to determine the root causes of such problems and may require detailed and time-consuming remediation efforts, which can further delay a return to normal manufacturing and production activities. Any failure by our own manufacturing operations or by the manufacturing operations of any of our CMOs or suppliers to comply with cGMP or, for devices, QSR, requirements or other FDA or similar foreign regulatory requirements could adversely affect our ability to manufacture our drug products, which could have a material adverse effect on our ability to manufacture a supply of commercial SURFAXIN drug product, or our products under development, and potentially adversely affect our research activities and our business and financial condition. Any interruption of our manufacturing at the Totowa Facility could result in a shortage of our commercial drug supply of SURFAXIN. We currently do not have a back-up facility for the Totowa Facility or our CMOs, or back-up suppliers of active pharmaceutical ingredients or excipients and other materials. A number of factors could cause interruptions, including:

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

In connection with our drug product manufacturing activities, we own certain specialized manufacturing equipment, employ experienced manufacturing senior executive and managerial personnel, and continue to invest in enhanced quality systems and manufacturing capabilities. However, we do not have fully-redundant systems and equipment to respond promptly in the event of a significant loss at our or a CMO's manufacturing operations. Under certain conditions, we may be unable to produce SURFAXIN at the required volumes or to appropriate standards, if at all. If we are unable to successfully maintain our manufacturing capabilities and at all times comply with cGMP, it will adversely affect our efforts to market and sell SURFAXIN and have an adverse effect on our sales.

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

To support our AEROSURF development program and potentially the commercial introduction of AEROSURF in markets outside the United States, we seek a significant strategic alliance that potentially could provide development, regulatory and commercial market expertise as well as financial resources for our AEROSURF development program, and, if approved, support for the commercial introduction of AEROSURF in the EU and other selected markets outside the United States. While we are engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses), there can be no assurance that we will ultimately secure such an alliance, if at all, on acceptable terms.

To support the commercial introduction of SURFAXIN and our other KL<sub>4</sub> surfactant products, including potentially SURFAXIN LS, in markets outside the United States, we may seek strategic alliances and/or collaboration arrangements potentially to gain regulatory approval for SURFAXIN and, if approved, SURFAXIN LS, and support the commercial introduction of these products in countries where regulatory marketing authorization is facilitated by an FDA-approved NDA.

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

For example, our collaboration arrangement with Laboratorios del Dr. Esteve, S.A. (Esteve) for SURFAXIN and certain other of our drug product candidates is focused on Andorra, Greece, Italy, Portugal and Spain (Esteve Territory). We have limited influence over the decisions made by Esteve or its sublicensees or the resources that they may devote to the marketing and distribution of our KL<sub>4</sub> surfactant products in their licensed territory, and Esteve or its sublicensees may not meet their obligations in this regard. Our marketing and distribution arrangement with Esteve may not be successful, and, as a result, we may not receive any revenues from it. In addition, we may not be able to enter into marketing and sales agreements for our KL<sub>4</sub> surfactant pipeline products on acceptable terms, if at all, in territories not covered by the Esteve agreement, or for any of our other drug product candidates. If Esteve or we should fail to conduct our respective collaboration-related activities in a timely manner, or otherwise breach or terminate the agreements that make up our collaboration arrangements, or if a dispute should arise under our collaboration arrangements, such events could impair our ability to commercialize or develop our products in the Esteve Territory. In that event, we may need to seek other partners and/or collaboration arrangements, or we may have to develop our own internal capabilities to market the covered products in the Esteve Territory.

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

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

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

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

**If our business development activities are unsuccessful, our business could suffer and our financial performance could be adversely affected.**

As part of our long-term growth strategy, we engage in business development activities intended to identify and develop strategic opportunities, including potential strategic alliances, joint development opportunities, acquisitions, technology licensing arrangements and other similar opportunities. Such opportunities may require substantial investments. Our success in developing products or expanding into new markets from such activities will depend on a number of factors, including our ability to identify suitable opportunities for investment, alliance or acquisition; whether we are able to complete an investment, alliance or acquisition on terms that are satisfactory to us; the strength of our underlying technology, products and our ability to execute our business strategies; any intellectual property and litigation related to these products or technology; and our ability to successfully execute the investment, alliance or acquisition into our existing operations, including to fund our share of any in-process research and development projects. If we are unsuccessful in our business development activities, we may be unable to meet our financial targets and our financial performance could be adversely affected.

**We may have difficulty managing our growth.**

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

**Our existing and future debt obligations could impair our liquidity and financial condition, and in the event we are unable to meet our debt obligations, the lenders could foreclose on our assets.**

In connection with the Deerfield Loan, we received from Deerfield \$30 million principal amount, which accrues interest at an annual rate of 8.75%, payable in cash quarterly, and which is secured by a security interest on substantially all of our assets. Principal repayments are required beginning in 2017, subject to certain potential deferrals. Our debt obligations:

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

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

**Our activities are subject to various and complex laws and regulations, and we are susceptible to a changing regulatory environment. Any failure to comply could adversely affect our business, financial condition and results of operations.**

Our products and our operations are regulated by numerous government agencies, both inside and outside the United States. Our drug product candidates and medical devices must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and foreign regulatory authorities. Our facilities and those of our third-party providers must be approved and licensed prior to production and remain subject to inspection at any time thereafter. Failure to comply with the requirements of the FDA or other regulatory authorities, including a failed inspection or a failure in our post-marketing reporting, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of our products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could damage our reputation and have a material adverse effect on our sales. In addition, requirements of the FDA and other regulatory authorities may change and implementing any additional compliance requirements may increase our costs, or force us or our third-party providers to suspend production, which could result in a shortage of our approved product or delays in the commercial introduction of our new product candidates, if approved.

With the commercial launch of SURFAXIN, AFECTAIR and, if approved, AEROSURF, we are and will be required to comply with not only the requirements of the FDA and potentially international regulators, but will also become subject to various federal, state and international laws regulating the sales, marketing, and distribution of healthcare-related products. These laws govern such activities as our relationships with healthcare providers, the promotion of our products, and pricing of prescription drug products and medical devices. The sales and marketing of products and relationships that pharmaceutical and medical device companies have with healthcare providers are under increasing scrutiny by federal, state and foreign government agencies. The FDA and other federal regulators have increased their enforcement activities with respect to the Anti-Kickback Statute, False Claims Act, off-label promotion of products, and other healthcare related laws, antitrust and other competition laws. The Department of Justice also has increased its focus on the enforcement of the United States Foreign Corrupt Practices Act, particularly as it relates to the conduct of pharmaceutical companies. Foreign governments have also increased their scrutiny of pharmaceutical companies' sales and marketing activities and relationships with healthcare providers.

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

We are continually evaluating our comprehensive compliance program, including policies, training and various forms of monitoring, designed to address the sales-and-marketing-related risks set forth above. However, no compliance program can mitigate risk in its entirety. Violations or allegations of violations of these laws may result in large civil and criminal penalties, debarment from participating in government programs, diversion of management time, attention and resources and may otherwise have a material adverse effect on our business, financial condition and results of operations.

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

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

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

We plan to pursue clinical development in the United States and potentially in the EU and other markets, and, if approved, market and sell our products in the United States and potentially in the EU and other major markets. To accomplish this objective, we must obtain and maintain regulatory approvals and comply with regulatory requirements in each jurisdiction. To avoid the significant expense and lengthy time required to complete multiple clinical programs, we expect to meet with relevant regulatory authorities with the goal of designing a single, global clinical program. There can be no assurance that our efforts will be successful. If we are unable to reach agreement with the various regulatory authorities, we may not be able to pursue regulatory approval of our products in all of our selected markets.

The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which would preclude us from commercializing products in those markets. In addition, some countries, particularly the countries of the EU, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of their product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the EU, we could be adversely affected.

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

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

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

The FDA has approved SURFAXIN for marketing in the United States. Our development program for AEROSURF is in phase 2 clinical trials. We currently are planning to seek regulatory advice from the FDA to determine if we could gain marketing authorization for SURFAXIN LS, a lyophilized dosage form of SURFAXIN, under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely seek to implement such a development plan. Foreign regulators have not yet approved SURFAXIN or any of our KL4 surfactant products under development. Without regulatory approval, we will not be able to market these products. Even if we were to succeed in gaining regulatory approvals for any of our products, the FDA or a foreign regulator could at any time withdraw any approvals granted if there is a later discovery of previously unidentified problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, or the FDA or a foreign regulator may restrict or delay our marketing of a product, including by requiring us to include warnings and other restrictions in the package inserts for our products, or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. Any withdrawal of our regulatory approval or significant restriction on our ability to market our products after approval would have a material adverse effect on our business.

**Our research and development programs, including for AEROSURF, involve significant risks and uncertainties that are inherent in the clinical development and regulatory approval processes.**

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

- competently execute and complete our preclinical and clinical trials of our KL4 surfactant product candidates with scientific results that are sufficient to support further development and regulatory approval;
- receive the necessary regulatory approvals;
- obtain adequate supplies of the active pharmaceutical ingredients, manufactured to our specifications and on commercially reasonable terms;
- perform under agreements to supply drug substances, medical devices and related components and related services necessary to manufacture our KL4 surfactant product candidates;
- provide for sufficient manufacturing capabilities to produce sufficient drug product, including for KL4 surfactant-related studies, AEROSURF and SURFAXIN LS development activities, and CAG devices and related materials to meet our preclinical and clinical development requirements; and
- obtain the capital necessary to fund our research and development efforts, including our business administration, preclinical and clinical organizations, and our quality and manufacturing operations.

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

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

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

**Failure to complete the development of our CAG device and related componentry in a timely manner, if at all, would have a material adverse effect on our efforts to develop AEROSURF or our other aerosolized KL4 surfactant products, and our business strategy.**

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

- We may not successfully develop a CAG device that is acceptable for use in a phase 3 program and commercial environment, if at all, on a timely basis and such inability may delay or prevent initiation of our phase 3 clinical trial.
- We will require access to sophisticated engineering capabilities. We have medical device engineering staff and we are currently working with Battelle Memorial Institute (Battelle), which has expertise in medical device development and medical device design and a successful track record in developing aerosolization systems for the medical and pharmaceutical industries. If for any reason we are unable to retain our own engineering capabilities, the agreement with Battelle is terminated, and we are unable to identify design engineers and medical device experts to support our development efforts, including for a clinic-ready CAG system for use in our planned clinical trials and, potentially, for commercial use and later versions of the CAG systems, it would have a material adverse effect on our business strategy and impair our ability to commercialize or develop AEROSURF or other aerosolized KL4 surfactant products.
- We will also require additional capital to advance our development activities and plan to seek a potential strategic partner or third-party collaborator to provide financial support and potentially medical device development and commercialization expertise. There can be no assurance, however, that we will successfully identify or be able to enter into agreements with such potential partners or collaborators on terms and conditions that are favorable to us. If we are unable to secure the necessary medical device development expertise to support our development program, this could impair our ability to commercialize or develop AEROSURF or other aerosolized KL4 surfactant products.

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

**If the parties we depend on for supplying our active drug substances, materials and excipients as well as manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to manufacture and market our approved products and execute our development plans for our pipeline products. Such delays could adversely impact our operations and financial performance.**

We rely on suppliers for our active drug substances, materials and excipients, and third parties for certain manufacturing-related services to manufacture drug product that meets appropriate content, quality and stability standards for commercial drug product use in preclinical programs and clinical trials and, for our approved products, commercial sales. Our ability to manufacture depends upon receiving adequate supplies and related services, which may be difficult or uneconomical to procure. Supply chain or manufacturing interruptions could negatively impact our operations and financial performance. The supply of any of our manufacturing materials may be interrupted because of supply shortages, poor vendor performance or other events outside our control, which may require us, among other things, to identify alternate vendors, which could involve a lengthy process, and result in lost sales and increased expenses.

