As filed with the Securities and Exchange Commission on December 15, 2004
Registration No. 333-[_____]

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

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

DISCOVERY LABORATORIES, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**94-3171943**
(State or Other Jurisdiction of Incorporation)	(I.R.S. Employer Identification Number)

2600 Kelly Road
Warrington, Pennsylvania 18976
(Address, Including Zip Code and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Robert J. Capetola, Ph.D.
Chief Executive Officer
2600 Kelly Road
Warrington, Pennsylvania 18976
(215) 488-9300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
Ira L. Kotel, Esq.
Dickstein Shapiro Morin & Oshinsky LLP
1177 Avenue of the Americas, 47th Floor
New York, New York 10036-2714
(212) 835-1400

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

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

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

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

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. |_|

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share(1)(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(1)(2)
common stock, $.001 par value	850,000	$8.49	$7,212,250	$848.88

(1) Also registered hereby are such additional and indeterminable number of shares as may be issuable due to adjustments for changes resulting from stock dividends, stock splits and similar changes.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) of the Securities Act and determined by multiplying $8.49 (which was the average of the high and low sales price of the common stock on the Nasdaq National Market on December 10, 2004) by the 850,000 shares of common stock issuable upon the exercise of that certain Warrant Agreement dated and entered into as of

November 3, 2004, by and between us and the Selling Stockholder named in this Registration Statement. Pursuant to Rule 416 under the Securities Act, we are also registering additional shares of common stock which may become issuable pursuant to the anti-dilution provisions set forth in such Warrant Agreement.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

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

SUBJECT TO COMPLETION
PRELIMINARY PROSPECTUS DATED DECEMBER 15, 2004

850,000 Shares

Discovery LABORATORIES

COMMON STOCK

This prospectus relates to the public offering, which is not being underwritten, of 850,000 shares of our common stock, par value $.001 per share, which may be sold by the selling stockholder listed on page 29 for its own account. Such shares are issuable upon exercise of an outstanding warrant.

Our common stock is quoted on the Nasdaq National Market under the trading symbol "DSCO." On December 10, 2004, the closing sales price of our common stock as reported by Nasdaq was $8.68 per share.

INVESTING IN OUR COMMON STOCK INVOLVES SIGNIFICANT RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE 10.

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. You should rely only on the information we have provided or incorporated by reference in this prospectus. Neither we nor the selling stockholder has authorized anyone to provide you with additional or different information. The selling stockholder is not making an offer of these securities in any jurisdiction where the offer is not permitted. You should assume that the information in this prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference. You should read both this prospectus and any and all prospectus supplements together with additional information described under the heading, "Where You Can Find More Information."

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 ____________________, 2004.

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ABOUT THIS PROSPECTUS

Because this is a summary, it does not contain all the details that may be important to you. You should read this entire prospectus, including "Risk Factors," carefully before you invest.

COMPANY SUMMARY

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases. Surfactant is produced naturally in the lungs and are essential for breathing. The absence or depletion of surfactant is involved in a number of respiratory diseases. Our technology produces a precision-engineered, peptide-containing surfactant that is designed to closely mimic the function of human lung surfactant. We believe that through this Surfactant Replacement Therapy technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the Neonatal Intensive Care Unit, critical care unit and other hospitalized settings, where there are few or no approved therapies available.

We have filed a New Drug Application with the FDA and a Marketing Authorization Application with the European Medicines Evaluation Agency for clearance to market Surfaxin®, our lead product, for the prevention and treatment of Respiratory Distress Syndrome ("RDS") in premature infants. The FDA has accepted our NDA filing for Surfaxin for the prevention of RDS in premature infants and had granted a Standard Review designation establishing a target date of February 13, 2005, for the completion of its review of the NDA. The European Medicines Evaluation Agency has validated our Marketing Authorization Application indicating that the application is complete and that its review process has begun.

In addition to Surfaxin for RDS, in an effort to enhance the potential commercial and medical value of our Surfactant Replacement Therapy by addressing the most prevalent respiratory disorders affecting infants in the Neonatal Intensive Care Unit, we are conducting several Neonatal Intensive Care Unit therapeutic programs targeting respiratory conditions cited as some of the most significant unmet medical needs for the neonatal community. We are set to initiate two Phase 2 clinical trials -- Surfaxin for the prevention of Bronchopulmonary Dysplasia ("BPD") in premature infants and aerosolized Surfactant Replacement Therapy administered through nasal continuous positive airway pressure (nasal CPAP) for Neonatal Respiratory Failures. We are also currently in a Phase 2 prophylactic/early treatment trial of Surfaxin for the treatment of Meconium Aspiration Syndrome in full-term infants.

In an effort to enhance the potential commercial and medical value of our Surfactant Replacement Therapy, we are also developing Surfactant Replacement Therapy to address unmet 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 for the treatment of Acute Respiratory Distress Syndrome ("ARDS") in adults in the intensive care unit (ICU), for which we announced preliminary data on December 7, 2004. With our aerosolized surfactant formulations, we are preparing to initiate a Phase 2 trial for patients with moderate to severe asthma (development name DSC-104). In addition, we are evaluating the development of aerosolized formulations of our precision-engineered Surfactant Replacement Therapy to potentially treat Acute Lung Injury, Chronic Obstructive Pulmonary Disease ("COPD") and rhinitis/sinusitis.

We are presently implementing a long-term business strategy which includes manufacturing for the production of our precision-engineered Surfactant Replacement Therapy to meet anticipated clinical and commercial needs, and developing the sales and marketing capabilities for the commercialization of Surfaxin, if approved, in the United States and Europe.

SURFACTANT TECHNOLOGY

Our precision-engineered surfactant 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 are born too soon and thus have an insufficient amount of their own natural surfactant. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Though 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. However, this product 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 is a potential for 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 humanized 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 engineered precision-engineered surfactant can be manufactured in sufficient quantities, in more exact and consistent pharmaceutical grade quality, less expensively than the animal-derived surfactants and has no potential to cause adverse immunological responses in young and older adults, all important attributes for our products to potentially meet significant unmet medical needs. In addition, we believe that our engineered 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").

Aerosolized Surfactant Formulations

Many respiratory diseases are associated with an inflammatory event that causes surfactant dysfunction and a loss of patency of the conducting airways. Scientific data support the premise that the therapeutic use of surfactants in aerosol form has the ability to reestablish airway patency, improve pulmonary mechanics and act as an anti-inflammatory. Surfactant normally prevents moisture from accumulating in the airways' most narrow sections and thereby helps maintain the patency of the conducting airways.

