

PROSPECTUS

12,167,047 Shares



Common Stock

This prospectus relates to the resale of up to 12,167,047 shares of our common stock that we may issue to Kingsbridge Capital Limited (“Kingsbridge”) pursuant to a Common Stock Purchase Agreement, dated April 17, 2006, between Kingsbridge and ourselves and a Class C Investor Warrant we issued to Kingsbridge on that date. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholder may sell its shares of common stock in the section titled “Plan of Distribution” on page 21. We will not be paying any underwriting discounts or commissions in this offering. We will pay the expenses incurred in registering the shares, including legal and accounting fees.

Our common stock is quoted on The Nasdaq National Market under the symbol “DSCO.” The last reported sale price for our common stock on April 27, 2006 was \$2.78 per share.

Investing in our common stock involves significant risks. See “Risk Factors” beginning on Page 7.

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

The date of this prospectus is May 12, 2006.

TABLE OF CONTENTS

	Page
ABOUT THIS PROSPECTUS	1
ABOUT DISCOVERY	1
RECENT DEVELOPMENTS	1
EQUITY FINANCING WITH KINGSBRIDGE CAPITAL	3
RISK FACTORS	7
FORWARD-LOOKING STATEMENTS	19
USE OF PROCEEDS	20
SELLING STOCKHOLDER	20
PLAN OF DISTRIBUTION	21
DESCRIPTION OF COMMON STOCK	23
EXPERTS	25
LEGAL MATTERS	25
INTERESTS OF NAMED EXPERTS AND COUNSEL	25
WHERE YOU CAN FIND MORE INFORMATION	25
INFORMATION INCORPORATED BY REFERENCE	26

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

ABOUT THIS PROSPECTUS

The following summary highlights information contained in this prospectus or incorporated by reference. While we have included what we believe to be the most important information about us and this offering, the following summary may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the risks of investing discussed under “Risk Factors” beginning on page 7, and the information to which we refer you and the information incorporated into this prospectus by reference, for a complete understanding of our business and this offering. Unless the context requires otherwise, in this prospectus the terms “Discovery,” “we,” “us” and “our” refer to Discovery Laboratories, Inc., a Delaware corporation, and its consolidated subsidiaries. References to “selling stockholder” refers to the stockholder listed herein under the heading “Selling Stockholder” on page 20, who may sell shares from time to time as described in this prospectus.

ABOUT DISCOVERY

We are a biotechnology company developing our proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Our technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. We believe that through this SRT technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the Neonatal Intensive Care Unit (NICU), critical care unit and other hospital settings, where there are few or no approved therapies available.

Our lead product, Surfaxin[®] (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received two Approvable Letters from the U.S. Food and Drug Administration (FDA) and is under review for approval in Europe by the European Medicines Evaluation Agency (EMA).

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the NICU. In addition to Surfaxin for RDS, Surfaxin is also being developed for the prevention and treatment of Bronchopulmonary Dysplasia (BPD, also known as Chronic Lung Disease) in premature infants. We are also preparing to conduct multiple Phase 2 pilot studies with Aerosurf[™], our proprietary aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for the treatment of neonatal respiratory failures.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, we recently concluded a Phase 2 clinical trial to treat Acute Respiratory Distress Syndrome (ARDS) in adults, and are also researching and developing aerosol SRT to address Acute Lung Injury (ALI) prophylaxis, chronic obstructive pulmonary disease (COPD), cystic fibrosis, asthma and other debilitating respiratory conditions.

RECENT DEVELOPMENTS

Recent events, described below, are expected to significantly delay the U.S. regulatory approval process for Surfaxin for the prevention of RDS in premature infants. This delay does not arise out of any issues related to the clinical data from our multinational SELECT Study, which demonstrates that Surfaxin was significantly more effective in the prevention of RDS and also improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants.

In February 2006, the Medicines and Health Products Regulatory Agency conducted an on-site inspection of our manufacturing facility on behalf of the EMA. An on-site inspection is required as part of the EMA regulatory approval process. We responded in writing to all of the EMA inspectional observations in March 2006. Since the timeline set forth in the EMA guidelines for providing further comments has expired, we believe that the EMA site inspection process has been completed. Nevertheless, the EMA can initiate a re-inspection of our manufacturing facility at any time.

In April 2006, we received from the FDA a second Approvable Letter related to our NDA for Surfaxin for the prevention of RDS in premature infants. The letter contained additional questions primarily related to Chemistry, Manufacturing and Control (CMC) areas and product labeling. We are currently analyzing the second Approvable Letter and preparing a comprehensive information package for the FDA addressing some of the issues in the second Approvable Letter. Once we have completed our analysis, we will request a meeting with the FDA and submit the comprehensive information package. Upon receipt of our request, procedurally the FDA must respond within 14 days and the meeting must occur within 75 days of the written request. At the meeting, we will seek to clarify the issues identified by the FDA in the second Approvable Letter. Thereafter, we will submit our formal response to the second Approvable Letter. At that time, the FDA will advise us of the time frame in which it will complete its review and advise us if it will accept our response to the second Approvable Letter as a complete response.

In December 2005, we purchased from Laureate Pharma, Inc., our contract manufacturer, its contract manufacturing operations and facility located in Totowa, NJ. This facility is our only validated clinical facility in which we produce clinical grade material of our drug substance for use in our ongoing clinical studies. The FDA concluded a three-week site re-inspection of our manufacturing facility on April 7, 2006. The focus of the FDA re-inspection centered on corrective actions implemented in response to the inspectional observations on Form 483 issued in January 2005, as well as ongoing manufacturing and quality control operations, systems and controls. Upon conclusion of the on-site inspection, the FDA issued a Form 483 containing inspectional observations related predominantly to the clarification of written procedures, documentation and preventive maintenance. We have submitted our response to the observations. One item noted on the site inspection Form 483 relates to certain drug product specification issues identified in the second Approvable Letter received in April 2006 and will be addressed in our response to the second Approvable Letter. Although the site inspection Form 483 does not cite a need for a re-inspection and we anticipate that our responses to the Form 483 inspectional observations will be satisfactory to the FDA, the FDA may re-inspect our manufacturing facility at any time.

