As filed with the Securities and Exchange Commission on August 21, 2003
Registration No. 333-107836

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

PRE-EFFECTIVE AMENDMENT NO. 1
to
FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

DISCOVERY LABORATORIES, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	350 South Main Street, Suite 307	94-3171943
(State or Other Jurisdiction of Incorporation)	Doylestown, Pennsylvania 18901	(I.R.S. Employer Identification Number)

(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.

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)
Common Stock, $.001 par value	8,288,369	$8.1555	$67,595,793	$5,468.50

(1) Includes 6,611,649 shares of common stock and 1,676,720 shares of common stock issuable upon the exercise of certain warrants issued by the registrant.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) of the Securities Act and determined by multiplying $8.1555 (which was the average of the high and low sales price of the common stock on the Nasdaq SmallCap Market on August 5, 2003) by: (i) 6,611,649 shares of common stock owned by the selling stockholders and registered for resale hereunder, (ii) 999,577 shares of common stock issuable upon the exercise of certain Class A Investor warrants, (iii)

357,143 shares of common stock issuable upon the exercise of certain Class G warrants and (iv) 320,000 shares of common stock issuable upon the exercise of certain Class H warrants. Pursuant to Rule 416 under the Securities Act, we are also registering additional shares of common stock which may become issuable pursuant to the anti-dilution provisions of the warrants referred to above.

(3) Previously paid in connection with our initial Registration Statement on Form S-3 filed with the Securities and Exchange Commission on August 11, 2003.

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 amended. The selling stockholders 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 AUGUST 20, 2003

8,288,369 Shares

DISCOVERY LABORATORIES, INC.

Common Stock

This prospectus relates to the public offering, which is not being underwritten, of 8,288,369 shares of our common stock, par value $.001 per share, which may be sold by the selling stockholders listed on page 23 for their own account. These shares include 1,676,720 shares that are issuable upon exercise of outstanding warrants.

Our common stock is traded on the Nasdaq SmallCap Market under the trading symbol "DSCO." On August 15, 2003, the closing sales price of our common stock was $7.45 per share.

Investing in our common stock involves risks. SEE "RISK FACTORS" BEGINNING ON PAGE 8.

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 August 20, 2003.

TABLE OF CONTENTS

PROSPECTUS SUMMARY

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 late-stage 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 is designed to precisely mimic the essential human lung surfactant protein B (SP-B). We believe that our proprietary surfactant technology is the only 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. Surfaxin is currently in a Phase 3 clinical trial for Respiratory Distress Syndrome in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome in full-term infants and a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults. Aerosolized formulations of our humanized surfactant are presently being developed to potentially treat hospitalized patients suffering from severe acute asthma and Acute Lung Injury (ALI), typically requiring mechanical ventilation. In addition, we believe that scientific rationale supports the development of aerosolized formulations of our humanized surfactant to potentially treat 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, S.A., 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 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 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.

We are conducting a pivotal, multinational landmark Phase 3 trial treating up to 1,500 patients for the treatment of Respiratory Distress Syndrome in premature infants. This trial is designed to demonstrate the superiority of Surfaxin over the only commercially available synthetic surfactant and has a reference arm comparing Surfaxin to a bovine (cow) -derived surfactant. This pivotal trial is intended, if successful, to provide the basis for New Drug Applications with the FDA and other worldwide regulatory authorities.

We have concluded enrollment and reported results of key endpoints of the supportive Phase 3 multinational clinical trial comparing Surfaxin to a certain porcine (pig) derived surfactant for treatment of Respiratory Distress Syndrome in premature infants. Further evaluation of secondary endpoints and safety parameters of this supportive clinical trial are currently being conducted. A detailed analysis of the data from this trial will be presented at the European Society for Pediatric Research (ESPR) meeting in Bilbao, Spain in September 2003.

Respiratory Distress Syndrome in premature infants affects approximately two million infants worldwide with approximately 270,000 cases occurring in the developed world. Due to limitations associated with the currently approved animal-derived products, only approximately 100,000 infants are estimated to be receiving surfactant therapy worldwide.

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) in adults 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. Up to 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.

In July 2002, we 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 Independent Safety Review Committee, comprised of three prominent pulmonologists, that was specifically assembled for this trial, 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, will 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 selected Laureate Pharma, L.P., as our current contract manufacturer to replace our previous contract manufacturer, Akorn, Inc., who has been experiencing certain operational difficulties which have delayed the completion of this part of the 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, of which $307,000 is still to be received, subject to certain performance criteria.

Meconium Aspiration Syndrome in Full-Term Infants

Meconium Aspiration Syndrome 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 is ongoing but has been slower than expected. Given our belief in the importance of the pivotal Phase 3 trial for Respiratory Distress Syndrome in premature infants to our present development plan, resources have been reallocated from the Meconium Aspiration Syndrome program to the Respiratory Distress Syndrome program.