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

**A catastrophic event at our Warrington, Pennsylvania facility or at our Totowa Facility or any of the facilities used by our CMOs and suppliers would prevent us from producing many of our drug products candidates and/or medical devices.**

Our facilities consist of our headquarters in Warrington, Pennsylvania and our Totowa Facility. We maintain our analytical testing and device development laboratories in Warrington, Pennsylvania. Our Totowa Facility is specifically designed for the aseptic manufacture and filling of sterile pharmaceuticals in compliance with cGMP and is our only drug manufacturing facility. While we manufacture our SURFAXIN liquid instillate at our Totowa Facility, we depend upon CMOs and suppliers to manufacture WARMING CRADLE dry-block heaters, our lyophilized KL<sub>4</sub> surfactant, our AFECTAIR device and our CAG. All of these products are or will be manufactured at a single facility. If a catastrophic event occurred at any our facilities or the facilities of any of our third-party manufacturers, such as a fire, flood or tornado, many of those products could not be produced until the manufacturing portion of such facility was restored and cleared by the FDA. With respect to our Totowa Facility, we maintain a disaster plan to minimize the effects of such a catastrophe, and we have obtained insurance to protect against certain business interruption losses. However, there can be no assurance that any such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.

**For the development and, if approved, commercialization of AEROSURE, we will depend in large measure upon the manufacturers and assemblers of our CAG devices. If we are unable to identify qualified manufacturers and assemblers, the timeline of our plans for the development and, if approved, commercialization of AEROSURE and any other aerosolized KL<sub>4</sub> surfactant products, could suffer. We are exposed to similar risks with respect to the manufacture of our AFECTAIR device.**

In connection with the development of AEROSURE, which is a combination drug/device product that produces our aerosolized KL<sub>4</sub> surfactant, we plan to rely on CMOs to manufacture and assemble the CAG and all subcomponents of the CAG to support our preclinical experiments, planned clinical trials and, if approved, commercial device. The CAG device includes an aerosol control unit and a disposable AEROSURE Dose Pack (ADP). The ADP includes the critical drug product-contact components that are either cleaned or manufactured in an environmentally-controlled, clean area. The control unit and ADPs are assembled and packaged in a clean area. Each of the ADP devices is tested for conformance to designated product specifications during assembly and each of the assembled control units must be quality control tested prior to release and monitored for conformance to designated product specifications.



We have worked with Battelle to develop a clinic-ready optimized CAG device to support our phase 2 clinical program. As with many device development initiatives, there is a risk that, even if we are able to finalize specifications for a CAG system that is suitable for use in a phase 3 trial and, if approved, commercial applications, we may have difficulty identifying manufacturers that are able to consistently manufacture and assemble the subcomponents of our CAG systems to our specified standards. In addition, we may not be able to identify qualified additional or replacement manufacturers and assemblers to manufacture subcomponents and assemble our optimized CAG system and, if developed, later versions of our CAG systems, or we may not be able to enter into agreements with them on terms and conditions favorable and acceptable to us. In addition, the manufacturers and assemblers that we identify may be unable to timely comply with FDA, or other foreign regulatory agency, regulatory manufacturing requirements. If we do not successfully identify and enter into contractual agreements with manufacturers and assemblers that have the required expertise to produce our CAG devices as and when needed, it will adversely affect our timeline for the development and, if approved, commercialization of our aerosolized KL4 surfactant, including AEROSURE.

We are exposed to similar risks in the manufacture of our AFECTAIR device. We rely on our CMO for, among other things, the manufacture, packaging and labeling of our AFECTAIR device. These activities must be performed to specifications and in compliance with the regulations of the FDA and foreign regulators. In the event of any release of defective product, our CMO is obligated to cooperate with us, including for those defects that result in product recalls or other similar events. If our CMO is unable to manufacture to our specifications, or if our CMO fails to comply with the regulations of the FDA or foreign regulators, it could have a material adverse effect on our development and commercial activities and our financial condition and prospects.

**Issues with product quality could have an adverse effect on our business, subject us to regulatory actions and costly litigation and cause a loss of customer confidence in our products or us.**

Our success depends upon the quality of our products. Our future revenues will depend upon our ability to develop, maintain, and continuously improve our quality management system, including an objective and systematic process for monitoring and the evaluation of key process indicators. Quality and safety issues may occur with respect to any of our products. We are dependent upon third-party suppliers, manufacturers and service providers to support our development and commercialization activities. Third-party suppliers are required to comply with our quality standards. Failure of a third-party supplier to provide compliant raw materials or supplies could result in delays or other quality-related issues. A quality or safety issue could have an adverse effect on our business, financial condition and results of operations and may result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in our current or future products or us, which may result in the loss of sales and difficulty in commercializing our products.

**Medical device product defects could lead to recalls and harm our reputation, business and financial results.**

The design, manufacture and marketing of our medical device products involve certain inherent risks. Our products must be designed, manufactured and marketed to specific product specifications. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products can lead to injury or other adverse events. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining marketing authorization, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory clearance. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a mandatory recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, initiate a field alert or action, known as a recall, for a product if any material deficiency in a device is found. A government mandated or voluntary recall by us or our third-party manufacturers or suppliers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. We are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that may cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

**Marketing authorization to promote, manufacture and/or sell our products will be limited and subject to continuing review.**

We have received marketing authorization in the United States for SURFAXIN. Our approved label contains, among other things, data from our pivotal phase 3 clinical trial, but there are limitations that affect the manner in which we may market and sell our SURFAXIN drug product. In addition, although we have registered the AFECTAIR device in the U.S, this registration does not include substantial claims with respect to potential use or efficacy. Moreover, if we register this product in the EU, that clearance also will be subject to limitations on the uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue.

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. If the FDA were to determine that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could direct us to cease or modify our training or promotional materials or subject us to serious regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities could take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. If we were found to have improperly promoted off-label uses, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Due to these legal constraints, our marketing and sales efforts for AFECTAIR will be limited. For SURFAXIN, our marketing and sales efforts must be based on the contents of our label, although there is other data and information available that speaks to the benefits of our KL4 surfactant.

In addition, we will have to comply with reporting requirements applicable to drug products and medical devices, including the reporting of adverse events and device malfunctions related to our products. Later discovery of previously unknown problems, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market or regulatory enforcement actions.

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

As we prepare for the commercialization of our first approved products, we will need extensive information technology (IT) systems in virtually all aspects of our business, including billing, customer service, logistics and management of clinical trial and medical data management. In selecting the appropriate software packages and systems to manage and support our activities, we will consider both in-house development and specialty software and system packages offered by third party vendors, service providers and consultants. The systems we select may not be adequate to meet our needs or may fail to perform to the specified requirements. We may be required to seek other sources of system support, which would increase our costs and potentially delay our implementation of necessary activities. There can be no assurance that the IT systems that we select or choose to develop will be adequate to our needs, that they will perform to our requirements or that we will be successful in integrating them into our operations.

In addition, our technology systems are potentially vulnerable to breakdown or other interruption by fire, power loss, system malfunction, unauthorized access and other events. Our success will depend, in part, on the continued and uninterrupted performance of our IT systems. IT systems may be vulnerable to damage, disruptions and shutdown from a variety of sources, including telecommunications or network failures, human acts and natural disasters. They also may be subject to physical or electronic intrusions, computer viruses, unauthorized tampering and similar disruptive problems. Likewise, data privacy breaches by employees and others with permitted access to our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. Along with our new IT systems, we plan to take precautionary measures to prevent unanticipated problems. Nevertheless, we may experience damages to our systems, system failures and interruptions and unauthorized disclosure of confidential information, and our data could be compromised.

There can be no assurance that our efforts will prevent significant breakdowns, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition of the company. In addition, there can be no assurances that a significant implementation issue may not arise as we continue to implement new systems and consolidate or replace existing (legacy) systems. If we experience systems problems, or if the systems we implement do not meet our expectations, they may interrupt our ability to operate. If we experience systems problems, or if we experience unauthorized disclosure of confidential information, it could adversely affect our reputation, result in a loss of customers and revenues and cause us to suffer financial damage, including significant costs to alleviate or eliminate the problem.

**Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our ATM Program, stock incentive plans and upon the exercise of outstanding securities exercisable for shares of our common stock, could result in substantial additional dilution of our stockholders, cause our stock price to fall and adversely affect our ability to raise capital.**

We will require additional capital to continue to execute our business plan and advance our research and development efforts. To the extent that we raise additional capital through the issuance of additional equity securities and through the exercise of outstanding warrants, our stockholders may experience substantial dilution. We may sell shares of our common stock in one or more transactions at prices that may be at a discount to the then-current market value of our common stock and on such other terms and conditions as we may determine from time to time. Any such transaction could result in substantial dilution of our existing stockholders. If we sell shares of our common stock in more than one transaction, stockholders who purchase our common stock may be materially diluted by subsequent sales. Such sales could also cause a drop in the market price of our common stock. The issuance of shares of our common stock under the ATM Program, the issuance of shares upon exercise of outstanding warrants, including those issued to Deerfield in connection with the Deerfield Loan, will have a dilutive impact on our other stockholders and the issuance, or even potential issuance, of such shares could have a negative effect on the market price of our common stock.

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

We have filed this universal shelf registration statement with the Commission on Form S-3 for the proposed offering from time to time of up to \$250 million of our securities, including common stock, preferred stock, varying forms of debt and warrant securities, or any combination of the foregoing. We may issue securities pursuant to this shelf registration statement on several occasions in the future in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

As of March 31, 2014, we had 85,052,281 shares of common stock issued and outstanding. In addition, as of March 31, 2014, approximately 22,817,770 shares of our common stock were reserved for potential issuance upon the exercise of outstanding warrants, pursuant to our equity incentive plans and pursuant to our 401(k) Plan. The exercise of stock options and other securities could cause our stockholders to experience substantial dilution. Moreover, holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. Such exercises, or the possibility of such exercises, may impede our efforts to obtain additional financing through the sale of additional securities or make such financing more costly. It may also reduce the price of our common stock.

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

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

- announcements of the results of clinical trials by us or our competitors;

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

Our common stock is listed for quotation on Nasdaq. During the 12-month period ended March 31, 2014, the price of our common stock ranged between \$1.50 and \$2.73. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended March 31, 2014, the average daily trading volume in our common stock was approximately 648,517 shares, and the average number of transactions per day was approximately 1,880. The instability observed in our daily volume and number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. Even if securities class actions that may be filed against us in the future were ultimately determined to be meritless or unsuccessful, they would involve substantial costs and a diversion of management attention and resources, which could negatively affect our business.

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

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

**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. Government and other healthcare payers increasingly challenge the price and examine the cost effectiveness of medical products and services. Moreover, the current political environment in the 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.

Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products may be subject to price controls in several of the world's principal markets, including many countries within the EU. In the United States, where pricing levels for our products are substantially established by third-party payers, if payers reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace. The existence of direct and indirect price controls and pressures over our products could materially adversely affect our financial prospects and performance.

### **The implementation of the 2010 Health Care Reform Law in the United States may adversely affect our business.**

The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, each enacted in March 2010, generally known as the Health Care Reform Law, significantly expands health insurance coverage to uninsured Americans and changes the way health care is financed by both governmental and private payers. We expect expansion of access to health insurance may increase the demand for our products, but other provisions of the Health Care Reform Law could affect us adversely. We also expect that further federal and state proposals for healthcare reform are likely. The changes contemplated by the health care reform law are subject to rule-making and implementation timelines that extend for several years, and this uncertainty limits our ability to forecast changes that may occur in the future. However, any changes that lower reimbursements for our products could adversely affect our business and results of operations.

