

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
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PRE-EFFECTIVE AMENDMENT NO. 1  
to  
FORM S-3

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933  
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DISCOVERY LABORATORIES, INC.  
(Exact Name of Registrant as Specified in its Charter)  
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Delaware  
(State or Other  
Jurisdiction  
of Incorporation) 350 South Main Street, Suite 307 (I.R.S. Employer  
Identification Number) 94-3171943  
(Address, Including Zip Code and Telephone Number, Including Area  
Code, of Registrant's Principal Executive Offices) Doylestown, Pennsylvania 18901  
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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)  
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Copies to:  
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1177 Avenue of the Americas, 41st Floor  
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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.

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.

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The Registrant hereby amends this Registration Statement on the 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 or until the Registration Statement shall become effective on the date as the Commission, acting pursuant to said Section 8(a), may determine.

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	4,440,222	\$3.125	\$13,875,694	\$3,468.92

(1) Includes 712,552 shares of common stock issuable upon the exercise of certain Class F warrants and 164,911 shares of common stock issuable upon the

exercise of certain placement 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 \$3.125 (which was the average of the high and low sales price of the common stock on the Nasdaq SmallCap Market on October 25, 2001) by: (i) 3,562,759 shares of common stock owned by the selling stockholders and registered for resale hereunder, (ii) 712,552 shares of common stock issuable upon the exercise of certain Class F warrants and (iii) 164,911 shares of common stock issuable on exercise of placement warrants. The proposed maximum offering price per share represents the weighted average price per share of the foregoing values. 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 in footnote 1 above.

(3) Previously paid in connection with our initial Registration Statement on Form S-3 filed with the Securities and Exchange Commission on November 1, 2001.



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## 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 critical care company that focuses on developing compounds to treat respiratory diseases that affect the ability of the lungs to absorb oxygen. We are currently developing products that are designed to treat a variety of conditions and diseases which cause the lungs to collapse and thereby inhibit the lungs' capacity to absorb oxygen. Our lead product candidate, Surfaxin(R), is intended to achieve this by reestablishing the lung's capacity to absorb oxygen. Surfaxin is in late stage development and we are initially focusing on developing it for use by critical care units of hospitals as a treatment for two respiratory conditions in newborn infants. We are also developing Surfaxin for the treatment of Acute Respiratory Distress Syndrome and Acute Lung Injury in adult patients. Surfaxin contains our proprietary synthetic peptide, which is known as sinapultide (a 21 amino acid protein-like substance that mimics an important human lung protein), and we believe that we can use other formulations of Surfaxin to treat other respiratory conditions. These include asthma and chronic obstructive pulmonary disease (commonly known as COPD, which is a chronic condition of the lung that prevents enough oxygen from reaching the blood). In addition, we believe we can use Surfaxin to efficiently deliver drugs through the respiratory tract that are currently delivered orally or by injection. These drugs include antibiotics, pulmonary vasodilators (drugs that lower blood pressure in the lung arteries), elastase inhibitors (drugs that inhibit a potentially destructive enzyme that comes from certain types of white blood cells), bronchodilators (drugs that increase the diameter of the windpipes), steroids and proteins. We are also evaluating the acquisition of licenses to other drug products for the treatment of respiratory and other neonatal critical care diseases. We may develop and market our products on our own or seek to enter into collaborations with corporate partners for the manufacturing and marketing of these drugs.

Surfaxin is a formulation of a humanized, synthetic lung surfactant containing a peptide, sinapultide, which, as explained above, mimics an important human lung protein. We patterned Surfaxin after human surfactant protein B. Surfactants are substances that are produced naturally in the lungs. They possess the ability to lower the surface tension of the fluid normally present within the air sacs that are inside of the lungs. In the absence of sufficient surfactants these air sacs tend to collapse. As a result, the lungs do not absorb sufficient oxygen.

We intend to use Surfaxin for the treatment of several respiratory conditions. Currently, we are developing Surfaxin for the treatment of Idiopathic Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Respiratory Distress Syndrome/Acute Lung Injury. We have also begun developing Surfaxin to treat other respiratory disorders.

Idiopathic Respiratory Distress Syndrome is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. Meconium Aspiration Syndrome is a similar condition, in which full-term infants are born with meconium in their lungs which depletes the natural surfactant in their lungs. Meconium is a baby's first bowel movement in its mother's womb. Meconium Aspiration Syndrome can occur if the baby breathes in meconium. Both Idiopathic Respiratory Distress Syndrome and Meconium Aspiration Syndrome can be life-threatening as a result of the failure of the lungs to absorb sufficient oxygen. These conditions can also deplete natural surfactants in the lungs and result in the need for mechanical ventilation. Acute Respiratory Distress Syndrome/Acute Lung Injury can result from a variety of events. Some of these events are pneumonia, septic shock (a severe blood infection associated with a severe drop in blood pressure), breathing in the contents of the stomach, trauma, smoke inhalation, near drowning, pancreatitis (inflammation of the pancreas) and head injury.