Surfaxin is a complex drug and, unlike many drugs, contains four active ingredients. Surfaxin is aseptically manufactured at our facility and presented as a sterile, liquid dispersion. The manufacturing process to produce Surfaxin is complex and requires ongoing monitoring of the stability and conformance to product specifications of each of the four active ingredients and must be conducted in a sterile environment. Each batch of drug produced at our manufacturing facility undergoes a stringent test regimen and a requisite number of lots per year are placed into a designed stability testing program consisting of specification testing conducted over multiple time intervals and storage conditions. A batch of drug product may fail to achieve the specified stability parameters. In April 2006, based on our stability testing program, we concluded that certain of the batches of Surfaxin that were identified in our new drug application (NDA) as "process validation batches" and manufactured in the period from June through August 2005 failed to achieve the designated stability parameters. We have initiated an investigation to determine the cause of the failure. Because these process validation batches are a part of our NDA, to complete our NDA, we will have to manufacture and designate new process validation batches and subject those new process validation batches to periodic stability testing. Accordingly, we anticipate a significant delay in the U.S. regulatory approval process for Surfaxin for the prevention of RDS in premature infants. We do not know at this time what exact impact this manufacturing issue will have on the Surfaxin European regulatory approval process, but such approval is likely to be delayed.

In March 2006, we completed our Phase 2 clinical trial to treat ARDS in adults. Although the results of the trial were mixed, due in part to a small patient enrollment, we observed a clinical and statistically significant improvement in oxygenation and, for those patients who responded to the surfactant treatment, a better clinical outcome. We have currently discontinued our ARDS development and will seek potential partners, with which we can apply the scientific and clinical observations generated from this trial to support the design of future trials to treat ARDS.

In early May 2006, a number of law firms issued press releases indicating that they had filed shareholder class actions against the Company in the United States District Court for the Eastern District of Pennsylvania. The Company has not been served with a complaint and has no basis on which to evaluate the class action claims at this time.

We are currently implementing a long-term business strategy which includes the following:

- We are analyzing all aspects of our business with an immediate intention to conserve cash while we remediate our manufacturing issues. The establishment of our own commercial infrastructure is no longer in our near-term plans. Our strategy includes, among other things, down-sizing our operations and potentially entering into strategic partnerships;
- We will use our newly-acquired manufacturing facility, which is critical to the production of Surfaxin and our SRT clinical programs, to produce Surfaxin, other SRT formulations and aerosol development capabilities. We view our acquisition of manufacturing operations as an initial step in our manufacturing strategy for the continued development of our SRT portfolio, including life cycle management of Surfaxin, potential formulation enhancements, and expansion of our aerosol SRT products, beginning with Aerosurf. Our long-term strategy includes building or acquiring additional manufacturing capabilities for the production of our precision-engineered surfactant drug products;
- We are investing in the development of our aerosol SRT pipeline programs, including Aerosurf, primarily utilizing the aerosol generating technology we licensed in December 2005 through a strategic alliance with Chrysalis Technologies, a division of Philip Morris USA Inc.; and
- We plan on securing corporate partnerships for the development and potential commercialization of our SRT pipeline for the NICU, including Surfaxin. We plan on securing corporate partnerships for the development and potential commercialization of our SRT pipeline addressing respiratory conditions affecting young adult and adult patients in the critical care and other hospital settings, including ARDS. We have entered into a corporate partnership with Laboratorios del Dr. Esteve, S.A., primarily for the marketing and sale of Surfaxin and certain of our other SRT products in Southern Europe.

EQUITY FINANCING WITH KINGSBRIDGE CAPITAL

On April 17, 2006, we entered into a Committed Equity Financing Facility (the "CEFF") with Kingsbridge by way of a Common Stock Purchase Agreement, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, the lesser of up to \$50 million or up to 11,677,047 shares of our common stock. In connection with the CEFF, we entered into a Registration Rights Agreement with Kingsbridge. We also issued a Class C Investor Warrant to Kingsbridge to purchase 490,000 shares of our common stock at a price of \$5.6186 per share, which is fully exercisable beginning October 17, 2006 and for a period of five years thereafter.

The Common Stock Purchase Agreement entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of three years, shares of our common stock for cash consideration up to an aggregate of the lesser of up to \$50 million or up to 11,677,047 shares of our common stock, subject to certain conditions and restrictions. The shares of common stock that may be issued to Kingsbridge under the Common Stock Purchase Agreement and upon exercise of the Class C Investor Warrant will be issued pursuant to an exemption from registration under the Securities Act of 1933, as amended (the "Securities Act"). Pursuant to the Registration Rights Agreement, we have filed a registration statement of which this prospectus is a part, covering the possible resale by Kingsbridge of any shares that we may issue to Kingsbridge under the Common Stock Purchase Agreement or the Registration Rights Agreement or upon exercise of the Class C Investor Warrant. Through this prospectus, Kingsbridge may offer to the public for resale the shares of our common stock that we may issue to it pursuant to the Common Stock Purchase Agreement, or that Kingsbridge may acquire upon exercise of the Class C Investor Warrant.

For a period of 36 months from the first trading day following the effectiveness of the registration statement of which this prospectus is a part, we may, from time to time, at our discretion, and subject to certain conditions that we must satisfy, draw down funds under the CEFF by selling shares of our common stock to Kingsbridge. The purchase price of these shares will be at a discount ranging from 6 to 10 percent of the volume weighted average of the price of our common stock for each of the eight trading days following our election to sell shares, or "draw down" under the CEFF. The discount on each of these eight trading days will be determined as follows:

VWAP*	Percent of VWAP (Applicable Discount)	
Greater than \$10.50 per share	94%	(6)%
Less than or equal to \$10.50 but greater than \$7.00 per share	92%	(8)%
Less than or equal to \$7.00 but greater than or equal to \$2.00 per share	90%	(10)%

* As set forth in the Common Stock Purchase Agreement, "VWAP" means the volume weighted average price (the aggregate sales price of all trades of our common stock during each trading day divided by the total number of shares of common stock traded during that trading day) of our common stock during any trading day as reported by Bloomberg, L.P. using the AQR function. The VWAP and corresponding discount will be determined for each of the eight trading days during a draw down pricing period.

