Filed pursuant to Rule 424(b)(5)
relating to Registration No. 333-128929

10,000,000 Shares

Common Stock

We are offering up to 10,000,000 shares of our common stock. Our common stock is listed on the Nasdaq Global Market under the symbol "DSCO." On December 6, 2007, the last reported sale price of our common stock on the Nasdaq Global Market was $3.04 per share.

Investing in our common stock involves significant risks. See "Risk Factors" beginning on page S-3.

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

	Per Share	Total
Public offering price	**$ 2.500**	**$ 25,000,000**
Placement agent's fees	**$ 0.125**	**$ 1,250,000**
Proceeds to Discovery Laboratories, Inc. (before expenses)	**$ 2.375**	**$ 23,750,000**

We estimate the total expenses of this offering payable by us, excluding the placement agent's fees, will be approximately $160,000. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent's fees and net proceeds to us, if any, in this offering are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. We are not required to sell any specific number or dollar amount of the shares of common stock offered in this offering, but the placement agent will use its best efforts to arrange for the sale of the shares of common stock offered. Pursuant to an escrow agreement among us, the placement agent and an escrow agent, a portion of the funds received in payment for the shares sold in this offering will be wired to an escrow account and held until we and the placement agent notify the escrow agent that the offering has closed, indicating the date on which the shares are to be delivered to the purchasers and the proceeds are to be delivered to us.

Jefferies & Company

The date of this Prospectus Supplement is December 7, 2007

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

We are making offers to sell and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. You should not consider this prospectus supplement and the accompanying prospectus to be an offer to sell, or a solicitation of an offer to buy, shares of common stock if the person making the offer or solicitation is not qualified to do so or if it is unlawful for you to receive the offer or solicitation.

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

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a "shelf" registration statement on Form S-3 that we filed with the Securities and Exchange Commission on October 11, 2005. This prospectus supplement describes the specific details regarding this offering, including the price, the amount of common stock being offered and the risks of investing in our common stock. The accompanying prospectus provides more general information, some of which may not apply to our common stock. You should read both this prospectus supplement and the accompanying prospectus together with the additional information about us described in the section entitled "Where You Can Find More Information and Incorporation by Reference."

If information contained in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on this prospectus supplement.

FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein, including in "Risk Factors," which are not historical, contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation statements concerning: our business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, our research and development programs and planning for and timing of any clinical trials; the possibility, timing and outcome of submitting regulatory filings for our products under development; remediation of manufacturing issues related to the April 2006 process validation stability failures and plans with respect to the release and stability testing of new process validation batches of Surfaxin®; plans regarding strategic alliances and collaboration arrangements with pharmaceutical companies and others to develop, manufacture and market our drug products; research and development of particular drug products, technologies and aerosolization drug devices; the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, 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. Forward-looking statements are subject to many risks and uncertainties that 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:

- the risk that we may not successfully and profitably develop and market our products;
- risks relating to our research and development activities, which are time-consuming, costly and involve pre-clinical studies, clinical trials and other studies, and the risk that such trials and studies may be delayed, halted or fail;
- risks relating to the rigorous regulatory approval process required for approval of any products that we may develop, independently, with our development partners or pursuant to collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of our drug product candidates;
- the risk that the FDA or other regulatory authorities may not accept, or may withhold or delay consideration of any applications that we may file or limit approval to particular indications or other label limitations;
- the risk that, after acceptance and review of applications that we file, the FDA or other regulatory authorities will not approve the marketing and sale of our drug product candidates;

- risks that we may not have successfully resolved the Chemistry, Manufacturing and Controls (CMC) and current Good Manufacturing Practices (cGMP)-related matters at our manufacturing operations in Totowa, New Jersey with respect to Surfaxin and our other Surfactant Replacement Therapies ("SRT") presently under development, including those identified in connection with our April 2006 process validation stability failures and matters noted by the FDA in its inspectional reports on Form FDA 483;

- risks that our recently submitted formal response to the April 2006 Approvable Letter will not satisfy the FDA;

- risks relating to our own drug manufacturing operations and the manufacturing operations of our third-party suppliers and contract manufacturers;

- risks relating to the ability of our development partners and third-party suppliers of materials, drug substance and aerosolization systems and related components to provide us with adequate supplies and expertise to support manufacture of drug product for initiation and completion of our clinical studies;

- risks relating to our ability and the ability of our collaborators and development partners to develop and successfully manufacture and commercialize products that combine our drug products with innovative aerosolization technologies;

- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;

- risks that financial market conditions may change, additional financings could result in equity dilution, or we will be unable to maintain the Nasdaq Global Market listing requirements, causing the price of our shares of common stock to decline;

- the risk that we will not be able to raise additional capital or enter into additional strategic alliances and collaboration arrangements (including strategic alliances in support of our aerosol and other SRT;

- the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;

- risks relating to our ability to develop or otherwise provide for a successful sales and marketing organization in a timely manner, if at all, and that we or our marketing partners will not succeed in developing market awareness of our products;

- the risk that we or our development partners, collaborators or marketing partners will not be able to attract or maintain qualified personnel;

- risks relating to the maintenance, protection and expiry of the patents and licenses related to our SRT and the potential development of competing therapies and/or technologies by other companies;

- risks relating to the impact of securities, product liability, and other litigation or claims that have been and may be brought against us and our officers and directors;

- risks relating to reimbursement and health care reform; and

- other risks and uncertainties detailed in "Risk Factors" and in the documents incorporated by reference in this report.

Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

The forward-looking statements contained in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference herein or therein speak only of their respective dates. Except to the extent required by applicable laws, rules and regulations, we do not undertake to publicly announce revisions to any of the forward-looking statements in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference herein or therein, whether as a result of new information, future events or otherwise.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider the following risk factors, as well as other information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus, including those risks discussed in Part I, Item 1A - Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2006, before deciding to purchase any shares of our common stock. The risks and uncertainties described below and incorporated by reference herein are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may become important factors that affect us. If any of these risks occur, our business could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

Risks Related to This Offering

A substantial number of shares may be sold in the market following this offering, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. Upon completion of this offering, we will have outstanding an aggregate of 96,590,393 shares of common stock, assuming no exercise of outstanding options or warrants. A substantial majority of the outstanding shares of our common stock are, and all of the shares sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act of 1933 unless these shares are purchased by affiliates. In addition, as of December 5, 2007, 18,526,270 shares of our common stock are issuable upon exercise of outstanding options and warrants and vesting of restricted stock units granted by us, which also have been registered for resale on registration statements filed with the Securities and Exchange Commission.

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

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

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

You will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering because the price per share of our common stock being offered hereby is substantially higher than the book value per share of our common stock. Based on the public offering price of $2.50 per share in this offering, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $2.06 per share in the net tangible book value of the common stock. See “Dilution” on page S-5 for a more detailed discussion of the dilution you will incur in this offering.