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. There are approximately 600,000 babies born each year that are at risk for Meconium Aspiration Syndrome, of which about 10% develop the condition. 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. 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 as 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 supports 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. However, use of currently available animal-derived surfactants is not considered feasible for aerosolization and because of their potential to cause an adverse immunological response such products may exacerbate the inflammatory event associated with such diseases.

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, hopefully avoiding or reducing the need for mechanical ventilation. 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;

Our lead programs for surfactant-based therapy as an aerosol are as follows:

Asthma

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.

Aerosolized Humanized Surfactants for Pulmonary Drug Delivery

We are evaluating formulations of our engineered humanized surfactants as novel pulmonary drug delivery vehicles with the potential to deliver other pharmaceutical products to the lungs so that such products can exert their pharmacological effects locally or systemically. Existing drug delivery technology has effectively addressed the development of delivery devices, drug storage systems and compatible drug formulations. However, a significant unmet need in pulmonary drug delivery is to provide better performance once a drug is deposited in the lungs.

We believe that an aerosol version of our humanized lung surfactant, with its ability to penetrate and spread in an even manner throughout the lungs, has the potential to more efficiently deliver certain drugs and other therapeutic substances via or within the respiratory tract. These drugs and substances include antibiotics, pulmonary vasodilators that lower blood pressure in the lung arteries, elastase inhibitors (drugs that are anti-inflammatory by inhibiting a potentially destructive enzyme that comes from certain types of white blood cells), bronchodilators (drugs that mitigate constriction of small airways), steroids and proteins.

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

The following risks, among others, could cause our actual results, performance, achievements or industry results to differ materially from those expressed in our forward-looking statements contained herein and presented elsewhere by management from time to time.

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 late stage specialty 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 June 30, 2003, we have incurred a deficit accumulated during the development stage of approximately $81.9 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 late-stage clinical trials for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants 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. Our lead product, Surfaxin, is currently in a Phase 3 clinical trial for Respiratory Distress Syndrome in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome in full-term infants and a Phase 2 clinical trial for Acute Respiratory Distress syndrome in adults.

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 Transnational Corp., 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.

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 2004, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for Surfaxin, 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: Meconium Aspiration Syndrome in full-term infants; Acute Respiratory Distress Syndrome in adults; and Respiratory Distress Syndrome in 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 competitors 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 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. We are currently negotiating the final terms and conditions of a definitive manufacturing agreement with Laureate Pharma. Until the execution of said agreement, Laureate Pharma is not obligated to manufacture any of our drug products. There can be no assurance that we and Laureate Pharma will ultimately execute such agreement nor that such agreement ultimately will be on terms favorable to us. If the agreement is not executed, we may pursue alternative manufacturing arrangements, which may delay or impair our ability to obtain regulatory approval for our products or be available only on terms that are not favorable to us.

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

Our strategy for the completion of the required development and clinical testing of our products and for the 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. In March 2002, we expanded our relationship with Esteve by entering into 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.

In December 2001, we 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 2017 or, in some cases, possibly later. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risk Factors-If we cannot meet requirements under our license agreements, we could lose the rights to our products."

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

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The United States Patent and Trademark Office

keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

If we cannot meet requirements under our license agreements, we could lose the rights to our products.

We depend on licensing 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.

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 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 marketingproducts.

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.

Forrest 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 July 28, 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 these "Risk Factors."

Our common stock is listed for quotation on the NASDAQ SmallCap Market. For the 12-month period ended July 28, 2003, the price of our common stock has ranged from $1.25 to $8.20. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ending July 28, 2003, the average daily trading volume in our common stock was approximately 177,111 shares and the average number of transactions per day was approximately 256. 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 July 28, 2003, we had 40,425,587 shares of common stock outstanding. In addition, as of July 28, 2003, up to approximately 10,601,300 shares of our common stock were issuable on 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 or rules, we do not undertake any obligation or duty to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

We will not receive any proceeds from the sales of common stock by the selling stockholders pursuant to this prospectus. However, we may receive cash consideration from the exercise of common stock warrants owned by the selling stockholders.