During the eight trading day pricing period for a draw down, if the VWAP for any one trading day is less than the greater of (i) \$2.00 or (ii) 85 percent of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down period, the VWAP from that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth of the draw down amount we had initially specified. In addition, if trading in our common stock is suspended for any reason for more than three consecutive or non-consecutive hours during any trading day during a draw down pricing period, that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one eighth of the draw down amount we had initially specified.

We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of stock under the CEFF provide an appropriate means of raising capital.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. Each draw down is limited to the lesser of 2.5 percent of the closing price market value of our outstanding shares of common stock at the time of the draw down or \$10 million. Unless Kingsbridge agrees otherwise, a minimum of three trading days must elapse between the expiration of any draw down pricing period and the beginning of the next draw down pricing period. Kingsbridge is not obligated to purchase shares at prices below \$2.00 per share.

During the term of the CEFF, we may not enter into any equity line or other financing that is substantially similar to the CEFF, under which we agree to issue any shares of common stock or securities of any type that are, or may become, convertible or exchangeable into shares of common stock where the purchase, conversion or exchange price for such common stock is determined using any floating discount or other post-issuance adjustable discount to the market price of common stock. Any future issuance by us of a convertible security that contains provisions that adjust the conversion price of such convertible security solely for stock splits, dividends, distributions or similar events is permitted so long as such convertible security does not contain a provision that adjusts the conversion price as a result of any decline in the market price of the common stock after the issue date of the convertible security, other than a decline resulting directly from stock splits, dividends, distributions or similar events including, without limitation, the type of conversion price adjustments customarily found in a firm commitment Rule 144A offering to qualified institutional buyers.

The issuance of our common stock under the CEFF or upon exercise of the Class C Investor Warrant will have no effect on the rights or privileges of existing holders of common stock except that the economic and voting interests of each stockholder will be diluted as a result of the issuance. Although the number of shares of common stock that stockholders presently own will not decrease, these shares will represent a smaller percentage of our total shares that will be outstanding after any issuances of shares of common stock to Kingsbridge. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Such issuances will have a dilutive effect and may further decrease our stock price.

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

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

- Each of our representations and warranties in the Common Stock Purchase Agreement must be true and correct in all material respects as of the date when made and as of the date of the applicable draw down notice as though made at that time, except for representations and warranties that are expressly made as of a particular date.
- We must have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required to be performed, satisfied or complied with by us under the Common Stock Purchase Agreement, the Registration Rights Agreement and the Class C Investor Warrant.
- We must have complied in all respects with all applicable federal, state and local governmental laws, rules, regulations and ordinances in connection with the execution, delivery and performance of the Common Stock Purchase Agreement and the consummation of the transactions it contemplates except for any failures to so comply that would not reasonably be expected to have a material adverse effect on us.
- The registration statement that includes this prospectus must be effective.
- We must not have knowledge of any event that could reasonably be expected to have the effect of causing the registration statement applicable to Kingsbridge’s resale of shares of our common stock to be suspended or otherwise ineffective.
- Trading in our common stock shall not have been suspended by the Securities and Exchange Commission (the “SEC”), The Nasdaq National Market or the National Association of Securities Dealers and trading in securities generally on The Nasdaq National Market shall not have been suspended or limited.
- No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any court or governmental authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by the Common Stock Purchase Agreement.
- No action, suit or proceeding before any arbitrator or any governmental authority shall have been commenced, and no investigation by any governmental authority shall have been threatened, against us or any of our officers, directors or affiliates seeking to enjoin, prevent or change the transactions contemplated by the Common Stock Purchase Agreement.
- We must have sufficient shares of common stock, calculated using the closing trade price of the common stock as of the trading day immediately preceding a draw down, registered under the registration statement to issue and sell such shares in accordance with such draw down.
- The Class C Investor Warrant must have been duly executed, delivered and issued to Kingsbridge, and we shall not be in default in any material respect thereunder.
- Kingsbridge must have received an opinion from our outside legal counsel in the form previously agreed to.
- We must be current on all undisputed expense invoices that we are required to pay under the Common Stock Purchase Agreement.

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

We also entered into a Registration Rights Agreement with Kingsbridge. Pursuant to the Registration Rights Agreement, we have filed a registration statement, which includes this prospectus, with the SEC relating to Kingsbridge's resale of any shares of common stock purchased by Kingsbridge under the Common Stock Purchase Agreement or issued to Kingsbridge under the Registration Rights Agreement or as a result of the exercise of the Class C Investor Warrant. The effectiveness of this registration statement is a condition precedent to our ability to sell common stock to Kingsbridge under the Common Stock Purchase Agreement. We are entitled in certain circumstances, including the existence of certain kinds of nonpublic information, to deliver a blackout notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement of which this prospectus is a part is not effective in circumstances not permitted by the Registration Rights Agreement, then we must pay amounts to Kingsbridge, or issue Kingsbridge additional shares in lieu of payment, calculated by means of a varying percentage of an amount based on the number of shares held by Kingsbridge that were purchased pursuant to the draw down and the change in the market price of our common stock between the date the blackout notice is delivered (or the registration statement is not effective) and the date the prospectus again becomes available.

Kingsbridge may terminate the CEFF upon one business day's notice to us if we enter into a transaction prohibited by the Common Stock Purchase Agreement without Kingsbridge's prior written consent or if a material adverse effect relating to our business continues for ten trading days after we receive notice from Kingsbridge of the material adverse effect. Kingsbridge may also terminate the CEFF upon one business day's notice to us at any time if a registration statement is not initially declared effective in accordance with the Registration Rights Agreement. Kingsbridge may terminate the CEFF upon ten business days' notice to us at any time if we fail to make cumulative draw downs of at least \$2 million during any 12-month period after the first 12 months of the term of the CEFF. We may terminate the CEFF upon one business day's notice to Kingsbridge, except that we may not terminate the CEFF during any draw down pricing period. In addition, either we or Kingsbridge may terminate the CEFF upon one business day's notice if the other party has breached a material representation, warranty or covenant to the Common Stock Purchase Agreement and such breach is not remedied within ten trading days after notice of such breach is delivered to the breaching party.

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

Corporate Information

Surfaxin® is our trademark. This prospectus also includes product names, trademarks and trade names of other companies, which names are the exclusive property of the holders thereof.