We are currently developing aerosolized formulations of our precision-engineered surfactant to potentially treat patients who could benefit from surfactant-based therapy to improve lung function and maintain proper airflow through the respiratory system. Our aerosol development program is initially focused on surfactant-based therapy to treat premature infants in the NICU suffering from neonatal respiratory failure and for hospitalized patients suffering from severe acute asthma or Acute Lung Injury. In addition, we believe that scientific rationale supports the development of aerosolized formulations of our precision-engineered surfactant to potentially treat COPD, sinusitis, rhinitis, sleep apnea and otitis media (inner ear infection).

The aerosolized formulations of our precision-engineered surfactant that we are currently developing are intended to be administered using various aerosol devices and, to date, we have achieved the following important development objectives:

— full retention of the surface-tension lowering properties of a functioning surfactant necessary to restore lung function and maintain patency of the conducting airways;
— full retention of the surfactant composition upon aerosolization;
— drug particle size suitable for deposition in the deep-lungs;
— delivery rates to achieve therapeutic dosages in a reasonable time period; and
— reproducible aerosol output and minimal waste of surfactant dose.

SURFACTANT THERAPY FOR RESPIRATORY MEDICINE

Products for Neonatal Intensive Care Indications

Surfaxin 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. In most cases, 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).

In April 2004, we filed an NDA with the FDA for the approval of Surfaxin in the United States for the prevention of RDS in premature infants. In June 2004, the FDA announced that it had accepted our NDA, granted a Standard Review designation to the NDA and established a target date of February 13, 2005, for completion of the review of the NDA. The NDA was based on the successful results obtained from the completion of both a landmark, pivotal Phase 3 clinical trial and a supportive Phase 3 clinical trial of Surfaxin for the treatment of RDS in premature infants. In October 2004, the European Medicines Evaluation Agency validated our Marketing Authorization Application that we filed previously for clearance to market Surfaxin for the same indication in Europe. This validation indicated that the Marketing Authorization Application was complete and that the review process had begun.

Our pivotal Phase 3 trial enrolled 1,294 patients and was designed as a multinational, multicenter, randomized, masked, controlled, prophylaxis, event-driven, superiority trial to demonstrate the safety and efficacy of Surfaxin over Exosurf®, an approved, non-protein containing synthetic surfactant. Survanta®, a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the trial. Key trial results were assessed by an independent adjudication committee comprised of leading neonatologists and pediatric radiologists. This committee provided a consistent and standardized method for assessing critical efficacy data in the trial. An independent Data Safety Monitoring Board (DSMB) was responsible for monitoring the overall safety of the trial and no major safety issues were identified. In accordance with the study's trial design, we continue to conduct six and twelve month clinical follow-up on all enrolled patients.

The supportive, multinational Phase 3 clinical trial enrolled 252 patients and was designed as a non-inferiority trial comparing Surfaxin to Curosurf®, a porcine (pig) derived surfactant and the leading surfactant used in Europe. This trial demonstrated the overall safety and non-inferiority of Surfaxin to Curosurf. In accordance with the study's trial design, we continue to conduct six and twelve month clinical follow-up on all enrolled patients.

There are over 3,000,000 premature infants born annually worldwide. More than 850,000 of these premature infants are considered “very low birth weight” infants (less than 1,250 grams), of which approximately 700,000 are considered at significant risk for RDS. Due to limitations associated with the animal-derived surfactant products that are currently approved to treat RDS in premature infants, access to such therapy is mainly limited to the approximately 170,000 very low birth weight infants born in the United States, Western Europe and Japan. This results in hundreds of thousands of premature infants born in the world each year who need, but do not receive, effective Surfactant Replacement Therapy.

The FDA has granted us Orphan Drug Designation for Surfaxin for RDS. Orphan drugs are pharmaceutical products that are intended to treat diseases affecting fewer than 200,000 patients in the United States. The Office of Orphan Product Development of the FDA grants certain advantages to the sponsors of orphan drugs including, but not limited to, seven years of market exclusivity upon approval of the drug, certain tax incentives for clinical research and grants to fund testing of the drug. Most recently, the Commission of the European Communities has designated Surfaxin as an Orphan Medicinal Product for the prevention and treatment of RDS in premature infants. This designation allows us exclusive marketing rights for Surfaxin for indications of RDS in Europe for 10 years (subject to revision after six years) following marketing approval by the European Medicines Evaluation Agency. In addition, the designation enables us to receive regulatory assistance in the further development process of Surfaxin, and to access reduced regulatory fees throughout its marketing life.

Surfaxin for the Prevention of Bronchopulmonary Dysplasia

BPD is a serious form of chronic lung disease that is associated with the prolonged use of mechanical ventilation and oxygen supplementation. Babies with BPD suffer from abnormal lung development and typically have a need for respiratory assistance, often times, for many months, as well as comprehensive care spanning multiple years. There are presently no approved drugs for the treatment of BPD.

We expect to initiate a Phase 2 clinical trial of Surfaxin for the prevention of BPD by the end of 2004 with enrollment beginning in January 2005. Surfaxin, in its pivotal, landmark, multinational Phase 3 clinical trial for the prevention of RDS in premature infants, demonstrated statistical benefit in the reduction of BPD compared with another approved surfactant. We believe that Surfaxin is the first surfactant that has been able to demonstrate such a statistical benefit in comparison to another surfactant.

Aerosolized Surfactant Replacement Therapy for Premature Infants

Serious respiratory problems are some of the most prevalent medical issues facing premature infants in Neonatal Intensive Care Units. On top of the approximately 700,000 premature infants born annually worldwide at risk for RDS, there are another approximately 1,000,000 premature infants, 300,000 of which are in the United States and Europe, born annually at risk for a range of other respiratory problems associated with surfactant dysfunction. These infants are usually at a birth weight greater than 1,250 grams and neonatologists generally try to avoid mechanically ventilating these patients because doing so requires intubation (the highly invasive process of inserting a breathing tube down the patient’s trachea). This reluctance is due to the perceived risks by many neonatologists regarding the intubation of these larger babies, such as the risk of trauma and infection, 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. We believe that there is growing recognition by the neonatal medical community for the potential utility of a non-invasive method of delivering Surfactant Replacement Therapy to treat premature infants suffering from respiratory disorders including BPD, bronchiolitis, acute hypoxia, pneumonia, and transient tachypnea.

We are preparing a Phase 2 clinical trial which we expect to initiate by the end of 2004, with enrollment beginning in January 2005, using aerosolized Surfactant Replacement Therapy with nasal continuous positive airway pressure (nasal CPAP) as a non-invasive means to potentially treat premature infants in Neonatal Intensive Care Units suffering from neonatal respiratory failure.