The Health Care Reform Law includes provisions, referred to as the federal "Open Payments" law (previously referred to as the "Sunshine Law"), that establish new reporting and disclosure requirements for pharmaceutical and medical device manufacturers. Under the law, pharmaceutical and device manufacturers are required to annually report various types of payments and other transfers of value to physicians and teaching hospitals. Implementation of the sunshine provisions has been subject to delay by the United States Centers for Medicare and Medicaid Services. Under the current regime, applicable manufacturers were to begin tracking relevant transfer-of-value data in August 2013, and must report data collected between August 1 and the end of 2013 to U.S. Centers for Medicare and Medicaid Services in a two-phased approach by March 31, and June 30, 2014, respectively. U.S. Centers for Medicare and Medicaid Services will publish the data on a public website later in the year. Inaccurate or incomplete reports may be subject to enforcement. Like the federal Sunshine Law, several states have existing laws that require manufacturers to report transfers of value to select healthcare providers licensed within the state, or even go so far as to prohibit certain marketing related activities. Other states, such as California, Nevada, Massachusetts and Connecticut, require pharmaceutical and/or device companies to implement compliance programs or marketing codes. In others, it is possible that we will be subject to the state's reporting requirements and prohibitions. Compliance activities with respect to these measures could increase our costs and adversely affect business operations.

The Health Care Reform Law contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of medical devices by manufacturers and importers beginning in 2013, and a fee on branded prescription drugs that was implemented in 2011, both of which may affect sales of our products. As U.S. net sales are expected to be a significant portion of our worldwide net sales in the coming years, this additional tax burden may have a material, negative impact on our results of operations and our cash flows. The Health Care Reform Law also mandates pharmacy benefit manager transparency regarding rebates, discounts and price concessions with respect to drug benefits under Medicare Part D, and in 2014 with respect to drug benefits offered through qualified health plans offered through state exchanges, which could affect pricing and competition.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements, are continuing in many countries where we plan to do business, including the United States.

The Health Care Reform Law establishes the Independent Payment Advisory Board, which will be responsible, beginning in 2014, annually to submit proposals aimed at reducing Medicare cost growth while preserving quality. These proposals automatically will be implemented unless Congress enacts alternative proposals that achieve the same savings targets. Further, the legislation calls for a Center for Medicare and Medicaid Innovation that will examine alternative payment methodologies and conduct demonstration programs. The legislation provides for extensive health insurance reforms, including the elimination of pre-existing condition exclusions and other limitations on coverage, fixed percentages on medical loss ratios, expansion in Medicaid and other programs, employer mandates, individual mandates, creation of state and regional health insurance exchanges, and tax subsidies for individuals to help cover the cost of individual insurance coverage. The legislation also permits the establishment of accountable care organizations, a new healthcare delivery model. While the ultimate impact of the legislation on the healthcare industry is unknown, it is likely to be extensive and may result in significant change. Our failure to adapt to these changes could have a material adverse effect on our business.

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

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

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

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

As we prepared for the commercial introduction of SURFAXIN, we implemented a plan to hire additional qualified personnel to support (i) the commercial introduction of SURFAXIN and AFECTAIR, and (ii) the advancement of our AEROSURF and, potentially, SURFAXIN LS development programs. In particular, we established our field-based sales and marketing and medical affairs organizations, and continue to invest in our regulatory affairs, quality control and assurance and administrative capabilities. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is significant and attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us.

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

We have entered into employment agreements with six executive officers, including the President and Chief Executive Officer; the Senior Vice President and Chief Financial Officer; the Senior Vice President and Chief Operating Officer; the Senior Vice President, General Counsel and Corporate Secretary; the Senior Vice President, Human Resources; and the Senior Vice President, Research and Development. These agreements expire on March 31, 2015, subject to automatic renewal for additional one-year periods, unless a party provides notice of non-renewal at least 90 days in advance. In addition, in March 2013, we entered into retention arrangements with five other officers that also expire on March 31, 2015. The loss of services from any of our executives could significantly adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key man life insurance.

As we proceed with the commercial introduction of SURFAXIN and undertake our AEROSURF phase 2 clinical program, we need to attract and retain highly-qualified personnel to join our management, commercial, medical affairs and development teams, although there can be no assurances that we will be successful in that endeavor. We may be unable to attract and retain necessary executive talent.

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

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

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

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

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

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or foreign regulatory approval or commercializing products before us. Our competitors may successfully secure regulatory exclusivities in various markets, which could have the effect of barring us or limiting our ability to market our products in such markets. As we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities that may successfully develop and commercialize products that are more effective or less expensive than our products. In addition, developments by our competitors may render our drug product candidates obsolete or noncompetitive.

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

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

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

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

The parties licensing technologies to us and we have filed various U.S. and foreign patent applications with respect to the products and technologies under our development, and the PTO 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 PTO 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 PTO or foreign patent offices were to issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from third parties may not provide us any protection against competitors.

The patents that we hold have a limited life. We have licensed a series of patents for our KL<sub>4</sub> 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 KL<sub>4</sub> surfactant products. These patents, which include important KL<sub>4</sub> composition of matter claims and relevant European patents, began to expire in November 2009, and will expire on various dates ending in 2017 or, in some cases, possibly later. Of the patents that have expired, we have extended the term of our most important patent until November 2014. For our aerosolized KL<sub>4</sub> surfactant, we hold worldwide exclusive licenses from Philip Morris, USA (PMUSA) and Philip Morris Products, SA (PMPSA) to the CAG technology for use with pulmonary surfactants together or in combination with other products for all respiratory diseases. Our exclusive license in the 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 CAG technology patents expire on various dates beginning in May 2016 and ending in 2031, or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the 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.

**Our technology platform is based solely on our proprietary KL<sub>4</sub> surfactant technology, our novel CAG technology, and our novel aerosol-conducting airway connector.**

Our technology platform is based on the scientific rationale of using our KL<sub>4</sub> surfactant technology, our CAG technology and our novel patient interface and related componentry to treat life-threatening respiratory disorders and to serve as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our drug product candidates and our combination drug-device products based on these technologies. Any material problems with our technology platforms could have a material adverse effect on our business.

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

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



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

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

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

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

Moreover, although all employees, including our executive officers, enter into agreements with us that include non-compete and non-solicitation covenants, such non-compete provisions can be difficult and costly to monitor and enforce, such that, if any should resign, we may not be successful in enforcing our noncompetition agreements with them. Despite the protective measures we employ, we still face the risk that:

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

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

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

Our business activities, including the design, manufacture and marketing of our drug products and medical devices also exposes us to liability risks. Using our drug product candidates or medical devices in clinical trials may expose us to product liability claims. For our products that are approved for commercial sale, the risk of product liability claims is increased. Even if approved, our products may be subject to claims resulting from unintended effects that result in injury or death. Product liability claims alleging inadequate disclosure and warnings in our package inserts and medical device disclosures also may arise.

Product liability claims may be brought by individuals or by groups seeking to represent a class. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, and the magnitude of the potential loss relating to such lawsuits may remain unknown for substantial periods of time.

We presently carry general liability, excess liability, products liability and property insurance coverage in amounts that are customary for companies in our industry of comparable size and level of activity. However, our insurance policies contain various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. There can be no assurance that the insurance coverage we maintain is sufficient or will be available in adequate amounts or at a reasonable cost. A successful claim brought against us in excess of available insurance or not covered by indemnification agreements, or any claim that results in significant adverse publicity against us, could have an adverse effect on our business and our reputation.

We may need to obtain additional product liability insurance coverage, including with locally-authorized insurers licensed in countries where we market our approved products or conduct our clinical trials, before initiating clinical trials; however, such insurance is expensive and may not be available when we need it. In the future, we may not be able to obtain adequate insurance, with acceptable limits and retentions, at an acceptable cost. Any product, general liability or product liability claim, even if such claim is within the limits of our insurance coverage or meritless and/or unsuccessful, could adversely affect the availability or cost of insurance generally and our cash available for other purposes, such as research and development. In addition, such claims could result in:

- uninsured expenses related to defense or payment of substantial monetary awards to claimants;
- a decrease in demand for our drug product candidates;
- damage to our reputation; and
- an inability to complete clinical trial programs or to commercialize our drug product candidates, if approved.

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

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

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

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

Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated By-Laws and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third-party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Amended and Restated Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. 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.

## USE OF PROCEEDS

We will retain broad discretion over the use of net proceeds to us from the sale of our securities offered hereby. Except as may be otherwise described in a prospectus supplement, we currently anticipate using any net proceeds to us for general corporate purposes. The amounts and timing of our actual expenditures may vary significantly depending upon numerous factors.

Pending the application of such proceeds, we may invest the proceeds in short-term, interest bearing, investment-grade marketable securities or money market obligations.

## 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, 2013 and in the three-month period ended March 31, 2014. 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.

	Fiscal Year Ended December 31,					Three Months Ended March 31,
	2009	2010	2011	2012	2013	2014
Ratio of earnings to fixed charges <sup>(1)</sup>						
Coverage deficiency	\$ (29,871)	\$ (19,175)	\$ (20,965)	\$ (37,315)	\$ (45,215)	\$ (11,476)

(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, 2014, we had \$30.1 million in outstanding indebtedness, including accrued interest. None of this indebtedness has been registered under the Securities Act.

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 depository 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 depository 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 depository 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 depository, 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 depository.

The depository policies and procedures may change from time to time. Neither we nor the trustee will have any responsibility or liability for the depository’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

As of the date of this prospectus, we have authorized 5,000,000 shares of preferred stock, par value \$.001 per share, none of which are outstanding. Under our Amended and 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 Amended and 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 Amended and 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 U.S. 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 Amended and 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.

As of the date of this prospectus, we have authorized 150 million shares of common stock, par value \$0.001 per share. As of May 23, 2014, there were 85,052,281 shares of common stock outstanding, which does not include:

- 6,829,535 shares of common stock issuable upon the exercise of certain stock options outstanding, at a weighted average exercise price of \$5.61 per share;
- 14,032,518 shares of common stock issuable upon the exercise of certain warrants outstanding, at a weighted average exercise price of \$3.47 per share (without giving effect to any of the anti dilution adjustment provisions thereof);
- 18,936 shares of common stock issuable upon vesting of restricted stock units;
- 59,948 shares of common stock reserved for potential future issuance pursuant to our 401(k) Plan;
- 1,472,833 shares of common stock available for future grant under our 2011 Long-Term Incentive Plan, as amended; 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 shares of our common stock.

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 Nasdaq under the symbol "DSCO."

### 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 By-Laws 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 23, 2014, 14,032,518 shares of common stock were issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$3.47, of which 6,957,518 shares of common stock are issuable under this prospectus upon the exercise of outstanding warrants.

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 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 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 Registrant's registration statement on Form S-3, initially filed with the Commission on June 13, 2008 (No. 333-151654) (2008 Registration Statement), on February 22, 2011 we issued warrants to purchase an aggregate of up to 5,000,000 shares of common stock. Of these, warrants to purchase 4,552,600 shares remain outstanding.

The warrants are exercisable at any time up to the date that is five years after such date at an exercise price of \$1.50 per share of common stock. The 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 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.

*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 warrants is subject to adjustment as described above.

**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 2008 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 2008 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 exercisable 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 a Common Stock Purchase Agreement with Kingsbridge Capital Limited (Kingsbridge), we also issued to Kingsbridge on June 11, 2010, pursuant to the 2008 Registration Statement, a warrant to purchase up to 83,333 shares of our common stock, which was 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.