Our executive offices are located at 2600 Kelly Road, Suite 100, Warrington, Pennsylvania 18976-3622. Our telephone number is (215) 488-9300 and our facsimile number is (215) 488-9301. We maintain a website on the Internet at www.discoverylabs.com. Information contained in our web site is not a part of this prospectus.

RISK FACTORS

An investment in our common stock involves significant risks. You should carefully consider the risks described below or in any applicable prospectus supplement and other information, including our financial statements and related notes previously included in our periodic reports filed with the SEC. If any of the factors or conditions summarized in the following risks actually occur, our business prospects, financial condition and results of operations could be materially harmed, the value or trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are those that we currently believe may materially affect us. Additional risks and uncertainties of which we are unaware or which we currently deem immaterial also may become important factors that affect us.

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

We currently have no products approved for marketing and sale and are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of our products. Our long-term viability will be impaired if we are unable to obtain regulatory approval for, or successfully market, our product candidates.

To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development before their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of December 31, 2005, we have an accumulated deficit of approximately \$202.0 million and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

Our technology platform is based solely on our proprietary precision-engineered surfactant technology.

Our precision-engineered surfactant technology platform is based on the scientific rationale of using SRT to treat life-threatening respiratory disorders and as the foundation for the development of novel respiratory therapies and products. Our business is dependent upon the successful development and approval of our product candidates based on this technology platform. Any material problems with our technology platform could have a material adverse effect on our business.

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

To sell Surfaxin or any of our other products under development, we must receive regulatory approvals for each product. The FDA and foreign regulators extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish the safety and effectiveness of each product and the confirmation by the FDA and foreign regulators that, in manufacturing the product, we maintain good laboratory and manufacturing practices during testing and manufacturing. Even if favorable testing data is generated by clinical trials of drug products, the FDA or EMEA may not accept or approve an NDA or Marketing Authorization Application (“MAA”) filed by a pharmaceutical or biotechnology company for such drug product. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products.

We have filed an NDA with the FDA for Surfaxin for the prevention of RDS in premature infants. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued a Form 483 to our then contract manufacturer, Laureate Pharma, Inc. citing inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with current good manufacturing practices (cGMPs). The FDA issued an Approvable Letter to us in February 2005 regarding our NDA. To address the Form 483 inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA’s regulatory requirements for the approval of Surfaxin. In October 2005, the FDA accepted our responses to the Approvable Letter as a complete response thereby establishing April 2006 as its target to complete its review of our NDA. In April 2006, the FDA issued a second Approvable Letter to us. We are preparing a comprehensive information package for the FDA addressing some of the issues in the second Approvable Letter. Once we have completed our analysis, we will request a meeting with the FDA, at which we will seek to clarify the issues identified by the FDA in the second Approvable Letter. Thereafter, we will submit our formal response to the second Approvable Letter. At that time, the FDA will advise us of the time frame in which it will complete its review and advise us if it will accept our response to the second Approvable Letter as a complete response. After we have submitted our complete response, the FDA might still delay its approval of our NDA or reject our NDA, which would have a material adverse effect on our business.

We have filed an MAA with the EMEA for clearance to market Surfaxin for the prevention of RDS in premature infants in Europe. In February 2006, we received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA. We plan to submit a written response to all of the CHMP's outstanding issues in early April 2006 with a possible Oral Explanation before the CHMP in late June 2006. According to standard CHMP procedures, the Committee is expected to make a recommendation on whether to grant a Marketing Authorization for Surfaxin and issue a formal Opinion in late July 2006. The EMEA, however, may delay its decision or not complete the review or may reject the MAA. In addition, we do not know at this time whether the failure of certain process validation batches to achieve stability parameters in periodic stability testing will have any impact on the Surfaxin European regulatory approval process, but such approval is likely to be delayed.

If the FDA and foreign regulators do not approve our products, we will not be able to market our products.

The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. The FDA or a foreign regulator could withdraw any approvals we obtain, if any. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA or a foreign regulator may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions.

Our pending NDA for Surfaxin for the prevention of RDS in premature infants may not be approved by the FDA in a timely manner or at all, which would adversely impact our ability to commercialize this product.

We submitted an NDA to the FDA for Surfaxin for the prevention of RDS in premature infants. In April 2006, we received a second Approvable Letter from the FDA, which contained a list of inspectional observations on Form 483. Thereafter, we learned that certain process validation batches, which are a part of our NDA, failed to achieve the designated stability parameters in periodic stability testing. These events are expected to significantly delay the review of our NDA. When we have completed and submitted our response to the second Approvable Letter and remediated our manufacturing issues, the FDA may request additional information from us, including data from additional clinical trials. Ultimately, the FDA may not approve Surfaxin for RDS in premature infants. Any failure to obtain FDA approval or further delay associated with the FDA's review process would adversely impact our ability to commercialize our lead product.

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

The FDA has notified us that two of our intended indications for our precision-engineered SRT, 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. Designation as a Fast Track product means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The FDA generally will review an NDA for a drug granted Fast Track designation within six months instead of the typical one to three years. 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 drug candidates may fail to qualify for Fast Track designation or expedited review.

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

Clinical trials generally take two to five years or more to complete. Like many biotechnology companies, we may suffer significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials or in preliminary findings for such clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which 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, among other factors, the rate at which patients are enrolled, which is a function of many factors, including:

- the number of clinical sites;
- the size of the patient population;
- the proximity of patients to the clinical sites;
- the eligibility and enrollment criteria for the study;
- the existence of competing clinical trials;
- the existence of alternative available products; and
- geographical and geopolitical considerations.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both. Patients may also suffer adverse medical events or side effects that are common to those administered with the surfactant class of drugs such as a decrease in the oxygen level of the blood upon administration.

It is also possible that the FDA or foreign regulators could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If we or any regulator believe that trial participants face unacceptable health risks, any one or more of our trials could be suspended or terminated. We also may not reach agreement with the FDA or a foreign regulator on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and foreign regulators on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials.

In addition to our efforts to commercialize Surfaxin for the prevention of RDS in premature infants, we are currently conducting a Phase 2 clinical trial to determine the safety and tolerability of administering Surfaxin as a therapeutic approach for the prevention and treatment of BPD in premature infants. We are preparing to conduct multiple Phase 2 pilot studies with Aerosurf for the potential treatment of premature infants in the NICU suffering from neonatal respiratory failure.

