As filed with the Securities and Exchange Commission on December 5, 2002
Registration No. 333-[_____]

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

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

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

(Address, Including Zip Code and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Robert J. Capetola, Ph.D.
Chief Executive Officer
350 South Main Street, Suite 307
Doylestown, Pennsylvania 18901
(215) 340-4699
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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

Approximate date of commencement of proposed sale to public: From time to time or at one time after this Registration Statement becomes effective.

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee
Common Stock, $.001 par value	9,301,399	$2.725	$25,346,312	$2,331.86

(1) Includes 2,878,882 shares of common stock issuable upon the exercise of certain Class I warrants issued by the registrant and 25,000 shares of common stock issuable upon the exercise of certain other 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 $2.725 (which was the average of the high and low sales price of the common stock on the Nasdaq SmallCap Market on December 2, 2002) by: (i) 6,397,517 shares of common stock owned by the selling stockholders and registered for resale hereunder, (ii) 2,878,882 shares of common stock issuable upon the exercise of certain Class I warrants, and (iii) 25,000 shares of common stock issuable upon the exercise of certain other warrants issued by the registrant. 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.

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

SUBJECT TO COMPLETION
PRELIMINARY PROSPECTUS DATED DECEMBER 5, 2002

9,301,399 Shares

DISCOVERY LABORATORIES, INC.

Common Stock

This prospectus relates to the public offering, which is not being underwritten, of 9,301,399 shares of our common stock, par value $.001 per share, which may be sold by the selling stockholders listed on page 17 for their own account. These shares include 2,903,882 shares that are issuable upon exercise of outstanding warrants.

Our common stock is traded on the Nasdaq SmallCap Market under the trading symbol "DSCO." On December 2, 2002, the closing sales price of our common stock was $2.65 per share.

Investing in our common stock involves risks. SEE "RISK FACTORS" BEGINNING ON PAGE 4.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus is December 5, 2002.

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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 development stage specialty pharmaceutical company leveraging our platform technology in humanized lung surfactants to develop potential novel respiratory therapies and pulmonary drug delivery products. Surfactants are substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen.

Our humanized surfactant technology is being developed initially for critical care patients with life-threatening respiratory disorders where there are few, if any, approved therapies. These severe respiratory disorders generally are associated with a lack of functional surfactant. Surfaxin(R), our lead product, is an engineered humanized surfactant and is currently in two Phase 3 clinical trials for Respiratory Distress Syndrome in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome in full-term infants, and a Phase 2 clinical trial for Acute Lung Injury/Acute Respiratory Distress Syndrome in adults.

We are currently conducting research and development of aerosolized formulations of our humanized surfactant to treat respiratory conditions such as asthma and as a novel pulmonary drug delivery vehicle to render drugs more effective when delivered to or via the respiratory tract.

We believe that our platform technology has the potential to generate products for the critical care markets as well as for use in the broad non-critical care, ambulatory markets. We are presently developing a dedicated sales and marketing capability through a collaboration with Quintiles Transnational to commercialize Surfaxin for Respiratory Distress Syndrome and Meconium Aspiration Syndrome in the United States. We also have expanded our strategic alliance with Laboratorios del Dr. Esteve to commercialize Surfaxin in Europe, Central and South America, and Mexico. In the non-critical care, ambulatory markets, we plan to establish strategic alliances for the development and commercialization of our products.

Surfactants are protein and lipid (fat) compositions that are produced naturally in the lungs and are critical to all air-breathing mammals. They facilitate respiration by continually modifying the surface tension of the fluid normally present within the air sacs, or alveoli, that line the inside of the lungs. In the absence of sufficient surfactant, these air sacs tend to collapse, and, as a result, the lungs do not absorb sufficient oxygen.

A lack of surfactant adversely affects both infants and adults. Premature infants born prior to 32 weeks gestation have not fully developed a natural lung surfactant and therefore need treatment to sustain life. In other clinical conditions, surfactant that normally exists in the lungs is degraded or otherwise destroyed, resulting in a variety of respiratory diseases.