### **Warrants Issued on April 30, 2010**

Pursuant to the 2008 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 2008 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.

## 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 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 can 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.

## LEGAL MATTERS

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

## 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, 2013, 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.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and periodic reports, proxy statements and other information with the Commission. You may read and copy any materials that we file with the Commission at the Commission'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 Commission at 1-800-SEC-0330. Many of our Commission filings are also available to the public from the Commission'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](mailto:ir@DiscoveryLabs.com) or contact William C. Roberts, our Vice President, Investor Relations and Corporate Communications, at the following address or telephone number: Discovery Laboratories, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, Attention: William C. Roberts; (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 our corporate 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 Commission 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 Commission, as described in the preceding paragraph.

## INCORPORATION BY REFERENCE

The Commission 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 Commission will automatically update and supersede this information. We incorporate by reference the documents filed with Commission listed below:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed on March 17, 2014;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, filed on May 12, 2014;
- our Current Reports on Form 8-K filed with the Commission on March 11, 2014, March 13, 2014 (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), March 26, 2014 and May 8, 2014 (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);
- our Definitive Proxy Statement filed with the Commission on April 28, 2014, including any amendments or supplements filed for the purpose of updating same; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the Commission on July 13, 1995.



All reports and other documents subsequently filed by us with the Commission pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act 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 Commission after the date that the initial registration statement is filed with the Commission 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](mailto:ir@DiscoveryLabs.com) and requesting any one or more of such filings or by contacting William C. Roberts, our Vice President, Investor Relations and Corporate Communications, at the following address or telephone number: Discovery Laboratories, Inc., 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976, Attention: William C. Roberts; (215) 488-9300. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

\$250,000,000



**Discovery Laboratories, Inc.**

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

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**PROSPECTUS**

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**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.**

, 2014

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the U.S. Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where an offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED MAY 30, 2014**

**PROSPECTUS**



**Up to \$23,038,092 of Shares  
Common Stock**

This prospectus relates to the offer and sale from time to time of shares of our common stock, par value \$0.001 per share, through Stifel, Nicolaus & Company, Incorporated (Stifel), as our exclusive sales agent for an “at the market offering” program (ATM Program). In accordance with the terms of the sales agreement, during its three-year term, we may offer and sell up to a maximum of \$25,000,000 of shares of our common stock from time to time through Stifel as our sales agent. Of this amount, at May 23, 2014, \$23,038,092 remains available for issuance under the ATM Program.

Our common stock is listed on The NASDAQ Capital Market® (Nasdaq) under the symbol “DSCO.” On May 23, 2014, the last reported sale price of our common stock on Nasdaq was \$1.79 per share.

Sales of shares of our common stock, if any, will be made at market prices prevailing at the time of sale, by any method deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (Securities Act), which may include ordinary brokers’ transactions on Nasdaq or as otherwise agreed by Stifel and us. See “Plan of Distribution” on page S-11 of this prospectus for more information. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

Subject to the terms and conditions of the sales agreement, Stifel will use its commercially reasonable efforts to sell on our behalf any shares of common stock to be offered by us under the sales agreement. The offering of our common stock pursuant to the sales agreement will terminate upon the earlier of: (1) the sale of all shares of our common stock subject to the sales agreement, (2) the third anniversary of the date of the sales agreement or (3) the termination of the sales agreement pursuant to its terms.

We will pay Stifel a commission equal to 3.0% of the gross sales price of the shares for amounts of shares sold under the sales agreement. In connection with any sale of our common stock, Stifel may be deemed to be an “underwriter” within the meaning of the Securities Act, and the compensation of Stifel may be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Stifel with respect to certain liabilities, including liabilities under the Securities Act.

**Investing in our common stock involves significant risks. See “Risk Factors” on page S-8 of this prospectus.**

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

**STIFEL**

The date of this prospectus is \_\_\_\_\_, 2014.

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## ABOUT THIS PROSPECTUS

This prospectus 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 documents incorporated by reference into this prospectus. This prospectus is part of a “shelf” registration statement on Form S-3 that we filed with the Commission on May 30, 2014. You should read this prospectus together with the additional information about us described in the sections entitled “Where You Can Find More Information” and “Information Incorporated by Reference.” To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference that was filed with the Commission before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in one of these documents is inconsistent with a statement in another document having a later date, 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 and the documents incorporated by reference herein. We 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 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 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 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. The term “you” refers to a prospective investor.

## PROSPECTUS SUMMARY

*This summary highlights certain information about us, this offering and information appearing elsewhere in this 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. 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 carefully, including the matters set forth under the caption "Risk Factors" on page S-8 of this prospectus, and the consolidated financial statements and related notes included or incorporated by reference in this prospectus, the accompanying prospectus and the other documents incorporated by reference herein.*

### **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 (KL<sub>4</sub> surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival. We are developing our KL<sub>4</sub> surfactant in liquid, lyophilized and aerosolized dosage forms. We are also developing novel drug delivery technologies potentially to enable efficient delivery of our aerosolized KL<sub>4</sub> surfactant using less invasive administration procedures than presently required. We believe that our proprietary technologies may make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies.

### **Initial Focus – Respiratory Distress Syndrome in Premature Infants**

We are initially focused on improving the management of respiratory distress syndrome (RDS) in premature infants. RDS is a serious respiratory condition caused by insufficient surfactant production in underdeveloped lungs of premature infants. RDS is the most prevalent respiratory disease in the neonatal intensive care unit (NICU) and can result in long-term respiratory problems, developmental delay and death.

Our first KL<sub>4</sub> surfactant drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants at high risk for RDS, was approved by the U.S. Food and Drug Administration (FDA) in 2012. SURFAXIN is our KL<sub>4</sub> surfactant in liquid form and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants currently used in the United States. SURFAXIN has been commercially available in the United States since November 2013.

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

AEROSURF® is our investigational combination drug/device product that combines our KL<sub>4</sub> surfactant with our proprietary capillary aerosol generator (CAG). With AEROSURF, if approved, neonatologists potentially will be able to administer aerosolized KL<sub>4</sub> surfactant to premature infants supported by nCPAP alone, without invasive intubation and mechanical ventilation. By enabling delivery of our KL<sub>4</sub> surfactant using less invasive procedures, we believe that AEROSURF may address a serious unmet medical need and potentially enable the treatment of a significantly greater number of premature infants with RDS who could benefit from surfactant therapy but are currently not treated.

We are also developing a lyophilized (freeze-dried) dosage form of our KL<sub>4</sub> surfactant that is stored as a powder and reconstituted to liquid form prior to use with the objective of improving ease of use for healthcare practitioners, as well as potentially to prolong shelf life and eliminate the need for cold-chain storage. We are initially developing this dosage form for use in our AEROSURF development program. We also plan to seek regulatory advice to determine if we could gain marketing authorization for a lyophilized dosage form of SURFAXIN under a development plan that would be both capital efficient and capable of implementation within a reasonable time. If feasible, we would likely implement such a development plan and, if successful, expect to commercially introduce this dosage form as a life-cycle extension of SURFAXIN under the name SURFAXIN LS™, in the United States and potentially in other markets.

To support the commercial introduction of SURFAXIN in the United States and our other KL<sub>4</sub> surfactant pipeline products, if approved, we have established our own specialty respiratory critical care commercial and medical affairs team. This team includes medical professionals with experience in neonatal/pediatric respiratory critical care, and has focused on products that address neonatal indications, beginning with SURFAXIN. We believe that this team will be positioned to efficiently introduce our other KL<sub>4</sub> surfactant products under development, if approved, including AEROSURF and potentially SURFAXIN LS and future applications of our aerosolized KL<sub>4</sub> surfactant.

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

### **Beyond Respiratory Distress Syndrome**

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

We also have developed a disposable aerosol-conducting airway connector for infants that is intended to simplify the delivery of aerosolized medications (including our aerosolized KL<sub>4</sub> surfactant) and other inhaled therapies to critical-care infants requiring ventilatory support. This device introduces aerosolized medications directly at the patient interface and minimizes the number of connections in the ventilator circuit. We have registered this device as a Class I, exempt medical device in the United States under the name AFECTAIR® and it is currently commercially available in the United States.

### **Trademark Notice**

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

### **Corporate Information**

We maintain our principal offices and research facilities at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976. Our telephone number is 215-488-9300. We maintain our corporate website at <http://www.DiscoveryLabs.com>. Our website and the information contained therein or connected thereto are not incorporated into this prospectus.

## THE OFFERING

Issuer:	Discovery Laboratories, Inc.
Common Stock offered by us:	Shares of our common stock, par value \$0.001 per share, with a maximum aggregate offering price of up to \$23,038,092.
Manner of Offering:	“At the market offering” that may be made from time to time, if at all, through Stifel, as sales agent. See “Plan of Distribution” on page S-11.
Use of Proceeds:	We will retain broad discretion over the use of the net proceeds from the sale of our securities offered by this prospectus and plan to use such net proceeds to meet our working capital requirements to execute our business plans, including, without limitation, to support our commercial activities, including the introduction in the United States of SURFAXIN for the prevention of RDS in premature infants at high risk for RDS, to advance our development programs, including AEROSURE, our combination drug / device product that combines our KL4 surfactant and CAG technologies to produce aerosolized KL4 surfactant, which we are developing for premature infants with RDS, and to execute our long-term manufacturing strategy, including with respect to our Totowa Facility and our CMOs; and for general corporate purposes. See “Use of Proceeds” on page S-9.
The NASDAQ Capital Market® Symbol:	DSCO
Risk Factors:	Investing in our common stock involves significant risks. See “Risk Factors” on page S-8 of this prospectus for a discussion of factors you should consider carefully when making an investment decision.



## SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus contains “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including such terms as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time during which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans, and our expectations related to the commercialization of SURFAXIN and our development and potential regulatory plans to secure marketing authorization for our products under development, starting with AEROSURF, if approved; our expectations, timing and anticipated outcomes of submitting regulatory filings for our products under development; our research and development programs, including planning for development activities, anticipated timing of clinical trials and potential development milestones, for our KL4 surfactant pipeline, our CAG for delivery of aerosolized medications; plans for the manufacture of drug products, active pharmaceutical ingredients and materials and medical devices; and plans regarding potential strategic alliances and other collaborative arrangements to develop, manufacture and market our products.

