As filed with the Securities and Exchange Commission on December 19, 2003 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)

350 South Main Street, Suite 307 Doylestown, Pennsylvania 18901 (Address, Including Zip Code and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

> Robert J. Capetola, Ph.D. Chief Executive Officer 350 South Main Street, Suite 307 Doylestown, Pennsylvania 18901 (215) 340-4699

(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

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

Proposed Maximum Proposed Maximum Amount of
Offering Price Aggregate Offering Registratio
Per Share(1)(2) Price(2) Fee(1)(2) Offering Price Per Share(1)(2) Registration Title of Securities Title of Securities Amount to be to be Registered Registered(1) Amount to be Price(2) Fee(1)(2) Common Stock, \$.001 par value 6,500,000 \$9.58 \$62,270,000 \$5,037.64

- (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) Pursuant to paragraphs (c) and (h) of Rule 457 of the Securities Act the

proposed maximum offering price per share of such shares of common stock is estimated solely for the purpose of determining the registration fee. The actual offering price per share of the common stock being registered will be determined from time to time by the registrant in connection with the issuance by the registrant of the shares registered hereunder. The aggregate amount of the registrant's common stock registered hereunder that may be sold in an "at the market" offering for the account of the registrant may not exceed 10% of the aggregate market value of our common stock held by non-affiliates that which is permissible under Rule 415(a)(4) promulgated under the Securities Act.

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 COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

[SIDE LEGEND] The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the 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 19, 2003

6,500,000 Shares

[LOGO] Discovery Laboratories, Inc.

COMMON STOCK

This prospectus relates to the public offering of up to 6,500,000 shares of our common stock, par value \$.001 per share, which we may sell to underwriters or dealers, through agents or directly to investors.

Our common stock is quoted on the Nasdaq SmallCap Market under the trading symbol "DSCO." On December 12, 2003, the closing sales price of our common stock as reported by Nasdaq was \$9.70 per share.

AN INVESTMENT IN OUR COMMON STOCK INVOLVES SIGNIFICANT RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE 7.

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. This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using the "shelf" registration process. Under the shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings. This prospectus provides you with a general description of the securities we may offer. Each time we offer to sell securities pursuant to this registration statement and the prospectus contained herein, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in such prospectus supplement. 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 December $_$, 2003.

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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

We are a biopharmaceutical company applying our humanized lung surfactant technology to develop potential novel respiratory therapies and products. Surfactants are substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system. The absence or depletion of surfactants is involved in a number of respiratory diseases.

Our humanized surfactant technology produces an engineered version of natural human lung surfactant and contains a peptide, sinapultide, that was designed to precisely mimic the essential attributes of human lung surfactant protein B (SP-B). We believe that our proprietary surfactant technology is the only late stage surfactant technology presently available to potentially treat a broad range of respiratory diseases including Respiratory Distress Syndrome in adults and infants, asthma, chronic obstructive pulmonary disease (often referred to as COPD, which is a chronic condition of the lung that prevents enough oxygen from reaching the blood), Acute Lung Injury (often referred to as ALI), and upper airway disorders such as sinusitis (infection of the sinuses) and sleep apnea.

Surfaxin(R), our lead product, is being developed initially for critical care patients with life-threatening respiratory disorders where there are few, if any, approved therapies. We recently completed and announced successful top-line results from two Phase 3 clinical trials of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants. We are conducting further evaluation of secondary endpoints and safety parameters and are preparing to file a new drug application (NDA) with the United States Food and Drug Administration and other regulatory authorities throughout the world. Surfaxin is also currently in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults and a Phase 3 and Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants.

Aerosolized formulations of our humanized surfactant are presently being developed to potentially treat hospitalized patients suffering from respiratory diseases. We recently initiated a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant delivered as an inhaleable aerosol for the treatment of asthma. In addition, we believe that scientific rationale supports the development of aerosolized formulations of our humanized surfactant to potentially treat Acute Lung Injury, chronic obstructive pulmonary disorder (COPD), sinusitis sleep apnea and otitis media (inner ear infection).

We are presently developing a dedicated sales and marketing capability through a collaboration with Quintiles Transnational Corp. to commercialize Surfaxin for neonatal indications in the United States. We also have entered into a strategic alliance with Laboratorios del Dr. Esteve to commercialize Surfaxin in Europe and Latin America. We intend to establish additional strategic alliances, where appropriate, for the development and commercialization of our products in other indications and markets.

SURFACTANT TECHNOLOGY

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 alveoli. Surfactants facilitate respiration by continually modifying the surface tension of the fluid normally present within the alveoli 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 which include 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 Respiratory Distress Syndrome in premature infants, a condition in which infants are born with 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 Respiratory Distress Syndrome 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.

Our humanized 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 precisely mimic the essential attributes of human surfactant protein B (SP-B). We believe that our engineered humanized surfactant can be manufactured less expensively than the animal-derived surfactants, in sufficient quantities, in more exact and consistent pharmaceutical grade quality, and has little or 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. Our products also have the ability to be more precisely formulated, such as in the form of aerosolized liquids or dry powders, to address various medical indications. In addition, we believe that our engineered humanized 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").

Respiratory Distress Syndrome in Premature Infants

Respiratory Distress Syndrome is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. Premature infants born prior to 32 weeks gestation have not fully developed a natural lung surfactant and therefore need treatment to sustain life. This condition often results in the need for mechanical ventilation.

During 2003, we completed a pivotal Phase 3 clinical trial and a supportive Phase 3 clinical trial of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants. We intend to use the results from these trials to form the basis for an NDA and regulatory applications for approval in the rest of the world.

Our pivotal, multinational landmark Phase 3 trial achieved positive primary endpoint results and concluded enrollment in December 2003. The independent Data Safety Monitoring Board (DSMB) for this trial informed the study's Steering Committee that Surfaxin had achieved statistical significance in its co-primary endpoints versus Exosurf(R) (a non-protein containing synthetic surfactant). Survanta(R), a cow-derived surfactant, served as a reference arm in the trial.

Earlier this year, we concluded our successful supportive, multinational Phase 3 clinical trial comparing Surfaxin to a certain porcine (pig) derived surfactant for the treatment of Respiratory Distress Syndrome in premature infants.

RDS in premature infants affects over two million infants annually worldwide. Due to limitations associated with the animal-derived surfactant products that are currently approved to treat Respiratory Distress Syndrome in premature infants, therapy is mainly limited to those born in the United States and Western Europe. There are hundreds of thousands of premature babies 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 Respiratory Distress Syndrome. 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. We are also seeking Orphan Product designation from the European Medicines Evaluation Agency (the European Union's regulatory approval agency that is similar to the FDA) for Surfaxin for indications of Respiratory Distress Syndrome in premature infants.

Acute Respiratory Distress Syndrome in Adults

Acute Respiratory Distress Syndrome (often referred to as 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 presently conducting a Phase 2 open-label, controlled, multi-center clinical trial of Surfaxin for adults with Acute Respiratory Distress Syndrome. Approximately 110 patients will receive high concentrations of Surfaxin via our proprietary lavage technique that administers the drug sequentially through a tube, called a bronchoscope. The procedure is intended to cleanse and remove inflammatory substances and debris from the lungs, while leaving amounts of Surfaxin behind to help re-establish the lungs' capacity to absorb oxygen. The objective is to restore functional surfactant levels and to allow critically ill patients to be removed from mechanical ventilation.

We have completed Part A of this Phase 2 trial, a dose escalation safety and tolerability study in 22 patients in four groups (of up to six patients per group). In consultation with the trial's Independent Safety Review Committee, comprised of three prominent pulmonologists, we determined that the Part A portion of the trial procedure is generally safe and tolerable and that it was appropriate for us to proceed onto the larger safety and efficacy portion of the trial.

The last part of this Phase 2 trial, Part B, is designed to evaluate safety and efficacy of Surfaxin in direct comparison to the current standard of care and will be conducted at approximately 40 centers throughout the United States. The primary endpoint of Part B is to determine the incidence rate of patients surviving and off mechanical ventilation at the end of day 28 with one of the key secondary endpoints being mortality. We have recently entered into a manufacturing and technology transfer agreement with a new contract manufacturer for drug product for this trial. See "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."

The current standard of care for Acute Respiratory Distress Syndrome includes placing patients on mechanical ventilators in intensive care units at a cost approximately equal to \$8,500 per day, typically for an average of 21 to 28 days. There are estimated to be between 150,000 and 250,000 adults per year in the United States suffering from Acute Respiratory Distress Syndrome with similar numbers afflicted in Europe. Because there are no approved treatments for these diseases, the mortality rate can range from 35% to 50%.

