

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933  
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DISCOVERY LABORATORIES, INC.  
(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or Other  
Jurisdiction of  
Incorporation)

350 South Main Street, Suite 307  
Doylestown, Pennsylvania 18901

94-3171943  
(I.R.S. Employer  
Identification Number)

(Address, Including Zip Code and Telephone Number, Including  
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Area Code, of Registrant's Principal Executive Offices)  
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Robert J. Capetola, Ph.D.  
Chief Executive Officer  
350 South Main Street, Suite 307  
Doylestown, Pennsylvania 18901  
(215) 340-4699

(Name, address, including zip code, and telephone number,  
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including area code, of agent for service)  
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Copies to:  
Ira L. Kotel, Esq.  
Dickstein Shapiro Morin & Oshinsky, LLP  
1177 Avenue of the Americas  
New York, New York 10036-2714  
(212) 835-1400

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

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

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

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

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

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

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The Registrant hereby amends this Registration Statement on such date or dates  
as may be necessary to delay its effective date until the Registrant shall file  
a further amendment which specifically states that this Registration Statement  
shall thereafter become effective in accordance with Section 8(a) of the  
Securities Act or until the Registration Statement shall become effective on  
such date as the Commission, acting pursuant to said Section 8(a), may  
determine.

CALCULATION OF REGISTRATION FEE  
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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
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Common Stock, \$.001 par value	4,440,222	\$3.125	\$13,875,694	\$3,468.92
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(1) Includes 712,552 shares of common stock issuable upon the exercise of  
certain Class F warrants and 164,911 shares of common stock issuable upon the  
exercise of certain placement warrants issued by the registrant.



TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY.....	1
COMPANY SUMMARY.....	1
RISK FACTORS.....	3
FORWARD-LOOKING STATEMENTS.....	8
USE OF PROCEEDS.....	8
SELLING STOCKHOLDERS.....	8
PLAN OF DISTRIBUTION.....	9
INTERESTS OF NAMED EXPERTS AND COUNSEL.....	10
WHERE YOU CAN FIND MORE INFORMATION.....	10
INFORMATION INCORPORATED BY REFERENCE.....	10
EXPERTS.....	11
LEGAL MATTERS.....	11
Item 14. Other Expenses of Issuance and Distribution.....	II-1
Item 15. Indemnification of Directors and Officers.....	II-1
Item 16. Exhibits.....	II-1
Item 17. Undertakings.....	II-1

## PROSPECTUS SUMMARY

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

## COMPANY SUMMARY

We are a critical care company that focuses on developing compounds to treat respiratory diseases that affect the ability of the lungs to absorb oxygen. We are in late stage development with our lead product candidate, Surfaxin(R), and are initially focusing on developing Surfaxin(R) for use by critical care units of hospitals as a treatment for two respiratory conditions in newborn infants. We are also developing Surfaxin(R) for the treatment of acute respiratory distress syndrome ("ARDS") in adult patients and acute lung injury ("ALI") in adult patients (ARDS and ALI may be referred to herein collectively as "ARDS/ALI"). We believe that we can use other formulations of Surfaxin(R) or our proprietary synthetic peptide, sinapultide, to treat other respiratory conditions. These include asthma and chronic obstructive pulmonary disease. In addition, we believe we can use Surfaxin(R) to efficiently deliver drugs through the respiratory tract that are currently delivered orally or by injection. These drugs include antibiotics, pulmonary vasodilators, elastase inhibitors, bronchodilators, steroids and proteins. We are also evaluating the acquisition of licenses to other drug products for the treatment of respiratory and other neonatal critical care diseases. We may develop and market our products on our own or seek to enter into collaborations with corporate partners for the manufacturing and marketing of these drugs.

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

We intend to use Surfaxin(R) for the treatment of several respiratory conditions. Currently, we are developing Surfaxin(R) for the treatment of idiopathic respiratory distress syndrome ("IRDS") in premature infants, meconium aspiration syndrome ("MAS") in full-term infants, and ARDS/ALI. We have also begun developing Surfaxin(R) to treat other respiratory disorders.

IRDS is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. MAS 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. MAS can occur if the baby breathes in meconium. Both IRDS and MAS 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. ARDS/ALI can result from a variety of events. Some of these events are pneumonia, septic shock, breathing in the contents of the stomach, trauma, smoke inhalation, near drowning, pancreatitis and head injury.

IRDS affects approximately 60,000 premature infants per year in the United States with an estimated approximately 120,000 infants receiving surfactant therapy worldwide. The incidence of ARDS/ALI ranges between approximately 150,000 and 250,000 patients per year in the United States with a fatality rate as high as 35% to 70%. MAS affects approximately 22,000 to 26,000 newborn infants per year in the United States with an estimated equal number of newborn infants afflicted per year in the rest of the developed world.