Idiopathic Respiratory Distress Syndrome affects approximately 60,000 premature infants per year in the United States with an estimated approximately 120,000 infants receiving surfactant therapy worldwide. The incidence of Acute Respiratory Distress Syndrome/Acute Lung Injury ranges between approximately 150,000 and 250,000 patients per year in the United States with a fatality rate as high as 35% to 70%. Meconium Aspiration Syndrome affects approximately 22,000 to 26,000 newborn infants per year in the United States with an estimated equal number of newborn infants afflicted per year in the rest of the developed world.

Presently, the FDA has only approved replacement surfactants for treating Idiopathic Respiratory Distress Syndrome in premature infants. The most commonly used of these approved replacement surfactants are products derived from pigs and cows and require relatively complex extractive manufacturing processes. In contrast, Surfaxin is a humanized, synthetic surfactant modeled after the most active protein found in human surfactant. We believe that we can manufacture Surfaxin less expensively than the animal derived surfactants. In addition we believe that Surfaxin might possess other pharmaceutical benefits not currently found with the animal-derived surfactants such as its resistance to proteolytic degradation (i.e., sinapultide is more resistant to digestion) and the absence of risk of potential transmission of animal-borne diseases including brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease").

There are presently no drug therapies approved for the treatment of Meconium Aspiration Syndrome and Acute Respiratory Distress Syndrome. The FDA has granted Surfaxin fast track designation for the indications of Meconium Aspiration Syndrome and Acute Respiratory Distress Syndrome. Fast track status does not accelerate our clinical trials nor does it mean that the regulatory



requirements are less stringent. However, the FDA will review the New Drug Application for a drug granted fast track status within six months. The FDA has awarded us an orphan drug grant to support our development of Surfaxin in Meconium Aspiration Syndrome and has designated Surfaxin as an orphan drug for the treatment of Meconium Aspiration Syndrome, Idiopathic Respiratory Distress Syndrome and Acute 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 have also recently received designation of Surfaxin as an orphan product for Meconium Aspiration Syndrome from the European Medicines Evaluation Agency. Additional applications for orphan product designation for Idiopathic Respiratory Distress Syndrome and Acute Respiratory Distress Syndrome/Acute Lung Injury are currently under review at the European Medicines Evaluation Agency. In October 2000, we were awarded a \$1 million Fast-Track Small Business Innovative Research Grant by the National Institutes of Health to develop Surfaxin for Acute Respiratory Distress Syndrome/Acute Lung Injury.

We have begun preclinical research into formulating Surfaxin into an aerosol spray for the treatment of asthma, chronic obstructive pulmonary disease, acute and chronic bronchitis and a variety of other respiratory diseases. We are also initiating preclinical research to evaluate Surfaxin or related formulations as a novel pulmonary drug delivery technology with the potential to deliver other pharmaceutical products to the lungs so that such products can exert their pharmacological effects locally or systemically.

We are presently evaluating if and how our second compound under development, SuperVent(TM) (active compound, tyloxapol), should be developed. We believe that SuperVent(TM) could be used to treat airway diseases such as Cystic Fibrosis and chronic bronchitis. Cystic Fibrosis is a progressive, lethal respiratory disease that afflicts approximately 28,000 patients in the United States and a comparable number in Europe. A new therapy that is intended to minimize the complications of Cystic Fibrosis could have a major impact on the length and quality of life of its patients. SuperVent(TM) is delivered to patients using a nebulizer, a device that turns liquid into mist, making it breathable.

We are presently enrolling patients in a pivotal Phase 3 clinical trial of Surfaxin for the treatment of Meconium Aspiration Syndrome in newborns and have designed pivotal Phase 3 multinational clinical trials intended to be conducted in North and South America, as well as Europe, for the treatment of Idiopathic Respiratory Distress Syndrome in premature infants. Given our belief in the importance of Idiopathic Respiratory Distress Syndrome to our present development plan, resources have been and may continue to be reallocated from the Meconium Aspiration Syndrome program to the Idiopathic Respiratory Distress Syndrome program, which, could effectively delay the completion of the Meconium Aspiration Syndrome trial. In July 2001, we commenced enrollment for the Phase 3 Idiopathic Respiratory Distress Syndrome program. In addition, we have initiated a Phase 2 clinical trial of Surfaxin for the treatment of Acute Respiratory Distress Syndrome. We are also evaluating whether to conduct further clinical trials of SuperVent(TM) for treatment of Cystic Fibrosis.