SELLING STOCKHOLDERS

On June 20, 2003, we entered into a Common Stock and Warrant Purchase Agreement with the selling stockholders listed in the table set forth below, with the exception of Qfinance, Inc., who is holding shares of common stock and warrants purchased pursuant to the Common Stock and Warrant Purchase Agreement as the nominee of PharmaBio. In addition, PharmaBio has exercised its contractual right to have shares of common stock, and shares of common stock issuable upon the exercise of certain warrants, previously issued to PharmaBio to be registered by this Registration Statement. The table

sets forth information with respect to the amount of common stock held by each selling stockholder as of June 20, 2003, and the shares being offered by the selling stockholders pursuant to this prospectus. The table indicates the nature of any position, office or other material relationship that the selling stockholder has had with us within the past three years or any of our predecessors or affiliates. This prospectus relates to the offer and sale of the selling stockholders of up to 8,288,369 shares of common stock, including 1,676,720 shares of common stock issuable upon the exercise of outstanding warrants issued by us. The selling stockholders may offer all or part of the shares of common stock covered by this prospectus. Information with respect to shares owned beneficially after the offering assumes the sale of all of the shares offered and no other purchases or sales of common stock. The common stock offered by this prospectus may be offered from time to time by the selling stockholders named below.

Name	Number of Shares of Common Stock, not including Warrants, Beneficially Owned	Number of Shares Represented by Warrants Beneficially Owned	Total Number of Shares of Common Stock Beneficially Owned	Percentage Beneficially Owned Before Offering	Number of Shares to be Offered for the Account of the Selling Stockholder	Number of Shares to be Owned after this Offering	Percentage to be Beneficially Owned after this Offering
ABN AMRO, Inc. F/A/O Expressway Partners, LTD	46,810	9,362	56,172	0	56,172	0	0
ABN AMRO, Inc. F/A/O Highway Partners, LP	6,540	1,308	7,848	0	7,848	0	0
ABN AMRO, Inc. F/A/O Thruway Partners, LP	28,895	5,779	34,674	0	34,674	0	0
Albert Fried & Company LLC	246,728	95,500	342,228	*	296,074	46,154	*
Baystar Capital II, L.P.	92,895	18,579	111,474	0	111,474	0	0
Biotechnology Development Fund II, L.P.	1,502,572	702,466	2,205,038	5.67%	89,719	2,115,319	5.22%
Castle Creek Healthcare Partners LLC	100,000	20,000	120,000	0	120,000	0	0
CC LifeScience, Ltd.	150,280	30,056	180,336	0	180,336	0	0
CC LifeScience Market Neutral Fund, Ltd.	37,570	7,514	45,084	0	45,084	0	0
Foster & Foster LLC	181,818	67,064	248,882	*	218,182	30,700	*
Laboratorios del Dr. Esteve S.A. (1, 2)	1,898,356	204,392	2,102,748	5.48%	1,128,908	973,840	2.44%
LCI Capital LLC	44,860	8,972	53,832	0	53,832	0	0
Oppenheimer Discovery Fund	619,540	123,908	743,448	1.94%	743,448	0	0
Oppenheimer Emerging Growth Fund	34,000	6,800	40,800	0	40,800	0	0
OppenheimerFunds plc US Emerging Growth Fund	4,400	880	5,280	0	5,280	0	0
Perceptive Life Sciences Master Fund, Ltd.	224,298	44,860	269,158	0	269,158	0	0
Qfinance, Inc. (as nominee for PharmaBio)(2)	1,276,210	840,566	2,116,776	5.43%	261,671	386,057	*
PharmaBio Development, Inc. (2)	1,276,210	840,566	2,116,776	5.43%	1,469,048	386,057	*
Quaker BioVentures Tobacco Fund, L.P.	272,727	54,545	327,272	0	327,272	0	0
Quaker BioVentures, L.P.	1,090,909	218,182	1,309,091	3.41%	1,309,091	0	0
Royal Bank of Canada	726,146	146,769	872,915	2.28%	696,000	176,915	*
Smithfield Fiduciary LLC	186,915	37,383	224,298	0	224,298	0	0
Special Situations Cayman Fund L.P.	158,285	112,216	270,501	*	84,000	186,501	*
Special Situations Fund III, L.P.	437,198	337,648	810,846	2.21%	258,000	552,846	1.38%
Special Situations Private Equity Fund LP	486,947	337,648	824,622	2.14%	258,000	566,622	1.41%

* Less than 1%.

The information contained in this table reflects "beneficial" ownership of common stock within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934. On July 28, 2003, we had 40,425,587 shares of common stock outstanding. Beneficial ownership information reflected in the table includes shares issuable upon the exercise of outstanding warrants issued by us at their initial exercise prices.

(1) An executive officer of Laboratorios del Dr. Esteve serves on our Board of Directors.

(2) The Company has entered into strategic alliances with Laboratorios del Dr. Esteve for the development and commercialization of Surfaxin throughout Europe and Latin America and with Quintiles Transnational Corp., and its affiliate, PharmaBio Development, Inc., to develop a sales & marketing capability to commercialize Surfaxin for neonatal indications in the United States.

Except as set forth above, none of the selling stockholders named in the preceding table has had any position, office or other material relationship with us or any of our affiliates within the past three years.