The manufacture of our products is a highly exacting and complex process, and if we or one of our materials suppliers encounter problems manufacturing our products, our business could suffer.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing our drug substance. Manufacturing or quality control problems have already and may again occur at our Totowa facility or our materials suppliers. Such problems, including, for example, our recent product stability testing program issues, require potentially complex, time-consuming and costly investigations to determine the causes and may also require detailed remediation plans, which can further delay the regulatory approval process. See also "Recent Developments" for a description of our recent manufacturing issues. Any failure to comply with cGMP requirements or other FDA or foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products.

In December 2005, we acquired Laureate's clinical manufacturing facility in Totowa, New Jersey. The facility has been qualified to produce appropriate clinical grade material of our drug product for use in our ongoing clinical studies. With this acquisition, we now maintain a complete manufacturing facility and we will be manufacturing our products. We currently own certain specialized manufacturing equipment, employ certain manufacturing managerial personnel, and we expect to invest in additional manufacturing equipment. We may be unable to produce Surfaxin and our other SRT drug candidates to appropriate standards for use in clinical studies or for commercialization. If we do not successfully develop our manufacturing capabilities, it will adversely affect the sales of our products.

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

We rely on suppliers for our drug substance raw materials and third parties for certain manufacturing-related services to produce material that meets appropriate standards for commercial distribution and use in clinical trials of our products. To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We will need additional capital and our ability to continue all of our existing planned research and development activities is uncertain. Any additional financing could result in equity dilution.

We will need substantial additional funding to conduct our presently planned research and product development activities. Based on our current operating plan, we believe that our currently available working capital will be adequate to satisfy our capital needs into 2007. Our future capital requirements will depend on a number of factors that are uncertain, including the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process, among others. We will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may also continue to seek additional funding through capital lease transactions. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

We have not entered into arrangements to obtain any additional financing, except for the CEFFs with Kingsbridge, our revolving credit facility with PharmaBio and our capital equipment lease financing arrangement with GECC. Kingsbridge has the right under certain circumstances to terminate the CEFF, including as a consequence of a material adverse effect, including, potentially, our recent issues with product stability testing. Any additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue certain of our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. If we are unable to raise required capital, we may be forced to limit many, if not all, of our research and development programs and related operations, curtail commercialization of our product candidates and, ultimately, cease operations. See also "Risk Factors - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders."

Furthermore, if the market price of our common stock declines as a result of the dilutive aspects of such potential financings, we could cease to meet the financial requirements to maintain the listing of our securities on The Nasdaq National Market. See "Risk Factors - The market price of our stock may be adversely affected by market volatility."

Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.

There are 12,167,047 shares of our common stock that are reserved for issuance under the CEFF arrangement we entered into with Kingsbridge on April 17, 2006, 490,000 of which are issuable upon exercise of the Class C Investor Warrant. The issuance of shares of our common stock under the CEFF and upon exercise of the warrant will have a dilutive impact on our other stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. In addition, if we access the CEFF, we will issue shares of our common stock to Kingsbridge at a discount of between 6% and 10% of the daily volume weighted average price of our common stock during a specified period of trading days after we access the CEFF. Issuing shares at a discount will further dilute the interests of other stockholders.

On July 7, 2004 we entered into a Committed Equity Financing Facility with Kingsbridge by way of a Common Stock Purchase Agreement, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to \$75 million of our common stock (the "2004 CEFF"). In 2005, \$20.2 million was successfully raised under the 2004 CEFF in two separate financings over 15 day periods in September and November, respectively. On the effective date of the registration statement of which this prospectus forms a part, the 2004 CEFF will be terminated. We anticipate using the new CEFF during 2006 to support corporate, manufacturing and development activities.

To the extent that Kingsbridge sells shares of our common stock issued under the CEFF to third parties, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Kingsbridge may cause holders of our common stock to sell their shares, or it may encourage short sales of our common stock or other similar transactions. This could contribute to a decline in the stock price of our common stock.

We may not be able to meet the conditions we are required to meet under the CEFF and we may not be able to access any portion of the up to \$50.0 million available under the CEFF. In addition, we are dependent upon the financial ability of Kingsbridge to fund the CEFF. Any failure by Kingsbridge to perform its obligations under the CEFF could have a material adverse effect upon us.

Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

Our strategy for the completion of the required development and clinical testing of our products and for the marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. Our collaboration arrangement with Esteve for Surfaxin and certain other of our product candidates is focused on key Southern European markets. Within these countries, Esteve will be responsible for the development and marketing of Surfaxin for a broader portfolio of indications, including the prevention of RDS in premature infants and ALI/ARDS in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining EMEA approval for commercialization of Surfaxin in Europe for several indications. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to EMEA filings.

If we or Esteve breach or terminate the agreements that make up such collaboration arrangements or Esteve otherwise fails to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin. Accordingly, we may need to enter into additional collaboration agreements and our success may depend upon obtaining additional collaboration partners. In addition, we may depend on our collaborators' expertise and dedication of sufficient resources to develop and commercialize our proposed products.

In December, 2005, we entered into a Strategic Alliance Agreement with Chrysalis to develop and commercialize aerosolized SRT to address a broad range of serious respiratory conditions. Under the agreement, we have exclusive rights to Chrysalis' proprietary aerosolization technology for use with pulmonary surfactants for all respiratory diseases and conditions in hospital and ambulatory settings. Chrysalis will assist with the development of certain combination drug-device surfactant products, and provide certain additional consultative services to us in connection with combination drug-device surfactant products, provided that certain terms and conditions are satisfied. Additionally, Chrysalis is responsible for developing the design for the aerosol device platform, patient interface and disposable dose packets. We are responsible for aerosolized SRT drug formulations, clinical and regulatory activities, and the manufacturing and commercialization of the drug-device products.

We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See “Risk Factors - We do not have sales and marketing experience and our lack of experience may restrict our success in commercializing our product candidates.”

If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products.

We seek patent protection for our drug candidates so as 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:

- defend our patents and otherwise prevent others from infringing on our proprietary rights;
- protect trade secrets; and
- operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

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

Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us.