Surfaxin(R) and SuperVent(TM) are our trademarks. 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.

#### RECENT DEVELOPMENTS

On December 10, 2001, we entered into a collaboration arrangement with Quintiles Transnational Corp., and its affiliate, PharmaBio Development Inc. We raised \$3.0 million in gross proceeds by issuing to PharmaBio (i) 791,905 shares of our common stock and (ii) warrants to purchase an aggregate of approximately 677,143 shares of our common stock, subject to adjustment. After payment of fees and associated expenses, we intend to use the net proceeds of approximately \$2.7 million, for working capital and general corporate purposes.

#### Transaction Overview

In connection with the collaboration, we entered into a series of agreements with Quintiles and PharmaBio. As further discussed below and subject to the terms and conditions set forth in the agreements, Quintiles will provide certain commercialization services in the United States for Surfaxin, for the treatment of Meconium Aspiration Syndrome and Idiopathic Respiratory Distress Syndrome. In addition, PharmaBio will fund up to \$70 million of the sales and marketing costs for Surfaxin for seven years of Surfaxin commercialization. In addition to the \$3.0 million equity investment, PharmaBio also will extend to us a credit facility of up to \$8.5 million to \$10 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States as we achieve certain milestones. Principal amounts owed by us under the credit facility may be repaid out of the proceeds of milestone payments to be paid by PharmaBio at certain intervals upon the achievement of certain corporate milestones that are discussed in greater detail below.

## Commercialization Arrangements

Pursuant to the Commercialization Agreement between Quintiles and us, Quintiles will provide pre- and post-launch marketing services for the promotion of Surfaxin for Meconium Aspiration Syndrome and Idiopathic Respiratory Distress Syndrome in the United States. Upon approval of Surfaxin by the FDA for sale in the United States for Meconium Aspiration Syndrome or Idiopathic Respiratory Distress Syndrome, Quintiles will hire and train a dedicated United States sales force that will be branded in the market as ours. Quintiles also will provide certain management and administrative personnel to assist in the collaboration. Among other things, Quintiles will provide a product manager to coordinate pre-launch marketing activities. Quintiles has been granted the opportunity to provide outsourced services to us for the development of Surfaxin for the treatment of an Acute Respiratory Distress Syndrome indication conditioned upon Quintiles' satisfaction of certain performance-related and competitive criteria regarding the provision of the services. In addition, Quintiles has been granted a right of first negotiations, solely as a preferred provider, to provide competitive clinical trial development and commercialization services for other products that we may develop and for which we intend to outsource the services, whether related to Surfaxin or otherwise. We will be responsible for order processing and fulfillment, invoicing and collection of accounts receivables from sales (which may upon agreement of Quintiles and us be performed by Quintiles or one of its affiliates). We will also be responsible for supply and inventories of Surfaxin, as well as regulatory and medical affairs. Under certain circumstances, we have the option to hire the sales force created by Quintiles.

Pursuant to a related Investment and Commission Agreement between PharmaBio and us, PharmaBio is obligated to pay 100% of specified sales and marketing expenses payable to Quintiles for services provided by it pursuant to the Commercialization Agreement. Following the commercial launch of Surfaxin for Meconium Aspiration Syndrome or Idiopathic Respiratory Distress Syndrome, the financial obligation is limited to a maximum of \$70 million over a seven-year period. In exchange, we will pay PharmaBio a commission on net sales in the United States of Surfaxin for Meconium Aspiration Syndrome, Idiopathic Respiratory Distress Syndrome and all "off-label" uses for 10 years following first launch of the product in the United States.

The collaboration will be managed and governed by a Joint Commercialization Committee, consisting of an equal number of representatives appointed by Quintiles and us. The Joint Commercialization Committee has final decision-making control on all strategic issues regarding Surfaxin throughout the term of the Commercialization Agreement. One of our representatives will chair the Joint Commercialization Committee and, subject to certain exceptions, we will have a tie-breaking vote on all matters to be considered by the Joint Commercialization Committee.

## Credit Facility

In connection with the collaboration, PharmaBio is providing us with a secured revolving credit facility. Under the credit facility, PharmaBio has committed to advance on a revolving basis up to \$8.5 million, which may be increased to \$10 million, at the discretion of the Joint Commercialization Committee. Interest on the credit facility will be payable on a quarterly basis in arrears. We are obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services to be provided by Quintiles pursuant to the Commercialization Agreement.

The credit facility of \$8.5 million (subject to increase as stated above) will be available for borrowing by us incrementally upon the occurrence of three milestones. PharmaBio will make one-third of the commitment available to us upon the later to occur of (i) the completion of a market opportunity assessment and report regarding Surfaxin and (ii) an extension for the deadline for the filing of a New Drug Application for Surfaxin with the FDA under our license agreement for Surfaxin until at least October 28, 2003.