PLAN OF DISTRIBUTION

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

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

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

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

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

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

- directly to one or more purchasers;

- through agents;

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

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

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

- in any combination of the above. In addition, any of the shares that qualify for sale pursuant to Rule 144 under the Securities Act of 1933 may be sold under Rule 144 rather than pursuant

to this prospectus provided they meet the criteria and conform to the requirements of such Rule.

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

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

- ordinary brokerage transactions; or

- transactions in which the broker-dealer solicits purchasers.

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

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

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

INTERESTS OF NAMED EXPERTS AND COUNSEL

The validity of the securities being registered hereunder is being 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 of 1933. The registration statement relates to the common stock offered by the selling stockholders. 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:

1. 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;

2. Our Quarterly Reports (unaudited) on Form 10-Q for the quarterly periods ended March 31, 2003, and June 30, 2003;

3. 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, and August 13, 2003; and

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 Securities Exchange Act of 1934 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.

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 is based on the report of Eisner LLP independent auditors. The consolidated statements of operations, changes in stockholders' equity and cash flows of Discovery for the period from May 18, 1993 (inception) through December 31, 1999, not presented separately therein, appearing in Discovery's Annual Report (Form 10-K) for the year ended December 31, 2002, have been audited by Eisner LLP independent auditors, as set forth in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

LEGAL MATTERS

Our legal counsel, Dickstein Shapiro Morin & Oshinsky LLP, has rendered an opinion to the effect that the common stock offered hereby is duly and validly issued, fully paid and non-assessable.

We have not authorized anyone to provide you with information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. The selling stockholders 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.

8,288,369 SHARES

DISCOVERY LABORATORIES, INC.

COMMON STOCK

August 20, 2003

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the various expenses payable by us in connection with the sale and distribution of the securities being registered hereby. Normal commission expenses and brokerage fees are payable individually by the selling stockholders. All amounts are estimated except the Securities and Exchange Commission registration fee.

	Amount
Securities and Exchange Commission registration fee	$5,468.50
Accounting fees and expenses	$8,000.00
Legal fees and expenses	$25,000.00
Miscellaneous fees and expenses	$3,500.00
Total	$41,968.50

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 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

Exhibit No.	Description
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.*
24.1	Powers of Attorney.*

* Filed as an exhibit to the Registration Statement on Form S-3 filed with the SEC on August 11, 2003.

ITEM 17. UNDERTAKINGS

We, the undersigned Registrant hereby undertake:

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

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

(ii) Reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) that individually or in the aggregate represent a fundamental change in the information set forth in the Registration Statement; 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.

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 20th day of August, 2003.

DISCOVERY LABORATORIES, INC.
(Registrant)

By: /s/ Robert J. Capetola

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

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	August 20, 2003
*	John G. Cooper Senior Vice President and Chief Financial Officer	August 20, 2003
*	Cynthia Davis Controller and Principal Accounting Officer	August 20, 2003
/S/ Herbert McDade, Jr.	Herbert McDade, Jr. Chairman of the Board of Directors	August 20, 2003
/s/ Max Link	Max Link, Ph.D. Director	August 20, 2003
	Antonio Esteve Director	August 20, 2003
/S/ Marvin E. Rosenthale	Marvin E. Rosenthale Director	August 20, 2003

* The undersigned, by signing his name hereto, does sign and execute this Amendment No. 1 to the Registration Statement on Form S-3 on behalf of the above-named Directors and Officers of the Registrant pursuant to a Power of Attorney executed by each such Director and Officer and filed with the Securities and Exchange Commission with the Registration Statement on Form S-3 on August 11, 2003.

By: /s/ Robert J. Capetola, Ph.D.
Robert J. Capetola, Ph.D.
As Attorney-in-fact

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

Exhibit No.	Description
23.1	Consent of Ernst & Young LLP, independent auditors.*
23.2	Consent of Eisner LLP independent auditors.*
24.1	Powers of Attorney (1).

- ----------

* Filed herewith.

(1) Filed as an exhibit to the Registration Statement on Form S-3, filed August 11, 2003.

Exhibit 23.1

Consent of Independent Auditors

We consent to reference to our firm under the caption "Experts" in the Registration Statement (Pre-effective Amendment No. 1 to Form S-3 No. 333-107836) and related prospectus of Discovery Laboratories, Inc. to be filed on or about August 20, 2003 for the registration of approximately 8,288,369 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
August 20, 2003

Exhibit 23.2

INDEPENDENT AUDITORS' CONSENT

We consent to the reference to our firm under the caption "Experts" in the Registration Statement on Form S-3 (333-107836, Amendment No. 1) of Discovery Laboratories, Inc. for the registration of its common stock and to the incorporation by reference therein of our report dated February 25, 2000, with respect to our audits 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/A for the year ended December 31, 2002, filed with the Securities and Exchange Commission.

Eisner LLP

New York, New York
August 20, 2003