USE OF PROCEEDS

We expect the net proceeds from this offering of common stock to be approximately $23.6 million after deducting the estimated placement agent's fees and offering expenses. Except as described in any later prospectus supplement or post effective amendment, we currently anticipate using the net proceeds from the sale of our common stock primarily for:

- Preparing for the anticipated U.S. commercial launch of Surfaxin® for Respiratory Distress Syndrome in premature infants, including establishing our own U.S. commercial sales and marketing organization specialized in neonatal and pediatric indications, enhancing our medical affairs capabilities with medical science liaison personnel deployed throughout the U.S. and enhancing our manufacturing, compliance and regulatory capabilities;

- Pursuing potential collaboration arrangements with international partners to co-develop and/or co-commercialize our neonatal and pediatric pipeline for Surfaxin and Aerosurf™, and potential world-wide strategic alliances for the development and/or commercialization of our novel Surfaxin Replacement Therapy (SRT) for respiratory conditions and disorders affecting adult patients;

- Research, development and clinical trial activities associated with ongoing development of Aerosurf, including development and manufacture of a second-generation aerosolization system that will potentially be used in anticipated Phase 2b/3 clinical trials for treatment of respiratory conditions prevalent in the NICU and PICU and, if approved, in the commercial market;

- Clinical trial costs associated with conducting clinical trials in 2008 and into 2009, including our ongoing Phase 2 and anticipated Phase 3 clinical trials for Surfaxin for the treatment of Acute Respiratory Failure and our anticipated Phase 2b/3 clinical trials for Surfaxin for the prevention of Bronchopulmonary Dysplasia; and

- Exploratory development of our aerosolized SRT platform in other disease targets, such as Acute Lung Injury and Cystic Fibrosis.

The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our research and development efforts, technological advances and the competitive environment for Surfaxin and our other SRT drug candidates and their intended uses. Pending the application of the net proceeds, we intend to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

DILUTION

The net tangible book value of our common stock on September 30, 2007, was approximately $18.5 million, or approximately $0.22 per share. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the aggregate number of shares of common stock outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the sale of 10,000,000 shares of our common stock in this offering at an offering price equal to $2.50 per share, and after deducting the estimated underwriting discount and the estimated offering expenses, our net tangible book value at September 30, 2007, would have been approximately $42.1 million, or approximately $0.44 per share. This represents an immediate increase in the net tangible book value per share of $0.22 per share to existing shareholders and an immediate dilution of $2.06 per share to new investors purchasing shares of common stock in this offering. The following table illustrates this dilution:

Offering price per share		$2.50
Net tangible book value per share as of September 30, 2007	$0.22	
Increase per share after the offering	$0.22	
Net tangible book value per share as of September 30, 2007, after giving effect to this offering		$0.44
Dilution per share to new investors		$2.06

The foregoing table does not take into account further dilution to new investors that could occur upon the exercise of outstanding options and warrants having a per share exercise price less than the per share offering price to the public in this offering. As of September 30, 2007, there were 84,681,221 shares of common stock outstanding, which does not include:

- 12,174,574 shares of common stock issuable upon exercise of options outstanding as of September 30, 2007, at a weighted average exercise price of $4.60 per share; and
- 6,339,196 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2007, at a weighted average exercise price of $5.00.
- 57,123 shares of common stock issuable upon the vesting of restricted stock awards outstanding as of September 30, 2007.
- 238,965 shares of common stock reserved for potential future issuance pursuant to a 401(k) Plan, as of September 30, 2007.
- 7,079,196 shares of common stock reserved for potential future issuance pursuant to a Committed Equity Financing Facility, as of September 30, 2007.

PLAN OF DISTRIBUTION

We are offering shares of our common stock through a placement agent. Subject to the terms and conditions contained in the placement agency agreement, dated December 7, 2007, Jefferies & Company, Inc. has agreed to act as the placement agent for the sale of up to 10,000,000 shares of our common stock. The placement agent is not purchasing or selling any shares by this prospectus supplement or accompanying prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of shares, but has agreed to use its best efforts to arrange for the sale of all 10,000,000 shares of our common stock.

The placement agency agreement provides that the obligations of the placement agent and the investors are subject to certain conditions precedent, including the absence of any material adverse change in our business and the receipt of customary legal opinions, letters and certificates from our counsel, our independent auditors and us. We will enter into subscription agreements directly with the investors in connection with this offering.

Confirmations and definitive prospectuses will be distributed to all investors who agree to purchase shares of our common stock, informing investors of the closing date as to such shares. We currently anticipate that closing of the sale of all 10,000,000 shares of our common stock will take place on or about December 12, 2007. Investors will also be informed of the date and manner in which they must transmit the purchase price for their shares.

On the scheduled closing date, the following will occur:

- we will receive funds in the amount of the aggregate purchase price; and
- Jefferies & Company, Inc. will receive the placement agent's fees in accordance with the terms of the placement agency agreement.

We will pay the placement agent a commission equal to 5% of the gross proceeds of the sale of shares of our common stock in this offering. In no event will the total amount of compensation paid to the placement agent and other securities brokers and dealers upon completion of this offering exceed 8% of the gross proceeds of this offering. The estimated offering expenses payable by us, in addition to the placement agent's fee of $1,250,000, are approximately $160,000, which includes legal, accounting and printing costs and various other fees associated with registering and listing the shares of common stock. After deducting fees due to the placement agent and our estimated offering expenses, we expect the net proceeds from this offering to be up to approximately $23,590,000.

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

The placement agent has provided, and may in the future provide, various investment banking, commercial banking, financial advisory and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees. In the course of their business, the placement agent may actively trade our securities or loans for its own account or for the accounts of customers, and, accordingly, the placement agent may at any time hold long or short positions in such securities or loans.

We and our directors and executive officers have agreed to certain lock-up provisions with regard to future sales of our common stock and other securities convertible into or exercisable or exchangeable for common stock for a period of 60 days after this offering as set forth in the placement agency agreement.

The placement agency agreement is included as an exhibit to our Current Report on Form 8-K that will be filed with the Securities and Exchange Commission in connection with the consummation of this offering.

The transfer agent for our common stock is Continental Stock Transfer & Trust Company.

Our common stock is traded on the Nasdaq Global Market under the symbol "DSCO."

LEGAL MATTERS

The validity of the issuance of the shares of common stock offered hereby will be passed upon by Dickstein Shapiro LLP, New York, New York. Goodwin Procter LLP, Boston, Massachusetts, is counsel for the placement agent in connection with this offering.

WHERE YOU CAN FIND MORE INFORMATION AND INCORPORATION BY REFERENCE

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 in the accompanying prospectus.

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

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

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2006;
- Our Quarterly Reports on Form 10-Q filed with the SEC on May 10, 2007, August 9, 2007 and November 8, 2007;
- Our Current Reports on Form 8-K filed with the SEC on January 22, 2007, February 28, 2007 (excluding the matters in Item 2.01 and Exhibit 99.1 therein, which are not incorporated by reference herein), April 3, 2007, April 6, 2007, April 9, 2007, April 27, 2007, May 3, 2007 (excluding the matters in Item 2.01 and Exhibit 99.1 therein, which are not incorporated by reference herein), May 24, 2007, June 28, 2007, August 7, 2007 (excluding the matters in Item 2.01 and Exhibit 99.1 therein, which are not incorporated by reference herein), October 4, 2007, November 2, 2007, November 5, 2007, November 6, 2007 (excluding the matters in Item 2.01 and Exhibit 99.1 therein, which are not incorporated by reference herein), December 4, 2007 and December 7, 2007; and
- The description of our capital stock contained in our Registration Statements on Form 8-A, filed on July 13, 1995 and on February 6, 2004.