We, and the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office 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 United States Patent and Trademark Office or foreign patent office issuing patents. Also, 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, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson and its wholly owned subsidiary, Ortho Pharmaceutical Corporation, which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017 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 additional products or processes that will be patentable or additional patents may not be issued to us. See also “Risk Factors - If we cannot meet requirements under our license agreements, we could lose the rights to our products.”

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

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The United States Patent and Trademark Office keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

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 and Chrysalis. These agreements require us to make payments and satisfy performance obligations to maintain our rights under these licensing agreements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

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

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

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

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

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

We do not have sales and marketing experience, and our lack of such experience may restrict our success in commercializing our product candidates.

We do not have experience in marketing or selling pharmaceutical products. As a result of our recent manufacturing problems, we have determined that the establishment of a commercial infrastructure is no longer in our near-term plans. To achieve commercial success for Surfaxin, or any other approved product, we will be dependent upon entering into arrangements with others to market and sell our products.

We may be unable to establish satisfactory arrangements for marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates. To obtain the expertise necessary to successfully market and sell Surfaxin, or any other product, will require the development of collaborative commercial arrangements and partnerships. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, the performance of third party collaborators with whom we may contract. Accordingly, we may not have sufficient funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

We may enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates.

We may rely on third-party distributors to distribute our products or enter into marketing alliances to sell our products. We may not be successful in entering into distribution arrangements and marketing alliances with third parties. Our failure to successfully enter into these arrangements on favorable terms could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Our dependence on distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including:

- we may be required to relinquish important rights to our products or product candidates;
- we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;
- our distributors or collaborators may experience financial difficulties;
- our distributors or collaborators may not devote sufficient time to the marketing and sales of our products thereby exposing us to potential expenses in terminating such distribution agreements; and
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

We may need to enter into additional co-promotion arrangements with third parties where our own sales force is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements may not be favorable to us. In addition, if we enter into co-promotion arrangements or market and sell additional products directly, we may need to further expand our sales force and incur additional costs.

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

We have announced our intention to seek to market and sell Surfaxin through one or more marketing partners both in the United States and abroad. Although our agreement with Esteve provides for collaborative efforts in directing a global commercialization effort, we have somewhat limited influence over the decisions made by Esteve or their sublicensees or the resources they devote to the marketing and distribution of Surfaxin products in their licensed territory, and Esteve or their sublicensees may not meet their obligations in this regard. Our marketing and distribution arrangement with Esteve may not be successful, and we may not receive any revenues from it. Also, we may not be able to enter into marketing and sales agreements on acceptable terms, if at all, for Surfaxin in territories not covered by the Esteve agreement, or for any of our other product candidates.

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

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. As of April 27, 2006, we have employment agreements with eight officers expiring in December 2006. Each employment agreement provides that its term shall automatically be extended for one additional year, unless at least 90 days before January 1 either party gives notice that it does not wish to extend the agreement. Although these employment agreements generally include non-competition covenants and provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the applicable non-compete provisions can be difficult and costly to monitor and enforce. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key-man life insurance.

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. We 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 suit from their former employers.

While we attempt to provide competitive compensation packages to attract and retain key personnel, some of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

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

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

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

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

Presently, four products are specifically approved for the prevention of RDS in premature infants. There are no approved drugs that are specifically indicated for the prevention and treatment of ALI/ARDS in adults and current therapy consists of general supportive care and mechanical ventilation. See Item 1: "Business - Competition" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005.

We also face, and will continue to face, competition from colleges, universities, governmental agencies and other public and private research organizations. These competitors are becoming more active in seeking 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 acquire companies, products or technologies, we may face risks associated with those acquisitions.

If we are presented with appropriate opportunities, we intend to acquire or make other investments in complementary companies, products or technologies. We may not realize the anticipated benefit of any acquisition or investment. If we acquire companies or technologies, we will likely face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of these operations and services of an acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired businesses and impairment charges if future acquisitions are not as successful as we originally anticipate. If we fail to successfully integrate other companies, products or technologies that we may acquire, our business could be harmed. Furthermore, we may have to incur debt or issue equity securities to pay for any additional future acquisitions or investments, the issuance of which could be dilutive to our existing shareholders. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets.

If product liability claims are brought against us, it may result in reduced demand for our products or damages that exceed our insurance coverage.

The clinical testing of, marketing and use of our products exposes us to product liability claims if the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to \$10 million per occurrence and \$10 million in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage before initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of 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 payors, which include government health administration authorities, managed care providers and private health insurers. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

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

As of March 31, 2006, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 15% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in the United States or foreign regulatory policy during the period of product development;
- 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”.

Our common stock is listed for quotation on The Nasdaq National Market. During the twelve month period ended April 27, 2006, the price of our common stock has ranged from \$2.18 to \$9.15. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the twelve month period ended April 27, 2006, the average daily trading volume in our common stock was approximately 745,000 shares and the average number of transactions per day was approximately 2,244. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of The Nasdaq National Market. If the common stock were no longer listed on The Nasdaq National Market, investors might only be able to trade on the Nasdaq Capital Market, in the over-the-counter market in the Pink Sheets® (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. This would 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 reduction in media coverage.

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. If we face securities litigation in the future, even if meritless or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital.

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of April 27, 2006, we had 61,223,973 shares of common stock issued and outstanding.

We have a universal shelf registration statement on Form S-3 (File No. 333-128929), filed with the SEC on October 11, 2005, for the proposed offering from time to time of up to \$100 million of our debt or equity securities, of which \$80 million is remaining. We have no immediate plans to sell any securities under this registration statement. However, we may issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time.

Additionally, there are 12,167,047 shares of our common stock that are currently reserved for issuance under the CEFF. See “Risk Factors - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.”

As of April 27, 2006, up to 12,147,777 shares of our common stock were issuable upon exercise of outstanding options and warrants. 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. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our common stock.

Provisions of our Certificate of Incorporation, Shareholders Rights Agreement and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

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

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

We are potentially susceptible to litigation. For example, as a public company, we are subject to claims asserting violations of securities laws, as well as derivative actions. In particular, in early May 2006, several law firms announced that class action lawsuits were filed against the Company and its Chief Executive Officer, Robert J. Capetola. The Company has not seen the complaints in these purported actions and, therefore, cannot, assess their merits or their effect on the Company at this time,

In addition, as a biotechnology company, our processes and potential products may conflict with patents that have been or may be granted to competitors, academic institutions or others. 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 filed and issued, the risk increases that our patents or patent applications for our product candidates may give rise to a declaration of interference by the U.S. Patent and Trademark Office, 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 substantial damages or seeking to enjoin us from researching.