Human surfactants include four known surfactant proteins, A, B, C and D. Surfactant protein B has been found essential for respiratory function in numerous studies. Our humanized surfactant platform

technology, including Surfaxin, is engineered to mimic human surfactant protein B and is based on our proprietary peptide, which is known as sinapultide (a 21 amino acid protein-like substance that mimics an important human lung protein). This technology was invented at The Scripps Research Institute and was exclusively licensed to Johnson & Johnson which, together with its wholly owned subsidiary, Ortho Pharmaceutical, developed it further. We acquired the exclusive worldwide sublicense to the technology from Johnson & Johnson in October 1996.

A lack of functional surfactant is associated with a variety of respiratory diseases such as Respiratory Distress Syndrome in premature infants, Acute Respiratory Distress Syndrome in adults, Meconium Aspiration Syndrome in full-term infants, asthma, chronic obstructive pulmonary disorder (COPD) and acute lung injury, among others. However, the FDA has only approved replacement surfactants for Respiratory Distress Syndrome in premature infants. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Though they are clinically effective, they have drawbacks and cannot readily be scaled and developed to treat broader populations for Respiratory Distress Syndrome in premature infants and other respiratory diseases. These animal-sourced products are prepared using a chemical extraction process from minced cow and pig lung. Because of the animal-sourced materials and the chemical extraction processes, there is significant variation in production lots and, consequently, product quality specifications must be broad. In addition, the protein levels of these animal-derived surfactants are inherently lower than the protein levels of native human surfactant. The production costs of these animal-derived surfactants are high, relative to other pharmaceutical products, generation of large quantities is severely limited, and these products cannot readily be reformulated for aerosol delivery to the lungs.

We believe that our potential products, based on engineered humanized surfactant, can be manufactured more economically than the animal-derived surfactants, in exact and consistent pharmaceutical grade quality, and in volumes to meet significant medical needs. In addition, we believe that our engineered humanized surfactants might possess other pharmaceutical benefits not currently found with the animal surfactants such as longer shelf-life, reduced number of administrations to the patient's lungs, and elimination of the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease") and adverse immunological responses in young and older adults. Our products also have the ability to be more precisely formulated, such as aerosolized liquids or dry powders, to potentially address various medical indications such as asthma, COPD, otitis media and acute lung injury.

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 and Meconium Aspiration Syndrome can occur if the baby breathes it in. Both 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 Lung Injury/Acute Respiratory Distress Syndrome in adults is a life-threatening disorder for which no approved therapies exist anywhere in the world. It is characterized by an excess of fluid in the lungs and decreased oxygen levels in the patient. One prominent characteristic is the destruction of surfactants present in lung tissue. The conditions are caused by illnesses including pneumonia and septic shock (a toxic condition caused by infection) and events such as smoke inhalation, near drowning, industrial accidents and other traumas.

Respiratory Distress Syndrome affects approximately 60,000 premature infants per year in the United States with an estimated approximately 100,000 infants presently receiving surfactant therapy worldwide. The incidence of Acute Lung Injury/Acute Respiratory Distress Syndrome ranges between approximately 150,000 and 250,000 patients per year in the United States, with a similar number of patients afflicted in Europe, 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.

In 2001, we initiated two Phase 3 clinical trials for the treatment of Respiratory Distress Syndrome in premature infants - a pivotal, multinational landmark trial in 1,500 patients and a 500 patient supportive, multinational trial. The landmark trial is designed to demonstrate the superiority of Surfaxin over certain commercially available treatments. The supportive trial is being conducted in Europe and is designed to demonstrate the safety and non-inferiority of Surfaxin over a certain animal-derived surfactant. The majority of our development resources are focused on these trials and we currently anticipate completing the trials, announcing data and filing a New Drug Application with the FDA in the second quarter of 2003.

For Acute Respiratory Distress Syndrome in adults, we currently are conducting a Phase 2 dose-ranging safety and efficacy study of up to 110 patients in the United States. In July 2002, we completed the dose escalation safety and tolerability part of the study and are currently enrolling patients in the final part of the trial. We currently expect data from the Acute Respiratory Distress Syndrome trial to be available in the first quarter of 2003. We are presently conducting a pivotal Phase 3 clinical trial of Surfaxin for the treatment of Meconium Aspiration Syndrome in newborns. This trial calls for the enrollment of up to 200 patients. Enrollment has been very slow and completion of this trial is currently anticipated not to occur until late 2003.