This prospectus supplement does not contain all of the information set forth in the registration statement, the exhibits, schedules and the prospectus attached thereto. Please refer to the registration statement, the exhibits, schedules and the prospectus attached thereto for further information with respect to us and the common stock offered hereby. Statements contained in this prospectus supplement 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. Each person to whom a copy of this prospectus supplement is delivered may request a copy of any or all of the information incorporated by reference in this prospectus supplement, including the exhibits to any filings incorporated by reference herein, from us, at no charge, or from the Securities and Exchange Commission in the above described manner.

PROSPECTUS

$100,000,000

Discovery Laboratories, Inc.

Debt Securities, Preferred Stock and Common Stock

We may sell from time to time in one or more offerings up to $100,000,000 in the aggregate of:

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

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

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

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

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 October 11, 2005.

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

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the "SEC") utilizing a "shelf" registration process or continuous offering process, which allows us to offer and sell any combination of the securities described in this prospectus in one or more offerings. Using this prospectus, we may offer up to a total dollar amount of $100,000,000 of these securities.

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

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

ABOUT DISCOVERY

Discovery Laboratories, Inc. is a biotechnology company developing its 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 our technology, pulmonary surfactants have the potential, for the first time, to address respiratory diseases where there are few or no approved therapies available.

Our SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. Our lead product, SurfaxinÒ (lucinactant), for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) and is under review for approval in Europe by the European Medical Evaluation Agency (EMEA). Surfaxin is also being developed for the treatment of Chronic Lung Disease (CLD, also known as Bronchopulmonary Dysplasia) in premature infants. In addition, we are developing Aerosurf™, aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), for neonatal respiratory failures.

Our SRT technology is also being developed to address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings. We are conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and are also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, Chronic Obstructive Pulmonary Disorder (COPD), and other respiratory conditions.

With the goal of becoming a fully integrated biotechnology company, we are implementing a long-term business strategy which includes: (i) investing in manufacturing capabilities for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States, Europe and other markets; (ii) building our own specialty pulmonary United States sales and marketing organization to focus initially on opportunities in the neonatal intensive care unit (NICU); (iii) securing aerosol generating technology and engineering capabilities through a corporate partnership for our aerosol SRT pipeline programs, including Aerosurf; and (iv) securing corporate partnerships for the development and potential commercialization of SRT, including Surfaxin, in Europe and the rest of the world.

SURFACTANT TECHNOLOGY

Our precision-engineered surfactant replacement technology was invented at The Scripps Research Institute and was exclusively licensed to Johnson & Johnson which, together with its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, developed it further. We acquired the exclusive worldwide sublicense to the technology in October 1996.

Surfactants are protein and lipid (fat) compositions that are produced naturally in the lungs and are critical to all air-breathing mammals. They cover the entire alveolar surface, or air sacs, of the lungs and the terminal conducting airways which lead to the air sacs. Surfactants facilitate respiration by continually modifying the surface tension of the fluid normally present within the alveoli, or air sacs, that line the inside of the lungs. In the absence of sufficient surfactant or should the surfactant degrade, these air sacs tend to collapse, and, as a result, the lungs do not absorb sufficient oxygen. In addition to lowering aveolar surface-tension, surfactants play other important roles in human respiration including, but not limited to, lowering the surface tension of the conducting airways and maintaining airflow and airway patency (keeping the airways open and expanded). Human surfactants include four known surfactant proteins, A, B, C and D. It has been established, through numerous studies, that surfactant protein B (SP-B) is essential for respiratory function.

Presently, the FDA has approved surfactants as replacement therapy only for RDS in premature infants, a condition in which infants born premature have an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from either pig or cow lungs. Although they are clinically effective, they have drawbacks and cannot readily be scaled or developed to treat broader populations for RDS in premature infants and other respiratory diseases. There is presently only one approved synthetic surfactant available, but it does not contain surfactant proteins, is not widely used and is not actively marketed by its manufacturer.

Animal-derived surfactant products are prepared using a chemical extraction process from minced cow and pig lung. Because of the animal-sourced materials and the chemical extraction processes, there can potentially be significant variation in production lots and, consequently, product quality specifications must be broad. In addition, the protein levels of these animal-derived surfactants are inherently lower than the protein levels of native human surfactant. The production costs of these animal-derived surfactants are high relative to other analogous pharmaceutical products, generation of large quantities is severely limited, and these products cannot readily be reformulated for aerosol delivery to the lungs.

Our precision-engineered surfactant product candidates, including Surfaxin, are engineered versions of natural human lung surfactant and contain a precision-engineered peptide, sinapultide. Sinapultide is a 21 amino acid protein-like substance that is designed to closely mimic the essential attributes of human surfactant protein B (SP-B), the surfactant protein that is most important for the proper functioning of the respiratory system. Our products have the ability to be precisely formulated, either as a liquid instillate, aerosolized liquid or dry powder, to address various medical indications.

We believe that our precision-engineered surfactant can be manufactured in sufficient quantities, of more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants and with no potential to cause adverse immunological responses in young and older adults, all important attributes for our products to potentially fulfill significant unmet medical needs. In addition, we believe that our precision-engineered surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient's lungs and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”).

DISCOVERY'S KEY SRT PROGRAMS

Our key SRT programs are focused on: (i) research and development projects for respiratory failures of patients in the NICU, critical care unit and other hospital settings, where there are few or no approved therapies, (ii) manufacturing capabilities for the production of our surfactant drug products, and (iii) sales and marketing capabilities in the United states to focus initially on opportunities in the NICU beginning with the execution of the launch of Surfaxin, if approved. These programs include:

SRT for Neonatal Intensive Care Unit

We are conducting several NICU therapeutic programs targeting respiratory conditions cited as some of the most prevalent respiratory disorders affecting infants in the NICU.

Surfaxin® (Lucinactant) for Respiratory Distress Syndrome in Premature Infants

RDS is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. Premature infants born prior to 32 weeks gestation have not fully developed their own natural lung surfactant and therefore need treatment to sustain life. This condition often results in the need for the infant to undergo surfactant replacement therapy or mechanical ventilation. RDS is experienced in approximately half of the babies born between 28 and 32 weeks gestational age. The incidence of RDS approaches 100% in babies born less than 26 weeks gestational age. Surfaxin is the first precision-engineered, protein B-based agent that mimics the surface-active properties of human surfactant. To treat premature infants suffering from RDS, surfactants, including Surfaxin, are delivered in a liquid form and injected through an endotracheal tube (a tube inserted into the infant's mouth and down the trachea).

We have received an Approvable Letter from the FDA for Surfaxin® (lucinactant), our lead product, for the prevention of RDS in premature infants, to which we submitted a Response Letter on July 29, 2005. We have received formal written notification from the FDA, following its review of our previously submitted response letter, outlining select items that need to be further addressed in order for the FDA to deem the response complete. We are in the process of addressing these items and anticipate submitting our response to the FDA in October 2005. Certain pre-approval activities are ongoing, including labeling discussions, process validation and re-inspection activities related to our Surfaxin manufacturing process. The approval of Surfaxin is anticipated in April 2006 with commercial launch to occur in the second quarter of 2006. We have also filed a Marketing Authorization Application (MAA) with the EMEA for clearance to market Surfaxin in Europe and anticipate potential EMEA approval to occur in the second quarter of 2006. See “Manufacturing” below.