FORWARD-LOOKING STATEMENTS

This prospectus contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “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. The forward-looking statements include all matters that are not historical facts and include, without limitation: statements concerning our research and development programs and clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; the seeking of collaboration arrangements with pharmaceutical companies or others to develop, manufacture and market products; the research and development of particular compounds and technologies; and the period of time for which our existing resources will enable us to fund our operations.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Examples of the risks and uncertainties include, but are not limited to:

- risk that financial conditions may change;
- risks relating to the progress of our research and development;
- the risk that we will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies);
- risk that we or our marketing partners will not succeed in developing market awareness of our products;
- risk that we or our marketing partners will not be able to attract or maintain qualified personnel;
- risk that the FDA or other regulatory authorities may not approve any applications that we file;
- risk of delay in the FDA’s or other health regulatory authorities’ approval of any applications we file;
- risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product;
- risks relating to the ability of our third party materials suppliers and development partners to provide us with adequate supplies of drug substance and drug products for completion of any of our clinical studies;
- risks relating to our drug manufacturing operations;
- risks relating to the integration of our recently-acquired manufacturing operations into our existing operations;
- risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of our clinical studies,
- risks relating to our ability and the ability of our collaborators to develop and successfully commercialize products that will combine our drug products with innovative aerosolization technologies;
- risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for any products that we may develop independently or in connection with our collaboration arrangements;
- risks relating to the development of competing therapies and/or technologies by other companies;
- risks relating to the impact of litigation that has been and may be brought against the Company and its officers and directors; and
- the other risks and certainties detailed in “Risk Factors” and in the documents incorporated by reference in this prospectus.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval.

Except to the extent required by applicable laws, rules and regulations, we do not undertake any obligation or duty to update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

We will not receive any proceeds from the sales of common stock by Kingsbridge pursuant to this prospectus.

SELLING STOCKHOLDER

This prospectus relates to the possible resale by the selling stockholder, Kingsbridge, of shares of common stock that we may issue pursuant to the Common Stock Purchase Agreement or the Registration Rights Agreement that we entered into with Kingsbridge on April 17, 2006, or upon exercise of the Class C Investor Warrant we issued to Kingsbridge. We are filing the registration statement of which this prospectus is a part pursuant to the provisions of the Registration Rights Agreement we entered into with Kingsbridge on April 17, 2006.

The selling stockholder may from time to time offer and sell pursuant to this prospectus any or all of the shares that it acquires under the Common Stock Purchase Agreement or upon exercise of the Class C Investor Warrant.

The following table presents information regarding Kingsbridge and the shares that it may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of April 17, 2006. As used in this prospectus, the term “selling stockholder” includes Kingsbridge and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from a selling stockholder as a gift, pledge or other non-sale related transfer. The number of shares in the column “Number of Shares Being Offered” represents all of the shares that the selling stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. The percentage of shares beneficially owned before the offering is based both on 61,223,973 shares of our common stock actually outstanding as of April 17, 2006 and on the assumption that all shares of common stock issuable to Kingsbridge under the Common Stock Purchase Agreement or upon exercise of the Class C Investor Warrant are outstanding as of that date.

Name	Total Number of Shares of Common Stock Beneficially Owned	Percentage Beneficially Owned Before Offering	Number of Shares Being Offered	Number of Shares Beneficially Owned after this Offering	Percentage to be Beneficially Owned after this Offering
Kingsbridge Capital Limited (1)	12,542,047(2)	20.5%	12,167,047	375,000	*

- (1) The address of Kingsbridge is Kingsbridge Capital Limited, c/o Kingsbridge Corporate Services, Kingsbridge House, New Abbey, County Kildare, Republic of Ireland.
- (2) Consists of (a) 11,677,047 shares of common stock issuable under the Common Stock Purchase Agreement or the Registration Rights Agreement we entered into with Kingsbridge on April 17, 2006, (b) 490,000 shares of common stock issuable upon exercise of the Class C Investor Warrant, which warrant is not exercisable before October 17, 2006 and (c) 375,000 shares of common stock issuable upon exercise of the Class B Investor Warrant issued to Kingsbridge on July 7, 2004. For the purposes hereof, we assume the issuance of all shares under the Common Stock Purchase Agreement and upon exercise of the Class C Investor Warrant. Adam Gurney and Maria O’Donoghue have shared voting and investment control of the securities held by Kingsbridge. Kingsbridge does not accept third party investments.

PLAN OF DISTRIBUTION

We are registering 12,167,047 shares of our common stock under this prospectus on behalf of Kingsbridge. Except as described below, to our knowledge, the selling stockholder has not entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the shares of common stock offered hereby, nor, except as described below, do we know the identity of the brokers or market makers that will participate in the sale of the shares.

The selling stockholder may decide not to sell any shares. The selling stockholder may from time to time offer some or all of the shares of common stock through brokers, dealers or agents who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder and/or the purchasers of the shares of common stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the selling stockholder may arrange for other broker-dealers to participate. Kingsbridge is an “underwriter” within the meaning of the Securities Act. Any brokers, dealers or agents who participate in the distribution of the shares of common stock may also be deemed to be “underwriters,” and any profits on the sale of the shares of common stock by them and any discounts, commissions or concessions received by any such brokers, dealers or agents may be deemed to be underwriting discounts and commissions under the Securities Act. Kingsbridge has advised us that it may effect resales of our common stock through any one or more registered broker-dealers. To the extent the selling stockholder may be deemed to be an underwriter, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on The Nasdaq National Market, on the over-the-counter market, in privately negotiated transactions or otherwise, or in a combination of such methods of sale, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares of common stock may be sold according to one or more of the following methods:

- a block trade in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus;
- an over-the-counter distribution in accordance with the NASDAQ rules;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- privately negotiated transactions;
- a combination of such methods of sale; and
- any other method permitted pursuant to applicable law.

Any shares covered by this prospectus which qualify for sale pursuant to Rule 144 of the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. In addition, the selling stockholder may transfer the shares by other means not described in this prospectus.