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

- the risk that we will require in the near term, but may be unable to secure, significant additional capital to continue our operations, fund our debt service and support our research and development activities, including expensive and time-consuming clinical trials, until such time, if ever, that our revenues from all sources are sufficient to offset our cash outflows. To the extent that we raise such capital through additional financings, such additional financings could result in equity dilution;
- the risk that, if we fail to successfully commercialize SURFAXIN, and if we do not achieve revenues consistent with our expectations, it may be more difficult to secure the additional capital we will require when needed, if at all, whether from strategic alliances or other sources, to continue our commercial and medical affairs activities, as well as our research and development programs and our operations would be impaired, which ultimately could have a material adverse effect on our business, financial condition and results of operations;
- risks relating to the ability of our sales and marketing organization to effectively introduce SURFAXIN in the United States and, if approved, our other product candidates, in a timely manner, if at all; and that we may not succeed in developing sufficient market awareness of our products or that our product candidates may not gain market acceptance by physicians, patients, healthcare payers and others in the medical community;
- risks relating to our ability to timely modify our business strategy to respond to changing circumstances, assumptions and forecasts, and otherwise as needed to manage growth effectively and respond to developments in our commercial operations and research and development activities, as well as our business, our industry and other factors;
- the risk that our AEROSURF phase 2 clinical program may be interrupted, delayed, or fail, which will harm our business;

- the risk that we and the FDA or other regulatory authorities will not be able to agree on matters raised during the regulatory review process, or that we may be required to conduct significant additional activities to potentially gain approval of our product candidates, if ever;
- risks relating to the transfer of our manufacturing technology to CMOs and assemblers;
- risks relating to our and our CMOs' ability to manufacture our KL<sub>4</sub> surfactant, in liquid and lyophilized dosage forms, which must be processed in an aseptic environment and tested using sophisticated and extensive analytical methodologies and quality control release and stability tests, for both commercial and research and development activities;
- risks relating to our and our CMOs' ability to develop and manufacture combination drug/device products based on our CAG technology, for preclinical and clinical studies of our product candidates and, if approved, for commercialization;
- the risk that we, our CMOs or any of our third-party suppliers, many of which are single-source providers, may encounter problems in manufacturing our KL<sub>4</sub> surfactant drug products and the active pharmaceutical ingredients used in the manufacture of our drug products, CAG devices and other materials on a timely basis or in an amount sufficient to support our needs;
- the risk that we may not succeed in implementing our long-term manufacturing strategy to assure continuity of SURFAXIN commercial drug product supply, which could expose us to risks that may affect our ability to maintain sufficient supplies of SURFAXIN commercial drug product;
- 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 United States with the development of our KL<sub>4</sub> surfactant pipeline products, beginning with AEROSURF, including development of our lyophilized KL<sub>4</sub> surfactant, and, if approved, commercialization of AEROSURF in markets outside the United States; support the commercialization of SURFAXIN in countries where regulatory approval is facilitated by the information contained in the SURFAXIN new drug application approved by the FDA; and potentially support the development and, if approved, commercialization, of our other pipeline products;
- risks relating to our plans potentially to secure marketing and distribution capabilities in certain markets through third-party strategic alliances and/or marketing alliances and/or distribution arrangements, that could require us to give up rights to our drug products, drug product candidates and drug delivery technologies;
- risks relating to our pledge of substantially all of our assets to secure our obligations under the Deerfield Loan, which could make it more difficult for us to secure additional capital to satisfy our obligations and require us to dedicate cash flow to payments for debt service, which would reduce the availability of our cash flow to fund working capital, capital expenditures and other investment;
- the risk that market conditions, the competitive landscape or other factors may make it difficult to launch and profitably sell our products;
- risks relating generally to our research and development activities, which among other things may involve time-consuming and expensive preclinical studies and potentially multiple clinical trials that may be subject to potentially significant delays or regulatory holds or fail;
- risks related to our efforts to gain regulatory approval, in the United States and elsewhere, for our drug products, medical device and combination drug/device product candidates, including AEROSURF, and our lyophilized KL<sub>4</sub> surfactant that we expect will be the drug component of AEROSURF and potentially be developed as a life cycle extension of SURFAXIN under the name SURFAXIN LS;
- risks relating to the rigorous regulatory approval processes, including pre-filing activities, required for approval of any drug, combination drug-device product or medical device that we may develop, whether independently, with strategic development partners or pursuant to collaboration arrangements;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of, any applications that we may file, or may not approve our applications or may limit approval of our products to particular indications or impose unanticipated label limitations;

- risks that unfavorable credit and financial markets may adversely affect our ability to fund our activities, through our “at the market offering” program (ATM Program) or otherwise, and that our ATM Program may expire unutilized or be exhausted; and that additional equity financings could result in substantial equity dilution or result in a downward adjustment to the exercise price of five-year warrants that we issued in February 2011 (which contain price-based anti-dilution adjustments);
- risks that reimbursement and health care reform may adversely affect us or that our products will not be accepted by physicians and others in the medical community;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug products and medical device candidates;
- the risk that if we fail to maintain compliance with continued listing requirements of Nasdaq, our common stock may be delisted and the value of our common stock decrease;
- the risks that we may be unable to maintain and protect the patents and licenses related to our products and that other companies may develop competing therapies and/or technologies;
- the risks that we may become involved in securities, product liability and other litigation and that our insurance may be insufficient to cover costs of damages and defense;
- the risk that we, our strategic partners or collaborators will be unable to attract and retain key employees, including qualified scientific, professional and other personnel, in a competitive market for skilled personnel, which could have a material adverse effect on our commercial and development activities and our operations; and
- other risks and uncertainties detailed in “Risk Factors” and elsewhere in this prospectus, and in the documents incorporated by reference in this prospectus.

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

The forward-looking statements contained in this prospectus 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

*Investing in our securities involves a high degree of risk. You should consider the following risk factors, the risk factors contained in the accompanying prospectus beginning on page 6 and our Form 10-K for the year ended December 31, 2013, as well as other information contained or incorporated by reference in this prospectus, before deciding to purchase any of our securities. The risks and uncertainties described below and incorporated by reference herein are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may become important factors that affect us. If any of these risks occur, our business could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our securities.*

### **Risks Related to this Offering and Our Common Stock**

#### **The number of shares available for future sale could adversely affect the market price of our common stock.**

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. We may issue shares of our common stock in this offering with maximum gross offering proceeds of up to \$23,038,092. 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 March 31, 2014, approximately 21.3 million 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 Commission. As of March 31, 2014, the outstanding options have a weighted average exercise price of \$5.67 per share and expire through March 2024. The outstanding warrants have a weighted average exercise price of \$3.92 per share and expire between May 2014 and February 2019. 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 “at the market offering” program (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 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. See “Plan of Distribution” for a more detailed discussion of the ATM Program.

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. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for our company.

#### **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 to the extent of the difference between the public offering price per share and the “as adjusted” net tangible book value per share after giving effect to the offering. After giving effect to an assumed sale of an aggregate of \$23,038,092 of our common stock at an assumed offering price of \$1.79 per share, the reported closing price of our common stock on Nasdaq on May 23, 2014, and after deducting the commissions and the estimated aggregate offering expenses payable by us, and our net tangible book value as of March 31, 2014, investors would suffer an immediate dilution of \$1.06 per share in the net tangible book value of their common stock. This calculation assumes that all sales in this offering will occur at once. Since the shares will be sold in this offering at various prices from time to time, this information is for illustration only. See “Dilution” for a more detailed discussion of the dilution you will incur in this offering.

#### **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.

## USE OF PROCEEDS

The amount of net proceeds from this offering will depend upon the number of shares of our common stock sold and the market prices at which they were sold over the course of this offering. We will retain broad discretion over the use of the net proceeds from the sale of our securities offered by this prospectus and plan to use such net proceeds to meet our working capital requirements to execute our business plans, including, without limitation, to support our commercial activities, including the introduction in the United States of SURFAXIN for the prevention of RDS in premature infants at high risk for RDS, to advance our development programs, including AEROSURE, our combination drug / device product that combines our KL4 surfactant and CAG technologies to produce aerosolized KL4 surfactant, which we are developing for premature infants with RDS, and to execute our long-term manufacturing strategy, including with respect to our Totowa Facility and our CMOs; and for general corporate purposes.

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 our surfactant drug 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.

## DILUTION

Investors who purchase our common stock in this offering will experience immediate dilution in the net tangible book value per share of common stock. The net tangible book value of our common stock on March 31, 2014, was approximately \$48.7 million or approximately \$0.57 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.

The shares sold in this offering, if any, will be sold from time to time at various prices that are not yet known. The table below assumes that an estimated aggregate number of shares of our common stock are sold in this offering on the same day. For that reason, the information in the table regarding potential dilution is illustrative and supplied for your information only.

Without taking into account any other changes in the net tangible book value after March 31, 2014, other than to give effect to our receipt of the estimated proceeds after giving effect to the assumed sale of all of \$23,038,092 of shares of common stock being offered in this offering, at an assumed offering price of \$1.79 per share (which represents 12,870,442 shares), the reported closing price of our common stock on Nasdaq on May 23, 2014, and after deducting the commissions payable by us, our net tangible book value as of March 31, 2014 after giving effect to the items above, our net tangible book value would have been approximately \$71.1 million, or approximately \$0.73 per share of common stock. This would represent an immediate increase of \$0.16 in net tangible book value per share to our existing stockholders and an immediate dilution of \$1.06 per share to purchasers of the common stock in this offering. The following table illustrates this per share dilution:

Assumed offering price per share of common stock	\$	1.79
Net tangible book value per share as of March 31, 2014	\$	0.57
Increase per share attributable to this offering	\$	0.16
Pro forma net tangible book value per share as of March 31, 2014, after giving effect to this offering	\$	0.73
Dilution per share to new investors	\$	1.06

Each \$0.20 increase/(decrease) in the assumed public offering price of \$1.79 per share would increase/(decrease) the pro forma net tangible book value per share after this offering by approximately \$0.01 per share, and the dilution per share to new investors by approximately \$0.19 per share, assuming the sale of all of \$23,038,092 of shares of common stock being sold in this offering and after deducting commissions payable by us.

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 March 31, 2014, there were 85,052,281 shares of common stock outstanding, which does not include:

- 6,808,860 shares of common stock issuable upon the exercise of certain stock options outstanding, at a weighted average exercise price of \$5.67 per share;
- 14,499,185 shares of common stock issuable upon the exercise of certain warrants outstanding, at a weighted average exercise price of \$3.92 per share (without giving effect to any of the anti dilution adjustment provisions thereof);
- 18,936 shares of common stock issuable upon vesting of restricted stock units;
- 59,948 shares of common stock reserved for potential future issuance pursuant to our 401(k) Plan;
- 1,494,841 shares of common stock available for future grant under our 2011 Long-Term Incentive Plan, as amended; 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 shares of our common stock.

## PLAN OF DISTRIBUTION

On February 11, 2013, we entered into an At-The-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated (Stifel) as our sales agent to initiate the ATM Program for the offering of our common stock. In accordance with the terms of the sales agreement, during its three-year term, we may offer and sell, up to a maximum of \$25,000,000 of shares of our common stock from time to time through Stifel as our sales agent. Of this amount, at May 23, 2014, \$23,038,092 remains available for issuance under the ATM Program.

The sales agreement provides that the obligations of the sales agent 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.

Sales of the shares, if any, will be made in (i) ordinary brokers' transactions on Nasdaq or otherwise at market prices prevailing at the time of sale, or (ii) by any other method or payment permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act. Our sales agent will not engage in any transactions that stabilize our common stock in connection with this offering.

We will designate the minimum price per share at which the shares may be sold and the maximum amount of shares of common stock to be sold through the sales agent during any selling period or otherwise determine such maximum amount together with the sales agent. Subject to the terms and conditions of the sales agreement, Stifel has agreed to use its commercially reasonable efforts to execute our orders to sell, as our sales agent and on our behalf, shares of our common stock submitted to Stifel from time to time pursuant to and subject to the terms of the sales agreement. We or Stifel may suspend the offering of shares of common stock under the sales agreement by proper notice to the other party.

We will pay Stifel an aggregate commission equal to 3.0% of the gross sales price of the shares for amounts of shares sold pursuant to the sales agreement. With the exception of expenses related to the shares, Stifel will pay all of its own costs and expenses, including the fees of its counsel. After deducting our estimated offering expenses, we expect the net proceeds from this offering, assuming the sale of a maximum of \$23,038,092 of shares of our common stock, to be approximately \$22.3 million.

Stifel will provide written confirmation to us following the close of trading on Nasdaq each day on which common stock is sold through it as sales agent under the sales agreement. Each confirmation will include the number of shares of common stock sold through it as sales agent on that day, the aggregate gross sales proceeds of the shares sold on such day, the net proceeds to us and the compensation payable by us to Stifel.