Surfaxin for Meconium Aspiration Syndrome in Full-Term Infants

Meconium Aspiration Syndrome is an inflammatory condition in which full-term infants are born with meconium in their lungs that depletes the natural surfactant in their lungs. Meconium is a baby’s first bowel movement in its mother’s womb and, when inhaled, Meconium Aspiration Syndrome can occur. Meconium Aspiration Syndrome can be life-threatening as a result of the failure of the lungs to absorb sufficient oxygen. There are no approved therapies for this condition and the standard of care principally consists of mechanical ventilation. Surfaxin has been shown to not only remove inflammatory and infectious infiltrates from the lungs when using our proprietary lavage (or “lung wash”) but to also replenish the vital surfactant levels in the babies’ lungs.

We are conducting a Phase 2 clinical trial of our proprietary Surfaxin lavage in up to 60 full-term infants for use as a prophylactic or early treatment for patients who are at risk of developing Meconium Aspiration Syndrome but have not shown symptoms of compromised respiratory function. Surfaxin is administered as a liquid bolus through an endotracheal tube as well as by our proprietary lavage (“lung-wash”) technique. We believe an effective and affordable surfactant prophylactic therapy could significantly lower the risk to meconium-stained infants of chronic respiratory conditions and reduce the need for costly and invasive mechanical ventilation.

There are presently no drug therapies approved for the treatment of Meconium Aspiration Syndrome in full-term infants and we believe that Surfaxin is the only product being developed worldwide to treat this syndrome. An estimated 60,000 infants are born in the United States and Europe that require treatment for Meconium Aspiration Syndrome, however, a significantly greater number of infants are born worldwide each year at risk. The FDA has granted us Fast-Track Status and Orphan Drug Designation for Surfaxin in this indication. We have also received orphan medical product designation of Surfaxin for this indication from the European Medicines Evaluation Agency.

Products for the Critical Care Unit and other Hospital Settings

Surfaxin for Acute Respiratory Distress Syndrome in Adults

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 and other traumas.

We are currently conducting a Phase 2 open-label, controlled, randomized, multi-center clinical trial of Surfaxin for the treatment of adults with ARDS. On December 7, 2004, we announced encouraging preliminary data from this trial and that we were modifying the trial protocol to allow for increased enrollment of up to 160 patients.

The Phase 2 trial is designed to compare the safety and efficacy of Surfaxin to current standard of care (mechanical ventilation only). In the trial, Surfaxin is administered to patients in a high concentration via our proprietary sequential bronchopulmonary segmental lavage technique (a “lung wash” where Surfaxin is delivered through a tube, called a bronchoscope, to each of the 19 to 20 segments of the lung), which is intended to cleanse and remove inflammatory substances from the lungs, while approximately one-half of the Surfaxin remains to help re-establish the lung’s capacity to absorb oxygen. In addition to the Surfaxin lavage, the Surfaxin patients may also receive up to two boluses of Surfaxin. The objective is to restore functional surfactant levels and to allow critically ill patients to be removed from mechanical ventilation sooner. 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 Surfaxin and the bronchoscopic lavage procedure. The Phase 2 trial is expected to be completed by the fourth quarter of 2005.

The current standard of care for ARDS includes placing patients on mechanical ventilators in intensive care units at a cost per patient of approximately $8,500 per day, typically for an average of 21 to 28 days. There are estimated to be between 150,000 and 200,000 adults per year in the United States suffering from ARDS with similar numbers afflicted in Europe. Because there are no approved treatments for these diseases, the mortality rate can range from 30% to 40%.

The FDA has granted us Fast-Track Status and Orphan Drug Designation for Surfaxin for the treatment of ARDS in adults. The European Medicines Evaluation Agency has granted us orphan medical product designation for Surfaxin for the treatment of Acute Lung Injury in adults (which in this circumstance is a larger patient population that encompasses ARDS). We were awarded and received a $1 million Fast-Track Small Business Innovative Research Grant by the National Institutes of Health to develop Surfaxin for the treatment of ARDS and Acute Lung Injury in adults.

Aerosolized Surfactant (development name DSC 104) for Severe, Acute Asthma

Asthma is a common disease characterized by sudden constriction and inflammation of the lungs. Constriction of the upper airway system occurs when the airway muscles tighten while inflammation is a swelling of the airways usually due to an allergic reaction caused by an airborne irritant. Both of these events cause airways to narrow and may result in wheezing, shortness of breath and chest tightness. Several studies have shown that surfactant damage and dysfunction is a significant component of asthma -- airway constriction occurs when there is a surfactant dysfunction in the airways of the deep lung of the type that develops during an asthma attack. We believe that Surfactant Replacement Therapy has the potential to relieve the constriction in the airways associated with asthma.

According to information provided by the American Lung Association, asthma afflicts more than 20,000,000 people in the United States and its incidence rate continues to rise. Asthma is a chronic disease; it is prevalent in people of all ages and an estimated 12,000,000 people have experienced an asthma attack within the past year. In the United States alone, there are roughly 1,000,000 hospital outpatient visits, approximately 1,800,000 emergency room visits and 9,300,000 physician visits each year due to asthma. Asthma ranks within the top 10 prevalent activity-limiting health conditions costing $14 billion in United States healthcare costs annually.

Asthma may require life-long therapy to prevent or treat episodes. Ten percent of patients are considered severe asthmatics and require moderate to high doses of drugs. Currently available asthma medications include inhaled and oral steroids, bronchodilators and leukotriene antagonists. Bronchodilators cannot be used to control severe episodes or chronic, severe asthma. Oral steroids can cause serious side effects when used for prolonged periods and, thus, are typically limited to severe asthmatic episodes and chronic, severe asthma. We believe that supplying surfactant as an inhaled aerosol may relieve airway obstruction in the deep lung and lead to a more rapid improvement in asthmatic symptoms.

We recently completed a Phase 1b clinical trial to evaluate the safety and lung tolerability and deposition characteristics of our precision-engineered lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from asthma. This masked, placebo-controlled, randomized, Phase 1b study included six healthy subjects and eight mild-persistent asthmatic patients. Results demonstrated that DSC-104 was safe and well tolerated, did not induce bronchospasm and was deposited to both the central and peripheral regions of the lungs in the mild-persistent asthmatic group and the healthy volunteers. We are presently preparing a Phase 2 clinical trial which we expect to initiate in the first half of 2005 for patients with moderate to severe asthma (development name DSC-104).

Aerosolized Surfactant for Acute Lung Injury

Acute Lung Injury is associated with conditions that either directly or indirectly injure the air sacs of the lung. Acute Lung Injury is a syndrome of inflammation and increased permeability of the lungs with an associated breakdown of the lungs’ surfactant layer. The most serious manifestation of Acute Lung Injury is ARDS.

Among the causes of Acute Lung Injury are complications typically associated with certain major surgeries, mechanical ventilator induced lung injury (often referred to as VILI), smoke inhalation, pneumonia and sepsis. There are an estimated 1 million patients at risk in the United States for Acute Lung Injury annually and there are no currently-approved therapies.