Given our belief in the importance of the pivotal Phase 3 trial for Respiratory Distress Syndrome in premature infants to our present development plan, resources have been and will continue to be reallocated from the Meconium Aspiration Syndrome program and other programs to the Respiratory Distress Syndrome program, as necessary.

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

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

Risk Factors

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

Because we are a development stage company, we may not successfully develop and market our products, and even if we do, we may not generate enough revenue or become profitable.

We are a 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, 2002, we have incurred a deficit accumulated during the development stage of approximately $66.6 million, and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

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 first half of 2004. 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.

We have not entered into arrangements to obtain any additional financing, except for the $8.5 million revolving credit facility with PharmaBio Development Inc., a subsidiary of Quintiles Transnational Corp., which may be expanded to $10 million 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 if the market price of our common stock declines as a result of the

dilutive aspects of such potential financings. See "Risk Factors-The market price of our stock may be adversely affected by market volatility."

The clinical trial and regulatory approval process for our products 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 (GMPs) 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 2004, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for Surfaxin, Meconium Aspiration Syndrome in full-term infants and Acute Respiratory Distress Syndrome in adults, have been granted designation as "fast track" products under provisions of the Food and Drug Administration Modernization Act of 1997, and the FDA has awarded us an Orphan Products Development 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 Status provisions are designed to shorten the waiting period between the time the New Drug Application is filed and the FDA's review of such application for 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. In early 2002, we expanded our relationship with Laboratorios Del Dr. Esteve, S.A., by entering into a collaboration arrangement with Esteve for Surfaxin covering all of Europe, Central America and South America, and Mexico. Esteve will be responsible for the marketing of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for the commercialization of Surfaxin in Europe for the Acute Lung Injury/Acute Respiratory Distress Syndrome indications. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to European Medicines Evaluation Agency filings.

In December 2001, we entered into an exclusive collaboration arrangement in the United States with Quintiles, and its affiliate, PharmaBio, to commercialize, sell and market Surfaxin in the United States for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants. As part of our collaboration with Quintiles, Quintiles will build a sales force solely dedicated to the sale of Surfaxin upon the approval of a New Drug Application for either of the two indications. If Quintiles and we fail to devote appropriate resources to commercialize, sell and market Surfaxin, sales of Surfaxin could be reduced. As part of the collaboration, PharmaBio is obligated to provide us with certain financial assistance in connection with the commercialization of Surfaxin, including, but not limited to, a secured, revolving credit facility for at least $8.5 million which may be increased to $10 million. A failure by us to repay amounts outstanding under the credit facility would have a material adverse effect on us. To obtain the benefits of such financing, we are obligated to meet certain development and performance milestones. The failure by us to meet the milestones, 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.

If Esteve, Quintiles or we breach or terminate the agreements that make up such collaboration arrangements or Esteve or Quintiles otherwise fail to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their respective obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin which Esteve and/or Quintiles have agreed to assist in commercializing. Accordingly, we may need to enter into additional collaboration agreements and our success, particularly outside of the United States, may depend upon obtaining additional collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See "Risk Factors-Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales."

If we cannot protect our intellectual property, other companies could use our technology in competitive products. If we infringe the intellectual property rights of others, other companies could prevent us from developing or marketing our products.

We seek patent protection for our drug candidates so as to prevent others from commercializing equivalent products in substantially less time and at substantially lower expense. The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in part on our ability and that of parties from whom we license technology to:

- -- defend our patents and otherwise prevent others from infringing on our proprietary rights;

- -- protect trade secrets; and

- -- operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

The patent position of firms relying upon biotechnology is highly uncertain and involves complex legal and factual questions for which important legal principles are unresolved. To date, the United States Patent and Trademark Office has not adopted a consistent policy regarding the breadth of claims that the United States Patent and Trademark Office allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

Even if we obtain patents to protect our products, those patents may not be sufficiently broad and others could compete with us.

We, or the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United

States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the United States Patent and Trademark Office or foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson, Inc., and Ortho Pharmaceutical Corporation which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2019. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risk Factors-If we cannot meet requirements under our license agreements, we could lose the rights to our products."