Settlement for sales of common stock will occur, unless the parties agree otherwise, on the third trading day following the date on which any sales were made against payment of the net proceeds to us. A trading day is any trading day on Nasdaq, other than a day on which Nasdaq is scheduled to close prior to its regular weekday closing time.

In connection with the sales of the common stock on our behalf, Stifel may be deemed to be an "underwriter" within the meaning of the Securities Act, and the compensation paid to Stifel may be deemed to be underwriting commissions or discounts. We have agreed to indemnify the sales agent against certain liabilities, including liabilities under the Securities Act, and liabilities arising from breaches of representations and warranties contained in the sales agreement. We have also agreed to contribute to payments the sales agent may be required to make in respect of such liabilities.

The offering of our common stock pursuant to the sales agreement will terminate upon the earlier of: (1) the sale of all shares of our common stock subject to the sales agreement, (2) the third anniversary of the date of the sales agreement or (3) the termination of the sales agreement pursuant to its terms.

Stifel may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Stifel will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

The sales agreement was included as an exhibit to our Current Report on Form 8-K that we filed with the Commission on February 13, 2013.

The transfer agent for our common stock to be issued in this offering is the Continental Stock Transfer & Trust Company.

Our common stock is traded on Nasdaq under the symbol “DSCO.”

### **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 (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 common stocks are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such common stocks 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 sales agent has represented and agreed that:

(a) it has 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 them in connection with the issue or sale of the common stocks in circumstances in which Section 21(1) of the FSMA does not apply to us, and

(b) it has complied with, and will comply with all applicable provisions of FSMA with respect to anything done by them in relation to the common stocks in, from or otherwise involving the United Kingdom.

### **European Economic Area**

To the extent that the offer of the common stocks is made in any Member State of the European Economic Area that has implemented the Prospectus Directive before the date of publication of a prospectus in relation to the common stocks 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 sales agent has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (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 it may, with effect from and including the Relevant Implementation Date, make an offer of common stock to the public in that Relevant Member State at any time:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Directive;



(b) to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive) as permitted under the Prospectus Directive, subject to obtaining the prior consent of the sales agent; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer of the common stock referred to in (a) to (c) above shall require us or the sales agent to publish a prospectus pursuant to Article 3 of the Prospective Directive.

For the purposes of this provision, the expression an “offer of common stocks 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 common stocks to be offered so as to enable an investor to decide to purchase or subscribe the common stocks, 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 common stock (other than the sales agent) will be deemed to have represented, acknowledged and agreed that it will not make an offer of common stock 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 common stocks 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 common stocks 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 common stocks to the public” in relation to any common stocks 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, New York, New York, is acting as counsel for Stifel, Nicolaus & Company, Incorporated 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, 2013, 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.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and periodic reports, proxy statements and other information with the Commission. You may read and copy any materials that we file with the Commission at the Commission'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 Commission at 1-800-SEC-0330. Many of our Commission filings are also available to the public from the Commission'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](mailto:ir@DiscoveryLabs.com) or contact William C. Roberts, our Vice President, Investor Relations and Corporate Communications, at our address as set forth in the accompanying prospectus.

We maintain a website at <http://www.DiscoveryLabs.com> (this is not a hyperlink, you must visit this website through an Internet browser). Our website and the information contained therein or connected thereto are not incorporated into this prospectus.

## INCORPORATION BY REFERENCE

We have filed with the Commission a registration statement on Form S-3 under the Securities Act relating to the common stock we are offering by this prospectus. The Commission 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 Commission will automatically update and supersede information in this prospectus. We incorporate by reference the documents listed below and any future filings we make with the Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, until this offering is completed:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, filed on March 17, 2014;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, filed on May 12, 2014;
- our Current Reports on Form 8-K filed with the Commission on March 11, 2014, March 13, 2014 (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), March 26, 2014 and May 8, 2014 (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);
- our Definitive Proxy Statement filed with the Commission on April 28, 2014, including any amendments or supplements filed for the purpose of updating same; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the Commission on July 13, 1995.

Furthermore, all reports and other documents subsequently filed (but not furnished) by us with the Commission pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act prior to the termination of this 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. We are not incorporating by reference any documents or portions thereof that are not deemed "filed" with the Commission, 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 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.

This prospectus and the accompanying prospectus are only part of a registration statement on Form S-3 that we have filed with the Commission 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 and the accompanying prospectus. Statements contained in this prospectus 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 is delivered may request a copy of any or all of the information incorporated by reference in this prospectus, including the exhibits to any filings incorporated by reference herein, from us, at no charge, or from the Commission in the above described manner.

Up to \$23,038,092 of Shares  
Common Stock



Discovery Laboratories, Inc.

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PROSPECTUS

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STIFEL

, 2014

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of the securities being registered. All of such fees expenses, except for the registration fee, are estimates:

	Amount <sup>(1)</sup>
U.S. Securities and Exchange Commission registration fee <sup>(2)</sup>	\$ 24,070
Accounting fees and expenses	\$ *
Legal fees and expenses	\$ *
Miscellaneous fees and expenses	\$ *
<b>Total</b>	<b>\$ *</b>

(1) Does not include expenses of preparing any accompanying prospectus supplements, FINRA filing fee, listing fees, transfer agent fees and other expenses related to future offerings of particular securities.

(2) Represents the registration fee of \$32,200, offset by \$8,130 previously paid in connection with unsold securities pursuant to Rule 415(a)(6).

\* The amount of securities and number of offerings are indeterminable and the expenses cannot be estimated at this time.

We shall bear all expenses in connection with the issuance and distribution of the securities being offered hereby.

**Item 15. Indemnification of Directors and Officers**

Article Eight of our Amended and Restated Certificate of Incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for (i) any breach of their duty of loyalty to the corporation or its stockholders, (ii) acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the General Corporation Law of the State of Delaware or (iv) any transaction from which the director derives an improper personal benefit.

Our By-Laws provide that we shall indemnify our directors and officers, the directors and officers of any of our subsidiaries and any other individuals acting as directors or officers of any other corporation at our request, to the fullest extent permitted by law.

We have entered into indemnification agreements with one director and certain of our executive officers containing provisions that may require us, among other things, to indemnify them against liabilities that may arise by reason of their status or service as director or officers other than liabilities arising from willful misconduct of a culpable nature and to advance certain expenses incurred as a result of any proceeding against them as to which they could be indemnified. We have obtained limited directors' and officers' liability insurance.

These provisions in our Amended and Restated Certificate of Incorporation and our By-Laws do not eliminate the officers' and directors' fiduciary duty, and in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under Delaware law. In addition, each officer and director will continue to be subject to liability for breach of their duty of loyalty to us for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for actions leading to improper personal benefit to the officer or director and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provisions also do not affect an officer's or director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

**Item 16. Exhibits**

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
1.1	Form of Underwriting Agreement.	To be filed, if necessary, by a Current Report on Form 8-K or by amendment.
1.2	At-the-Market Equity Offering Sales Agreement dated February 11, 2013 between Discovery and Stifel Nicolaus & Company, Incorporated.	Incorporated by reference to Exhibit 10.1 to Discovery's Current Report on Form 8-K, as filed with the Commission on February 13, 2013.
3.1	Amended and Restated Certificate of Incorporation of Discovery Laboratories, Inc. (Discovery) dated as of July 25, 2013 and filed as of August 1, 2013.	Incorporated by reference to Exhibit 3.1 to Discovery's Quarterly Report on Form 10-Q, as filed with the Commission on August 8, 2013.
3.2	Amended and Restated By-Laws of Discovery, as amended effective September 3, 2009.	Incorporated by reference to Exhibit 3.1 to Discovery's Current Report on Form 8-K, as filed with the Commission on September 4, 2009.
4.1	Form of Stock Purchase Warrant issued in February 2010.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the Commission on February 18, 2010.
4.2	Warrant Agreement, dated as of April 30, 2010, by and between Discovery and PharmaBio Development Inc. (PharmaBio).	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the Commission on April 28, 2010.
4.3	Warrant Agreement dated June 11, 2010 by and between Kingsbridge Capital Limited and Discovery.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the Commission on June 14, 2010.
4.4	Form of Warrant issued on June 22, 2010	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the Commission on June 17, 2010.
4.5	Warrant Agreement, dated October 14, 2010, by and between Discovery and PharmaBio.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the Commission on October 13, 2010.
4.6	Form of Warrant.	Incorporated by reference to Exhibit 4.1 to Discovery's Current Report on Form 8-K, as filed with the Commission on February 16, 2011.
4.7	Form of Senior Indenture between Discovery and The Bank of New York Mellon, as trustee.	Incorporated by reference to Exhibit 4.11 to Discovery's registration statement on Form S-3, as filed with the Commission on June 13, 2008.
4.8	Form of Subordinated Indenture between Discovery and The Bank of New York Mellon, as trustee.	Incorporated by reference to Exhibit 4.12 to Discovery's registration statement on Form S-3, as filed with the Commission on June 13, 2008.
4.9	Form of Senior Debt Security.	To be filed, if necessary, by a Current Report on Form 8-K or by amendment.
4.10	Form of Subordinated Debt Security.	To be filed, if necessary, by a Current Report on Form 8-K or by amendment.

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
4.11	Form of Certificate of Designations of Preferred Stock.	To be filed, if necessary, by a Current Report on Form 8-K or by amendment.
4.12	Form of Warrant Agreement, including Form of Warrant Certificate.	To be filed, if necessary, by a Current Report on Form 8-K or by amendment.
<a href="#">5.1</a>	Opinion of Dentons US LLP, legal counsel.	Filed herewith.
<a href="#">12.1</a>	Statement regarding computation of ratios of earnings to fixed charges.	Filed herewith.
<a href="#">23.1</a>	Consent of Ernst & Young LLP, independent registered public accounting firm.	Filed herewith.
23.2	Consent of Dentons US LLP, legal counsel.	Filed herewith (included in the opinion filed as Exhibit 5.1).
24.1	Powers of Attorney.	Filed herewith (included in signature page to this registration statement).
<a href="#">25.1</a>	Form T-1 Statement of Eligibility of Trustee for the Senior Indenture under the Trust Indenture Act of 1939.	Filed herewith.
<a href="#">25.2</a>	Form T-1 Statement of Eligibility of Trustee for the Subordinated Indenture under the Trust Indenture Act of 1939.	Filed herewith.

## **Item 17. Undertakings**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*provided, however, that*

(A) paragraphs (1)(i) and (1)(ii) do not apply if the registration statement is on Form S-8 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(B) paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(6) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) The undersigned registrant hereby undertakes to supplement the prospectus, after the expiration of the subscription period, to set forth the results of the subscription offer, the transactions by the underwriters during the subscription period, the amount of unsubscribed securities to be purchased by the underwriters, and the terms of any subsequent reoffering thereof. If any public offering by the underwriters is to be made on terms differing from those set forth on the cover page of the prospectus, a post-effective amendment will be filed to set forth the terms of such offering.

(h) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.



(i) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(j) The undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under section 305(b)(2) of the Act.

**SIGNATURES**

Pursuant to the requirement of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Warrington, Commonwealth of Pennsylvania, on the 30th day of May, 2014.