Provided that the first milestone has occurred, PharmaBio will make one-third of the commitment available to us for borrowing upon the later to occur of (i) our successful completion of an aggregate of \$10 million capital raise for general corporate purposes or (ii) the public disclosure by us of Phase III clinical trial data for Idiopathic Respiratory Distress Syndrome and the completion by Quintiles of a favorable written assessment and report regarding us and the data.

Provided that the first and second milestones have occurred, PharmaBio will make one-third of the commitment available to us available for borrowing upon the later to occur of (i) the completion by Quintiles of a written assessment and report indicating the "approvability" by the FDA of our New Drug Application for Surfaxin for either Idiopathic Respiratory Distress Syndrome or Meconium Aspiration Syndrome or (ii) the issuance by the FDA of a letter indicating that our New Drug Application for Surfaxin is "approvable" with respect to our New Drug Application for either Idiopathic Respiratory Distress Syndrome or Meconium Aspiration Syndrome.

We are also entitled to two milestone payments under the Investment and Commission Agreement with PharmaBio, which will be used to offset and prepay principal amounts due under the credit facility.

Upon the occurrence of FDA approval for the commercialization of Surfaxin for Meconium Aspiration Syndrome or Idiopathic Respiratory Distress Syndrome, the first milestone payment will equal 70% of the outstanding amount of advances under the credit facility. This milestone payment will be used to offset and prepay the advances, and the available commitment under the credit facility will be reduced by an equivalent amount.

Upon the earlier to occur of (i) the completion by Quintiles of a written assessment and report indicating the "approvability" by the FDA of our New Drug Application for Surfaxin for whichever of the Meconium Aspiration Syndrome or Idiopathic Respiratory Distress Syndrome indications was not approved previously, or (ii) the issuance by the FDA of a letter indicating that our New Drug Application for Surfaxin for the indication is "approvable," the second milestone payment will equal the outstanding amount of advances under the credit facility. The milestone payment will be used to offset and prepay the advances, and the commitment under the credit facility will be terminated.

Notwithstanding the prepayment milestones, the credit facility will be payable in full on December 10, 2004.

Our obligations to PharmaBio under the credit facility are secured by limited collateral relating to Surfaxin pursuant to a Security Agreement. The pledged collateral includes all revenues derived from sales in the United States of Surfaxin for Meconium Aspiration Syndrome, Idiopathic Respiratory Distress Syndrome and for Acute Respiratory Distress Syndrome, as well as all clinical data and regulatory filings relating thereto, but does not include any intellectual property rights. Upon the occurrence of FDA approval for the commercialization of Surfaxin for Meconium Aspiration Syndrome or Idiopathic Respiratory Distress Syndrome, all pledged collateral that relates to Acute Respiratory Distress Syndrome will be released by Quintiles.

#### Equity Investment

Pursuant to the Common Stock and Warrant Purchase Agreement between PharmaBio and us, PharmaBio purchased 791,905 shares of our common stock at a price of \$3.79 per share. In addition, PharmaBio purchased two separate classes of warrants to purchase shares of our common stock. Pursuant to the Class G warrant, PharmaBio may purchase 357,143 shares of common stock (subject to adjustment), at a price of \$3.485 per share. PharmaBio also purchased a Class H warrant to purchase 320,000 shares of common stock at a price of \$3.03 per share. The Class H warrant vests in three equal increments equal to one-third of the shares of common stock issuable thereunder, upon the occurrence of each of the three milestones pursuant to which the commitment under the credit facility becomes available. The Class G warrant and Class H warrant each expire on December 10, 2011. To the extent that the commitment under the credit facility is increased to an amount greater than \$8.5 million, the amount of shares of common stock issuable pursuant to the Class H warrant will increase proportionally. Accordingly, for each additional \$1 million that PharmaBio makes available to us under the credit facility, the amount of shares of common stock issuable pursuant to the Class H warrant will be increased by approximately 38,500 shares.

The shares of common stock purchased by PharmaBio, or issuable pursuant to the Class G warrant and the Class H warrant, have not been registered under the Securities Act and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act. In addition, all of the shares of our common stock that PharmaBio bought pursuant to the Common Stock and Warrant Purchase Agreement are subject to certain restrictions on transfer as set forth in the Common Stock and Warrant Purchase Agreement. PharmaBio will have up to two "demand" registration rights that require us to register its shares of our common stock that it bought pursuant to the Common Stock and Warrant Purchase Agreement for resale under the Securities Act, including shares issuable pursuant to the Class G warrant and the Class H warrant. In addition, subject to certain limitations, PharmaBio has customary "piggyback" rights to include its shares of our common stock that it bought pursuant to the Common Stock and Warrant Purchase Agreement in other registrations of securities filed by us for resale under the Securities Act.