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

Our commercial success also significantly depends on our ability to operate without infringing the patents or violating the proprietary rights of others. The United States Patent and Trademark Office keeps United States patent applications confidential while the applications are pending. As a result, we cannot determine which inventions third parties claim in pending patent applications that they have filed. We may need to engage in litigation to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. It will be expensive and time consuming to defend and enforce patent claims. Thus, even in those instances in which the outcome is favorable to us, the proceedings can result in the diversion of substantial resources from our other activities. An adverse determination may subject us to significant liabilities or require us to seek licenses that third parties may not grant to us or may only grant at rates that diminish or deplete the profitability of the products to us. An adverse determination could also require us to alter our products or processes or cease altogether any related research and development activities or product sales.

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

We depend on licensing arrangements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Johnson & Johnson and Ortho Pharmaceutical. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing arrangements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

In addition, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We rely on confidentiality agreements that could be breached and may be difficult to enforce.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to obtain these types of agreements from our consultants, advisors and research collaborators, to the extent that they apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with our employees, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- -- they will breach these agreements;

- -- any agreements we obtain will not provide adequate remedies for this type of breach or that our trade secrets or proprietary know-how will otherwise become known or competitors will independently develop similar technology; and

- -- our competitors will independently discover our proprietary information and trade secrets.

If the parties we depend on for manufacturing our pharmaceutical products do not timely supply these products, it may delay or impair our ability to develop and market our products.

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies for our products. We have validated only a single clinical manufacturing facility owned and operated by Akorn, Inc., to produce appropriate clinical grade material of our drug substance that meets standards for use in our ongoing clinical studies. 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. Although we own certain specialized manufacturing equipment and employ certain manufacturing managerial personnel, we are considering an investment in additional manufacturing equipment. We do not presently maintain a complete manufacturing facility or manufacturing department and we do not anticipate manufacturing on our own any of our products during the next 12 months. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

The FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with good manufacturing practices (GMPs) or similar requirements that the FDA or corresponding foreign regulators establish. Manufacturing or quality control problems could occur at the contract manufacturers causing product production and shipment delays or a situation where the contractor may not be able to maintain compliance with the FDA's current GMP requirements necessary to continue manufacturing our drug substance. If our third-party foreign or domestic suppliers or manufacturers of our products or, if we decide to manufacture our products on our own, we, fail to comply with GMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our clinical research activities and our ability to market and develop our products.

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

We do not have marketing, sales or distribution experience or marketing or sales personnel. As a result, we will depend on our collaboration with Quintiles for the marketing and sales of Surfaxin for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants in the United States and with Esteve for the marketing and sales of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in all of Europe, Central America and South 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 Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in the relevant territories depends, in part, on Quintiles' and Esteve's performance of their contractual obligations. The failure of either party to do so would have a material adverse effect on the sales and marketing of Surfaxin. We may not succeed

in entering into any satisfactory third party arrangements for the marketing and sale of our remaining products. In addition, we may not succeed in developing marketing and sales capabilities, our commercial launch of certain products may be delayed until we establish marketing and sales capabilities or we may not have sufficient resources to do so. If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties, in a timely manner, it will adversely affect sales of our products.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have an employment agreement with Dr. Capetola that expires on December 31, 2005. We also have employment agreements with other key personnel with termination dates in 2004 and 2005. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

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

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

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

Our industry is highly competitive and subject to rapid technological innovation and evolving industry standards. We compete with numerous existing companies intensely in many ways. We intend to market our products under development for the treatment of diseases for which other technologies and treatments are rapidly developing and, consequently, we expect new companies to enter our industry and that competition in the industry will increase. Many of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and

managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

- -- developing products;

- -- undertaking preclinical testing and human clinical trials;

- -- obtaining FDA and other regulatory approvals or products; and

- -- manufacturing and marketing products.

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

Presently, there are no approved drugs that are specifically indicated for Meconium Aspiration Syndrome in full-term infants or Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Current therapy consists of general supportive care and mechanical ventilation. Four products are specifically approved for the treatment of Respiratory Distress Syndrome in premature infants. Curosurf(TM) is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Exosurf(TM) is marketed by GlaxoSmithKline, plc, outside the United States and contains only phospholipids (the fats normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. 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. Forrest Laboratories, Inc., markets its calf lung surfactant, Infasurf(TM) in the United States for the treatment of Respiratory Distress Syndrome in premature infants. Although none of the four approved surfactants for Respiratory Distress Syndrome in premature infants is approved for Acute Lung Injury or Acute Respiratory Distress Syndrome in adults, which are significantly larger markets, there are a significant number of other potential therapies in development for the treatment of Acute Lung Injury/Acute Respiratory Distress Syndrome that are not surfactant-related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin. We believe that engineered humanized surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products approved for the treatment of Respiratory Distress Syndrome in premature infants and will have no capability of transmitting the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease") or causing adverse immunological responses in young and older adults.