The FDA has granted us Fast-Track Approval Status and Orphan Drug Designation for Surfaxin for the treatment of Acute Respiratory Distress Syndrome for adults. The European Medicines Evaluation Agency has granted us Orphan Product designation for Surfaxin for the treatment of Acute Lung Injury in adults (which in this circumstance encompasses Acute Respiratory Distress Syndrome). We were awarded a \$1 million Fast-Track Small Business Innovative Research Grant by the National Institutes of Health to develop Surfaxin for the treatment of Acute Respiratory Distress Syndrome and Acute Lung Injury in adults.

Meconium Aspiration Syndrome in Full-Term Infants

Meconium Aspiration Syndrome (often referred to as MAS) is a 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. This condition results in the infant's need for mechanical ventilation.

Surfaxin is being evaluated in a Phase 3 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants. To our knowledge, Surfaxin is the only product being developed worldwide to treat this syndrome. The trial is designed for the enrollment of up to 200 infants at medical centers throughout the United States to compare our proprietary Surfaxin lavage to the current standard of care. Enrollment has been slower than expected and resources have been reallocated from the MAS program to the RDS program to facilitate the completion of the follow-up phase and preparation and filing of the NDA for that indication.

We also have initiated a Phase 2 clinical trial of our proprietary Surfaxin lavage in up to 60 full-term infants for use as a prophylactic or in the early treatment for patients who are at risk for Meconium Aspiration Syndrome but have not shown symptoms of compromised respiratory function. 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 mechanical ventilation.

There are presently no drug therapies approved for the treatment of Meconium Aspiration Syndrome in full-term infants. An estimated 60,000 infants are born in the United States and Europe that require treatment for MAS, however, a significantly greater number of infants are born worldwide each year at risk for MAS. The FDA has granted us Fast-Track Approval Status and Orphan Drug Designation for Surfaxin for the treatment of Meconium Aspiration Syndrome in full-term infants. We have also received Orphan Product designation of Surfaxin for the treatment of Meconium Aspiration Syndrome from the European Medicines Evaluation Agency.

Our Aerosolized Humanized Surfactants for Respiratory Therapy

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 maintains the patency of the conducting airways.

We are currently developing aerosolized formulations of our humanized 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 for hospitalized patients suffering from severe acute asthma or Acute Lung Injury. For asthma, we recently initiated a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant delivered as an inhaleable aerosol. In addition, we believe that scientific rationale supports the development of aerosolized formulations of our humanized surfactant to potentially treat COPD, sinusitis, sleep apnea and otitis media (inner ear infection).

We are presently working with various aerosol devices towards achieving 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 of the lungs 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.

Asthma

We recently initiated a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from asthma. This single-blind, placebo-controlled, randomized, dose-escalation study, is being conducted at a pulmonary research facility and is designed to enroll 6 healthy subjects and up to 12 mild-persistent asthmatic patients. The primary study objective is to assess preliminary safety and tolerability as well as to establish the deposition characteristics of this aerosolized formulation of our surfactant technology.

Asthma is a common disease characterized by sudden constriction and inflammation of the lungs. Constriction of the upper airway system is caused by a tightening of airway muscles, while inflammation is a swelling of the airways usually due to an allergic reaction due to 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 obstruction 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 obstruction in the airways associated with asthma.

According to information provided by the American Lung Association, asthma afflicts approximately 20.3 million people in the United States and its incidence rate is rising. Asthma is a chronic disease; prevalent in people of all ages and an estimated 12 million people have experienced an asthma attack within the past year. In the United States alone, there are roughly 1 million hospital outpatient visits, approximately 1.8 million emergency room visits and 9.3 million 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 medications to treat and control asthma include inhaled and oral steroids and bronchodilators. Bronchodilators cannot be used to control severe episodes or chronic, severe asthma. Steroidal medications are used to address these conditions, however, steroids can cause serious side effects when used for prolonged periods. As a result, steroid use is typically limited to severe asthmatic episodes and chronic, severe asthma.

Several small scientific studies report that patients suffering from a severe, acute asthma attack were relieved when they inhaled aerosolized surfactant. We believe that supplying surfactant as an aerosol spray may be a simple and gentle way of relieving airway obstruction thereby augmenting currently available conventional asthma therapies and leading to a more rapid improvement in asthmatic symptoms.

Acute Lung Injury

Acute Lung Injury is associated with conditions that either directly or indirectly injure the air sacs of the lung, the alveoli. 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 Acute Respiratory Distress Syndrome.

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 believe that our proprietary humanized 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 and shorter periods of therapy - thus offering cost savings in the hospital setting.

CORPORATE INFORMATION

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

Our executive offices are located at 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901. Our telephone number is (215) 340-4699 and our facsimile number is (215) 340-3940.

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 SEC. If any of the factors or conditions summarized in the following risks actually occur, our business prospects, financial condition and results of operations could be materially harmed, the 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 development stage 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 developmental stage 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 these 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, 2003, we have incurred a deficit accumulated during the development stage of approximately \$88.2 million, and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

Our technology platform is based solely on our proprietary humanized, engineered surfactant technology and only our lead product candidate, Surfaxin, has been subject to clinical studies. Our ongoing clinical trials for Surfaxin and other product candidates based upon our Surfactant Replacement Technologies may be delayed, or fail, which will harm our business.

Our humanized, engineered surfactant platform technology is based on the scientific rationale for 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 announced top-line results from a pivotal Phase 3 clinical trial and supportive Phase 3 clinical trial with our lead product, Surfaxin, for the treatment of Respiratory Distress Syndrome in premature infants. In addition, we are conducting a Phase 2 clinical trial for Acute Respiratory Distress syndrome in adults and a Phase 3 and Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants. We recently initiated a Phase 1b clinical trial to evaluate the safety and tolerability of our humanized lung surfactant, delivered as an inhaled aerosol to treat individuals who suffer from 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 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 the credit facility with PharmaBio Development Inc., a subsidiary of Quintiles, 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.

Furthermore, we could cease to qualify for listing of our securities on the NASDAQ SmallCap 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."

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 its safety and effectiveness and confirmation by the FDA and comparable agencies in foreign countries that the manufacturer 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 may not approve an NDA filed by a pharmaceutical or biotechnology company for such drug product.

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 humanized surfactant-based therapy, Meconium Aspiration Syndrome in full-term infants and Acute Respiratory Distress Syndrome 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, Acute Respiratory Distress Syndrome in adults and Respiratory Distress Syndrome 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 New Drug Application for a drug granted Fast-Track Status within six months instead of the typical one to three years. 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. 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 and competitor's 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. We recently transferred our manufacturing capabilities from our single validated clinical manufacturing facility, owned and operated by Akorn, Inc., to a new contract manufacturer, Laureate Pharma, with the objective of producing appropriate clinical grade material of our drug substance that meet the standards for use in our ongoing clinical studies. Laureate Pharma 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, we have no validated clinical manufacturing facility to produce appropriate clinical grade material of our drug substance for use in our ongoing clinical studies.

Laureate Pharma or other outside manufacturers may not be able to (i) produce our drug substance to appropriate standards for use in clinical studies, (ii) perform under the definitive manufacturing agreement once such agreements are executed, if at all, 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 to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. 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 or manufacturing department 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 good manufacturing practices (GMPs) 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 GMP requirements necessary to continue manufacturing our drug substance. If our third-party foreign or domestic suppliers or manufacturers of our products, or, if we decide to manufacture our products on our own, we, fail to comply with GMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products.

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 covering all of Europe and Latin America. Esteve will be responsible for the marketing of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for commercialization

of Surfaxin in Europe for the Acute Lung Injury/Acute Respiratory Distress Syndrome indications. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to European Medicines Evaluation Agency filings.

We have entered into an exclusive collaboration arrangement in the United States with Quintiles, and its affiliate, PharmaBio, to commercialize, sell and market Surfaxin in the United States for indications of Respiratory Distress Syndrome and Meconium Aspiration Syndrome. As part of our collaboration with Quintiles, Quintiles will build a sales force solely dedicated to the sale of Surfaxin upon the approval of a New Drug Application for either of the two indications. If Quintiles and we fail to devote appropriate resources to commercialize, sell and market Surfaxin, sales of Surfaxin could be reduced. As part of the collaboration, PharmaBio is obligated to provide us with certain financial assistance in connection with the commercialization of Surfaxin, including, but not limited to, a secured, revolving credit facility for at least \$8.5 million which may be increased to \$10 million. A failure by us to repay amounts outstanding under the credit facility would have a material adverse effect on us. To obtain the benefits of such financing, we are obligated to meet certain development and performance milestones. The failure by us to meet the milestones or other terms and conditions of the financing leading to PharmaBio's termination thereof or the failure by PharmaBio to fulfill its obligation to partially fund the commercialization of Surfaxin, may affect our ability to successfully market Surfaxin.