Surfaxin® for Chronic Lung Disease (CLD, also known as Bronchopulmonary Dysplasia)

Chronic Lung Disease is a costly syndrome associated with surfactant and SP-B deficiency, and the prolonged use of mechanical ventilation and oxygen supplementation, usually associated with a premature infant being treated for RDS. Presently there are no approved drugs for the treatment of CLD. These babies suffer from abnormal lung development and typically have a need for respiratory assistance - oftentimes, for many months, as well as comprehensive care spanning years.

We are conducting a Phase 2 double-blind, controlled trial (that will enroll up to 210 very low birth weight premature infants born at risk for developing CLD) to determine the safety and tolerability of administering up to 5 total doses of Surfaxin in the first 10 days of life as a therapeutic approach for the prevention of CLD. This study is designed to determine whether such treatment can decrease the proportion of infants on mechanical ventilation or oxygen or the incidence of death or CLD. The results of this trial are expected to be available in the first quarter of 2006.

Aerosurf™ for Neonatal Respiratory Failures

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in the NICU. There are approximately 1.5 million premature infants born annually worldwide at risk for respiratory problems associated with surfactant dysfunction. The majority of these infants are usually at a birth weight greater than 1250 grams, and neonatologists generally try to avoid mechanically ventilating these patients because doing so requires intubation (the invasive process of inserting a breathing tube down the trachea). This reluctance is due to the risks associated with intubation and the need for paralytic agents and sedation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits clearly outweigh the risks. Noted neonatologists have commented on the potential utility of a non-invasive method of delivering SRT to treat premature infants suffering from respiratory disorders including RDS, CLD, bronchiolitis, acute hypoxia, pneumonia, and transient tachypnea.

Aerosurf is our precision-engineered aerosolized SRT administered via nCPAP intended to treat premature infants at risk for respiratory failures. We recently completed and announced the results of our first pilot Phase 2 clinical study of Aerosurf, which was designed as an open label, multicenter study to evaluate the feasibility, safety and tolerability of Aerosurf delivered via nCPAP for the prevention of RDS in premature infants administered within 30 minutes of birth over a three hour duration. The study showed that it is feasible to deliver Aerosurf via nCPAP and the treatment was generally safe and well tolerated. We are currently in the process of evaluating a collaborative partnership to secure a specific aerosol generation technology and engineering solution which we believe may enhance the delivery of Aerosurf. If we can successfully secure such collaboration, we anticipate conducting multiple Phase 2 clinical studies of Aerosurf in 2006.

SRT for Critical Care and Hospital Indications

SRT for Acute Respiratory Distress Syndrome (ARDS)

ARDS is a life-threatening disorder for which no approved therapies exist anywhere in the world. It is characterized by an excess of fluid in the lungs and decreased oxygen levels in the patient. One prominent characteristic of this disorder is the destruction of surfactants naturally present in lung tissue. The conditions are caused by illnesses including pneumonia and septic shock (a toxic condition caused by infection) and events such as smoke inhalation, near drowning, industrial accidents, major surgery and other traumas.

We are presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of our SRT for the treatment of adults with ARDS. In December 2004, we announced what we believe to be encouraging preliminary data from this trial and that we were modifying the trial protocol to allow for increased enrollment of up to 160 patients. Patients will be randomized to either receive our SRT or the current standard of care, which is mechanical ventilation and support therapies. The primary endpoint of this trial is the incidence rate of patients being alive and off mechanical ventilation at Day 28. Key secondary endpoints include mortality at the end of Day 28 and safety and tolerability of our SRT and the bronchoscopic lavage procedure. Results of the Phase 2 trial are anticipated to be available in the first quarter of 2006.

Our SRT is administered to patients in high concentration and large volume via a proprietary sequential lavage technique, or lung wash, delivered through a bronchoscope to each of the 19 segments of the lung. The procedure is intended to cleanse and remove inflammatory substances and debris from the lungs, while leaving sufficient amounts of our precision-engineered surfactant behind to help re-establish the lungs' capacity to absorb oxygen. The objective is to restore functional surfactant levels and to allow critically ill patients to be removed from mechanical ventilation sooner.

The FDA has granted us Fast-Track Status and Orphan Drug Designation for our SRT for the treatment of ARDS in adults. The EMEA has granted us Orphan Product designation for our SRT for the treatment of ALI in adults (which in this circumstance is a larger patient population that encompasses ARDS).

Manufacturing

Our precision-engineered surfactant product candidates, including Surfaxin, must be manufactured in a sterile environment and in compliance with current good manufacturing practice requirements (cGMPs) set by the FDA and other relevant worldwide regulatory authorities. These product candidates are manufactured through the combination of sinapultide and certain other active ingredients, including certain lipids, that are provided by our suppliers. Using these ingredients, our surfactant drug products, including Surfaxin, are manufactured at the sterile facilities of our contract manufacturer, Laureate Pharma, Inc. (Laureate), with our own specialized equipment under the direction and supervision of our manufacturing and quality control personnel. The termination, disruption or expiration of the manufacturing relationships with any of these parties would have a material adverse effect on our business.

In January 2005, the FDA issued an inspection report (FDA Form-483) to Laureate citing certain observations concerning Laureate's compliance with cGMPs in connection with the FDA's review of our New Drug Application (NDA) for Surfaxin for the prevention of RDS in premature infants. We are in the process of addressing these items and anticipate submitting our response to the FDA in October 2005. We believe that the quality systems and documentation control enhancements that we have implemented jointly with Laureate to support our response to the FDA prepare us for the FDA's reinspection of Laureate's Totowa facility. Assuming the adequacy of such corrective actions and the approval of the NDA, we anticipate that the commercial launch of Surfaxin will occur in the second quarter of 2006.

We are implementing a long-term manufacturing strategy for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States, Europe and other markets. We are investing in the further development and scale-up of the current contract manufacturer of our SRT, Laureate, and conducting evaluations with the purpose of securing additional manufacturing capabilities in order to meet production needs as they expand, including alternative contract manufacturers and acquiring or building our own manufacturing facility.

Sales & Marketing

We are building our own specialty pulmonary United States sales and marketing organization to execute the launch of Surfaxin, if approved, in the United States. Our sales and marketing force will be initially focused on opportunities in the NICU and, as products are developed, on expanding such opportunities to critical care and hospital settings. This strategic initiative, led by the anticipated launch of Surfaxin, is intended to allow us to manage and administer our own sales and marketing operation, establish a strong presence in the NICU and optimize company economics.

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. 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 securities 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 securities 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.

Because we are a biotechnology company, we may not successfully develop and market our products, and even if we do, we may not generate enough revenue or become profitable.