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

There are presently no drug therapies approved for the treatment of MAS and ARDS. The FDA has granted Surfaxin(R) fast track designation for the indications of MAS and ARDS. Fast track status does not accelerate our clinical trials nor does it mean that the regulatory requirements are less stringent. However, the FDA will review the New Drug Application (an "NDA") for a drug granted fast track status within six months. The FDA has awarded us an orphan drug grant to support our development of Surfaxin(R) in MAS and has designated Surfaxin(R) as an orphan drug for the treatment of MAS, IRDS and ARDS. We have also recently received designation of Surfaxin(R) as an orphan product for MAS from the European Medicines Evaluation Agency ("EMA"). Additional applications for orphan product designation for IRDS and ARDS/ALI are currently under review at the EMA. In October 2000, we were awarded a \$1 million Fast-Track Small Business Innovative Research ("SBIR") grant by the National Institutes of Health to develop Surfaxin(R) for ARDS/ALI.

We have begun preclinical research into formulating Surfaxin(R) into an aerosol spray for the treatment of asthma, chronic obstructive pulmonary disease, acute and chronic bronchitis and a variety of other respiratory diseases. We are also initiating preclinical research to evaluate Surfaxin(R) or related formulations

as a novel pulmonary drug delivery technology with the potential to deliver other pharmaceutical products to the lungs so that such products can exert their pharmacological effects locally or systemically.

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

We are presently enrolling patients in a pivotal Phase 3 clinical trial of Surfaxin(R) for the treatment of MAS in neonates, and have designed pivotal Phase 3 multinational clinical trials intended to be conducted in North and South America, as well as Europe, for the treatment of IRDS in premature infants. Given our belief in the importance of IRDS to our present development plan, resources have been and may continue to be reallocated from

the MAS program to the IRDS program, which, could effectively delay the completion of the MAS trial. In July 2001, we commenced enrollment for the Phase 3 IRDS program. In addition, we have initiated a Phase 2 clinical trial of Surfaxin(R) for the treatment of ARDS. We are also evaluating whether to conduct further clinical trials of SuperVent(TM) for treatment of Cystic Fibrosis.

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

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

## RISK FACTORS

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

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

We are a development stage company. Therefore, you must evaluate us in light of the uncertainties and complexities present in a development stage biotechnology company. We are conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of these products. 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. To date, we have generated significant and increasing operating losses, 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 cannot assure you that we will generate sufficient or sustainable revenues or that we will be profitable.

The types of products we are developing are subject to risks that are difficult to foresee and we may not succeed in our development efforts.

The development of our products is subject to the risks of failure inherent in the development of new pharmaceutical products that utilize innovative or new technologies. During the development process we could experience unforeseen problems that could delay us from completing the development of one or more of our products. As a result, we may terminate development of any such products or applications. We cannot assure you:

--that we will succeed in our research and development; or

--that we will be able to successfully and economically manufacture and market our proposed products.

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 third quarter of 2002. Our future capital requirements will depend on the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. If our operations do not become profitable before we exhaust our resources, we will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development. We cannot assure you that we will obtain necessary financing.

Other than in connection with this Offering, we have not entered into arrangements to obtain any additional financing. 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 SmallCap Market. See "Risk Factors--The market price of our stock may be adversely affected by market volatility."

The clinical trial and regulatory approval process for the Company's products will be expensive and time consuming, and the outcome is uncertain.

In order to sell our products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation by such agencies that the manufacturer maintains good laboratory and manufacturing practices during testing and manufacturing. The process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt our clinical trials. If we, or such 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 such agencies on our clinical trials could significantly increase the time required for completion of our clinical trials and the costs of conducting such 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.

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least 2002, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for Surfaxin(R), MAS and ARDS, have been granted designation as "fast track" products under provisions of the Food and Drug Administration Modernization Act of 1997, and the FDA has awarded us an orphan drug grant to support our development of Surfaxin(R) in MAS. Fast track status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The fast track provisions are designed to



expedite the FDA's review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the NDA 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 enter into these agreements and the third parties do not perform, 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. We have entered into a sublicense agreement for Surfaxin(R) covering southern Europe and Latin America with an option for Italy. We may need to enter into additional collaboration agreements. Our success may depend upon obtaining 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. Such rights 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.

Discoveries or developments of new technologies by our competitors or others may make our products less competitive or make our products obsolete.

There are rapidly changing technologies and evolving industry standards in the biotechnology and pharmaceutical markets. We intend to market our products under development for the treatment of diseases for which other technologies and proposed treatments are rapidly developing. Third parties conducting research include governments, major research facilities and large multinational corporations. Many of the third parties have greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than we have, and therefore have the potential to successfully develop and commercialize products that are more effective or less expensive than ours. The research and development efforts of others may render our research and product development efforts obsolete or noncompetitive.

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 ("USPTO") has not adopted a consistent policy regarding the breadth of claims that the USPTO allows in biotechnology patents or the degree of protection that these types of patents afford. As a result, there are risks that we may not develop or obtain rights to products or processes that are or may seem to be patentable.

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

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

technologies under our development and the USPTO 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 USPTO 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 USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors. In particular, our issued and pending patents relating to SuperVent(TM) solely cover relatively high concentrations of tyloxapol.