If Esteve, Quintiles, PharmaBio or we breach or terminate the agreements that make up such collaboration arrangements or Esteve, Quintiles or PharmaBio otherwise fail to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their respective 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, Quintiles and/or PharmaBio have agreed to assist in commercializing. 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-Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales."

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, Inc., and 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 2020 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 arrangements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Johnson & Johnson and Ortho Pharmaceutical. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing arrangements. 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 this 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.

Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales.

We do not have marketing, sales or distribution experience or marketing or sales personnel. As a result, we will depend on our collaboration with Quintiles for the marketing and sales of Surfaxin for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants in the United States and with Esteve for the marketing and sales of Surfaxin for the treatment of Respiratory Distress Syndrome, Meconium Aspiration Syndrome and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in all of Europe and Latin America. See "Risk Factors-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." If we do not develop a marketing and sales force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products.

The sales and marketing of Surfaxin for indications of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in the relevant territories depends, in part, on Quintiles' and Esteve's performance of their contractual obligations. The failure of either party to do so would have a material adverse effect on the sales and marketing of Surfaxin. We may not succeed in entering into any satisfactory third party arrangements for the marketing and sale of our remaining products. In addition, we may not succeed in developing marketing and sales capabilities, our commercial launch of certain products may be delayed until we establish marketing and sales capabilities or we may not have sufficient resources to do so. If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties, either in a timely manner, it will adversely affect sales of our products.

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 from 2003 through 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 Meconium Aspiration Syndrome in full-term infants or Acute Lung Injury/Acute Respiratory Distress Syndrome 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 Respiratory Distress Syndrome in premature infants. Exosurf(R) 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. Curosurf(R) 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(R), 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(R) in the United States for the treatment of Respiratory Distress Syndrome in premature infants. Although none of the four approved surfactants for Respiratory Distress Syndrome in premature infants is approved for Acute Lung Injury or Acute Respiratory Distress Syndrome in adults, which are significantly larger markets, there are a significant number of other potential therapies in development for the treatment of Acute Lung Injury/Acute Respiratory Distress Syndrome that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered humanized surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products approved for the treatment of Respiratory Distress Syndrome in premature infants and will have no capability of transmitting the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease") or causing adverse immunological responses in young and older adults.

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

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

The clinical testing of, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to \$10,000,000 per occurrence and \$10,000,000 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, 2003, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 15% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

The market price of our common stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be

volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- -- announcements of the results of clinical trials by us or our competitors;
- --adverse reactions to products;
- -- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- --changes in the United States or foreign regulatory policy during the period of product development;
- --developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- --announcements of technological innovations by us or our competitors; --announcements of new products or new contracts by us or our competitors;
- --actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- --changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- --conditions and trends in the pharmaceutical and other industries;
- -- new accounting standards; and
- --the occurrence of any of the risks described in this "Management's Discussion and Analysis-Risk Factors."

Our common stock is listed for quotation on the NASDAQ SmallCap Market. Year to date through December 12, 2003, the price of our common stock has ranged from \$1.32 to \$10.27. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. Year to date through December 12, 2003, the average daily trading volume in our common stock was approximately 395,000 shares and the average number of transactions per day was approximately 697. 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 SmallCap Market. If the common stock were no longer listed on the SmallCap Market, investors might only be able to trade in the over-the-counter market in the Pink Sheets(R) (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board(R) 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 November 30, 2003, we had 42,378,483 shares of common stock outstanding. In addition, as of November 30, 2003, up to approximately 8,798,000 shares of our common stock were issuable upon exercise of outstanding options and warrants.

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

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval, including large blocks of preferred stock. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock.

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; 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(R), 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 and the failure of collaborators to perform under their agreements with us; the progress of the FDA 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 FDA in connection with obtaining the required approvals.

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

DESCRIPTION OF COMMON STOCK

General

This prospectus summarizes the general terms of our common stock. For a more detailed description of the common stock, you should read the applicable provisions of Delaware law and our restated certificate of incorporation and bylaws. Under our restated certificate of incorporation, the total number of shares of all classes of stock that we have authority to issue is 65,000,000, consisting of 60,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share.

Common Stock

This description of our common stock is a summary. You should keep in mind, however, that it is our restated certificate of incorporation and our bylaws, and not this summary, which defines any rights you may acquire as a shareholder. There may be other provisions in such documents which are also important to you. You should read such documents for a full description of the terms of our capital stock.

Subject to any preferential rights of any preferred stock created by our board of directors, as a holder of our common stock you are entitled to such dividends as our board of directors may declare from time to time out of funds that we can legally use to pay dividends. The holders of common stock possess exclusive voting rights, except to the extent our board of directors specifies voting power for any preferred stock that, in the future, may be issued.

As a holder of our common stock, you are entitled to one vote for each share of common stock and do not have any right to cumulate votes in the election of directors. In the event of our liquidation, dissolution or winding-up, you will

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

Preferred Stock

We currently have no outstanding shares of preferred stock. Under our certificate of incorporation, our board of directors is authorized to issue shares of our preferred stock from time to time, in one or more classes or series, without stockholder approval. Prior to the issuance of shares of each series, the board of directors is required by the General Corporation Law of the State of Delaware and our certificate of incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. Any exercise of our Board of Directors of its rights to do so may effect the rights and entitlements of the holders of our common stock as set forth above.

Anti-Takeover Provisions

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

- --prior to becoming an interested stockholder, our board of directors approves either the business combination or the transaction in which the stockholder becomes an interested stockholder;
- --upon consummation of the transaction in which the stockholder becomes an interested stockholder, the interested stockholder owns at least 85% of our voting stock outstanding at the time the transaction commenced, subject to exceptions; or
- --on or after the date a stockholder becomes an interested stockholder, the business combination is both approved by our board of directors and authorized at an annual or special meeting of our stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Number of Directors; Removal

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

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

Transfer Agent and Registrar

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

USE OF PROCEEDS

We will retain broad discretion over the use of the net proceeds from the sale of our common stock offered hereby. Except as described in any prospectus supplement or post effective amendment, we currently anticipate using the net proceeds from the sale of our common stock hereby primarily for clinical development of Surfaxin, as well as commercialization activities and general corporate and administrative purposes, including working capital and research and development expenses. In addition, we may use some of the net proceeds to hire additional personnel or to pursue internal manufacturing capabilities. The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our research and development efforts, technological advances and the competitive environment for Surfaxin and its intended uses. We might also use a portion of the net proceeds to acquire or invest in complementary businesses, products and technologies. Pending the application of the net proceeds, we expect to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

DILUTION

The net tangible book value of our common stock on September 30, 2003, was approximately \$31.6 million, or approximately \$0.75 per share. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the aggregate number of shares of common stock outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the sale of 6,500,000 shares of common stock in this offering at an assumed public offering price of \$9.58 per share, and after deducting estimated underwriting discounts and commissions and offering expenses, our net tangible book value at September 30, 2003 would have been approximately \$90.1 million, or approximately \$1.85 per share. This represents an immediate dilution of \$7.73 per share to new investors purchasing shares of common stock in this offering. The following table illustrates this dilution:

Assumed public offering price per share	\$ 9	.58
Net tangible book value per share as of September 30, 2003	\$ 0	.75
Increase per share attributable to new investors	1	10
Net tangible book value per share as of September 30, 2003 after giving effect to this offering	1	85
Dilution per share to new investors	\$ 7	.73

The foregoing table does not take into account further dilution to new investors that could occur upon the exercise of outstanding warrants and options having a per share exercise price less than the per share offering price to the public in this offering. As of September 30, 2003, there were 42,080,094 shares of common stock outstanding, which does not include:

- --5,678,323 shares of common stock issuable upon exercise of options outstanding as of September 30, 2003, at a weighted average exercise price of \$3.68 per share:
- --3,347,552 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2003 at a weighted average exercise price of \$5.41;
- --159,509 shares of common stock available for future grant under our Amended and Restated 1998 Employee Stock Option Plan and 150,000 shares of common stock available for future issuance under our 401(k) Plan, all as of September 30, 2003.

The above table does not reflect the expected reported loss for the last quarter of fiscal quarter 2003, which would increase the dilution per share.

PLAN OF DISTRIBUTION

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

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

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

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

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

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

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

Any underwriter may engage in over-allotment, stabilizing and syndicate short covering transactions and penalty bids in accordance with Regulation M of the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions involve bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate short covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. Penalty bids permit the underwriters to reclaim selling concessions from dealers when the shares originally sold by such dealers

are purchased in covering transactions to cover syndicate short positions. These transactions may cause the price of the shares sold in an offering to be higher than it would otherwise be. These transactions, if commenced, may be discontinued by the underwriters at any time.