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

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

The clinical testing of, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to $10,000,000 per occurrence and $10,000,000 in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is without merit 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 November 25, 2002, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 15.2% 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."

Our common stock is listed for quotation on the NASDAQ SmallCap Market. For the 12-month period ended November 25, 2002, the price of our common stock has ranged from $0.90 to $4.38. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ending November 25, 2002, the average daily trading volume in our common stock was 49,450 shares and the average number of transactions per day was approximately 53. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the SmallCap Market. If our 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 without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

A substantial number of our securities are eligible for future sale and this could affect the market price for our stock and our ability to raise capital.

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of November 25, 2002, we had 32,849,683 shares of common stock outstanding. In addition, as of November 25, 2002, up to approximately 11,203,232 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 of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements regarding the expectations, beliefs, intentions or strategies for the future. We intend that all forward-looking

statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to, the inherent risks and uncertainties in developing products of the type we are developing; possible changes in our financial condition; the progress of our research and development (including the 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 9,301,399 shares of common stock, including 2,903,882 shares of common stock issuable upon the exercise of outstanding warrants issued by us. The selling stockholders may offer all or part of the shares of common stock covered by this prospectus. Information with respect to shares owned beneficially after the offering assumes the sale of all of the shares offered and no other purchases or sales of common stock. The common stock offered by this prospectus may be offered from time to time by the selling stockholders named below.

Name	Number of Shares of Common Stock, not including Warrants, Beneficially Owned	Number of Shares Represented by Warrants Beneficially Owned	Total Number of Shares of Common Stock Beneficially Owned	Percentage Beneficially Owned Before Offering	Number of Shares to be Offered for the Account of the Selling Stockholder	Number of Shares to be Owned after this Offering	Percentage to be Beneficially Owned after this Offering
Biotechnology Development Fund II, L.P.	1,527,806	687,513	2,215,319	*	2,215,319	0	0
Bristol Investment Partners I, LP		25,000	25,000	*	25,000	0	0
DMG Legacy Fund LLC	21,826	9,822	31,648	*	31,648	0	0
DMG Legacy Institutional Fund LLC	202,980	91,341	294,321	*	294,321	0	0
DMG Legacy International, Ltd.	211,710	95,269	306,979	*	306,979	0	0
U.S. Bank, N.A(1)	1,742,790	784,256	2,527,046	*	2,527,046	0	0
Jeffrey R. Jay	250,470	112,711	363,181	*	363,181	0	0
Laboratorios del Dr. Esteve, S.A.	1,644,284	153,218	1,797,502	5.45%	493,703	1,303,799	3.97%
PharmaBio Development Inc.	1,058,151	690,288	1,748,439	5.21%	386,057	1,362,382	4.08%
SDS Merchant Fund L.P.	218,258	98,216	316,474	*	316,474	0	0
Special Situations Cayman Fund, L.P.	218,258	98,216	316,474	*	316,474	0	0
Special Situations Fund III, L.P.	654,774	294,648	949,422	*	949,422	0	0
Special Situations Private Equity Fund, L.P.	654,774	294,648	949,422	*	949,422	0	0
Scalloptide & Co. (2)	87,140	39,213	126,353	*	126,353	0	0

* Less than 1%.

(1) As nominee for Heartland Value Fund.

(2) As nominee for State Street Research Health Sciences Fund.

The information contained in this table reflects "beneficial" ownership of common stock within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934. On November 25, 2002, we had 32,849,683 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.

PLAN OF DISTRIBUTION

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

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

these prevailing market prices or at negotiated prices. The shares may be sold by means of one or more of the following methods:

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

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

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

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

- directly to one or more purchasers;

- through agents;

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

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

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

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

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

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

- ordinary brokerage transactions; or

- transactions in which the broker-dealer solicits purchasers.