We are evaluating aerosolized formulations of our precision-engineered surfactant to potentially treat Acute Lung Injury. We believe that our proprietary precision-engineered aerosol surfactant may be effective as a preventive measure for patients at risk for Acute Lung Injury. This prophylactic approach may result in fewer patients requiring costly intensive care therapy, thereby eliminating long periods of therapy and offering cost savings in the hospital setting.

Restructured Commercialization Arrangements

Quintiles

In November 2004, we reached an agreement with Quintiles Transnational Corp. to restructure our business arrangements and terminate our commercialization agreements for Surfaxin in the United States. We will now have full commercialization rights for Surfaxin in the United States. Under the commercialization agreement we entered into with Quintiles in 2001, Quintiles and its affiliates would have provided commercialization services for seven years post-launch, with an obligation to fund such services up to $10 million per year. Such services included the hiring and training by Quintiles of a dedicated United States sales force for Surfaxin that would have been branded as Discovery’s sales force in the market. Quintiles was entitled to a commission on net sales in the United States of Surfaxin for the treatment of RDS and Meconium Aspiration Syndrome for 10 years following launch. Pursuant to the restructuring, Quintiles is no longer obligated to provide any commercialization services and our obligation to pay a commission on net sales in the United States of Surfaxin for the treatment of RDS and Meconium Aspiration Syndrome to Quintiles has been terminated. In addition, we have entered into a three-year limited preferred-provider arrangement with Quintiles. See “Risk Factors - 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 to successfully commercialize Surfaxin or our other potential products, which could require us to give up rights to such products. Our limited sales and marketing experience may restrict our success in commercializing our product candidates.”

In connection with obtaining full commercialization rights for Surfaxin, we have entered into a warrant agreement pursuant to which we issued to QFinance, Inc., a Quintiles affiliate, a warrant to purchase 850,000 shares of our common stock at an exercise price equal to $7.19 per share. The warrant has a 10-year term and is exercisable for total proceeds equal to approximately $6 million in cash (or as an offset to cancel indebtedness of the Company to PharmaBio Development, Inc., Quintiles’ strategic investment affiliate, in connection with the existing secured revolving credit facility of $8.5 million. We expect to take a charge against earnings equal to approximately $4 million for the fourth quarter of 2004 in connection with the issuance of such warrant. The existing secured revolving credit facility of $8.5 million with PharmaBio will remain available to us and the original maturity date of December 10, 2004, is now extended until December 31, 2006. Amounts to be drawn down under the credit facility will remain available up to the date of the commercial launch of Surfaxin.

Esteve

On December 3, 2004, we restructured our strategic alliance with Laboratorios del Dr. Esteve S.A. for the development, marketing and sales of our products in Europe and Latin America. In this restructuring, we regained full commercialization rights for our Surfactant Replacement Therapies, including Surfaxin for RDS and ARDS in Central America, South America and most countries in Europe. Esteve retained the commercialization rights for Andorra, Greece, Italy (including the Republic of San Marino and the Vatican City), Portugal, and Spain. Under the restructured collaboration, Esteve will pay us a transfer price on sales of Surfaxin and our other Surfactant Replacement Therapies that is increased from those provided for in our previous collaborative arrangement. We will be responsible for the manufacture and supply of all of the covered products and Esteve will be responsible for all sales and marketing in the revised territory.

Esteve has also agreed to pay us stipulated cash fees upon our achieving certain milestones, primarily upon marketing regulatory approvals for the covered products. In addition, Esteve has agreed to contribute to Phase 3 clinical trials for the covered products, by conducting and funding development performed in the revised territory.

In consideration for regaining commercial rights in the restructuring, we issued to Esteve 500,000 shares of common stock for no cash consideration and granted to Esteve rights to additional potential Surfactant Replacement Therapy products in our pipeline. We expect to take a charge against earnings equal to approximately $4.2 million for the fourth quarter of 2004 in connection with the issuance of such shares. We also agreed to pay to Esteve 10% of cash up-front and milestone fees that we receive in connection with any future strategic collaborations for the development and commercialization of Surfaxin for RDS, ARDS or certain of our other Surfactant Replacement Therapies in the territory for which we had previously granted a license to Esteve. Any such up-front and milestone fees that we may pay to Esteve are not to exceed $20 million in the aggregate.

CORPORATE INFORMATION

Surfaxin® is our trademark. This prospectus may also include 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, Warrington, Pennsylvania 18976. Our telephone number is (215) 488-9300 and our facsimile number is (215) 488-9301.

RISK FACTORS

An investment in our common stock involves significant risks. You should carefully consider the risks described below and other information, including our financial statements and related notes previously included in our periodic reports filed with the Commission. 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 trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are those that we currently believe may materially affect us. Additional risks and uncertainties of which we are unaware or which we currently deem immaterial also may become important factors that affect us.

Because we are a biopharmaceutical 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 biopharmaceutical 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 September 30, 2004, we have an accumulated deficit of approximately $123 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, 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 Surfactant Replacement Therapy 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. Recently, we completed and filed an NDA with the FDA and a Marketing Authorization Application with the European Medicines Evaluation Agency based on results from a pivotal Phase 3 clinical trial and supportive Phase 3 clinical trial of our lead product, Surfaxin, for the prevention of RDS in premature infants. In addition, we are conducting a Phase 2 clinical trial for the treatment of ARDS in adults and a Phase 2 trial for the prevention of Meconium Aspiration Syndrome in full-term infants. We are preparing for the initiation of a Phase 2 clinical trial using aerosolized Surfactant Replacement Therapy via nasal continuous positive airway pressure (nasal CPAP) to potentially treat premature infants in the Neonatal Intensive Care Units suffering from neonatal respiratory failures, a Phase 2 clinical trial using Surfaxin for the prevention of BPD, and a Phase 2 trial using DSC-104 to treat patients with moderate to severe asthma.

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.

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 the second half of 2005. 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 our Committed Equity Financing Facility with Kingsbridge Capital Limited, our credit facility with PharmaBio Development, Inc., Quintiles' strategic investment affiliate, and our capital equipment lease financing arrangement with General Electric Capital Corporation. 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 "Risk Factors - 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 “Risk Factors - The market price of our stock may be adversely affected by market volatility”.