PharmaBio has agreed to certain limitations on its trading of, and purchase of additional shares of, our common stock, as well as certain prescriptions regarding the voting of its shares. PharmaBio also has the right pursuant to the Common Stock and Warrant Purchase Agreement to maintain its percentage equity ownership of our capital stock by purchasing additional securities on the same terms as any transaction in which we propose to raise additional equity capital. This right will be inapplicable to (i) underwritten public offerings, (ii) bona fide acquisitions, mergers, joint ventures, collaborative arrangements, strategic alliances or similar transactions, the terms of which are approved by our Board of Directors, or (iii) pursuant to any stock option, stock purchase or similar plan or arrangement for the benefit of our employees.

## RISK FACTORS

The following important factors, among others, could cause the Company's actual results, performance, achievements or industry results to differ materially from those expressed in the Company's 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 development stage company. Therefore, you must evaluate us in light of the uncertainties and complexities present in a development stage biotechnology company. We 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. To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of September 30, 2001, we have incurred an accumulated net operating loss of \$50,241,000 since inception, 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.

If we cannot raise additional capital we may need to discontinue our research and development activities. In addition, any additional financing could result in equity dilution.

We may need substantial additional funding to conduct our research and product development activities. Based on our current operating plan, we believe that our currently available resources will be adequate to satisfy our capital needs into the fourth quarter of 2002. Our future capital requirements will depend on the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. If our operations do not become profitable before we exhaust our resources, 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 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.

However, we have not entered into arrangements to obtain any additional financing, except for the credit facility with PharmaBio. 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 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. Furthermore, we could cease to qualify for listing of our securities on the NASDAQ SmallCap Market. See "Risk Factors--The market price of our stock may be adversely affected by market volatility."

The clinical trial and regulatory approval process for the Company's products will be 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. The process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, the trials could be suspended or terminated. We also may not reach agreement with the FDA and/or comparable foreign agencies on the design of clinical studies necessary for approval. In addition, conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of our clinical trials and the costs of conducting the clinical trials.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture, and sufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, the nature of the protocol, the proximity of the patients to the trial sites and the eligibility criteria for the clinical trials. 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 2002, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for Surfaxin, Meconium Aspiration Syndrome and Acute Respiratory Distress



Syndrome, have been granted designation as "fast track" products under provisions of the Food and Drug Administration Modernization Act of 1997, and the FDA has awarded us an orphan drug grant to support our development of Surfaxin for the treatment of Meconium Aspiration Syndrome. Fast track status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The fast track 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.

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

Our strategy for the completion of the required development and clinical testing of our products and for the manufacturing, marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. We have entered into a sublicense agreement with Laboratorios Del Dr. Esteve, S.A., for Surfaxin covering several countries in southern Europe including, but not limited to, Spain, Portugal and Greece, and, at the option of Esteve, Italy, and covering Central and South America and Mexico. Esteve will be responsible for the marketing of Surfaxin for Acute Respiratory Distress Syndrome/Acute Lung Injury and other neonatal indications. Esteve will also be responsible for conducting a phase 3 clinical trial for Idiopathic Respiratory Distress Syndrome and a phase 2 clinical trial for Acute Respiratory Distress Syndrome/Acute Lung Injury in the relevant countries.

On December 10, 2001, we entered into an exclusive collaboration with Quintiles, and its affiliate, PharmaBio, to commercialize, sell and market Surfaxin for indications of Meconium Aspiration Syndrome and Idiopathic Respiratory Distress Syndrome in the United States. 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. If Quintiles or we breach or terminate the agreements that make up the collaboration arrangements or Quintiles otherwise fails to conduct its Surfaxin-related activities in a timely manner or if there is a dispute about its obligations, we may need to seek another partner or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin which Quintiles has agreed to assist in commercializing. In that event, we may not be able to obtain another partner on favorable terms, if at all, and the need to develop an internal sales and marketing capability could 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".

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 line of credit for at least \$8.5 million which may be increased to \$10 million. A failure by us to repay the line of credit, 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, our failure to meet other terms and conditions of the financing leading to PharmaBio's termination thereof or the failure of PharmaBio to fulfill its obligation to partially fund the commercialization of Surfaxin, may affect our ability to successfully market Surfaxin.

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.



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, or the parties licensing technologies to us, have filed various United States and foreign patents 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. In particular, our issued and pending patents relating to SuperVent(TM) solely cover relatively high concentrations of tyloxapol.

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. 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, Inc., and its wholly-owned subsidiary, Ortho Pharmaceutical Corporation, and the Charlotte-Mecklenburg Hospital Authority. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing arrangements. All 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.