Each issuance of shares offered under this prospectus will be a new issue of our common stock, which is currently listed on the Nasdaq SmallCap Market. Any shares of our common stock sold pursuant to a prospectus supplement will be listed on the Nasdaq SmallCap Market or on the exchange on which the stock offered is then listed, subject (if applicable) to official notice of issuance. Any underwriters to whom we sell shares for public offering and sale may make a market in the shares that they purchase, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

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

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

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

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 Securities and Exchange Commission. You may read and copy any document we file at the Securities and Exchange Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of our Securities and Exchange Commission filings are also available to the public from the Securities and Exchange 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 Securities and Exchange Commission a registration statement (which contains this prospectus) on Form S-3 under the Securities Act relating to the 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. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

INFORMATION INCORPORATED BY REFERENCE

The Securities and Exchange 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 Securities and Exchange Commission listed below:

- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2002, as amended by our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2002 filed on April 30, 2003;
- Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2003, June 30, 2003, and September 30, 2003;
- Our Current Reports on Form 8-K filed with the Securities and Exchange Commission on February 26, 2003, May 21, 2003, June 5, 2003, June 20, 2003, August 13, 2003, October 22, 2003, and November 25, 2003;
- 4. The description of our capital stock contained in our Registration Statement on Form 8-A filed with the Securities and Exchange Commission on July 13, 1995.
- 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., 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901, Attention: John G. Cooper; (215) 340-4699. 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 Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 after the date of this prospectus and prior to the termination of the offering shall be deemed to be incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of such reports and documents. This prospectus also incorporates by reference any documents that we file with the Securities and Exchange 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 SEC. You should rely only on the information contained in this prospectus. We have authorized no one to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the 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, 2002, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference, which, as to the period from May 18, 1993 (inception) through December 31, 1999, (not presented separately therein) is based on the report of Eisner LLP (formerly Richard A. Eisner & Co. LLP) independent auditors. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

LEGAL MATTERS

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.

6,500,000 Shares

[LOGO] Discovery Laboratories, Inc.

COMMON STOCK

December ___, 2003

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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 the registrant in connection with the registration of the common stock offered hereby. All of such fees expenses, except for the Registration Fee, are estimated:

	Amount
Securities and Exchange Commission registration fee	\$ 5,037.64
Accounting fees and expenses	\$ 10,000.00
Legal fees and expenses	\$ 70,000.00
Miscellaneous fees and expenses	\$ 20,000.00
Total	\$105,037.64

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

Item 15. Indemnification of Directors and Officers

Article Eighth of our Certificate of Incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for (i) any breach of their duty of loyalty to the corporation or its stockholders, (ii) acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the 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 the Certificate of Incorporation and the By-Laws do not eliminate the officers' and directors' fiduciary duty, and in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under Delaware law. In addition, each officer and director will continue to be subject to liability for breach of their duty of loyalty to us for acts or omissions not in good faith or involving intentional misconduct, for knowing

violations of law, for actions leading to improper personal benefit to the officer or director and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provisions also do not affect an officer's or director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

Item 16. Exhibits

3.1	Restated Certificate of Incorporation of Discovery, dated September 18, 2002.
3.2	Amended and Restated By-laws of Discovery, dated December 12, 2003.
5.1	Opinion of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel.
23.1	Consent of Ernst & Young LLP, independent auditors.
23.2	Consent of Eisner LLP independent auditors.
23.3	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:

Description

Exhibit No.

- (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 Doylestown, Commonwealth of Pennsylvania, on the 19th day of December, 2003.

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 19, 2003
/s/ John G. Cooper	John G. Cooper Senior Vice President and Chief Financial Officer	December 19, 2003
/s/Cynthia Davis	Cynthia Davis Controller and Principal Accounting Officer	December 19, 2003
/s/ Herbert McDade	Herbert McDade, Jr. Chairman of the Board of Directors	December 19, 2003
/s/ Max Link	Max Link, Ph.D. Director	December 19, 2003
/s/ Antonio Esteve	Antonio Esteve Director	December 19, 2003
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale Director	December 19, 2003

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	Amended and Restated By-laws of Discovery, dated December 12, 2003.*
5.1	Opinion of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel.*
23.1	Consent of Ernst & Young LLP, independent auditors.*
23.2	Consent of Eisner LLP independent auditors.*
23.3	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).*

^{*} Filed herewith.

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

AMENDED AND RESTATED
BY-LAWS OF
DISCOVERY LABORATORIES, INC.
(A Delaware Corporation)

ARTICLE I

Meetings of Stockholders

Section 1. Annual Meeting. The annual meeting of the stockholders of Discovery Laboratories, Inc. (the "Corporation"), for the election of directors and for the transaction of such other business as may come before the meeting shall be held at such date and time as shall be designated by the Board of Directors (the "Board"), the Chairman of the Board or the President.

Section 2. Special Meeting. Special meetings of the stockholders, unless otherwise prescribed by statute, may be called at any time by the Board, the Chairman of the Board or the Chief Executive Officer. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

Section 3. Notice of Meetings. Notice of the place, date and time of the holding of each annual and special meeting of the stockholders and, in the case of a special meeting, the purpose or purposes thereof shall be given personally or by mail in a postage prepaid envelope to each stockholder entitled to vote at such meeting, not less than 10 nor more than 60 days before the date of such meeting, and, if mailed, it shall be directed to such stockholder at his or her address as it appears on the records of the Corporation, unless such stockholder shall have filed with the Secretary of the Corporation a written request that notices to such stockholder be mailed to some other address, in which case it shall be directed to the stockholder at such other address. If mailed, such notice shall be deemed to be delivered when deposited in United States mail so addressed with postage thereon prepaid. Notice of any meeting of stockholders shall not be required to be given to any stockholder who shall attend such meeting in person or by proxy and shall not, at the beginning of such meeting, object to the transaction of any business because the meeting is not lawfully called or convened, or who shall, either before or after the meeting, submit a signed waiver of notice, in person or by proxy. Unless the Board shall fix after the adjournment a new record date for an adjourned meeting, notice of such adjourned meeting need not be given if the time and place to which the meeting shall be adjourned were announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which may have been transacted at the original meeting. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

Section 4. Place of Meetings. Meetings of the stockholders my be held at such place, within or without the State of Delaware, as the Board or other officer calling the same shall specify in the notice of such meeting, or in a duly executed waiver of notice thereof.

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Section 5. Quorum. At all meetings of the stockholders, the holders of a majority of the votes of the shares of stock of the Corporation issued and outstanding and entitled to vote shall be present in person or by proxy to constitute a quorum for the transaction of any business, except when stockholders are required to vote by class, in which event a majority of the issued and outstanding shares of the appropriate class shall be present in person or by proxy, or except as otherwise provided by statute or in the Corporation's Restated Certificate of Incorporation (the "Certificate of Incorporation"). In the absence of a quorum, the holders of a majority of the votes of the shares of stock present in person or by proxy and entitled to vote, or if no stockholder entitled to vote is present, then the chairman of the meeting, as set forth in Section 6 below, may adjourn the meeting from time to time. At any such adjourned meeting at which a quorum may be present, any business may be transacted which might have been transacted at the meeting as originally called.

Section 6. Organization. At each meeting of the stockholders, the Chairman of the Board, or in his absence or inability to act, the President, or in the absence or inability to act of the Chairman of the Board and the President or an Executive Vice President, or in the absence of all the foregoing, any person chosen by a majority of those stockholders present shall act as chairman of the meeting. The Secretary, or, in his absence or inability to act, the Assistant Secretary or any person appointed by the chairman of the meeting shall act as secretary of the meeting and keep the minutes thereof.

Section 7. Order of Business. The order of business at all meetings of the stockholders shall be as determined by the chairman of the meeting.