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

There are 15,375,000 shares of our common stock that are reserved for issuance under our Committed Equity Financing Facility arrangement with Kingsbridge Capital Limited, 375,000 of which are issuable under the warrant we granted to Kingsbridge. The number of shares that we may actually issue to Kingsbridge under the Committed Equity Financing Facility may be less than the shares so reserved as the amount of shares we may purchase under the Committed Equity Financing Facility is dependent on a formula that is based on the market value of our common stock at the time or times we access the Committed Equity Financing Facility. The issuance of shares of our common stock under the Committed Equity Financing Facility and upon exercise of the warrant will have a dilutive impact on other stockholders of the Company 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 Committed Equity Financing Facility, 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 Committed Equity Financing Facility. 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 Committed Equity Financing Facility 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 the Committed Equity Financing Facility and we may not be able to access any portion of the $75 million available under the Committed Equity Financing Facility. In addition, we are dependent upon the financial ability of Kingsbridge to fund the Committed Equity Financing Facility. Any failure by Kingsbridge to perform its obligations under the Committed Equity Financing Facility 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 our 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 European Medicines Evaluation Agency may not accept or approve an NDA or Marketing Authorization Application 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 has established February 13, 2005 as a target date for completion of the review. However, the FDA may not complete the review by such time or may reject the NDA. We have also submitted a Marketing Authorization Application with the European Medicines Evaluation Agency for clearance to market Surfaxin for the prevention and treatment of RDS in premature infants. The European Medicines Evaluation Agency has validated the Marketing Authorization Application indicating that the application is complete and that the review process has begun. However, the European Medicines Evaluation Agency may not complete the review or may reject the Marketing Authorization Application.

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. 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 2005, 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, Meconium Aspiration Syndrome 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 Meconium Aspiration Syndrome in full-term infants. To support our development of Surfaxin for the treatment of Meconium Aspiration Syndrome, 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 NDA for a drug granted Fast-Track Status within six months instead of the typical one to three years.

The European Medicines Evaluation Agency has granted Orphan Medicinal Product designation for three of our intended indications for Surfaxin: RDS in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury 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.

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 Pharma, L.P., our contract manufacturer, may not be able to produce Surfaxin to appropriate standards for use in clinical studies. A failure by Laureate to do so may delay or impair our ability to obtain regulatory approval for Surfaxin. See also “Risk Factors - 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.”

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.

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) perform under any definitive manufacturing agreements with us or (iii) 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. Although we own certain specialized manufacturing equipment, are considering an investment in additional manufacturing equipment and employ certain manufacturing managerial personnel, we do not presently maintain a complete manufacturing facility and we do not anticipate manufacturing on our own any of our products during the next 12 months. 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 current Good Manufacturing Practices (cGMPs) or similar requirements that the FDA or corresponding foreign regulators establish. Manufacturing or quality control problems could occur at the contract manufacturers causing product production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA’s current cGMP requirements 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.

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 collaboration arrangement with Esteve for Surfaxin and certain other of our Surfactant Replacement Therapy products covering Andorra, Greece, Italy (including the Republic of San Marino and the Vatican City), Portugal, and Spain. In such territories, Esteve will be responsible for the marketing and sales of Surfaxin for the prevention/treatment of RDS in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/ARDS in adults and certain of our other Surfactant Replacement Therapy products. Esteve will also be responsible for the sponsorship of certain clinical trials and related costs in each of such territories that are related to obtaining European Medicines Evaluation Agency approval for commercialization of Surfaxin and our other Surfactant Replacement Therapy products.

If Esteve or we breach or terminate the agreements that make up such collaboration arrangements or Esteve otherwise fails to conduct its Surfaxin-related activities in a timely manner or if there is a dispute about its 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 "Risk Factors - 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 “Risk Factors - If we cannot meet requirements under our license agreements, we could lose the rights to our products.”

Intellectual property rights of third parties could limit our ability to 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 Corporation. 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.

In addition, 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 to successfully commercialize Surfaxin or our other potential products, which could require us to give up rights to such products. Our limited sales and marketing experience may restrict our success in commercializing our product candidates.

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 team and related infrastructure, license some or all of such products to large pharmaceutical companies or enter into arrangements with others to market and sell our products. We are currently promoting Surfaxin in the United States through our own dedicated marketing and sales team. Recruiting, training and retaining qualified sales personnel are 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 on a commercial basis. Accordingly, we may be unable to establish marketing, sales and distribution capabilities necessary to commercialize and gain market acceptance for Surfaxin.

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 team, or if our internal sales and marketing team is unable to promote sufficient market awareness of our products, 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 of our other product candidates, will require a substantial capital investment. We expect to incur significant expenses in developing our internal marketing and sales team. Our ability to make such 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, if any. Accordingly, when required, we may not have the 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 marketing and sales team is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any such 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 Surfaxin or any other product candidates 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.

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 in certain territories outside of the United States through one or more marketing partners upon receipt of foreign approval in such territories. Our agreement with Esteve provides for collaborative efforts in directing a commercialization effort in Andorra, Greece, Italy (including the Republic of San Marino and the Vatican City), Portugal, and Spain, we have somewhat limited influence over the decisions made by Esteve or its sublicensees or the resources they devote to the marketing, sale and distribution of Surfaxin products in such territories, and Esteve may not be able to meet its obligations in this regard. Our marketing, sale and distribution arrangement with Esteve may not be successful, and we may not receive any revenues from it. Further, we may not be able to enter into distribution, 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.

If we fail to establish an internal marketing and sales capabilities or fail to enter into arrangements with third parties for territories not covered by the Esteve arrangements in a timely manner or if Esteve or they fail to perform, it will adversely affect sales of our Surfaxin and our other product candidates. We, Esteve and any of our third-party collaborators must also market our products in compliance with federal, state and local laws and regulations relating to the providing of incentives and inducements. Violation of these laws and regulations may result in substantial penalties. If we are unable to successfully motivate and expand our marketing and sales team and further develop our sales and marketing capabilities, or if our distributors fail to promote Surfaxin and our other product candidates, we will have difficulty maintaining and increasing our sales.

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. We have an employment agreement with Dr. Capetola that expires on December 31, 2005. We also have employment agreements with other key personnel with termination dates in 2005. 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 Meconium Aspiration Syndrome in full-term infants or Acute Lung Injury/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 treatment 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 treatment of RDS in premature infants. Although none of the four approved surfactants for RDS in premature infants is approved for Acute Lung Injury 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 treatment 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, 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 September 30, 2004, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 16% 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 challenge of our intellectual property rights;
— announcements of technological innovations by us or our competitors;
— announcements of new products or new contracts by us or our competitors;
— actual or anticipated variations in our operating results due to the level of development expenses and other factors;
— changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
— conditions and trends in the pharmaceutical and other industries;
— new accounting standards; and
— the occurrence of any of the risks described in these Risk Factors.