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; or
- --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, including Akorn, Inc., Genzyme Pharmaceuticals, a division of the Genzyme Corporation, Avanti Polar Lipids, Inc., and BACHEM California, Inc., for our drug substance and other active ingredients for Surfaxin and to produce appropriate clinical grade material that meets standards for use in clinical studies for our products. We will also rely on outside manufacturers for production of our products after marketing approval. We may also enter into arrangements with other manufacturers for the manufacture of materials for use in clinical testing and after marketing approval.

Our outside manufacturers may not perform as they have agreed or may not 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. We do not currently have a manufacturing facility, manufacturing experience or manufacturing personnel 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.

In addition, the FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators inspect these facilities to confirm compliance with GMP or similar requirements that the FDA or corresponding foreign regulators establish. 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 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 Meconium Aspiration Syndrome and Idiopathic Respiratory Distress Syndrome in the United States and with Esteve for the marketing and sales of Surfaxin for Acute Respiratory Distress Syndrome in certain countries in Southern Europe, Central America and Mexico. 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 Meconium Aspiration Syndrome and Idiopathic Respiratory Distress Syndrome in the relevant territories depends, in part, on Quintiles and Esteve to perform 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, Robert J. Capetola, Ph.D., and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have an employment agreement with Dr. Capetola that expires on December 31, 2005. We also have employment agreements with other key personnel with termination dates in 2003 and 2004. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers.

While we attempt to provide competitive compensation packages to attract and retain key personnel, some of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

Our industry is highly competitive and we have less capital and resources than many of our competitors, which may give them an advantage in developing and marketing products similar to ours or make our products obsolete.

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies intensely in many ways. We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

- --developing products;
- --undertaking preclinical testing and human clinical trials;
- --obtaining FDA and other regulatory approvals or products; and
- --manufacturing and marketing products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or comparable foreign approval or commercializing products before us. If we commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities who may successfully develop and commercialize products that are more effective or less expensive than ours. These are areas in which, as yet, we have limited or no experience. In addition, developments by our competitors may render our product candidates obsolete or noncompetitive.

Presently, there are no approved drugs that are specifically indicated for Meconium Aspiration Syndrome or Acute Respiratory Distress Syndrome/Acute Lung Injury. Current therapy consists of general supportive care and mechanical ventilation. Four products are specifically approved for the treatment of Idiopathic Respiratory Distress Syndrome. Curosurf(TM), marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc., is a porcine lung extract. Exosurf(TM), marketed by GlaxoSmithKline, plc, contains only phospholipids (the fats normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. Survanta(TM), marketed by the Ross division of Abbot Laboratories, Inc., is an extract of bovine lung that contains the cow version of surfactant protein B. Forest Laboratories, Inc., markets its calf lung surfactant, Infasurf(TM), for use in Idiopathic Respiratory Distress Syndrome. Although none of the four approved surfactants for Idiopathic Respiratory Distress Syndrome is approved for Acute Respiratory Distress Syndrome or Acute Lung Injury, which are significantly larger markets, there are a significant number of other potential therapies in development for the treatment of Acute Respiratory Distress Syndrome/Acute Lung Injury that are not surfactant related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. The Company believes that synthetic surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products approved for the treatment of Idiopathic Respiratory Distress Syndrome and will have no capability of



transmitting the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease"). Genentech, Inc., has marketed Pulmozyme(TM) in the United States and Canada as a Cystic Fibrosis therapy since early 1994. Pulmozyme(TM) reduces the viscosity of Cystic Fibrosis mucus by cleaving the DNA released from destroyed inflammatory, epithelial (lung surface) and bacterial cells which collect in mucus and contribute to its abnormal viscosity and adherence.

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 SuperVent(TM) and 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. In addition, significant uncertainty exists as to the reimbursement status of newly approved health care products. Our products may not be considered cost effective. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in the research and development of our products.

The United States and other countries continue to propose and pass legislation designed to reduce the cost of healthcare. Accordingly, legislation and regulations affecting the pricing of our products may change before the products are approved for marketing to the public. Adoption of new legislation and regulations could further limit reimbursement for our products. If third party payors fail to provide adequate coverage and reimbursement rates for our products, the market acceptance of the products may be adversely affected. In that case, our business and financial condition will suffer.

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 October 25, 2001, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 29% 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 the 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 U.S. 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."

The Company's common stock is listed for quotation on the NASDAQ SmallCap Market. For the 12-month period ended October 25, 2001, the price of our common stock has ranged from \$2.00 to \$6.375. We expect the price of our common stock to remain volatile. The average daily trading volume in the Company's common stock varies significantly. For the 12-month period ending October 25, 2001, the average daily trading volume in our common stock was approximately 45,500 shares and the average number of transactions per day was approximately 56. The Company's 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 October 25, 2001, we had 24,753,138 shares of common stock outstanding. In addition, as of October 25, 2001, up to 6,383,791 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. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock.