Section 8. Voting. Except as otherwise provided by statute, the Certificate of Incorporation or any certificate duly filed in the office of the Secretary of

State of the State of Delaware, each holder of record of shares of stock of the Corporation having voting power shall be entitled at each meeting of the stockholders to one vote for every share of such stock standing in his name on the record of stockholders of the Corporation on the date fixed by the Board as the record date for the determination of the stockholders who shall be entitled to notice of and to vote at such meeting; or if such record date shall not have been so fixed, then at the close of business on the day next preceding the day on which the meeting is held; or each stockholder entitled to vote at any meeting of stockholders may authorize another person or persons to act for him by a proxy signed by such stockholder or his attorney-in-fact. Any such proxy shall be delivered to the secretary of such meeting at or prior to the time designated in the order of business for so delivering such proxies. No proxy shall be valid after the expiration of three years from the date thereof, unless otherwise provided in the proxy. Every proxy shall be revocable at the pleasure of the stockholder executing it, except in those cases where an irrevocable proxy is permitted by law. Except as otherwise provided by statute, these Amended and Restated By-Laws (the "By-Laws"), or the Certificate of Incorporation, any corporate action to be taken by vote of the stockholders shall be authorized by a majority of the total votes, or when stockholders are required to vote by class by a majority of the votes of the appropriate class, cast at a meeting of stockholders by the holders of shares present in person or represented by proxy and entitled to vote on such action. Unless required by statute, or determined by the chairman of the meeting to be advisable, the vote on any question need not be by written ballot. On a vote by written ballot, each ballot shall be signed by the stockholder voting, or by his proxy, if there be such proxy, and shall state the number of shares voted.

candidates to elections of the Board of Directors or to fill vacancies, as applicable, shall be administered by the Company's Nomination Committee. For nominations for election to the Board or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely written notice thereof to the Secretary of the Company. In addition to other applicable requirements, to be timely, a notice of nominations or other business to be brought before an annual meeting of stockholders must be substantially in the form set forth below and delivered to the Secretary not later than the date set forth in the "Stockholder Proposals" section of the Proxy Statement delivered by the Company to its stockholders, and filed with the Securities and Exchange Commission, in connection with the preceding year's annual meeting. If the Company did not deliver a Proxy Statement in connection with the preceding year's annual meeting, such notice must be delivered not less than 120 nor more than 150 days prior to the first anniversary of the date of the Company's proxy statement delivered to stockholders in connection with the preceding year's annual meeting; provided, that if (A) the date of an annual meeting is more than 30 days before or more than 60 days after such anniversary, or (B) no proxy statement was delivered to stockholders by the Company in connection with the preceding year's annual meeting, all notices must be delivered not earlier than 90 days prior to such annual meeting and not later than the later of (i) 60 days prior to the annual meeting or (ii) 10 days following the date on which public announcement of the date of such annual meeting is first made by the Company. With respect to special meetings of stockholders, such notice must be delivered to the Secretary not more than 90 days prior to such meeting and not later than the later of (i) 60 days prior to such meeting or (ii) 10 days following the date on which public announcement of the date of such meeting is first made by the Company. Any stockholder delivering notice to the Secretary under this Section 9, Article I must be a stockholder of record on the date such notice is delivered. The Secretary shall deliver the notice to the Nomination Committee. No stockholder nominee may be a candidate for election at any meeting of stockholders or otherwise elected to fill a vacancy in the Board unless such person has been approved by the Nomination Committee and was nominated in accordance with the procedures set forth in this Section 9, Article I. If the facts warrant, the Board, or the chairman of a stockholders meeting at which Directors are to be elected may determine and declare that a nomination was not made in accordance with the foregoing procedure and, if it is so determined, no election may be made with respect to such nominee. The right of stockholders to make nominations pursuant to the foregoing procedure is subject to the superior rights, if any, of the holders of any class or series of stock having a preference over the common stock. The procedures set forth in this Section 9 of Article I for nomination for the election of Directors by stockholders are in addition to, and not in limitation of, any procedures now in effect or hereafter adopted by or at the direction of the Board or any committee thereof.

Section 9. Nominations. The procedures governing stockholder nominees of

If a stockholder attempts to nominate a candidate to the Board and complies with the procedure set forth in this Section 9, Article I but the Nomination Committee rejects such stockholder's nomination, such stockholder may nominate such candidate notwithstanding the decision of the Nomination Committee at the next election of Directors after such candidate was rejected by the Nomination Committee if such stockholder delivers to the Secretary written requests that such person be nominated to the Board from stockholders holding at least 50% of the eligible votes as of the record date of such election.

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To be in proper written form, each such notice to the Secretary delivered in connection with a stockholder nomination must set forth as to each person whom the stockholder proposes to nominate for election as a director:

- (i) the name, age, business address and residence address of the person;
- (ii) the principal occupation or employment of the person;
- (iii) the class or series and number of shares of capital stock of the Company that are owned beneficially or of record by the person; and
- (iv) any other information relating to the person that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of Directors pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder.

Each such notice to the Secretary must also set forth as to the stockholder giving the notice:

- (i) the name and record address of such stockholder;
- (ii) the class or series and number of shares of capital stock of the Company that are owned beneficially or of record by such stockholder;
- (iii) a description of all arrangements or understandings between such stockholder and each proposed nominee and any other person or persons (including their names) pursuant to which the nomination(s) are to be made by such stockholder;
- (iv) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the persons named in its notice; and
- (v) any other information relating to such stockholder that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of Directors pursuant to Section 14 of the Securities Exchange Act of 1934 (the "Exchange Act") and the rules and regulations promulgated thereunder.

All notices delivered to the Secretary in connections must be accompanied by a written consent of each proposed nominee to being named as a nominee and to serve as a Director if elected.

Section 10. Stockholder Proposals. The procedures governing stockholder proposals of business to be conducted at meetings of stockholders shall be administered by the Company's Nomination Committee. At any meeting of the stockholders, only such business shall be conducted as shall have been properly brought before such meeting. To be properly brought before a meeting, business must be: (a) as specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board; (b) otherwise properly brought before the meeting by or at the direction of the Board; or (c) otherwise properly brought before the meeting by a stockholder. For business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely written notice thereof to the Secretary of the Company. In addition to other applicable requirements set forth in the Exchange Act, to be timely, a notice of other business to be brought before an annual meeting of stockholders must be substantially in the form set forth below and delivered to

the Secretary not later than the date set forth in the "Stockholder Proposals" section of the Proxy Statement delivered by the Company to its stockholders, and filed with the Securities and Exchange Commission, in connection with the preceding year's annual meeting. If the Company did not deliver a Proxy Statement in connection with the preceding year's annual meeting, such notice must be delivered not less than 120 nor more than 150 days prior to the first anniversary of the date of the Company's proxy statement delivered to stockholders in connection with the preceding year's annual meeting; provided, that if (A) the date of an annual meeting is more than 30 days before or more than 60 days after such anniversary, or (B) no proxy statement was delivered to stockholders by the Company in connection with the preceding year's annual meeting, all notices must be delivered not earlier than 90 days prior to such annual meeting and not later than the later of (i) 60 days prior to the annual meeting or (ii) 10 days following the date on which public announcement of the date of such annual meeting is first made by the Company. With respect to special meetings of stockholders, such notice must be delivered to the Secretary not more than 90 days prior to such meeting and not later than the later of (i) 60 days prior to such meeting or (ii) 10 days following the date on which public announcement of the date of such meeting is first made by the Company. Any stockholder delivering notice to the Secretary under this Section 10 of Article I must be a stockholder of record on the date such notice is delivered. The Nomination Committee must approve each stockholder proposal of other business before such proposal may be voted on at any meeting of stockholders or otherwise. No stockholder proposal of other business before such proposal may be voted on at any meeting of stockholders or otherwise unless such proposal was approved in accordance with the procedures set forth in this Section 10 of Article I. The procedures set forth in this Section 10 of Article I for nomination for the election of Directors by stockholders are in addition to, and not in limitation of, any procedures now in effect or hereafter adopted by or at the direction of the Board or any committee thereof. If the chairman of a meeting of stockholders determines that business was not properly brought before the meeting in accordance with the foregoing procedures, the chairman shall declare to the meeting that the business was not properly brought before the meeting and such business shall not be transacted.

To be in proper written form, a stockholder's notice to the Secretary must set forth as to each matter such stockholder proposes to bring before the meeting:

- (i) a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting;
- (ii) the name and record address of such stockholder;
- (iii) the class or series and number of shares of capital stock of the Company that are owned beneficially or of record by such stockholder;
- (iv) a description of all arrangements or understandings between such stockholder and any other person or persons (including their names) in connection with the proposal of such business by such stockholder and any material interest of such stockholder in such business;
- (v) a representation that such stockholder intends to appear in person or by proxy at the meeting to bring such business before the meeting; and
- (vi) any other information that is required by law to be provided by the stockholder in his capacity as proponent of a stockholder proposal.

Section 11. List of Stockholders. The officer who has charge of the stock ledger of the Corporation, or the transfer agent of the Corporation's stock, if there be one then acting, shall prepare and make, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least 10 days prior to the meeting, either at a place within the city where the meeting is to be held, at the place where the meeting is to be held or at the office of the transfer agent. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.