Our common stock is listed for quotation on the Nasdaq National Market. During the nine-month period ended September 30, 2004, the price of our common stock has ranged from $5.75 to $13.90. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ended September 30, 2004, the average daily trading volume in our common stock was approximately 537,000 shares and the average number of transactions per day was approximately 1,499. 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 our 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 December 10, 2004, we had 47,530,196 shares of common stock outstanding and up to approximately 9,689,619 shares of our common stock were issuable upon exercise of outstanding options and warrants. shares of our common stock were issuable upon exercise of outstanding options and warrants. In December 2003, we filed a Form S-3 shelf registration statement with the Commission for the proposed offering from time to time of up to 6,500,000 shares of common stock. Since the shelf registration statement was filed, we have sold 2,200,000 shares under the registration statement leaving 4,300,000 shares of our common stock available for us to sell in registered transactions under the shelf registration statement. We have no immediate plans to sell any securities under the shelf registration. However, subject to the effectiveness of the shelf registration statement, we may issue securities from time to time in response to market conditions or other circumstances on terms and conditions that will be determined at such time. Additionally, there are 15,000,000 shares of our common stock that are reserved for issuance under the Committed Equity Financing Facility arrangement with Kingsbridge. See “Risk Factors - Our Committed Equity Financing Facility may have a dilutive impact on our stockholders.

Holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our common stock.

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

Provisions of our Restated Certificate of Incorporation, as amended, our Shareholders Rights Agreement and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Restated Certificate of Incorporation, as amended, allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of our 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 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, including statements regarding the expectations, beliefs, intentions or strategies for the future. 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: the inherent risks and uncertainties in developing products of the type we are developing; delays in our preparation and filing of applications for regulatory approval; delays in the FDA’s or other health regulatory authorities’ approval or potential rejection of any applications we file, including the NDA we filed in April 2004 and the Marketing Approval Application 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 filed by us for any such drug product; possible changes in our financial condition; 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); clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture; timely obtaining sufficient patient enrollment in our clinical trials; the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research programs; our ability to enter into agreements with collaborators (including strategic alliances for our aerosol and Surfactant Replacement Therapies) and the failure of collaborators to perform under their agreements with us; 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; risks relating to the development of competing therapies and/or technologies by other companies; the progress of the regulatory approvals in connection with the conduct of our clinical trials and the marketing of our products; and the additional costs and delays which may result from requirements imposed by the health regulatory authorities in connection with obtaining the required approvals. 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. Those associated risks and other risks and uncertainties are detailed in “Risk Factors” and in any documents incorporated by reference in this registration statement.

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

USE OF PROCEEDS

We will not receive any proceeds from the sales of common stock by the selling stockholder pursuant to this prospectus. However, we may receive cash consideration from the exercise of the warrant owned by the selling stockholder, which proceeds are expected to be used for general corporate purposes.

SELLING STOCKHOLDER

In November 2004, we entered into a Warrant Agreement with the selling stockholder listed in the table set forth below. The table sets forth information with respect to the amount of common stock held by the selling stockholder as of December 10, 2004, and the shares being offered by the selling stockholder pursuant to this prospectus. This prospectus relates to the offer and sale of the selling stockholder of up to 850,000 shares of common stock issuable upon the exercise of a warrant issued by us. The selling stockholder may offer all or part of the shares of common stock covered by this prospectus. Information with respect to shares owned beneficially after the offering assumes the sale of all of the shares offered under this prospectus and no other purchases or sales of common stock. The common stock offered by this prospectus may be offered from time to time by the selling stockholder named below.

Name	Number of Shares of Common Stock, not including shares represented by Warrants, Beneficially Owned	Number of Shares Represented by Warrants Beneficially Owned	Total Number of Shares of Common Stock Beneficially Owned(1)	Percentage Beneficially Owned Before Offering(1)	Number of Shares to be Offered for the Account of the Selling Stockholder	Number of Shares to be Owned after this Offering, including shares represented by Warrants(1)	Percentage to be Beneficially Owned after this Offering(1)
QFinance, Inc.	1,567,741	893,612	2,461,353	5.08%	850,000	1,611,353	3.33%

* Less than 1%.

(1) The number of shares of common stock beneficially owned by the selling stockholder prior to the offering is deemed to include the 893,612 shares of common stock issuable upon the exercise of warrants held by such selling stockholder, 850,000 of which are being registered hereunder. The 850,000 shares of common stock are issuable upon exercise of a warrant which has a 10-year term and is exercisable upon the earlier to occur of FDA approval of Surfaxin for RDS or Meconium Aspiration Syndrome, on the one hand and May 2, 2005, on the other hand. The number of shares of common stock beneficially owned by the selling stockholder after the offering is deemed to include the 43,612 shares of common stock issuable upon the exercise of a warrant held by such selling stockholder, none of which are being registered hereunder.

The information contained in this table reflects "beneficial" ownership of common stock within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934. As of December 10, 2004, we had 47,530,196 shares of common stock outstanding. Beneficial ownership information reflected in the table includes shares issuable upon the exercise of outstanding warrants issued by us at their initial exercise prices.

The selling stockholder named in the preceding table has not had any position, office or other material relationship with us or any of our affiliates within the past three years, except for the relationship between its affiliates, Quintiles Transnational Corp. and PharmaBio Development, Inc., Quintiles' strategic investment affiliate, and us pursuant to a recently terminated commercialization arrangement and related matters. PharmaBio continues to be the provider of a secured revolving credit facility of $8.5 million that is expected to remain available to us until the commercial launch of Surfaxin and which will mature on December 31, 2006. In November 2004, we entered into an agreement that provides, among other things, for a limited preferred provider arrangement between us and PharmaBio.

PLAN OF DISTRIBUTION

We are registering shares of common stock covered by this prospectus on behalf of the selling stockholder, the beneficial owners of such shares. The selling stockholder and any of its pledgees, donees, assignees and successors-in-interest may offer and sell, at one time or from time to time, some or all of their shares. We have registered the shares for sale by the selling stockholder so that the shares will be freely tradable by it. Registration of the shares does not mean, however, that the shares necessarily will be offered or sold. We will not receive any proceeds from any offering or sale by the selling stockholder of the shares. We will pay customary costs, expenses and fees in connection with the registration of the shares. The selling stockholder will pay all brokerage commissions and similar selling expenses, if any, attributable to the sale of the shares and will reimburse us for up to $20,000 of our expenses.

The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale. We have been advised by the selling stockholder that the shares may be sold by or for the account of the selling stockholder at one time or from time to time in transactions on the Nasdaq National Market, the over-the-counter market or otherwise. These sales may be at fixed prices or prices that may be changed, at market prices prevailing at the time of sale, at prices related to these prevailing market prices or at negotiated prices. The shares may be sold by means of one or more of the following methods:

-- in a block trade in which a broker-dealer will attempt to sell a block of shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

-- purchases by a broker-dealer as principal and resale by that broker-dealer for its account pursuant to this prospectus;

-- on markets where our common stock is traded or in an exchange distribution in accordance with the rules of the exchange;

-- through broker-dealers, that may act as agents or principals;

-- directly to one or more purchasers;

-- through agents;

-- in connection with the loan or pledge of shares to a broker-dealer, and the sale of the shares so loaned or the sale of the shares so pledged upon a default;

-- in connection with put or call option transactions, in hedge transactions and in settlement of other transactions in standardized or over-the-counter options;

-- through short sales of the shares by the selling stockholder or counterparties to those transactions, in privately negotiated transactions; or

-- in any combination of the above. In addition, any of the shares that qualify for sale pursuant to Rule 144 under the Securities Act of 1933 may be sold under Rule 144 rather than pursuant to this prospectus provided they meet the criteria and conform to the requirements of such Rule.