**DISCOVERY LABORATORIES, INC.**

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

We, the undersigned officers and directors of Discovery Laboratories, Inc., and each of us, do hereby constitute and appoint each of John G. Cooper, Mary B. Templeton, Esq., and John A. Tattory, or any of them, each acting alone, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, to do any and all acts and things in our name, place and stead, in any and all capacities, in connection with this registration statement on Form S-3 under the Securities, or any registration statement for the same offering that is to be effective upon filing under the Securities Act, including, without limitation, to sign for us or any of us in our names in the capacities indicated below any and all amendments or supplements to this registration statement, including any and all stickers and post-effective amendments to the registration statement, and to sign any and all additional registration statements relating to the same offering of securities as this registration statement that are filed pursuant to Rule 462(b) under the Securities Act, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission and any applicable securities exchange or securities self-regulatory body, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Name and Title</b>	<b>Date</b>
<u>/s/ John G. Cooper</u>	John G. Cooper President, Chief Executive Officer and Director (Principal Executive Officer)	May 30, 2014
<u>/s/ John A. Tattory</u>	John A. Tattory Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 30, 2014
<u>/s/ John R. Leone</u>	John R. Leone Chairman of the Board of Directors	May 30, 2014
<u>/s/ Joseph M. Mahady</u>	Joseph M. Mahady Director	May 30, 2014
<u>/s/ Bruce A. Peacock</u>	Bruce A. Peacock Director	May 30, 2014
<u>/s/ Marvin E. Rosenthale</u>	Marvin E. Rosenthale Director	May 30, 2014



Dentons US LLP  
1221 Avenue of the Americas

T+1 212 768 6700  
F+1 212 768 6800

New York, New York 10020

**Salans FMC SNR Denton**  
dentons.com

May 30, 2014

Board of Directors  
Discovery Laboratories, Inc.  
2600 Kelly Road, Suite 100  
Warrington, Pennsylvania 18976

Re: Discovery Laboratories, Inc.  
Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to Discovery Laboratories, Inc., a corporation organized under the laws of the State of Delaware (the "Company"), in connection with the registration under the Securities Act of 1933, as amended (the "Securities Act"), of the issuance and sale from time to time pursuant to Rule 415(a)(1)(x), promulgated under the Securities Act, of securities (collectively, the "Securities") with an aggregate public offering price of \$250,000,000 on a Registration Statement on Form S-3 (as it may be amended, the "Registration Statement") being filed on the date hereof by the Company with the U.S. Securities and Exchange Commission (the "Commission"), with such Securities consisting of: (i) senior debt securities, in one or more series (the "Senior Debt Securities"), which may be issued under the Indenture (the "Senior Indenture") to be dated on or about the first issuance of the Senior Debt Securities thereunder, by and between the Company and The Bank of New York Mellon, as trustee (the "Trustee"), the form of which is filed as Exhibit 4.11 to the Company's registration statement on Form S-3, as filed with the Commission on June 13, 2008 (the "2008 Registration Statement"); (ii) subordinated debt securities, in one or more series (the "Subordinated Debt Securities" and together with the Senior Debt Securities, the "Debt Securities"), which may be issued under the indenture (the "Subordinated Indenture") to be dated on or about the date of the first issuance of the Subordinated Debt Securities thereunder, by and between the Company and the Trustee, the form of which is filed as Exhibit 4.12 to the 2008 Registration Statement; (iii) shares of preferred stock, par value \$0.001 per share, of the Company (the "Preferred Stock"); (vi) shares of common stock, par value \$0.001 per share, of the Company (the "Common Stock"); and (v) warrants to purchase shares of Preferred Stock and shares of Common Stock (the "Warrants").

We are delivering this opinion to you in accordance with the requirements of Item 16 of Form S-3 and Item 601(b)(5)(i) of Regulation S-K promulgated by the Commission.

In connection with rendering this opinion, we have examined originals, certified copies or copies otherwise identified as being true copies of the following:

- (a) the Registration Statement;
  - (b) the Amended and Restated Certificate of Incorporation of the Company, as amended and restated to date (as so amended and restated, the "Certificate of Incorporation");
  - (c) the Amended and Restated By-Laws of the Company, as amended to date (as so amended, the "By-Laws");
  - (d) corporate proceedings of the Company relating to its proposed issuance of the Securities; and
  - (e) such other instruments and documents as we have deemed relevant or necessary in connection with our opinions set forth herein.
-

In making the aforesaid examinations, we have assumed (i) that the Debt Securities and Warrants are or will be governed by the internal laws of the State of New York or the State of Delaware; (ii) the genuineness and authenticity of all documents examined by us and all signatures therein and the conformity to originals of all copies of all documents examined by us; and (iii) the corporate records furnished to us by the Company include all corporate proceedings taken by it to date.

Based on and subject to the assumptions, qualifications and limitations set forth herein, we are of the opinion that:

(1) When (i) the Registration Statement has become effective under the Securities Act and (ii) with respect to Debt Securities to be issued under either the Senior Indenture or the Subordinated Indenture, when (A) the Trustee is qualified to act as Trustee under the Senior Indenture or Subordinated Indenture, as applicable, (B) the Trustee has duly executed and delivered the Senior Indenture or Subordinated Indenture, as applicable, (C) the Senior Indenture or Subordinated Indenture, as applicable, has been duly authorized and validly executed and delivered by the Company to the Trustee, (D) the Senior Indenture or Subordinated Indenture, as applicable, has been duly qualified under the Trust Indenture Act of 1939, as amended, (E) the Board of Directors of the Company or a duly constituted and acting committee thereof (such Board of Directors or committee being hereinafter referred to as the "Board") and any officers of the Company to whom such authority has been delegated by the Board has taken all necessary corporate action to approve the issuance and terms of a particular issue of such Debt Securities, the terms of the offering thereof and related matters, and (F) such Debt Securities have been duly executed, authenticated, issued and delivered in accordance with the provisions of (i) the Senior Indenture or Subordinated Indenture, as applicable, and (ii) the applicable definitive purchase, underwriting or similar agreement approved by the Board upon payment of the consideration therefor provided for therein, then such Debt Securities will be validly issued and will constitute binding obligations of the Company.

(2) When (i) the Registration Statement has become effective under the Securities Act and (ii) an issuance of the Common Stock has been duly authorized by the Company and, upon issuance and delivery of certificates for the Common Stock against payment therefor in accordance with the terms of such corporate proceeding taken by the Company and any applicable underwriting agreement or purchase agreement, and as contemplated by the Registration Statement and/or the applicable prospectus supplement, or upon the exercise of any Warrants to purchase Common Stock in accordance with the terms thereof, or conversion or exchange of Preferred Stock that, by its terms, is convertible into or exchangeable for Common Stock, and receipt by the Company of any additional consideration payable upon such conversion, exchange or exercise, as applicable, the shares of Common Stock represented by such certificates will be validly issued, fully paid and nonassessable.

(3) When (i) the Registration Statement has become effective under the Securities Act, (ii) a series of Preferred Stock has been duly authorized and established by the Company in accordance with the terms of the Certificate of Incorporation, the By-Laws and applicable law, and (iii) the issuance of such series of Preferred Stock has been appropriately authorized by the Company and, upon issuance and delivery of certificates for such series of Preferred Stock against payment therefor in accordance with the terms of such corporate proceeding taken by the Company and any applicable underwriting agreement or purchase agreement, and as contemplated by the Registration Statement and/or the applicable prospectus supplement, or upon the exercise of any Warrants for such series of Preferred Stock in accordance with the terms thereof, and receipt by the Company of any additional consideration payable upon conversion, exchange or exercise, as applicable, such series of Preferred Stock represented by such certificates will be validly issued, fully paid and nonassessable.

(4) When (i) the Registration Statement has become effective under the Securities Act, (ii) the Warrants and, if applicable, a warrant agreement conforming to the description thereof in the Registration Statement and/or the applicable prospectus supplement have been duly authorized by the Company, and any such warrant agreement has been executed and delivered by the Company and the warrant agent named therein, and (iii) Warrants conforming to the requirements of any related warrant agreement have been duly authenticated by the applicable warrant agent and the Warrants have been duly executed and delivered on behalf of the Company against payment therefor in accordance with the terms of such corporate proceeding taken by the Company, any applicable underwriting agreement or purchase agreement and any applicable warrant agreement, and as contemplated by the Registration Statement and/or the applicable prospectus supplement, the Warrants will constitute binding obligations of the Company.

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Our opinions are subject to the effect of federal and state bankruptcy, insolvency, reorganization, arrangement, moratorium, fraudulent conveyance and other laws relating to or affecting the rights of secured or unsecured creditors generally (or affecting the rights of only creditors of specific types of debtors), with respect to which we express no opinion.

Our opinions are subject to the effect of general principals of equity, whether applied by a court of law or equity, including, without limitation, concepts of materiality, good faith and fair dealing and upon the availability of injunctive relief or other equitable remedies, and the application of principles of equity (regardless of whether enforcement is considered in proceedings at law or in equity).

The Company has informed us that it intends to issues Securities from time to time on a delayed or continuous basis. The opinions set forth above are limited to applicable laws as in effect on the date hereof. Prior to issuing any Securities pursuant to the Registration Statement (i) the Company will advise us in writing of the terms thereof, and (ii) the Company will afford us an opportunity to review the documents pursuant to which such Securities are to be issued or sold (including the applicable offering documents) and the Company will file such supplement or amendment to this opinion (if any) as we may reasonably consider necessary or appropriate.

We express no opinion as to the laws of any jurisdiction other than the corporate laws of the State of Delaware (including the Delaware General Corporation Law and applicable provisions of the Delaware constitution, as well as reported judicial decisions interpreting the same, but excluding local laws), the federal laws of the United States of America, and with respect to the opinions set forth in paragraphs (1) and (4) above, the internal laws of the State of New York.

We hereby consent to the use of our opinion as herein set forth as an exhibit to the Registration Statement and to the use of our name under the caption "Legal Matters" in the prospectus forming a part of the Registration Statement. We do not, by giving such consent, admit that we are within the category of persons whose consent is required under Section 7 of the Act.

Very truly yours,  
/s/ Dentons US LLP

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Discovery Laboratories, Inc.  
 Computation of Ratio of Earnings to Fixed Charges  
*(in thousands)*

Our earnings were insufficient to cover fixed charges in each of the years in the five-year period ended December 31, 2013 and in the three-month period ended March 31, 2014. 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.

	Fiscal Year Ended December 31,					Three Months Ended March 31,
	2009	2010	2011	2012	2013	2014
Ratio of earnings to fixed charges <sup>(1)</sup>						
Coverage deficiency	\$ (29,871)	\$ (19,175)	\$ (20,965)	\$ (37,315)	\$ (45,215)	\$ (11,476)

<sup>(1)</sup> 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.

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3 No. 333- ) and related Prospectus of Discovery Laboratories, Inc. for the registration of up to \$250,000,000 of its common stock, debt securities, preferred stock, debt warrants, and equity warrants and to the incorporation by reference therein of our reports dated March 17, 2014, with respect to the consolidated financial statements of Discovery Laboratories, Inc., and the effectiveness of internal control over financial reporting of Discovery Laboratories, Inc., included in its Annual Report (Form 10-K) for the year ended December 31, 2013, filed with the U.S. Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
May 30, 2014

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

FORM T-1

STATEMENT OF ELIGIBILITY  
UNDER THE TRUST INDENTURE ACT OF 1939 OF A  
CORPORATION DESIGNATED TO ACT AS TRUSTEE

CHECK IF AN APPLICATION TO DETERMINE  
ELIGIBILITY OF A TRUSTEE PURSUANT TO  
SECTION 305(b)(2)

**THE BANK OF NEW YORK MELLON**  
(Exact name of trustee as specified in its charter)

New York  
(Jurisdiction of incorporation if not a U.S. national bank)

13-5160382  
(I.R.S. employer identification no.)

One Wall Street, New York, N.Y.  
(Address of principal executive offices)

10286  
(Zip code)

**DISCOVERY LABORATORIES, INC.**  
(Exact name of obligor as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

94-3171943  
(I.R.S. employer identification no.)