Section 12. Inspectors. The Board may, in advance of any meeting of stockholders, appoint one or more inspectors to act at such meeting or any adjournment thereof. If the inspectors shall not be so appointed or if any of them shall fail to appear or act, the chairman of the meeting may, and on the request of any stockholder entitled to vote thereat shall, appoint inspectors. Each inspector, before entering upon the discharge of his duties, shall take and sign an oath faithfully to execute the duties of inspector at such meeting with strict impartiality and according to the best of his ability. The inspectors shall determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting, the existence of a quorum, the validity and effect of proxies, and shall receive votes, ballots or consents, hear and determine all challenges and questions arising in connection with the right to vote, count and tabulate all votes, ballots or consents, determine the result, and do such acts as are proper to conduct the election or vote with fairness to all stockholders. Upon the request of the chairman of the meeting or any stockholder entitled to vote thereat, the inspectors shall make a report in writing of any challenge, request or matter determined by them and shall execute a certificate of any fact found by them. No director or candidate for the office of director shall act as inspector of an election of directors. Inspectors need not be stockholders.

Section 13. Consent of Stockholders in Lieu of Meeting. Unless otherwise provided in the Certificate of Incorporation, any action required by Subchapter VII of the General Corporation Law of the State of Delaware, to be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the corporation by delivery to its registered office in this State, its principal place of business, or an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to a corporation's registered office shall be by hand or by certified or registered mail, return receipt requested.

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ARTICLE II

Board Of Directors

Section 1. General Powers. The business and affairs of the Corporation shall be managed by the Board. The Board may exercise all such authority and powers of the Corporation and do all such lawful acts and things as are not by statute or the Certificate of Incorporation or by these By-Laws directed or required to be exercised or done by the stockholders.

Section 2. Number, Qualifications, Elections and Term of Office. The number of directors of the Corporation ("Directors") shall be fixed from time to time by the vote of a majority of the entire Board then in office and the number thereof may thereafter by like vote be increased or decreased to such greater or lesser number (not less than three) as may be so provided, subject to the provisions of Section 11 of this Article II. All of the Directors shall be of full age and need not be stockholders. Except as otherwise provided by statute or these By-Laws, the Directors shall be elected at the annual meeting of the Stockholders for the election of Directors at which a quorum is present, and the persons receiving a plurality of the votes cast at such meeting shall be elected. Each Director shall hold office until the next annual meeting of the stockholders and until his successors shall have been duly elected and qualified, or until such Director's death, or until such Director shall have resigned, or have been removed, as hereinafter provided in these By-Laws, or as otherwise provided by statute or the Certificate of Incorporation.

Section 3. Place of Meetings. Meetings of the Board may be held at such place, within or without the State of Delaware, as the Board may from time to time determine or as shall be specified in the notice or waiver of notice of such meeting.

Section 4. Annual Meeting. The Board shall meet for the purpose of organization, the election or appointment of officers and the transaction of other business, as soon as practicable after each annual meeting of the stockholders, on the same day and at the same place where such annual meeting shall be held. Notice of such meeting need not be given. Such meeting may be held at any other time or place (within or without the State of Delaware) which shall be specified in a notice thereof given as hereinafter provided in Section 7 of this Article II.

Section 5. Regular Meetings. Regular meetings of the Board shall be held at such time and place as the Board may from time to time determine. If any day fixed for a regular meeting shall be a legal holiday at the place where the meeting is to be held, then the meeting which would otherwise be held on that day shall be held at the same hour on the next succeeding business day. Notice of regular meetings of the Board need not be given except as otherwise required by statute or these By-Laws.

Section 6. Special Meetings. Special meetings of the Board may be called by the Chairman of the Board, two or more directors or the President of the Corporation.

Section 7. Notice of Meetings. Notice of each special meeting of the Board (and of each regular meeting for which notice shall be required) shall be given by the Secretary as hereinafter provided in this Section 7 of Article II, in which notice shall be stated the time and place (within or without the State of Delaware) of the meeting. Notice of each such meeting shall be delivered to each Director either personally or by telephone, telegraph, cable or wireless, at least 24 hours before the time at which such meeting is to be held or by first-class mail, postage prepaid, addressed to him at his residence, or usual place of business, at least three days before the day on which such meeting is to be held. If mailed, such notice shall be deemed to be delivered when deposited in the United States mail. Notice of any such meeting need not be given to any director who shall, either before or after the meeting, submit a signed waiver of notice or who shall attend such meeting without protesting, prior to or at its commencement, the lack of notice to him. Except as otherwise specifically required by these By-Laws, a notice or waiver of notice of any regular or special meeting need not state the purposes of such meeting.

Section 8. Quorum and Manner of Acting. A majority of the entire Board shall be present in person at any meeting of the Board in order to constitute a quorum for the transaction of business at such meeting, and, except as otherwise expressly required by statute or the Certificate of Incorporation, the act of a majority of the Directors present at any meeting at which a quorum is present shall be the act of the Board. Any one or more members of the Board or any committee thereof may participate in a meeting of the Board or such committee by means of a conference telephone or similar communications equipment allowing all participants in the meeting to hear each other at the same time and participation by such means shall constitute presence in person at a meeting. In the absence of a quorum at any meeting of the Board, a majority of the directors present thereat, or if no director be present, the Secretary, may adjourn such meeting to another time and place, or such meeting, unless it be the annual meeting of the Board, need not be held. At any adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally called. Except as provided in Article III of these By-Laws, the directors shall act only as a Board and the individual directors shall have no power as such.

Section 9. Organization. At each meeting of the Board, the Chairman of the Board (or, in his or her absence or inability to act, the President, or, in his or her absence or inability to act, another Director chosen by a majority of the Directors present) shall act as chairman of the meeting and preside thereat. The Secretary (or, in his or her absence or inability to act, any person appointed by the chairman of the meeting) shall act as secretary of the meeting and keep the minutes thereof.

Section 10. Resignations. Any Director may resign at any time by giving written notice of his resignation to the Board, the Chairman of the Board, the President or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time when it shall become effective shall not be specified therein, immediately upon its receipt; and unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

Section 11. Vacancies. Vacancies, including newly created directorships, may be filled by the decision of majority of the Directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this Section for the filling of other vacancies.

Section 12. Removal of Directors. Except as otherwise provided in the Certificate of Incorporation or in these By-Laws, any Director may be removed, either with or without cause, at any time, by the affirmative vote of a majority of the votes of the issued and outstanding shares of stock entitled to vote for the election of the stockholders called and held for that purpose, or by a majority vote of the Board at a meeting called for such purpose, and the vacancy in the Board caused by any such removal may be filled by such stockholders or Directors, as the case may be, at such meeting, and if the stockholders shall fail to fill such vacancy, such vacancy shall be filled in the manner as provided by these By-Laws.

Section 13. Compensation. The Board shall have authority to fix the compensation, including fees and reimbursement of expenses, of Directors for services to the Corporation in any capacity, provided no such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor.

Section 14. Action by the Board. To the extent permitted under the laws of the State of Delaware, any action required or permitted to be taken at any meeting of the Board or of any committee thereof may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing, and the writing or writings are filed with the minutes of the proceedings of the Board or committee.

ARTICLE III

Executive and Other Committees

Section 1. Executive and Other Committees. The Board may, by resolution passed by a majority of the whole Board, designate one or more committees, each committee to consist of two or more of the directors of the Corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the Committee. Any such committee, to the extent provided in the resolution, shall have and may exercise the powers of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it, provided, however, that in the absence or disqualification of any member of such committee or committees, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Each committee shall keep minutes of its proceedings and shall, report such minutes to the Board when required. All such proceedings shall be subject to revision or alteration by the Board; provided, however, that third parties shall not be prejudiced by such revision or alteration.

Section 2. General. A majority of any committee may determine its action and fix the time and place of its meetings, unless the Board shall otherwise provide. Notice of such meetings shall be given to each member of the committee in the manner provided for in Article II, Section 7. The Board shall have the power at any time to fill vacancies in, to change the membership of, or to dissolve any such committee. Nothing herein shall be deemed to prevent the Board from appointing one or more committees consisting in whole or in part of persons who are directors of the Corporation; provided, however, that no such committee shall have or may exercise any authority of the Board.

ARTICLE IV

Officers

Section 1. Number and Qualifications. The officers of the Corporation shall include the Chairman of the Board, the President, one or more Vice Presidents (one or more of whom may be designated an Executive Vice President or a Senior Vice President), the Treasurer and the Secretary. Any two or more offices may be held by the same person. Such officers shall be elected or appointed from time to time by the Board, each to hold office until the meeting of the Board following the next annual meeting of the stockholders, or until his or her successor shall have been duly elected or appointed and shall have qualified, or until such Officer's death, or until such Officer shall have resigned, or have been removed, as hereinafter provided in these By-Laws. The Board may from time to time elect a Vice Chairman of the Board, and the Board may from time to time elect, or the Chairman of the Board, or the President may appoint, such other officers (including one or more Assistant Vice Presidents, Assistant Secretaries and Assistant Treasurers), as may be necessary or desirable for the business of the Corporation. Such other officers and agents shall have such duties and shall hold their offices for such terms as may be prescribed by the Board or by the appointing.