We are a biotechnology company, therefore, you must evaluate us in light of the uncertainties and complexities present in such companies. 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 prior to 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 June 30, 2005, we have an accumulated deficit of approximately $162.2 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 ongoing clinical trials for our lead surfactant replacement technologies may be delayed, or fail, which will harm our business.

Our precision-engineered surfactant platform technology is based on the scientific rationale of 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 platform technology. We have received an Approvable Letter from the FDA for Surfaxin, our lead product, for the prevention of RDS in premature infants, and have filed an MAA with the EMEA for clearance to market Surfaxin in Europe. The Approvable Letter from the FDA contains conditions that we must meet in order to obtain approval and they primarily involve finalizing labeling and correcting previously reported manufacturing issues. We submitted a Response Letter to the FDA's Approvable Letter on July 29, 2005. We have received formal written notification from the FDA, following its review of our Response Letter, outlining select items that need to be further addressed in order for the FDA to deem the response complete. We are in the process of addressing these items and anticipate submitting our response to the FDA in October 2005. Certain pre-approval activities are ongoing, including labeling discussions, process validation and reinspection activities related to our Surfaxin manufacturing process. The approval of Surfaxin is now anticipated in April 2006 with commercial launch to occur in the second quarter of 2006. Currently, we are conducting a Phase 2 clinical trial for the treatment of ARDS in adults and we have initiated a Phase 2 clinical trial using aerosolized SRT via nCPAP to potentially treat premature infants in the NICU suffering from Neonatal Respiratory Failures and a Phase 2 clinical trial using Surfaxin for the prevention of CLD.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests 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 criteria for the study;
--the existence of competing clinical trials; and
--the existence of alternative available products.

Delays in patient enrollment in clinical trials may occur, which would likely result in increased costs, program delays or both.

If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products.

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of our products. Presently, Laureate is our sole clinical manufacturing facility that has been qualified to produce appropriate clinical grade material of our drug product for use in our ongoing clinical studies.

In January 2005, the FDA issued an inspection report (FDA Form-483) to Laureate, citing certain observations concerning Laureate's compliance with current cGMPs in connection with the FDA's review of our NDA for Surfaxin for the prevention of RDS in premature infants. The general focus of the inspection observations relates to basic quality controls, process assurances and documentation requirements to support the commercial production process. Certain quality systems and documentation control enhancements have been implemented by us and Laureate in response to the FDA's inspection report. In preparation for the FDA's reinspection of Laureate's Totowa facility certain pre-approval manufacturing activities are ongoing including process validation and reinspection activities related to our Surfaxin manufacturing process. We have received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants, which contains conditions that we must meet in order to obtain approval and they primarily involve finalizing labeling and correcting previously reported manufacturing issues. We submitted a Response Letter to the FDA's Approvable Letter on July 29, 2005. We have received formal written notification from the FDA, following its review of our Response Letter, outlining select items that need to be further addressed in order for the FDA to deem the response complete. We are in the process of addressing these items and anticipate submitting our response to the FDA in October 2005. Certain pre-approval activities are ongoing, including labeling discussions, process validation and reinspection activities related to our Surfaxin manufacturing process. Assuming the adequacy of such corrective actions and the approval of our NDA for Surfaxin, we anticipate that the commercial launch of Surfaxin will occur in the second quarter of 2006. We anticipate that our manufacturing capabilities through Laureate, upon successful completion and implementation of our Action Plan should allow sufficient commercial production of Surfaxin, if approved, to supply the present worldwide demand for the prevention of RDS in premature infants and our other Surfactant Replacement Therapies for our planned clinical trials. If the FDA does not accept the cGMP Action Plan, or we or Laureate do not adequately address the initiatives set forth therein, the FDA may delay its approval of our NDA for Surfaxin or reject our NDA. Any delay in the approval of the NDA, or the rejection thereof, will have a material adverse effect on our business.

Laureate or other outside manufacturers may not be able to (i) produce our drug substance or drug product to appropriate standards for use in clinical studies, (ii) comply with remediation activities set forth in the cGMP Action Plan (iii) perform under any definitive manufacturing agreements with us or (iv) remain in the contract manufacturing business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer 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, 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 may, in the future, elect to manufacture some of our products on our own. We currently own certain specialized manufacturing equipment, employ certain manufacturing managerial personnel, and we are considering an investment in additional manufacturing equipment; however, we do not presently maintain a complete manufacturing facility. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

The FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with cGMPs or similar requirements that the FDA or corresponding foreign regulators establish. Contract manufacturers may face manufacturing or quality control problems causing product production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's cGMP requirements, or those of comparable foreign regulatory authorities, necessary to continue manufacturing our drug substance. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to market and develop our products. See also “Risks Related to Our Business - In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product, which may not be readily available.”

In order to conduct our clinical trials we need adequate supplies of our drug substance and drug product, which may not be readily available.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We rely on third party contract manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical trials of our products. Laureate, our contract manufacturer, may not be able to produce Surfaxin to appropriate standards for use in clinical studies. Manufacturing or quality control problems have already and may again occur at Laureate or our other contract manufacturers, causing production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's cGMP requirements necessary to continue manufacturing our ingredients or drug product. If any such suppliers or manufacturers of our products fail to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products. See also “Risks Related to Our Business - If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products.”

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 financial resources will be adequate to satisfy our capital needs into 2006. 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 Committed Equity Financing Facility (CEFF) with Kingsbridge, our revolving credit facility with PharmaBio and our capital equipment lease financing arrangement with GECC. 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 “Risks Related to Our Business - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.”

Furthermore, we could cease to qualify for listing of our securities on the NASDAQ National Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See “Risks Related to Our Business - 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.

We have a CEFF with Kingsbridge, pursuant to which Kingsbridge is committed to finance up to $75.0 million of capital to support our future growth, which expires in October 2007. Subject to certain conditions and limitations, from time to time under the CEFF, we may require Kingsbridge to purchase newly-issued shares of its common stock at a discount between 6% and 10% of the volume weighted average price of our common stock and thus raise capital as required, at the time, price and in amounts deemed suitable to us. 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.

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 either 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 CEFF and we may not be able to access any portion of the remaining capital 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.

The clinical trial and regulatory approval process for our products is expensive and time consuming, and the outcome is uncertain.

In order to sell Surfaxin and our other products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries 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 comparable agencies in foreign countries that the manufacturer of the product maintains good laboratory and manufacturing practices during testing and manufacturing. Although we are involved in certain late-stage clinical trials, pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials or in preliminary findings for such clinical trials. Further, 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 MAA filed by a pharmaceutical or biotechnology company for such drug product. On April 13, 2004, we filed an NDA for Surfaxin for the prevention of RDS in premature infants. The FDA accepted the NDA filing and in February 2005 we received an Approvable Letter from the FDA with respect to our NDA. The Approvable Letter contains conditions that we must meet prior to obtaining final U.S. marketing approval for Surfaxin. We submitted a Response Letter to the FDA's Approvable Letter on July 29, 2005. We have received formal written notification from the FDA, following its review of our Response Letter, outlining select items that need to be further addressed in order for the FDA to deem the response complete. We are in the process of addressing these items and anticipate submitting our response to the FDA in October 2005. Certain pre-approval activities are ongoing, including labeling discussions, process validation and reinspection activities related to our Surfaxin manufacturing process. The conditions that we must meet primarily involve finalizing labeling and correcting previously reported manufacturing issues, however, the FDA might still reject the NDA. We have also submitted an MAA with the EMEA for clearance to market Surfaxin for the prevention and treatment of RDS in premature infants. The EMEA has validated the MAA indicating that the application is complete and that the review process has begun. However, the EMEA may not complete the review or may reject the MAA.