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

18976  
(Zip code)

Senior Debt Securities  
(Title of the indenture securities)



**1. General information. Furnish the following information as to the Trustee:**

**(a) Name and address of each examining or supervising authority to which it is subject.**

Name	Address
Superintendent of Banks of the State of New York	One State Street, New York, N.Y. 10004-1417, and Albany, N.Y. 12223
Federal Reserve Bank of New York	33 Liberty Street, New York, N.Y. 10045
Federal Deposit Insurance Corporation	Washington, D.C. 20429
New York Clearing House Association	New York, N.Y. 10005

**(b) Whether it is authorized to exercise corporate trust powers.**

Yes.

**2. Affiliations with Obligor.**

**If the obligor is an affiliate of the trustee, describe each such affiliation.**

None.

**16. List of Exhibits.**

**Exhibits identified in parentheses below, on file with the Commission, are incorporated herein by reference as an exhibit hereto, pursuant to Rule 7a-29 under the Trust Indenture Act of 1939 (the "Act") and 17 C.F.R. 229.10(d).**

1. A copy of the Organization Certificate of The Bank of New York Mellon (formerly known as The Bank of New York, itself formerly Irving Trust Company) as now in effect, which contains the authority to commence business and a grant of powers to exercise corporate trust powers. (Exhibit 1 to Amendment No. 1 to Form T-1 filed with Registration Statement No. 33-6215, Exhibits 1a and 1b to Form T-1 filed with Registration Statement No. 33-21672, Exhibit 1 to Form T-1 filed with Registration Statement No. 33-29637, Exhibit 1 to Form T-1 filed with Registration Statement No. 333-121195 and Exhibit 1 to Form T-1 filed with Registration Statement No. 333-152735).
4. A copy of the existing By-laws of the Trustee (Exhibit 4 to Form T-1 filed with Registration Statement No. 333-188382).
6. The consent of the Trustee required by Section 321(b) of the Act (Exhibit 6 to Form T-1 filed with Registration Statement No. 333-188382).
7. A copy of the latest report of condition of the Trustee published pursuant to law or to the requirements of its supervising or examining authority.

SIGNATURE

Pursuant to the requirements of the Act, the Trustee, The Bank of New York Mellon, a corporation organized and existing under the laws of the State of New York, has duly caused this statement of eligibility to be signed on its behalf by the undersigned, thereunto duly authorized, all in The City of New York, and State of New York, on the 28th day of May, 2014.

THE BANK OF NEW YORK MELLON

By: /s/ Francine Kincaid \_\_\_\_\_

Name: Francine Kincaid

Title: Vice President

## Consolidated Report of Condition of

## THE BANK OF NEW YORK MELLON

of One Wall Street, New York, N.Y. 10286  
 And Foreign and Domestic Subsidiaries,

a member of the Federal Reserve System, at the close of business March 31, 2014, published in accordance with a call made by the Federal Reserve Bank of this District pursuant to the provisions of the Federal Reserve Act.

**ASSETS**

Dollar amounts in  
 thousands

Cash and balances due from depository institutions:	
Noninterest-bearing balances and currency and coin	4,798,000
Interest-bearing balances	117,806,000
Securities:	
Held-to-maturity securities	18,480,000
Available-for-sale securities	77,008,000
Federal funds sold and securities purchased under agreements to resell:	
Federal funds sold in domestic offices	67,000
Securities purchased under agreements to resell	4,438,000
Loans and lease financing receivables:	
Loans and leases held for sale	0
Loans and leases, net of unearned income	33,479,000
LESS: Allowance for loan and lease losses	182,000
Loans and leases, net of unearned income and allowance	33,297,000
Trading assets	6,825,000
Premises and fixed assets (including capitalized leases)	1,162,000
Other real estate owned	3,000
Investments in unconsolidated subsidiaries and associated companies	1,111,000
Direct and indirect investments in real estate ventures	0
Intangible assets:	
Goodwill	6,487,000
Other intangible assets	1,255,000
Other assets	15,439,000
Total assets	<u><u>288,176,000</u></u>

**LIABILITIES**

Deposits:	
In domestic offices	122,415,000
Noninterest-bearing	79,457,000
Interest-bearing	42,958,000
In foreign offices, Edge and Agreement subsidiaries, and IBFs	121,648,000
Noninterest-bearing	8,862,000
Interest-bearing	112,786,000
Federal funds purchased and securities sold under agreements to repurchase:	
Federal funds purchased in domestic offices.	2,270,000
Securities sold under agreements to repurchase	3,511,000
Trading liabilities	4,618,000
Other borrowed money: (includes mortgage indebtedness and obligations under capitalized leases)	5,928,000
Not applicable	
Not applicable	
Subordinated notes and debentures	1,065,000
Other liabilities	6,134,000
Total liabilities	<u>267,589,000</u>

**EQUITY CAPITAL**

Perpetual preferred stock and related surplus	0
Common stock	1,135,000
Surplus (exclude all surplus related to preferred stock)	9,954,000
Retained earnings	9,711,000
Accumulated other comprehensive income	-563,000
Other equity capital components	0
Total bank equity capital	20,237,000
Noncontrolling (minority) interests in consolidated subsidiaries	350,000
Total equity capital	<u>20,587,000</u>
Total liabilities and equity capital	<u>288,176,000</u>

I, Thomas P. Gibbons, Chief Financial Officer of the above-named bank do hereby declare that this Report of Condition is true and correct to the best of my knowledge and belief.

Thomas P. Gibbons,  
Chief Financial Officer

We, the undersigned directors, attest to the correctness of this statement of resources and liabilities. We declare that it has been examined by us, and to the best of our knowledge and belief has been prepared in conformance with the instructions and is true and correct.

Gerald L. Hassell  
Catherine A. Rein  
Michael J. Kowalski

]

Directors

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

## FORM T-1

STATEMENT OF ELIGIBILITY  
UNDER THE TRUST INDENTURE ACT OF 1939 OF A  
CORPORATION DESIGNATED TO ACT AS TRUSTEE

CHECK IF AN APPLICATION TO DETERMINE  
ELIGIBILITY OF A TRUSTEE PURSUANT TO  
SECTION 305(b)(2)

THE BANK OF NEW YORK MELLON  
(Exact name of trustee as specified in its charter)

New York 13-5160382  
(Jurisdiction of incorporation if not a U.S. national bank) (I.R.S. employer identification no.)

One Wall Street, New York, N.Y. 10286  
(Address of principal executive offices) (Zip code)

DISCOVERY LABORATORIES, INC.  
(Exact name of obligor as specified in its charter)

Delaware 94-3171943  
(State or other jurisdiction of incorporation or organization) (I.R.S. employer identification no.)

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

Subordinated Debt Securities  
(Title of the indenture securities)

**1. General information. Furnish the following information as to the Trustee:**

**(a) Name and address of each examining or supervising authority to which it is subject.**

Name	Address
Superintendent of Banks of the State of New York	One State Street, New York, N.Y. 10004-1417, and Albany, N.Y. 12223
Federal Reserve Bank of New York	33 Liberty Street, New York, N.Y. 10045
Federal Deposit Insurance Corporation	Washington, D.C. 20429
New York Clearing House Association	New York, N.Y. 10005

**(b) Whether it is authorized to exercise corporate trust powers.**

Yes.

**2. Affiliations with Obligor.**

**If the obligor is an affiliate of the trustee, describe each such affiliation.**

None.

**16. List of Exhibits.**

**Exhibits identified in parentheses below, on file with the Commission, are incorporated herein by reference as an exhibit hereto, pursuant to Rule 7a-29 under the Trust Indenture Act of 1939 (the "Act") and 17 C.F.R. 229.10(d).**

1. A copy of the Organization Certificate of The Bank of New York Mellon (formerly known as The Bank of New York, itself formerly Irving Trust Company) as now in effect, which contains the authority to commence business and a grant of powers to exercise corporate trust powers. (Exhibit 1 to Amendment No. 1 to Form T-1 filed with Registration Statement No. 33-6215, Exhibits 1a and 1b to Form T-1 filed with Registration Statement No. 33-21672, Exhibit 1 to Form T-1 filed with Registration Statement No. 33-29637, Exhibit 1 to Form T-1 filed with Registration Statement No. 333-121195 and Exhibit 1 to Form T-1 filed with Registration Statement No. 333-152735).
  4. A copy of the existing By-laws of the Trustee (Exhibit 4 to Form T-1 filed with Registration Statement No. 333-188382).
  6. The consent of the Trustee required by Section 321(b) of the Act (Exhibit 6 to Form T-1 filed with Registration Statement No. 333-188382).
  7. A copy of the latest report of condition of the Trustee published pursuant to law or to the requirements of its supervising or examining authority.
-

SIGNATURE

Pursuant to the requirements of the Act, the Trustee, The Bank of New York Mellon, a corporation organized and existing under the laws of the State of New York, has duly caused this statement of eligibility to be signed on its behalf by the undersigned, thereunto duly authorized, all in The City of New York, and State of New York, on the 28th day of May, 2014.

THE BANK OF NEW YORK MELLON

By: /s/ Francine Kincaid  
Name: Francine Kincaid  
Title: Vice President

---



## Consolidated Report of Condition of

## THE BANK OF NEW YORK MELLON

of One Wall Street, New York, N.Y. 10286  
 And Foreign and Domestic Subsidiaries,

a member of the Federal Reserve System, at the close of business March 31, 2014, published in accordance with a call made by the Federal Reserve Bank of this District pursuant to the provisions of the Federal Reserve Act.

**ASSETS**

Dollar amounts in  
 thousands

Cash and balances due from depository institutions:	
Noninterest-bearing balances and currency and coin	4,798,000
Interest-bearing balances	117,806,000
Securities:	
Held-to-maturity securities	18,480,000
Available-for-sale securities	77,008,000
Federal funds sold and securities purchased under agreements to resell:	
Federal funds sold in domestic offices	67,000
Securities purchased under agreements to resell	4,438,000
Loans and lease financing receivables:	
Loans and leases held for sale	0
Loans and leases, net of unearned income	33,479,000
LESS: Allowance for loan and lease losses	182,000
Loans and leases, net of unearned income and allowance	33,297,000
Trading assets	6,825,000
Premises and fixed assets (including capitalized leases)	1,162,000
Other real estate owned	3,000
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Direct and indirect investments in real estate ventures	0
Intangible assets:	
Goodwill	6,487,000
Other intangible assets	1,255,000
Other assets	15,439,000
<b>Total assets</b>	<b>288,176,000</b>

**LIABILITIES**

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Federal funds purchased and securities sold under agreements to repurchase:	
Federal funds purchased in domestic offices.	2,270,000
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Not applicable	
Not applicable	
Subordinated notes and debentures	1,065,000
Other liabilities	6,134,000
Total liabilities	<u>267,589,000</u>

**EQUITY CAPITAL**

Perpetual preferred stock and related surplus	0
Common stock	1,135,000
Surplus (exclude all surplus related to preferred stock)	9,954,000
Retained earnings	9,711,000
Accumulated other comprehensive income	-563,000
Other equity capital components	0
Total bank equity capital	20,237,000
Noncontrolling (minority) interests in consolidated subsidiaries	350,000
Total equity capital	<u>20,587,000</u>
Total liabilities and equity capital	<u>288,176,000</u>

I, Thomas P. Gibbons, Chief Financial Officer of the above-named bank do hereby declare that this Report of Condition is true and correct to the best of my knowledge and belief.

Thomas P. Gibbons,  
Chief Financial Officer

We, the undersigned directors, attest to the correctness of this statement of resources and liabilities. We declare that it has been examined by us, and to the best of our knowledge and belief has been prepared in conformance with the instructions and is true and correct.

Gerald L. Hassell  
Catherine A. Rein  
Michael J. Kowalski

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Directors