Section 2. Resignation. Any officer of the Corporation may resign at any time by giving written notice of his resignation to the Board, the Chairman of the Board, the President or the Secretary. Any such resignation shall take effect at the time specified therein or, if the time when it shall become effective shall not be specified therein, immediately upon its receipt; and unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

Section 3. Removal. Any officer or agent of the Corporation may be removed, either with or without cause, at any time, by the vote of the majority of the entire Board at any meeting of the Board or, except in the case of an officer or agent elected or appointed by the Board, by the Chairman of the Board or the President. Such removal shall be without prejudice to the contractual rights, if any, of the person so removed.

Section 4. Vacancies. A vacancy in any office, whether arising from death, disability, resignation, removal or any other cause, may be filled for the unexpired portion of the term of the office which shall be vacant, in the manner prescribed in these By-Laws for the regular election or appointment to such office.

Section 5. a. The Chairman of the Board. The Chairman of the Board, if one be elected, shall, if present, preside at each meeting of the stockholders and of the Board and shall be an ex officio member of all committees of the Board. He shall perform all duties incident to the office of Chairman of the Board and such other duties as may from time to time be assigned to him by the Board.

b. The Vice Chairman of the Board. The Vice Chairman of the Board, if one be elected, shall have such powers and perform all such duties as from time to time may be assigned to him by the Board or the Chairman of the Board and, unless otherwise provided by the Board, shall in the case of the absence or inability to act of the Chairman of the Board, perform the duties of the Chairman of the Board and when so acting shall have all the powers of, and be subject to all the restrictions upon, the Chairman of the Board.

Section 6. The President. The President shall be the chief executive officer of the Corporation and shall have general and active supervision and direction over the business and affairs of the Corporation and over its several officers, subject, however, to the direction of the Chairman of the Board and the control of the Board. If no Chairman of the Board is elected or at the request of the Chairman of the Board, or in the case of his absence or inability to act, unless there be a Vice Chairman of the Board so designated to act, the President shall perform the duties of the Chairman of the Board and when so acting shall have all the powers of, and be subject to all the restrictions upon, the Chairman of the Board. He shall perform all duties incident to the office of President and such other duties as from time to time may be assigned to him by the Board or the Chairman of the Board.

Section 7. Vice Presidents. Each Executive Vice President, each Senior Vice President and each Vice President shall have such powers and perform all such duties as from time to time may be assigned to such person by the Board, the Chairman of the Board or the President. They shall in the order of their seniority, have the power and may perform the duties of the Chairman of the Board and the President.

Section 8. The Treasurer. The Treasurer shall exercise general supervision over the receipt, custody and disbursement of corporate funds. He or she shall have such further powers and duties as may be conferred upon him from time to time by the President or the Board of Directors. He or she shall perform the duties of controller if no one is elected to that office.

Section 9. The Secretary. The Secretary shall:

- (a) keep or cause to be kept in one or more books provided for the purpose, the minutes of all meetings of the Board, the committees of the Board and the stockholders;
- (b) see that all notices are duly given in accordance with the provisions of these By-Laws and as required by law;
- (c) be custodian of the records and the seal of the Corporation and affix and attest the seal to all stock certificates of the Corporation (unless the seal be a facsimile, as hereinafter provided) and affix and attest the seal to all other documents to be executed on behalf of the Corporation under its seal;

- (d) see that the books, reports, statements, certificates and other documents and records required by law to be kept and filed are properly kept and filed; and
- (e) in general, perform all the duties incident to the office of Secretary and such other duties as from time to time may be assigned to him by the Board, the Chairman of the Board, or the President.

Section 10. Officer's Bonds or Other Security. If required by the Board, any officer of the Corporation may be required to give a bond or other security for the faithful performance of his duties, in such amount and with such surety or sureties as the Board may require.

Section 11. Compensation. The compensation of the officers of the Corporation for their services as such officers shall be fixed from time to time by the Board; provided, however, that the Board may delegate to the Chairman of the Board or the President the power to fix the compensation of officers and agents appointed by the Chairman of the Board or the President, as the case may be. An officer of the Corporation shall not be prevented from receiving compensation by reason of the fact that he is also a director of the Corporation, but any such officer who shall also be a Director shall not have any vote in the determination of the amount of compensation paid to him.

ARTICLE V

Indemnification

The Corporation shall, to the fullest extent permitted by the laws of the state of Delaware, indemnify any and all persons whom it shall have power to indemnify against any and all of the costs, expenses, liabilities or other matters incurred by them by reason of having been officers or Directors of the Corporation, any subsidiary of the Corporation or of any other corporation for which such person acted as officer or director at the request of the Corporation.

ARTICLE VI

Contracts, Checks, Drafts, Bank Account, Etc.

Section 1. Execution of Contracts. Except as otherwise required by statute, the Certificate of Incorporation or these By-Laws, any contracts or other instruments may be executed and delivered in the name and on behalf of the Corporation by such officer or officers (including any assistant officer) of the Corporation as the Board may, from time to time, direct. Such authority may be general or confined to specific instances as the Board may determine. Unless authorized by the Board or expressly permitted by these By-Laws, an officer or agent or employee shall not have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it pecuniarily liable for any purpose or to any amount.

Section 2. Loans. Unless the Board shall otherwise determine, either (a) the Chairman of the Board, the Vice Chairman of the Board or the President, singly, or (b) a Vice President, together with the Treasurer, may effect loans and advances at any time for the Corporation or guarantee any loans and advances to any subsidiary of the Corporation, from any bank, trust company or other institution, or from any firm, corporation or individual, and for such loans and advances way make, execute and deliver promissory notes, bonds or other certificates or evidences of indebtedness of the Corporation, or guarantee of indebtedness of subsidiaries of the Corporation, but no officer or officers shall mortgage, pledge, hypothecate or transfer any securities or other property of the Corporation, except when authorized by the Board.

Section 3. Checks, Drafts, Etc. All checks, drafts, bills of exchange or other orders for the payment of money out of the funds of the Corporation, and all notes or other evidences of indebtedness of the Corporation, shall be signed in the name and on behalf of the Corporation by such persons and in such manner as shall from time to time be authorized by the Board.

Section 4. Deposits. All funds of the Corporation not otherwise employed shall be deposited from time to time to the credit of the Corporation in such banks, trust companies or other depositories as the Board may from time to time designate or as may be designated by any officer or officers of the Corporation to whom such power of designation may from time to time be delegated by the Board. For the purpose of deposit and for the purpose of collection for the account of the Corporation, checks, drafts and other orders for the payment of money which are payable to the order of the Corporation my be endorsed, assigned and delivered by any officer or agent of the Corporation, or in such manner as the Board may determine by resolution.

Section 5. General and Special Bank Accounts. The Board may, from time to time, authorize the opening and keeping of general and special bank accounts with such banks, trust companies or other depositories as the Board may designate or as may be designated by any officer or officers of the Corporation to whom such power of designation may from time to time be delegated by the Board. The Board may make such special rules and regulations with respect to such bank accounts, not inconsistent with the provisions of these By-Laws, as it may deem expedient.

Section 6. Proxies in Respect of Securities of Other Corporations. Unless otherwise provided by resolution adopted by the Board, the Chairman of the Board, the President or a Vice President may from time to time appoint an attorney or attorneys or agent or agents of the Corporation, in the name and on behalf of the Corporation, to cast the votes which the Corporation may be entitled to cast as the holder of stock or other securities in any other corporation, any of whose stock or other securities may be held by the Corporation, at meetings of the holders of the stock or other securities of such other corporation, or to consent in writing, in the name of the Corporation as such holder, to any action by such other corporation, and may instruct the person or persons so appointed as to the manner of casting such votes or giving such consent, and may execute or cause to be executed, in the name and on behalf of the Corporation, and under its corporate seal, or otherwise, all such written proxies or other instruments as he or she may deem necessary or proper in the premises.

ARTICLE VII

Shares, Etc.

Section 1. Stock Certificates. Each holder of shares of stock of the Corporation shall be entitled to have a certificate, in such form as shall be approved by the Board, certifying the number of shares of the Corporation owned by such stockholder. The certificates representing shares of stock shall be signed in the name of the Corporation by (A) the Chairman or Vice Chairman of the Board or the President or a Vice President, and (B) the Secretary or an Assistant Secretary or the Treasurer or an Assistant Treasurer, and sealed with the seal of the Corporation (which seal may be a facsimile, engraved or printed); provided, however, that where any such certificate is countersigned by a transfer agent other than the Corporation or its employee, or is registered by a registrar other than the Corporation or one of its employees, the signature of the officers of the Corporation upon such certificates may be facsimiles, engraved or printed. In case any officer who shall have signed or whose facsimile signature has been placed upon such certificates shall have ceased to be such officer before such certificates shall be issued, they may nevertheless be issued by the Corporation with the same effect as if such officer were still in office at the date of their issue.