In effecting sales, brokers or dealers engaged by the selling stockholder may arrange for other brokers or dealers to participate. The broker-dealer transactions may include:

-- purchases of the shares by a broker-dealer as principal and resales of the shares by the broker-dealer for its account pursuant to this prospectus;

-- ordinary brokerage transactions; or

-- transactions in which the broker-dealer solicits purchasers.

The selling stockholder and any broker-dealers or agents participating in the distribution of the shares may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act of 1933, and any profit on the sale of the shares by the selling stockholder and any commissions received by a broker-dealer or agents, acting in such capacity, may be deemed to be underwriting discounts or commissions under the Securities Act of 1933. The selling stockholder may agree to indemnify any agent or broker-dealer that participates in transactions involving sales of the shares against certain liabilities, including liabilities arising under the Securities Act of 1933.

The selling stockholder has advised us that it has not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of the shares, nor is there an underwriter or coordinating broker acting in connection with the proposed sale of the shares by the selling stockholder. If we are notified by the selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file, or cause to be filed, a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act of 1933, disclosing (i) the name of such selling shareholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus and (vi) other facts material to the transaction.

The selling stockholder is not restricted as to the price or prices at which it may sell its shares. Sales of the shares may have an adverse effect on the market price of the common stock. Moreover, the selling stockholder is not restricted as to the number of shares that may be sold at any time, and it is possible that a significant number of shares could be sold at the same time, which may have an adverse effect on the market price of the common stock.

INTERESTS OF NAMED EXPERTS AND COUNSEL

If and when offered, the validity of the securities being registered hereunder will be passed upon for us by Dickstein Shapiro Morin & Oshinsky LLP. Attorneys of Dickstein Shapiro Morin & Oshinsky LLP beneficially own shares of common stock and warrants to purchase additional shares of our common stock, the aggregate value of which exceeds $50,000.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Commission. One may read and copy any document we file at the Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549; the Commission's Midwest Regional Office at Citicorp Center, Suite 1400, 14th Floor, 500 West Madison Street, Chicago, Illinois 60601; and at the Commission's Northeast Regional Office at 233 Broadway, New York, New York 10279. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of our Commission filings are also available to the public from the Commission's Website at "http://www.sec.gov." We make available free of charge our annual, quarterly and current reports, proxy statements and other information upon request. To request such materials, please send an e-mail to ir@DiscoveryLabs.com or contact John G. Cooper, our Senior 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 Commission a registration statement (which contains this prospectus) on Form S-3 under the Securities Act relating to the shares of our common stock 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 the common stock. 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. One may read and obtain a copy of the registration statement and its exhibits and schedules from the Commission, as described in the preceding paragraph.

INFORMATION INCORPORATED BY REFERENCE

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

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2003;

2. Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2004, June 30, 2004, and September 30, 2004;

3. Our Current Reports on Form 8-K filed with the Securities and Exchange Commission on February 6, 2004, February 19, 2004, March 30, 2004, May 10, 2004, June 15, 2004, June 30, 2004, July 9, 2004, August 5, 2004, September 20, 2004, October 28, 2004, November 4, 2004 and December 9, 2004; and

4. The description of our capital stock contained in our Registration Statements on Form 8-A filed with the Securities and Exchange Commission on July 13, 1995, and February 6, 2004.

5. All documents we have filed with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the 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 Senior Vice President, Chief Financial Officer, at the following address or telephone number: Discovery Laboratories, Inc., 2600 Kelly Road, 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 Commission pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act 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 Commission 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.

This prospectus is part of a registration statement we filed with the Commission. One should rely only on the information contained in this prospectus. We have authorized no one to provide any different information. We are not making an offer of these securities in any state where the offer is not permitted. One should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document.

EXPERTS

The consolidated financial statements of Discovery Laboratories, Inc. (“Discovery”), appearing in Discovery’s Annual Report (Form 10-K) for the year ended December 31, 2003, have been audited by Ernst & Young LLP, 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 report given on the authority of such firm as experts in accounting and auditing.

LEGAL MATTERS

Our legal counsel, Dickstein Shapiro Morin & Oshinsky LLP, will render an opinion to the effect that the common stock issued pursuant to this prospectus, if at all, is duly and validly issued, fully paid and non-assessable.

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 SHARES OF DISCOVERY LABORATORIES, INC., COMMON STOCK 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.

850,000 Shares

Discovery LABORATORIES

COMMON STOCK

_________________, 2004

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth an estimate of the fees and expenses payable by us in connection with the registration of the common stock offered hereby. Normal commission expenses and brokerage fees are payable individually by the selling stockholder. All amounts are estimated except the Securities and Exchange Commission registration fee.

		Amount
Securities and Exchange Commission registration fee	$	848.88
Accounting fees and expenses	$	7,500.00
Legal fees and expenses	$	25,000.00
Miscellaneous fees and expenses	$	1,651.12
Total	$	35,000.00

We shall bear all expenses in connection with the issuance and distribution of the securities being offered hereby. However, the selling stockholder will reimburse us for up to $20,000 of our expenses.

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

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

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

We have entered into indemnification agreements with certain of our executive officers containing provisions that may require us, among other things, to indemnify them against liabilities that may arise by reason of their status or service as officers other than liabilities arising from willful misconduct of a culpable nature and to advance certain expenses incurred as a result of any proceeding against them as to which they could be indemnified. We have obtained limited directors’ and officers’ liability insurance. These provisions in our Restated Certificate of Incorporation, as amended, and our Bylaws do not eliminate the officers’ and directors’ fiduciary duty, and in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under Delaware law. In addition, each officer and director will continue to be subject to liability for breach of their duty of loyalty to us for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for actions leading to improper personal benefit to the officer or director and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provisions also do not affect an officer’s or director’s responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

Item 16. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.
3.2	Certificate of Amendment to the Certificate of Incorporation, dated May 28, 2004.
3.3	Amended and Restated Bylaws of Discovery, dated December 12, 2003.
3.4	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.
5.1	Opinion of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.
23.2	Consent of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel (included in Exhibit 5.1).
24.1	Powers of Attorney (included in Signature Pages to this Registration Statement on Form S-3).

ITEM 17. UNDERTAKINGS

We, the undersigned Registrant hereby undertake:

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

(i) Include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

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

(iii) Include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

provided, however, that paragraphs (i) and (ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the Registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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

(4) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(5) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(6) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(7) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirement of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Warrington, Commonwealth of Pennsylvania, on the 15th day of December, 2004.