The approval process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt any one or more of our clinical trials for any of our product candidates. If we, or any regulatory authorities, 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 and/or comparable foreign agencies on the design of any one or more of the clinical studies necessary for approval. Conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of such clinical trials and the costs of conducting the clinical trials. Data obtained from clinical trials are susceptible to varying interpretations which may delay, limit or prevent regulatory approval.

Delays and terminations of the clinical trials we conduct could result from insufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, stringent enrollment criteria, the proximity of the patients to the trial sites, having to compete with other clinical trials for eligible patients, geographical and geopolitical considerations and others. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects that are common to this class of drug such as a decrease in the oxygen level of the blood upon administration.

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least the second quarter of 2006, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for our precision-engineered surfactant-based therapy, MAS in full-term 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. The FDA has also granted us Orphan Drug Designation for three of our intended indications for Surfaxin: ARDS in adults; RDS in infants; and MAS in full-term infants. To support our development of Surfaxin for the treatment of MAS, the FDA has awarded us an Orphan Products Development Grant. Fast-Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast-Track Status provisions are designed to expedite the FDA's review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years.

The EMEA has granted Orphan Medicinal Product designation for three of our intended indications for Surfaxin: RDS in premature infants, MAS in full-term infants and ALI in adults.

Our products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. 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 and comparable foreign agencies 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 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. 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. The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve our products, we will not be able to market our products.

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 manufacturing, 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. We have a revised collaboration arrangement with Esteve for Surfaxin and certain other of our product candidates that is now 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/treatment of RDS in premature infants, MAS in full-term 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 which Esteve. Accordingly, we may need to enter into additional collaboration agreements and our success, particularly outside of the United States, may depend upon obtaining additional collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed 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 “Risks Related to Our Business - We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing 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 “Risks Related to Our Business - 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 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 and Ortho Pharmaceutical. These agreements require us to make payments and satisfy performance obligations in order 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:

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

We currently have a limited sales and marketing team and, therefore, must develop a sales and marketing team or enter into distribution arrangements and marketing alliances, which could require us to give up rights to our product candidates. Our limited sales and marketing experience may restrict our success in commercializing our product candidates.

If we successfully develop and obtain regulatory approval for Surfaxin and the other product candidates that we are currently developing, we may: (1) market and sell them through our sales force, (2) license some of them to large pharmaceutical companies and/or (3) market and sell them through other arrangements, including co-promotion arrangements.

We currently have a limited sales and marketing team and we plan to further develop our marketing and sales team as we expect to rely primarily on such team to market Surfaxin in the United States, if Surfaxin is approved by the FDA. Recruiting, training and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is intense, and we may be unable to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Additionally, we may not be able to provide adequate incentive to our sales force. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin or our other product candidates.

Developing a marketing and sales team to market and sell products is a difficult, significantly expensive and time-consuming process. We have no prior experience developing a marketing and sales team and may be unsuccessful in our attempt to do so. If we are unable to develop an internal sales and marketing operation, we may not be able to increase market awareness and sell our products.

Establishing the expertise necessary to successfully market and sell Surfaxin, or any other product, will require a substantial capital investment. We expect to incur significant expenses in developing our marketing and sales team. 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 also 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.

We may also 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 develop a marketing and sales team or to 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. 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 also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement.

If we fail to establish marketing and sales capabilities or 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. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, or if our distributors fail to promote our products, we will have difficulty maintaining and increasing the sales of our products.

We may be unable to either establish marketing and sales capabilities or enter into corporate collaborations necessary to successfully commercialize Surfaxin or our other potential products.

We have limited experience in marketing or selling pharmaceutical products and have limited marketing and sales resources. To achieve commercial success for Surfaxin, or any other approved product, we must either rely upon our limited marketing and sales force and related infrastructure, or enter into arrangements with others to market and sell our products. We intend to promote Surfaxin in the United States through our own dedicated marketing and sales team. Recruiting, training and retaining qualified sales personnel is therefore critical to our success. Competition for skilled personnel is intense, and we may not be able to attract and retain a sufficient number of qualified individuals to successfully launch Surfaxin. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin.

In addition, establishing the expertise necessary to successfully market and sell Surfaxin, or any other product, will require a substantial capital investment. Our ability to make that investment and also execute our current operating plan is dependent on numerous factors, including, as described above, partnering of clinical programs at opportune times and continued prudent fiscal management. Accordingly, we may not have the funds to successfully commercialize Surfaxin or any other potential product in the United States or elsewhere.

Moreover, Surfaxin competes, and our product candidates in development are likely to compete, with products of other companies that currently have extensive and well-funded marketing and sales operations. Because these companies are capable of devoting significantly greater resources to their marketing and sales efforts, our marketing and sales efforts may not compete successfully against the efforts of these other companies.

We have also announced our intention to market and sell Surfaxin outside of the United States through one or more marketing partners upon receipt of approval 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. Currently, we have employment agreements with seven officers expiring in December 2005. However, commencing on January 1, 2006, and on each January 1st thereafter, the term of these agreements shall automatically be extended for one additional year, unless at least 90 days prior to such January 1st date, either we or the officer shall have given notice that such party does not wish to extend the agreement. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. 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, including marketing and sales staff. 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, there are no approved drugs that are specifically indicated for the prevention and treatment of MAS in full-term infants or ALI/ARDS in adults. Current therapy consists of general supportive care and mechanical ventilation.

Four products, three that are animal-derived and one that is a synthetic, are specifically approved for the prevention of RDS in premature infants. Exosurf® is synthetic and is marketed by GlaxoSmithKline, plc, outside the United States and contains only phospholipids (the fats normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. This product, however, does not contain any surfactant proteins, is not widely used and its active marketing recently has been discontinued by its manufacturer. Curosurf® is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Survanta® , marketed by the Ross division of Abbott Laboratories, Inc., is an extract of bovine lung that contains the cow version of surfactant protein C. Forest Laboratories, Inc., markets its calf lung surfactant, Infasurf® in the United States for the prevention of RDS in premature infants. Although none of the four approved surfactants for RDS in premature infants is approved for ALI or ARDS in adults, which are significantly larger markets, there are a significant number of other potential therapies in development for these indications that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered precision-engineered surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products approved for the prevention of RDS in premature infants and will have no capability of transmitting the brain-wasting bovine spongiform encephalopathy (commonly called “mad-cow disease”) or causing adverse immunological responses in young and older adults.

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 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 in the event that 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 $10.0 million per occurrence and $10.0 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 prior to 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 June 30, 2005, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 14% 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 “Management's Discussion and Analysis of Financial Condition and Results of Operations - Risks Related to Our Business.”