## 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 and Section 21E of the Exchange Act, 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 risk that our lead product candidate, Surfaxin, will not prove to be safe or useful for the treatment of certain indications); 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 results of clinical trials being conducted by the Company; the progress of the FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; the additional cost and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; and the other risks and certainties detailed in "Risk Factors", in this prospectus generally and in the documents incorporated by reference in this prospectus.

Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to publicly announce revisions to any of the Forward-Looking Statements.

## 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

The following table sets forth information with respect to the amount of common stock held by each selling stockholder as of the date of this prospectus and the shares being offered by the selling stockholders. 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 4,440,222 shares of common stock, including 877,463 shares of common stock issuable upon the exercise of outstanding warrants issued by Discovery Laboratories. 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
Concordia Partners LP	363,776	45,977	409,753	*	275,862	133,891	*
Coralbasin & Co.	1,149,425	229,885	1,379,310	5.52	1,379,310	0	0
Coralrock & Co.	574,713	114,943	689,656	2.77	689,656	0	0
Gary B. Davis	60,977	9,195	70,172	*	55,172	15,000	*
Deutsche Bank AG, London Branch	229,885	45,977	275,862	1.11	275,862	0	0
Milton H. Dresner Revocable Living Trust	11,494	2,299	13,793	*	13,793	0	0
Boro Durakovic	13,793	2,759	16,552	*	16,552	0	0
First Investors Holding Co.	137,931	27,586	165,517	*	165,517	0	0
Jesup & Lamont Securities Corp.		164,911	164,911	*	164,911	0	0
Keys Foundation	306,808	45,977	352,785	1.42	275,862	76,923	*
Maria Molinsky	52,774	7,675	60,449	*	27,587	32,862	*
Tis Prager	42,175	6,897	49,072	*	41,380	7,692	*
Roseworth Group Limited	114,937	22,987	137,924	*	137,924	0	0
Wayne Saker	45,977	9,195	55,172	*	55,172	0	0
Shipman & Goodwin LLP Profit Sharing	11,500	2,300	13,800	*	13,800	0	0
Peter Stern	11,494	2,299	13,793	*	13,793	0	0
Ursus Capital LP	343,896	33,793	377,689	1.52	202,759	174,930	*
Ursus Offshore Ltd.	357,932	35,172	393,104	1.59	211,034	182,070	*
Valor Capitol Management, LP	392,950	64,368	457,318	1.84	386,207	71,111	*
Jacqueline Waterman	5,517	1,103	6,620	*	6,620	0	0
Bruno Widmer	22,989	4,598	27,587	*	27,587	0	0
William Wolff, MD	3,218	644	3,862	*	3,862	0	0

\* Less than 1%.

The information contained in this table reflects "beneficial" ownership of common stock within the meaning of Rule 13d-3 under the Exchange Act. On October 25, 2001, the Company had 24,752,112 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.

Except as set forth below, 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. Jesup & Lamont Securities Corp., was the placement agent for our private placement that closed on October 1, 2001, through which all the selling stockholders bought the shares that are being registered hereby. Jesup & Lamont's shares represent shares of common stock that are issuable pursuant to the placement warrant issued to it for acting as our placement agent. Gary B. Davis, Peter Stern and Jacqueline Waterman are registered representatives of Jesup & Lamont.

#### PLAN OF DISTRIBUTION

The shares of common stock covered by this prospectus are beneficially owned by the selling stockholders. The selling stockholders and any of their pledgees, assignees and successors-in-interest may offer and sell, at one time or from time to time, some or all of the shares. We have registered the shares for sale by the selling stockholders so that the shares will be freely tradeable 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 all 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 may be sold under Rule 144 rather than pursuant to this prospectus.

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.

If a material arrangement with any broker-dealer or other agent is entered into for the sale of any shares through a block trade, special offering, exchange distribution, secondary distribution or a purchase by a broker or dealer, a prospectus supplement will be filed, if necessary, pursuant to Rule 424(b) under the Securities Act disclosing the material terms and conditions of these arrangements.

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 the Securities Act, 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 this capacity, may be deemed to be underwriting 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 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 SEC. You may read and copy any document we file at the SEC's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549, 233 Broadway, New York, New York 10279, and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661- 2511. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public from the SEC's Website at "<http://www.sec.gov>."