DISCOVERY LABORATORIES, INC.
(Registrant)

By: /s/ Robert J. Capetola

Robert J. Capetola, Ph.D.
President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Robert J. Capetola, Ph.D., and David L. Lopez, C.P.A., Esq., or any of them, each acting alone, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person in his name, place and stead, in any and all capacities, in connection with the Registrant's Registration Statement on Form S-3 under the Securities Act of 1933, as amended, including, without limiting the generality of the foregoing, to sign the Registration Statement in the name and on behalf of the Registrant or on behalf of the undersigned as a director or officer of the Registrant, and any and all amendments or supplements to the Registration Statement, including any and all stickers and post-effective amendments to the Registration Statement, and to sign any and all additional registration statements relating to the same offering of securities as the Registration Statement that are filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission and any applicable securities exchange or securities self-regulatory body, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities indicated on the dates indicated.

Signature	Name & Title	Date
/s/ Robert J. Capetola	Robert J. Capetola, Ph.D. President, Chief Executive Officer and Director	December 15, 2004
/s/ John G. Cooper	John G. Cooper Executive Vice President and Chief Financial Officer	December 15, 2004
/s/ Cynthia Davis	Cynthia Davis Controller and Principal Accounting Officer	December 15, 2004
/s/ Herbert McDade	Herbert McDade, Jr. Chairman of the Board of Directors	December 15, 2004
/s/ W. Thomas Amick	W. Thomas Amick Director	December 15, 2004
/s/ Antonio Esteve	Antonio Esteve, Ph.D. Director	December 15, 2004
/s/ Max Link	Max Link, Ph.D. Director	December 15, 2004
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	December 15, 2004

Discovery Laboratories, Inc.
Form S-3
Index to Exhibits

Exhibit No.	Description
3.1(1)	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.
3.2(2)	Certificate of Amendment to the Certificate of Incorporation, dated May 28, 2004.
3.3(3)	Amended and Restated Bylaws of Discovery, dated December 12, 2003.
3.4(4)	Shareholder Rights Agreement, dated as of February 6, 2004, by and between Discovery and Continental Stock Transfer & Trust Company.
5.1	Opinion of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel.*
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.*
23.2	Consent of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel (included in Exhibit 5.1).*
24.1	Powers of Attorney (included in Signatures Page to this Registration Statement on Form S-3).*

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* Filed herewith.

(1) Incorporated by reference to Discovery's Annual Report on Form 10-K for the year ended December 31, 2002.

(2) Incorporated by reference to Discovery's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.

(3) Incorporated by reference to Discovery's Annual Report on Form 10-K for the year ended December 31, 2003.

(4) Incorporated by reference to Discovery's Current Report on form 8-K filed with the Commission on February 6, 2004
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Exhibit 5.1

[Letterhead of]
Dickstein Shapiro Morin & Oshinsky LLP
1177 Avenue of the Americas
New York, NY 10036

December 15, 2004

Board of Directors
Discovery Laboratories, Inc.
2600 Kelly Road
Warrington, PA 18976

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

Ladies and Gentlemen:

We have acted as counsel for Discovery Laboratories, Inc., a Delaware corporation (the "Company"), in connection with the preparation of the registration statement on Form S-3, and any amendments or supplements thereto (the "Registration Statement"), as filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933 (the "Act"), on December 15, 2004, for the registration under the Act of up to 850,000 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"),to be issued and sold by QFinance, Inc., and which are issuable upon the exercise of a warrant issued by the Company pursuant to that certain Warrant Agreement, dated as of November 3, 2004, by and between QFinance, Inc. and the Company (the “Warrant Agreement”). The Shares are to be offered for resale on a delayed or continuous basis pursuant to Rule 415 promulgated under the Act by the selling stockholder of the Company named in the Registration Statement.

In rendering this opinion, we have relied upon, among other things, our examination of certain records of the Company, including without limitation, the Company's Restated Certificate of Incorporation, as amended, the Company's Bylaws and resolutions of the Board of Directors. We have also examined certificates of the Company's officers and of public officials, and have reviewed such questions of law and made such other inquiries, as we have deemed necessary or appropriate for the purpose of rendering this opinion. As to various questions of fact material to this opinion, we have also relied upon representations and warranties of the Company and upon such certificates and other instruments of officers of the Company and public officials furnished to us by the Company, in each case without independent investigation or verification.

In addition, without any independent investigation or verification, we have assumed (i) the genuineness of all signatures, (ii) the authenticity of all documents submitted to us as originals and the conformity with the original documents of all documents submitted to us as certified, conformed or photostatic copies, (iii) the authority of all persons signing any document other than the officers of the Company, where applicable, signing in their capacity as such, (iv) the enforceability of all the documents we have reviewed in accordance with their respective terms against the parties thereto and (v) the truth and accuracy of all matters of fact set forth in all certificates and other instruments furnished to us.

Based on and subject to the assumptions, qualifications and limitations set forth herein, we are of the opinion that the Shares have been duly authorized by all necessary corporate action of the Company, and upon issuance, delivery and payment therefor in the manner contemplated by the Warrant Agreement, will be validly issued, fully paid and nonassessable.

We do not express any opinion as to the laws of any states or jurisdictions other than the laws of the State of New York and the General Corporation Law of the State of Delaware. No opinion is expressed as to the effect that the law of any other jurisdiction may have upon the subject matter of the opinion expressed herein under conflicts of law principles, rules and regulations or otherwise.

This opinion is limited to the specific issues addressed herein, and no opinion may be inferred or implied beyond that expressly stated herein. We assume no obligation to revise or supplement this opinion should the present laws of the State of New York or the state Constitution or the General Corporation Law of the State of Delaware be changed by legislative action, judicial decision or otherwise.

We hereby consent to the filing of this opinion with the Commission as Exhibit 5.1 to the Registration Statement and the reference to us under the heading "Legal Matters" in the prospectus included in Part I of the Registration Statement. In giving this consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act or the rules and regulations promulgated thereunder by the Commission.

This opinion is furnished to you in connection with the filing of the Registration Statement and is not to be used, circulated, quoted or otherwise relied upon for any other purposes.

We wish to call your attention to the fact that the fair market value of all securities of the Company that are beneficially owned by attorneys of this Firm exceeds $50,000.

Very truly yours,

/s/ Dickstein Shapiro Morin & Oshinsky LLP

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3 No. 333-00000) and related prospectus of Discovery Laboratories, Inc. to be filed on or about December 14, 2004 for the registration of approximately 850,000 shares of its common stock and to the incorporation by reference therein of our report dated February 13, 2004, with respect to the consolidated financial statements of Discovery Laboratories, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 2003, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
December 14, 2004