Our common stock is listed for quotation on the NASDAQ National Market. Year to date through September 23, 2005, the price of our common stock has ranged from $9.15 to $5.05. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. Year to date through September 23, 2005, the average daily trading volume in our common stock was approximately 593,000 shares and the average number of transactions per day was approximately 1,800. 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 National Market. If the common stock were no longer listed on the National Market, investors might only be able to trade on the Nasdaq SmallCap 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 August 31, 2005, we had 53,776,796 shares of common stock issued and outstanding. In addition, as of August 31, 2005, up to 10,632,177 shares of our common stock were issuable upon exercise of outstanding options and warrants. In December 2003, we filed a shelf registration statement on Form S-3 with the Commission for the proposed offering from time to time of up to 6,500,000 shares of common stock. In connection with our December 2003 shelf registration statement, we registered an additional 1,468,592 shares of common stock in February 2005. Under these shelf registration statements, 708,952 shares of our common stock currently remain available for us to sell in registered transactions. We have no immediate plans to sell any securities under the shelf registration. 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, shares of common stock remain reserved for issuance pursuant to the terms and conditions of the CEFF with Kingsbridge.

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 Restated 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 "Certificate of Incorporation"), 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 Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to 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.

FORWARD-LOOKING STATEMENTS

The statements set forth under the captions "Company Summary" and elsewhere in this prospectus, including in "Risk Factors," and those incorporated by reference herein, which are not historical, including, without limitation, statements concerning our research and development programs and clinical trials, the possibility, timing and outcome of submissions of 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, constitute "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. 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 (including the results of clinical trials being conducted by us and the risk that our lead product candidate, Surfaxin® , or other drug candidates will not prove to be safe or useful for the treatment of certain indications); 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 will not be able to develop a successful sales and marketing organization in a timely manner, if at all; risk that our internal sales and marketing organization will not succeed in developing market awareness of our products; risk that our internal sales and marketing organization will not be able to attract or maintain qualified personnel; delays in the FDA's or other health regulatory authorities' approval or potential rejection of any applications we file, including the New Drug Application (NDA) we filed in April 2004 and the Marketing Approval Application (MAA) we submitted in October 2004; 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 contract manufacturers to provide us with adequate supplies of drug substance and drug products for completion of any of our clinical studies or commercialization; risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of our clinical studies, and risks relating to the development of competing therapies and/or technologies by other companies; and the other risks and uncertainties detailed under the heading “Risk Factors” and in the documents incorporated by reference in this report. 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 publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

Except as described in any prospectus supplement or post-effective amendment, we will retain broad discretion over the use of the net proceeds from the sale of our securities offered hereby and the net proceeds from the sales of securities offered by this prospectus will be used to meet working capital requirements for: (i) the development of manufacturing capabilities for the production of our precision-engineered surfactant drug products to meet anticipated clinical and commercial needs, if approved, in the United States, Europe and other markets; (ii) building our own specialty pulmonary United States commercial organization to focus initially on opportunities in the neonatal intensive care unit (NICU), including commercialization activities associated with the potential launch of Surfaxin in 2006; (iii) the advancement of our SRT product candidates in clinical trials, including our aerosol formulations to address various respiratory diseases; (iv) business development and commercialization activities associated with securing partnerships for the development and potential commercialization of SRT in Europe and the rest of the world; and (v) general corporate purposes. We expect, from time to time, to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used.

The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our research and development efforts, technological advances and the competitive environment for Surfaxin and its intended uses. Pending the application of the net proceeds, we expect to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

RATIO OF EARNINGS TO FIXED CHARGES

Our earnings were insufficient to cover fixed charges in each of the years in the five-year period ended December 31, 2004 and in the three-month period ended June 30, 2005. Our fixed charges do not include any dividend requirements with respect to preferred stock because, as of the date of this prospectus and for the five preceding fiscal years, we have had no preferred stock outstanding.

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

	Fiscal year Ended December 31,					Three Months Ended June 30, 2005
	2000	2001	2002	2003	2004	
	(in thousands)					
Ratio of earnings to fixed charges [1]						
Coverage deficiency	$ (10,861)	$ (11,146)	$ (17,443)	$ (24,280)	$ (46,203)	$ (19,142)

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

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we offer under a prospectus supplement may differ from the terms we describe below. However, no prospectus supplement shall fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. As of June 30, 2005, we have $11.2 million in outstanding indebtedness including accrued interest.

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

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

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

General

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

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

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

· any other specific terms of such debt securities.

Unless otherwise specified in the prospectus supplement:

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

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

Exchange and Transfer

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

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

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

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

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

Global Securities

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

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

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

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

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

- will not be entitled to have the debt securities registered in their names,

- will not be entitled to physical delivery of certificated debt securities, and

- will not be considered to be holders of those debt securities under the indentures.

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

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

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

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

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

Payment and Paying Agent

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

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

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

Consolidation, Merger and Sale of Assets

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

- the successor, if any, is a U.S. corporation, limited liability company, partnership, trust or other entity;

- the successor assumes our obligations on the debt securities and under the indenture;

- immediately after giving effect to the transaction, no default or event of default shall have occurred and be continuing; and

- certain other conditions are met.

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

Events of Default

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

(1) failure to pay principal of or any premium on any debt security of that series when due;

(2) failure to pay any interest on any debt security of that series for 90 days when due;

(3) failure to deposit any sinking fund payment when due;

(4) failure to perform any other covenant in the indenture continued for 90 days after being given the notice required in the indenture;

(5) our bankruptcy, insolvency or reorganization; and

(6) any other event of default specified in the prospectus supplement.

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

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

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

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

Other than the duty to act with the required care during an event of default, the trustee will not be obligated to exercise any of its rights or powers at the request of the holders unless the holders shall have offered to the trustee reasonable indemnity. Generally, the holders of a majority in aggregate principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee.

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

(1) the holder has previously given to the trustee written notice of a continuing event of default with respect to the debt securities of that series;

(2) the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made a written request and have offered reasonable indemnity to the trustee to institute the proceeding; and

(3) the trustee has failed to institute the proceeding and has not received direction inconsistent with the original request from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series within 90 days after the original request.

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

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

Modification and Waiver

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

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

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

Satisfaction and Discharge; Defeasance

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

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

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

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

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

Notices

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

Governing Law

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

Regarding the Trustee

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

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

Subordinated Debt Securities

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

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

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

- a default in the payment of the principal, premium, if any, interest, rent or other obligations in respect of designated senior indebtedness occurs and is continuing beyond any applicable period of grace, which is called a “payment default”; or

- a default other than a payment default on any designated senior indebtedness occurs and is continuing that permits holders of designated senior indebtedness to accelerate its maturity, and the trustee receives notice of such default, which is called a “payment blockage notice from us or any other person permitted to give such notice under the indenture, which is called a “non-payment default”.

We may resume payments and distributions on subordinated debt securities:

- in the case of a payment default, upon the date on which such default is cured or waived or ceases to exist; and

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

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

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

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

As of June 30, 2005, $11.2 million in senior indebtedness was outstanding. Unless we inform you otherwise in the prospectus supplement, we will not be prohibited from incurring debt, including senior indebtedness, under any indenture relating to subordinated debt securities. We may from time to time incur additional debt, including senior indebtedness.