The selling stockholders and any broker-dealers or agents participating in the distribution of the shares may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act of 1933, and any profit on the sale of the shares by the selling stockholders and any commissions received by a broker-dealer or agents, acting in such capacity, may be deemed to be underwriting discounts or

commissions under the Securities Act of 1933. 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 of 1933.

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

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

INTERESTS OF NAMED EXPERTS AND COUNSEL

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

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the Securities and Exchange Commission's public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference rooms. Many of our Securities and Exchange Commission filings are also available to the public from the Securities and Exchange Commission's Website at "http://www.sec.gov."

We have filed with the Securities and Exchange Commission a registration statement (which contains this prospectus) on Form S-3 under the Securities Act of 1933. The registration statement relates to the common stock offered by the selling stockholders. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. Please refer to the registration statement and its exhibits and schedules for further

information with respect to us and the common stock. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of that contract or document filed as an exhibit to the Registration Statement. You may read and obtain a copy of the registration statement and its exhibits and schedules from the SEC, as described in the preceding paragraph.

INFORMATION INCORPORATED BY REFERENCE

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

1. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001;

2. Our Quarterly Reports (unaudited) on Form 10-Q for the quarterly periods ending March 31, 2002, June 30, 2002, and September 30, 2002;

3. Our Current Reports on Form 8-K filed with the Securities and Exchange Commission on January 14, 2002, March 8, 2002, and November 12, 2002; and

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

In addition, all documents we have filed with the Securities and Exchange Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 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 or telephone number: Discovery Laboratories, Inc., 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901, Attention: Lisa Caperelli; (215) 340-4699, extension 147. 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") appearing in Discovery's Annual Report (Form 10-KSB) for the year ended December 31, 2001, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference, which, as to the period from May 18, 1993 (inception) through December 31, 1999 is based on the report of Eisner LLP (formerly Richard A. Eisner & Company, LLP), independent auditors. In addition, the consolidated statements of operations, changes in stockholders' equity and cash flows of Discovery for the period from May 18, 1993 (inception) through December 31, 1999 (the consolidated statements of operations and cash flows are not presented separately therein) included in Discovery's Annual Report (Form 10-KSB) for the year ended December 31, 2001, have been audited by Eisner LLP (formerly Richard A. Eisner & Company, LLP), independent auditors, as set forth in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon reports given upon the authority of such firms as experts in accounting and auditing.

LEGAL MATTERS

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

We have not authorized anyone to provide you with information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. The selling stockholders are offering to sell, and seeking offers to buy, only the shares of Discovery Laboratories, Inc., common stock covered by this prospectus, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or of any sale of the shares.

9,301,399 SHARES

DISCOVERY LABORATORIES, INC.

COMMON STOCK

December 5, 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 Securities and Exchange Commission registration fee.

	Amount
Securities and Exchange Commission registration fee	$ 2,332
Accounting fees and expenses	$ 8,000
Legal fees and expenses	$25,000
Miscellaneous fees and expenses	$ 3,500
Total	$38,832

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

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

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

We have entered into indemnification agreements with certain of our executive officers containing provisions that may require us, among other things, to indemnify them against liabilities that may arise by reason of their status or service as officers other than liabilities arising from willful misconduct of a culpable nature and to advance certain expenses incurred as a result of any proceeding against them as to which they could be indemnified. We have obtained directors' and officers' liability insurance. These provisions in the Certificate of Incorporation and the By-Laws do not eliminate the officers' and directors' fiduciary duty, and in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under Delaware law. In addition, each officer and director will continue to be subject to liability for breach of their duty of loyalty to us for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law,

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

ITEM 16. EXHIBITS

Exhibit No.	Description
5.1	Opinion of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel.
23.1	Consent of Ernst & Young LLP, independent auditors.
23.2	Consent of Richard A. Eisner LLP, independent auditors.
23.3	Consent of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel (included in Exhibit 5.1).
24.1	Powers of Attorney (included in Signature Pages to this Registration Statement on Form S-3).

ITEM 17. UNDERTAKINGS

We, the undersigned Registrant hereby undertake:

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

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

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

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

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

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

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

SIGNATURES

Pursuant to the requirement of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Doylestown, Commonwealth of Pennsylvania, on the 5th day of December, 2002.