We have filed with the SEC a registration statement (which contains this prospectus) on Form S-3 under the Securities Act. 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 SEC allows us to "incorporate by reference" the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents filed with SEC listed below:

1. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2000, and Amendment No. 1 to the Annual Report on Form 10-KSB/A filed on January 10, 2002;
2. Our Quarterly Reports (unaudited) on Form 10-QSB for the quarterly periods ending March 31, 2001, June 30, 2001, and September 30, 2001;
3. Our Form 8-Ks dated December 19, 2001, October 5, 2001, May 7, 2001, and March 2, 2001; and
4. The description of our capital stock contained in our Form 8-A dated July 13, 1995.

In addition, all documents we have filed with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act 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 writing or telephoning us at the following address: Discovery Laboratories, Inc., 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901, Attention: Cynthia Davis. Telephone requests may be directed to (215) 340-4699, extension 112. 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., and subsidiary (collectively, "Discovery") as of December 31, 2000, and for the year then ended, and for the period from May 18, 1993 (inception), through December 31, 2000 included in Discovery's Annual Report (Form 10-KSB/A), have been incorporated by reference in this registration statement in reliance on the report of Ernst & Young LLP, independent auditors, appearing therein. In addition, the consolidated financial statements of Discovery for the year ended December 31, 1999 and for the period from May 18, 1993 (inception) through December 31, 1999 (from inception through December 31, 1999 not presented separately therein except for the consolidated statement of changes in stockholders' equity) included in such Annual Report (Form 10-KSB/A), have been incorporated by reference in this Registration Statement in reliance on the report of Richard A. Eisner & Company, LLP, independent auditors, appearing therein. Such reports have been given upon the authority of the respective independent auditors reporting thereon 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.

4,440,222 SHARES

DISCOVERY LABORATORIES, INC.

COMMON STOCK

January 10, 2002

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 SEC registration fee.

	Amount
SEC registration fee.....	\$ 3,178.10
Accounting fees and expenses.....	\$ 7,000.00
Legal fees and expenses.....	\$25,000.00
Miscellaneous fees and expenses.....	\$ 4,821.90
	-----
Total .....	\$40,000.00
	=====

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 Richard A. Eisner & Company, LLP, predecessor independent auditors.
23.2	Consent of Ernst & Young LLP, independent auditors.
23.3	Consent of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel (included in Exhibit 5.1).*
24.1	Powers of Attorney.*

\* Filed as an exhibit to the Registration Statement on Form S-3 filed with the SEC on November 1, 2001.

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;
  - (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 Exchange Act that are incorporated by reference in the Registration Statement.

- (2) That, for the purpose of determining any liability under the Securities Act, 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.

SIGNATURES

Pursuant to the requirement of the Securities Act, 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 10th day of January, 2002.

DISCOVERY LABORATORIES, INC.  
(Registrant)

By: /s/ Robert J. Capetola, Ph.D.  
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Robert J. Capetola, Ph.D.  
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, Ph.D. -----	Robert J. Capetola, Ph.D. Chief Executive Officer	January 10, 2002
/s/ John G. Cooper -----	John G. Cooper Principal Financial Officer	January 10, 2002
/s/ * -----	Cynthia Davis Controller	January 10, 2002
/s/ * -----	Herbert McDade, Jr. Chairman of the Board of Directors	January 10, 2002

/s/ \*  
-----

Max Link, Ph.D.  
Director

January 10, 2002

/s/ \*  
-----

Richard Power  
Director

January 10, 2002

\* 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 November 1, 2001.

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

23.1 Consent of Richard A. Eisner & Company, LLP, predecessor independent auditors.\*

23.2 Consent of Ernst & Young LLP, independent auditors.\*

24.1 Powers of Attorney (1)

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\* Filed herewith.

(1) Filed as an exhibit to the Registration Statement on Form S-3, filed November 1, 2001.

INDEPENDENT AUDITORS' CONSENT

We consent to the reference to our firm under the caption "Experts" in the Registration Statement on Form S-3 Amendment No. 1 (File No. 333-72614) and the related Prospectus of Discovery Laboratories, Inc. for the registration of 4,440,222 shares 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 as of and for the year ended December 31, 1999 and for the period from May 18, 1993 (inception) through December 31, 1999 (from inception through December 31, 1999 not presented separately therein except for the consolidated statement of changes in stockholders' equity) included in its annual report on Form 10-KSB/A for the year ended December 31, 2000, filed with the Securities and Exchange Commission.

Richard A. Eisner & Company, LLP

New York, New York  
January 8, 2002

## Consent of Independent Auditors

We consent to reference to our firm under the caption "Experts" in the Registration Statement (Form S-3 No. 333-72614, as amended) and related prospectus of Discovery Laboratories, Inc. for the registration of 4,440,222 shares of its common stock and to the incorporation by reference therein of our report dated March 27, 2001, with respect to the consolidated financial statements of Discovery Laboratories, Inc. included in its Annual Report (Form 10-KSB/A) for the year ended December 31, 2000, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
January 8, 2002