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

Certain Definitions

“indebtedness” means:

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

(2) all reimbursement obligations and other liabilities with respect to letters of credit, bank guarantees or bankers' acceptances;

(3) all obligations and liabilities in respect of leases required in conformity with generally accepted accounting principles to be accounted for as capitalized lease obligations on our balance sheet;

(4) all obligations and liabilities, contingent or otherwise, as lessee under leases for facility equipment (and related assets leased together with such equipment) and under any lease or related document (including a purchase agreement, conditional sale or other title retention or synthetic lease agreement) in connection with the lease of real property or improvement thereon (or any personal property included as part of any such lease) which provides that such Person is contractually obligated to purchase or cause a third party to purchase the leased property or pay an agreed upon residual value of the leased property, including the obligations under such lease or related document to purchase or cause a third party to purchase such leased property (whether or not such lease transaction is characterized as an operating lease or a capitalized lease in accordance with GAAP) or pay an agreed upon residual value of the leased property to the lessor;

(5) all obligations with respect to an interest rate or other swap, cap or collar agreement or other similar instrument or agreement or foreign currency hedge, exchange, purchase agreement or other similar instrument or agreement;

(6) all direct or indirect guaranties or similar agreements in respect of, and our obligations or liabilities to purchase, acquire or otherwise assure a creditor against loss in respect of, indebtedness, obligations or liabilities of others of the type described in (1) through (5) above;

(7) any indebtedness or other obligations described in (1) through (6) above secured by any mortgage, pledge, lien or other encumbrance existing on property which is owned or held by us; and

(8) any and all refinancings, replacements, deferrals, renewals, extensions and refundings of, or amendments, modifications or supplements to, any indebtedness, obligation or liability of the kind described in clauses (1) through (7) above.

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

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

DESCRIPTION OF PREFERRED STOCK

We currently have authorized 5,000,000 shares of preferred stock, par value $.001 per share. As of June 30, 2005, we do not have any shares of preferred stock outstanding. Under our Certificate of Incorporation, our Board of Directors is authorized to issue shares of our preferred stock from time to time, in one or more classes or series, without stockholder approval. Prior to the issuance of shares of each series, the Board of Directors is required by the General Corporation Law of the State of Delaware and our Certificate of Incorporation to adopt resolutions and file a Certificate of Designation with the Secretary of State of the State of Delaware, fixing for each such series the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series. Any exercise of our Board of Directors of its rights to do so may affect the rights and entitlements of the holders of our common stock as set forth below.

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

General

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

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

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

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

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

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

Transfer Agent and Registrar

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

DESCRIPTION OF COMMON STOCK

General

This prospectus summarizes the general terms of our common stock. For a more detailed description of the common stock, you should read the applicable provisions of Delaware law and our Certificate of Incorporation and By-Laws.

We currently have authorized 180,000,000 shares of common stock, par value $0.001 per share. As of September 30, 2005, there were 56,791,243 shares of common stock outstanding, which does not include:

- 8,201,573 shares of common stock issuable upon exercise of options outstanding, at a weighted average exercise price of $6.26 per share;
- 2,463,770 shares of common stock issuable upon exercise of warrants outstanding, at a weighted average exercise price of $7.67;
- 11,086,203 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;
- 708,592 shares of common stock available for future issuance under our shelf registration statement on Form S-3MEF (No. 333-122887) dated February 17, 2005;
- 1,914,270 shares of common stock available for future grant under our Amended and Restated 1998 Employee Stock Option Plan; and
- 88,231 shares of common stock available for future issuance under our 401(k) Plan.

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.

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. In the event of our liquidation, dissolution or winding-up, you will be entitled to receive on a proportionate basis any assets remaining after provision for payment of creditors and after payment of any liquidation preferences to holders of preferred stock. Holders of our common stock have no preemptive rights and no conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. All the outstanding shares of common stock are, and the shares offered by this prospectus, when issued and paid for, will be, validly issued, fully paid and nonassessable. Our common stock is quoted on Nasdaq under the symbol “DSCO”.

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 prior to 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. In the event of 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. In the event of 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 prior to 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:

--prior to 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.

PLAN OF DISTRIBUTION

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

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

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

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

We may solicit directly offers to purchase securities. We may also designate agents from time to time to solicit offers to purchase securities. Any agent that we designate, who may be deemed to be an underwriter as that term is defined in the Securities Act, may then resell such securities to the public at varying prices to be determined by such agent at the time of resale. We may engage in at the market offerings of our common stock. An at the market offering is an offering of our common stock at other than a fixed price to or through a market maker. Under Rule 415(a)(4) promulgated under the Securities Act, the total value of at the market offerings made under this prospectus may not exceed 10% of the aggregate market value of our common stock held by non-affiliates. We shall name any underwriter that we engage for an at the market offering in a post-effective amendment to the registration statement containing this prospectus. We shall also describe any additional details of our arrangement with such underwriter, including commissions or fees paid, or discounts offered, by us and whether such underwriter is acting as principal or agent, in the related prospectus supplement. If we use underwriters to sell securities, we will enter into an underwriting agreement with the underwriters at the time of the sale to them, which agreement shall be filed as an exhibit to the related prospectus supplement. Underwriters may also receive commissions from purchasers of the securities.

Underwriters may also use dealers to sell securities. In such an event, the dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agents.

Underwriters, dealers, agents and other persons may be entitled, under agreements that may be entered into with us, to indemnification by us against certain civil liabilities, including liabilities under the Securities Act or to contribution with respect to payments which they may be required to make in respect of such liabilities. Underwriters and agents may engage in transactions with, or perform services for, us in the ordinary course of business. If so indicated in the applicable prospectus supplement, we may authorize underwriters, dealers or other persons to solicit offers by certain institutions to purchase the securities offered by us under this prospectus pursuant to contracts providing for payment and delivery on a future date or dates. The obligations of any purchaser under these contracts will be subject only to those conditions described in the applicable prospectus supplement, and the prospectus supplement will set forth the price to be paid for securities pursuant to those contracts and the commissions payable for solicitation of the contracts.

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

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

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

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

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

EXPERTS

Our consolidated financial statements and management's assessment of the effectiveness of our internal control over financial reporting, appearing in our Annual Report on Form 10-K for the year ended December 31, 2004, have been audited by Ernst & Young LLP, our independent registered public accounting firm, as set forth in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firms 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 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" (this is not a hyperlink, you must visit this website through an Internet browser). Our Website and the information contained therein or connected thereto are not incorporated into this Registration Statement.

We have filed with the SEC a registration statement (which contains this prospectus) 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, 2004, filed on March 16, 2005;

2. Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2005 and June 30, 2005;

3. Our Current Reports on Form 8-K filed with the SEC on February 2, February 14, February 18, February 22, March 17, April 28, August 1, August 3, August 15, August 19, and September 9, 2005;

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 initial registration statement and prior to the effectiveness of the registration statement, as well as subsequent to the date of this prospectus and prior to 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, 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 prior to 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 prior to 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.

$100,000,000

Discovery Laboratories, Inc.

Debt Securities, Preferred Stock and Common Stock

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

October 11, 2005

10,000,000 Shares

Common Stock

PROSPECTUS SUPPLEMENT

Jefferies & Company

December 7, 2007