Any broker-dealer participating in such transactions as agent may receive commissions from Kingsbridge (and, if they act as agent for the purchaser of such shares, from such purchaser). Broker-dealers may agree with Kingsbridge to sell a specified number of shares at a stipulated price per share, and, to the extent such a broker-dealer is unable to do so acting as agent for Kingsbridge, to purchase as principal any unsold shares at the price required to fulfill the broker-dealer commitment to Kingsbridge. Broker-dealers who acquire shares as principal may thereafter resell such shares from time to time in transactions (which may involve crosses and block transactions and which may involve sales to and through other broker-dealers, including transactions of the nature described above) on The Nasdaq National Market, on the over-the-counter market, in privately-negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such shares commissions computed as described above. To the extent required under the Securities Act, an amendment to this prospectus, or a supplemental prospectus may be filed, disclosing:

- the name of any such broker-dealers;
- the number of shares involved;
- the price at which such shares are to be sold;
- the commission paid or discounts or concessions allowed to such broker-dealers, where applicable;
- that such broker-dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented; and
- other facts material to the transaction.

Underwriters and purchasers that are deemed underwriters under the Securities Act may engage in transactions that stabilize, maintain or otherwise affect the price of the securities, including the entry of stabilizing bids or syndicate covering transactions or the imposition of penalty bids. Kingsbridge and any other persons participating in the sale or distribution of the shares will be subject to the applicable provisions of the Securities Exchange Act and the rules and regulations thereunder including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of, purchases by the selling stockholder or other persons or entities. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time before the commencement of such distributions, subject to special exceptions or exemptions. Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making and certain other activities with respect to those securities. In addition, the anti-manipulation rules under the Securities Exchange Act may apply to sales of the securities in the market. All of these limitations may affect the marketability of the shares and the ability of any person to engage in market-making activities with respect to the securities.

We have agreed to pay the expenses of registering the shares of common stock under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees, as well as certain fees of counsel for the selling stockholder incurred in the preparation of the CEFF agreements and the registration statement of which this prospectus forms a part. The selling stockholder will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as transfer taxes and certain other expenses associated with the sale of securities.

Under the terms of the Common Stock Purchase Agreement and the Registration Rights Agreement, we have agreed to indemnify the selling stockholder and certain other persons against certain liabilities in connection with the offering of the shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute toward amounts required to be paid in respect of such liabilities.

At any time a particular offer of the shares of common stock is made, a revised prospectus or prospectus supplement, if required, will be distributed. Such prospectus supplement or post-effective amendment will be filed with the SEC to reflect the disclosure of required additional information with respect to the distribution of the shares of common stock. We may suspend the sale of shares by the selling stockholder pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

DESCRIPTION OF COMMON STOCK

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

We currently have authorized 180,000,000 shares of common stock, par value \$0.001 per share. As of April 27, 2006, there were 61,223,973 shares of common stock outstanding, which does not include:

- 9,294,007 shares of common stock issuable upon exercise of options outstanding, at a weighted average exercise price of \$6.36 per share;
- 2,853,770 shares of common stock issuable upon exercise of warrants outstanding, at a weighted average exercise price of \$7.24;
- 10,587,651 shares of common stock available for future issuance under our shelf registration statement on Form S-3 (No. 333-118595) dated August 26, 2004, which was filed in connection with the CEFF;
- an indeterminate number of shares of common stock issuable under our shelf registration statement on Form S-3 (No. 333-128929) dated October 11, 2005;
- 704,088 shares of common stock available for future grant under our Amended and Restated 1998 Employee Stock Option Plan; and
- 44,591 shares of common stock available for future issuance under our 401(k) Plan.

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 The Nasdaq National Market under the symbol "DSCO".

Stockholder Rights Plan

The summary description of the Rights set out herein does not purport to be complete, and is qualified in its entirety by reference to the terms and provision of our Shareholder Rights Agreement, dated as of February 6, 2005.

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

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

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

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

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

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

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

At any time before the time an Acquiring Person becomes such, our Board of Directors may redeem the Rights in whole, but not in part, at a price of \$.001 per Right, subject to adjustment.

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

Anti-Takeover Provisions

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

—before becoming an interested stockholder, our Board of Directors approves either the business combination or the transaction in which the stockholder becomes an interested stockholder;

—upon consummation of the transaction in which the stockholder becomes an interested stockholder, the interested stockholder owns at least 85% of our voting stock outstanding at the time the transaction commenced, subject to exceptions; or

—on or after the date a stockholder becomes an interested stockholder, the business combination is both approved by our Board of Directors and authorized at an annual or special meeting of our stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Number of Directors; Removal

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

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

Transfer Agent and Registrar

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

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, 2005, and management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and management's assessment are incorporated by reference in reliance on Ernst & Young LLP's reports, given on their authority as experts in accounting and auditing.

LEGAL MATTERS

If and when offered, the validity of the securities being registered hereunder will be passed upon for us by Dickstein Shapiro Morin & Oshinsky LLP.

INTERESTS OF NAMED EXPERTS AND COUNSEL

Attorneys of Dickstein Shapiro Morin & Oshinsky LLP beneficially own shares of our common stock, the aggregate value of which exceeds \$50,000.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and periodic reports, proxy statements and other information with the SEC. You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Many of our SEC filings are also available to the public from the SEC's Website at "<http://www.sec.gov>." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to ir@DiscoveryLabs.com or contact John G. Cooper, our Executive Vice President, Chief Financial Officer, at our address as set forth above.

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

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

INFORMATION INCORPORATED BY REFERENCE

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

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2005, filed on March 16, 2006;
2. Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2006, filed on May 10, 2006;
3. Our Current Reports on Form 8-K filed with the SEC on March 31, 2006, April 5, 2006, April 18, 2006, April 21, 2006, April 26, 2006 and May 4, 2006;
4. The description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on July 13, 1995; and
5. All documents we have filed with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this registration statement and before the effectiveness of the registration statement, as well as after the date of this prospectus and before the termination of this offering, shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of the documents.

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

All reports and other documents subsequently filed by us with the SEC pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 after the date of this prospectus and before the termination of the offering shall be deemed to be incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of such reports and documents. This prospectus also incorporates by reference any documents that we file with the SEC after the date of the initial registration statement 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.