Section 2. Books of Account and Record of Shareholders. The books and records of the Corporation may be kept at such places within or without the state of incorporation as the Board of Directors may from time to time determine. The stock record books and the blank stock certificate books shall be kept by the Secretary or by any other officer or agent designated by the Board of Directors.

Section 3. Transfer of Shares. Transfers of shares of stock of the Corporation shall be made on the stock records of the Corporation only upon authorization by the registered holder thereof, or by his attorney thereunto authorized by power of attorney duly executed and filed with the Secretary or with a transfer agent or transfer clerk, and on surrender of the certificate or certificates for such shares properly endorsed or accompanied by a duly executed stock transfer power and the payment of all taxes thereon. Except as otherwise provided by applicable law, the Corporation shall be entitled to recognize the exclusive right of a person in whose name any share or shares stand on the record of stockholders as the owner of such share or shares for all purposes, including, without limitation, the rights to receive dividends or other distributions and to vote as such owner, and the Corporation may hold any such stockholder of record liable for calls and assessments and the Corporation shall not be bound to recognize any equitable or legal claim to or interest in any such share or shares on the part of any other person whether or not it shall have express or other notice thereof. Whenever any transfers of shares shall be made for collateral security and not absolutely, and both the transferor and transferee request the Corporation to do so, such fact shall be stated in the entry of the transfer.

Section 4. Regulations. The Board may make such additional rules and regulations, not inconsistent with these By-Laws, as it may deem expedient concerning the issue, transfer and registration of certificates for shares of stock of the Corporation. It may appoint, or authorize any officer or officers to appoint, one or more transfer agents or one or more transfer clerks and one or more registrars and may require all certificates for shares of stock to bear the signature or signatures of any of them.

Section 5. Lost, Destroyed or Mutilated Certificates. The holder of any certificate representing shares of stock of the Corporation shall immediately notify the Corporation of any loss, destruction or mutilation of such certificate, and the Corporation may issue a new certificate of stock in the place of any certificate theretofore issued by it which the owner thereof shall allege to have been lost, stolen or destroyed or which shall have been mutilated, and the Board may, in its discretion, require such owner or his legal representative to give the Corporation a bond in such sum, limited or unlimited, and in such form and with such surety or sureties as the Board in its absolute discretion shall determine, to indemnify the Corporation against any claim that way be made against it on account of the alleged loss, theft or destruction of any such certificate, or the issuance of a new certificate. Anything herein to the contrary notwithstanding, the Board, in its absolute discretion, may refuse to issue any such new certificate, except pursuant to legal proceedings under the laws of the State of Delaware.

Section 6. Fixing of Record Date. In order that the Corporation may determine the stockholders entitled to notice of, or to vote at, any meeting of stockholders or any adjournment thereof, or to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix in advance a record date, which shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 60 days prior to any other action. A determination of stockholders of record entitled to notice of, or to vote at, a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for the adjourned meeting.

ARTICLE VIII

Offices

Section 1. Principal or Registered Office. The principal registered office of the Corporation shall be at such place as may be specified in the Certificate of Incorporation or other certificate filed pursuant to law, or if none be so specified, at such place as may from time to time be fixed by the Board.

Section 2. Other Offices. The Corporation also may have an office or offices other than said principal or registered office, at such place or places either within or without the State of Delaware.

ARTICLE IX

Fiscal Year

The fiscal year of the Corporation shall be determined by the Board.

ARTICLE X

Seal

The Board shall provide a corporate seal which shall contain the name of the Corporation, the words "Corporate Seal" and the year and State of Delaware.

ARTICLE XI

Amendments

Section 1. Stockholders. These By-Laws may be amended or repealed, or new By-Laws may be adopted, at any annual or special meeting of the stockholders, by a majority of the total votes of the stockholders or when stockholders are required to vote by class by a majority of the appropriate class, in person or represented by proxy and entitled to vote on such action; provided, however, that the notice of such meeting shall have been given as provided in these By-Laws, which notice shall mention that amendment or repeal of these By-Laws, or the adoption of new By-Laws, is one of the purposes of such meeting.

Section 2. Board of Directors. These By-Laws may also be amended or repealed or new By-Laws may be adopted by the Board at any meeting of the Board; provided, however, that notice of such meeting shall have been given as provided in these By-Laws, which notice shall mention that amendment or repeal of the By-Laws, or the adoption of new By-Laws, is one of the purposes of such meetings. By-Laws adopted by the Board may be amended or repealed by the stockholders as provided in Section 1 of this Article XI.

ARTICLE XII

Miscellaneous

Section 1. Interested Directors. No contract or other transaction between the Corporation and any other corporation shall be affected and invalidated solely by the fact that any one or more of the Directors of the Corporation is or are interested in or is a director or officer or are directors or officers of such other corporation, and any Director or Directors, individually or jointly, may be a party or parties to or may be interested in any contract or transaction of the Corporation or in which the Corporation is interested; and no contract, act or transaction of the Corporation with any person or persons, firm or corporation shall be affected or invalidated by the fact that any Director of the Corporation is a party or are parties to or interested in such contract, act or transaction, or in any way connected with such person or persons, firms or associations, and each and every person who may become a Director of the Corporation is hereby relieved from any liability that might otherwise exist from contracting with the Corporation for the benefit of himself or herself, any firm, association or corporation in which such Director may be in any way interested.

Section 2. Ratification. Any transaction questioned in any stockholders derivative suit on the grounds of lack of authority, defective or irregular execution, adverse interest of director, officer or stockholder, nondisclosure, miscomputation, or the application of improper principles or practices of accounting, may be ratified before or after judgment, by the Board or, by the stockholders in case less than a quorum of Directors are qualified, and, if so ratified, shall have the same force and effect as if the questioned transaction had been originally duly authorized, and said ratification shall be binding upon the Corporation and its stockholders, and shall constitute a bar to any claim or execution of any judgment, in respect of such questioned transaction.

[Dickstein Shapiro Morin & Oshinsky LLP Letterhead]

December 19, 2003

Board of Directors Discovery Laboratories, Inc. 350 South Main Street, Suite 307 Doylestown, PA 18901

> 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 "Securities Act"), on December 19, 2003, for the registration under the Securities Act of up to 6,500,000 shares (the "Shares") of the Company's common stock, par value \$0.001 per share (the "Common Stock"), to be offered by the Company to the public from time to time pursuant to Rule 415 promulgated under the Securities Act as described in the Registration Statement. The Registration Statement provides that the Shares may be offered in such amounts and at such prices, terms and conditions as the Company shall, from time to time, set forth in one or more prospectus supplements (each, a "Prospectus Supplement") to the prospectus contained 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, the Company's Bylaws and resolutions of the Company's 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

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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.

When, if at all, the Shares are authorized for issuance by a resolution of the Company's Board of Directors (the "Authorizing Resolution") and issued pursuant to the Registration Statement as shall be amended and supplemented by the relevant Prospectus Supplement in effect at the time of issuance, subject to the receipt of consideration for each such issuance in accordance with the terms and conditions of the relevant Authorizing Resolution, such Shares shall be duly and validly authorized and issued, fully paid and nonassessable.

No opinion is expressed herein with respect to any laws other than the General Corporation Law and the Constitution 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. We assume no obligation to supplement this letter if any applicable laws change after the date hereof or if we become aware of any new facts that might effect any view expressed herein after the date hereof.

To the extent it may be relevant to the opinion expressed herein, we have assumed that the Company will have sufficient authorized but unissued shares of Common Stock on the date of issuance of Shares registered pursuant to the Registration Statement.

We hereby consent to the filing of this opinion as Exhibit 5.1 to 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.

The foregoing opinion is delivered to the Board of Directors of the Company in connection with the Registration Statement, and may not be relied upon by any other person or for any other purpose.

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

Consent of Independent Auditors

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 16, 2003 for the registration of approximately 6,500,000 shares of its common stock and to the incorporation by reference therein of our report dated February 26, 2003, 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, 2002, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania December 16, 2003

INDEPENDENT AUDITORS' CONSENT

We consent to the reference to our firm under the caption "Experts" in this Registration Statement on Form S-3 of Discovery Laboratories, Inc. and to the incorporation by reference therein of our report dated February 25, 2000, with respect to our audit of the consolidated financial statements for the period from May 18, 1993 (inception) through December 31, 1999, not presented separately, included in its annual report on Form 10-K for the year ended December 31, 2002, filed with the Securities and Exchange Commission.

Eisner LLP

New York, New York December 16, 2003