DISCOVERY LABORATORIES, INC.
(Registrant)

By: /s/ Robert J. Capetola

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

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

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

Signature	Name & Title	Date
/s/ Robert J. Capetola	Robert J. Capetola, Ph.D. Chief Executive Officer and Director	December 5, 2002
/s/ John G. Cooper	John G. Cooper Senior Vice President and Chief Financial Officer	December 5, 2002
/s/ Cynthia Davis	Cynthia Davis Controller and Principal Accounting Officer	December 5, 2002
	Herbert McDade, Jr. Chairman of the Board of Directors	December 5, 2002
/s/ Max Link, Ph.D.	Max Link, Ph.D. Director	December 5, 2002
	Antonio Esteve Director	December 5, 2002
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale Director	December 5, 2002

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

Exhibit No.	Description
5.1	Opinion of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel.
23.1	Consent of Ernst & Young LLP, independent auditors.
23.2	Consent of Richard A. Eisner, LLP, independent auditors.
23.3	Consent of Dickstein Shapiro Morin & Oshinsky LLP, legal counsel (included in Exhibit 5.1).
24.1	Powers of Attorney (included in Signature Pages to this Registration Statement on Form S-3).

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Exhibit 5.1

Dickstein Shapiro Morin & Oshinsky LLP
1177 Avenue of the Americas, 47th Floor
New York, NY 10036-2714
Tel: (212) 835-1400
Fax: (212) 997-9880

December 4, 2002

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

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

Gentlemen:

We have acted as counsel for Discovery Laboratories, Inc., a Delaware corporation (the "Company"), in connection with the preparation of the registration statement on Form S-3, and any amendments thereto (the "Registration Statement"), as filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933 (the "Securities Act"), on December 4, 2002, for the registration under the Act of up to 9,301,399 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), of which there are (i) 6,397,517 shares of Common Stock issued and outstanding (the "Shares"), and (ii) 2,903,882 shares of Common Stock (the "Warrant Shares") which are issuable upon the exercise of certain warrants issued by the Company (the "Warrants"). The Shares and the Warrant Shares are to be offered for resale on a delayed or continuous basis pursuant to Rule 415 promulgated under the Securities Act by the selling stockholders of the Company named in the Registration Statement.

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

In addition, without any independent investigation or verification, we have assumed (i) the genuineness of all signatures, (ii) the authenticity of all documents submitted to us

as originals and the conformity with the original documents of all documents submitted to us as certified, conformed or photostatic copies, (iii) the authority of all persons signing any document other than the officers of the Company, where applicable, signing in their capacity as such, (iv) the enforceability of all the documents we have reviewed in accordance with their respective terms against the parties thereto and (v) the truth and accuracy of all matters of fact set forth in all certificates and other instruments furnished to us.

Based on and subject to the assumptions, qualifications and limitations set forth herein, we are of the opinion that:

1. The Shares that are presently issued and outstanding have been duly and validly authorized and issued and are fully paid and nonassessable.

2. The Warrant Shares have been duly authorized for issuance pursuant to the Warrants, and when issued and delivered in the manner described in the Warrants against full payment of the consideration set forth therein, will be validly issued, fully paid and nonassessable.

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

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

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

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

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

Very truly yours,

/s/ Dickstein Shapiro Morin &
Oshinsky LLP

EXHIBIT 23.1

Consent of Independent Auditors

We consent to reference to our firm under the caption "Experts" in the Registration Statement (Form S-3 No. 333-XXXXX) and related prospectus of Discovery Laboratories, Inc. to be filed on or about December 4, 2002 for the registration of 9,301,399 shares of its common stock and to the incorporation by reference therein of our report dated March 15, 2002, 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, 2001, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP
Philadelphia, Pennsylvania
December 4, 2002

Exhibit 23.2

INDEPENDENT AUDITORS' CONSENT

We consent to the reference to our firm under the caption "Experts" in the Registration Statement on Form S-3 and the related Prospectus of Discovery Laboratories, Inc. for the registration of 9,301,399 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 for the period from May 18, 1993 (inception) through December 31, 1999, not presented separately except for the consolidated statement of changes in stockholders' equity, included in its annual report on Form 10-KSB for the year ended December 31, 2001, filed with the Securities and Exchange Commission.

Eisner LLP
(formerly Richard A. Eisner & Company, LLP)

New York, New York
December 4, 2002