

650,000 Shares



Common Stock

Discovery Laboratories, Inc. is offering up to 650,000 shares of its common stock. See “Plan of Distribution” beginning on page S-16 of this prospectus supplement for more information regarding this arrangement.

Our common stock is quoted on the Nasdaq National Market under the symbol “DSCO.”

Investing in our common stock involves significant risks. See “Risks Related to Our Business” set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, and “Risk Factors” beginning on page S-2 of this prospectus supplement and page 7 of the accompanying prospectus for a discussion of some important risks you should consider before buying our common stock.

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	Maximum Offering
Public offering price	\$6.88	\$4,472,000
Placement agent fee	N/A	N/A
Proceeds to Discovery Laboratories, Inc. (before expenses)	\$6.88	\$4,472,000

We estimate the total expenses of this offering will be approximately \$20,000.

October 27, 2005

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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 this 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 subsidiaries, 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 (“SEC”) on December 19, 2003, as extended by the registration statement on Form S-3 MEF that we filed with the SEC on February 17, 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. 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.”

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

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, Surfaxin[®] (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 (EMA). 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.

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, before deciding to purchase any shares of our common stock. The risks and uncertainties described below 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.

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. Our previously submitted responses to the Approvable Letter have been accepted by the FDA as a complete response as of October 5, 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. Our previously submitted responses to the Approvable Letter have been accepted by the FDA as a complete response as of October 5, 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. Our previously submitted responses to the Approvable Letter have been accepted by the FDA as a complete response as of October 5, 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 October 26, 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 October 26, 2005, the average daily trading volume in our common stock was approximately 582,000 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 10,652,177 shares of our common stock were issuable upon exercise of outstanding options and warrants. In October 2005, we filed a universal shelf registration statement with the SEC for the proposed offering from time to time of up to \$100 million of our debt or equity securities. We have not sold, nor do we have any 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.

Risks Related to This Offering

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

We have not designated the amount of net proceeds we will receive from this offering for any particular purpose. Accordingly, 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.

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, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of \$6.88 per share in this offering, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$6.24 per share in the net tangible book value of the common stock. See “Dilution” on page S-15 for a more detailed discussion of the dilution you will incur in this offering.

FORWARD-LOOKING STATEMENTS

The statements set forth in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein, including in “Risk Factors,” 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.

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 any obligation or duty to publicly update or revise any 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.

DILUTION

The net tangible book value of our common stock on June 30, 2005, was approximately \$30.2 million, or approximately \$0.56 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 650,000 shares of our common stock in this offering at an offering price equal to \$6.88 per share, and after deducting the estimated offering expenses, our net tangible book value at June 30, 2005, would have been approximately \$34.6 million, or approximately \$0.64 per share. This represents an immediate increase in the net tangible book value per share equal to \$0.08 per share to existing shareholders and an immediate dilution equal to \$6.24 per share to new investors purchasing shares of common stock in this offering. The following table illustrates this dilution:

Offering price per share	\$	6.88
Net tangible book value per share as of June 30, 2005	\$	0.56
Increase per share after the offering	\$	0.08
Net tangible book value per share as of June 30, 2005, after giving effect to this offering	\$	0.64
Dilution per share to new investors	\$	6.24

Note: Table does not include activity between June 30, 2005 and the date of this prospectus supplement.

The foregoing table does not take into account further dilution to new investors that could occur upon the exercise of outstanding warrants and options having a per share exercise price less than the per share offering price to the public in this offering. As of August 31, 2005, 53,776,796 shares of our common stock were outstanding, which does not include:

- 8,188,407 shares of common stock issuable upon exercise of options outstanding as of August 31, 2005, at a weighted average exercise price of \$6.26 per share; and
- 2,463,770 shares of common stock issuable upon exercise of warrants outstanding as of August 31, 2005, at a weighted average exercise price of \$7.67.

PLAN OF DISTRIBUTION

We have entered into a stock purchase agreement, dated as of October 27, 2005, with Laboratorios del Dr. Esteve, S.A. (“Esteve”) whereby Esteve will purchase all of the shares of our common stock offered pursuant to this prospectus supplement, upon the terms and subject to the conditions of such agreement. We currently anticipate that closing of the sale of 650,000 shares of common stock will take place on or about October 31, 2005. Esteve will be informed of the date and manner in which it must transmit the purchase price for their shares.

On the scheduled closing date, we anticipate receipt of funds in the amount of the aggregate purchase price.

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

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

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 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 registration statement.

On December 19, 2003, we filed a registration statement on Form S-3 with the SEC. On February 17, 2005, we filed with the SEC a registration statement on Form S-3 MEF pursuant to Rule 462(b) promulgated under the Securities Act, to register an additional number of shares in connection with the December 2003 shelf registration statement. The common stock we are offering under this prospectus supplement are being drawn-down from the remaining shares available under such additional shelf registration statement. 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. 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.



Common Stock

PROSPECTUS SUPPLEMENT

October 27, 2005