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 USPTO 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, such 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 such 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 to maintain rights to our products under development. These agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these licensing arrangements. In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

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

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, such 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. In such a case, 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. We cannot assure you:

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

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

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

Our outside manufacturers may not perform as they have agreed or may not remain in the contract manufacturing business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, there can be no assurance that we will be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We may in the future elect to manufacture some of our products on our own. We do not currently have a manufacturing facility, manufacturing experience or manufacturing personnel. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

In addition, the FDA and foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators inspect these facilities to confirm compliance with GMP or similar requirements that the FDA or corresponding foreign regulators establish. If our third-party foreign or domestic suppliers or manufacturers of our products or, if we decide to manufacture our products on our own, we, fail to comply with GMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our ability to market and develop our products.

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

We do not have marketing and sales experience or marketing or sales personnel. If we do not develop a marketing and sales force, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our products. We may not succeed in entering into any satisfactory third party arrangements for the marketing and sale of our products. In addition, we may not succeed in developing 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, 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 personal, 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 Robert J. Capetola, Ph.D., and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. 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 2001 and 2002. 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.

Our industry is highly competitive and subject to rapid technological innovation. We compete with numerous existing companies intensely in many ways. We expect new companies to enter our industry and we expect competition to 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. 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. Our competitors may succeed in developing and marketing products that are more effective than ours.

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 relating to our clinical trials of SuperVent(TM) and Surfaxin(R). 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, such insurance is expensive and insurance companies may not issue this type of insurance when we need it. We cannot provide assurance that we can obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our Common Stock.

We expect to face uncertainty over reimbursement and healthcare reform.

In both the United States and other countries, sales of our products will depend in part upon the availability of reimbursement from third-party payors, which include government health administration authorities, managed care providers, and private health insurers. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved health care products. Our products may not be considered cost effective. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in the research and development of our products.

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

Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you do not consider to be in your best interest.

As of October 25, 2001, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 29% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of the Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

The market price of our Common Stock, like that of many other development stage pharmaceutical or biotechnology companies, has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

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

The Company's Common Stock is listed for quotation on the NASDAQ SmallCap Market. For the 12-month period ended October 25, 2001, the price of our Common Stock has ranged from \$2.00 to \$6.375. We expect the price of our Common Stock to remain volatile. The average daily trading volume in the Company's Common Stock varies significantly. For the 12-month period ending October 25, 2001, the average daily trading volume in our Common Stock was approximately 45,500 shares and the average number of transactions per day was approximately 56. The Company's relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we cannot assure investors that we will be able to continue to adhere to the strict listing criteria of the SmallCap Market. If the Common Stock were no longer listed on the SmallCap Market, investors might only be able to trade in the over-the-counter market in the Pink Sheets(R) (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board(R) of the National Association of Securities Dealers, Inc (the "NASD"). 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 such companies. If we face such litigation in the future, even if meritless or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

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

The market price of our Common Stock could drop due to sales of a large number of shares of our Common Stock or the perception that these sales could occur. As of October 25, 2001, there were 24,753,138 shares of Common Stock outstanding. In addition, as of October 25, 2001, up to 6,383,791 shares of Common Stock were issuable on exercise of outstanding options and warrants.

Holder 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.

Anti-takeover provisions of our Certificate of Incorporation and Delaware law could delay actual or potential changes of control, which could affect our stockholders' ability to benefit from market fluctuations and changes in management.

Our Certificate of Incorporation and Delaware law contain provisions that may discourage transactions involving actual or potential changes in control. 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 such 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 such 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 to fend against unwanted tender offers or hostile takeovers.

We are also subject to provisions of Delaware law that could delay or make more difficult a merger, tender offer or proxy contest involving us. In particular, we are subject to Section 203 of the Delaware General Corporation Law that prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years unless the Board of Directors and stockholders approve the transactions in a prescribed manner. In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by this type of entity or person. The possible issuance of preferred stock and the provisions of Delaware law may have the effect of preventing changes in our management and could have the effect of discouraging others from making tender offers for our securities even if the events could be beneficial to our stockholders. As a consequence, they also may inhibit fluctuations, even favorable ones, in the market price of our Common Stock that otherwise could result from actual or rumored takeover attempts.

#### FORWARD-LOOKING STATEMENTS

The statements set forth under the captions "Company Summary" and elsewhere in this prospectus, including in "Risk Factors," and those incorporated herein which are not historical constitute "Forward Looking Statements" within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including statements regarding the expectations, beliefs, intentions or strategies for the future. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect our views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause our actual results to differ materially from any future results expressed or implied by such forward-looking statements.

Examples of such 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(R), 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", and in the documents incorporated by reference in this prospectus.

We do not undertake to update any 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.

#### 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 within the past three years with Discovery Laboratories or any of its predecessors or affiliates. This prospectus relates to the offer and sale of the selling stockholders of up to 4,440,222 shares of common stock, including 877,463 shares of common stock issuable upon the exercise of outstanding warrants issued by Discovery Laboratories. The selling stockholders may offer all or part of the shares of common stock covered by this prospectus. Information with respect to shares owned beneficially after the offering assumes the sale of all of the shares offered and no other purchases or sales of common stock. The common stock offered by this prospectus may be offered from time to time by the selling stockholders named below.

Name	Number of Shares of Common Stock, not including Warrants, Beneficially Owned	Number of Shares Represented by Warrants Owned	Total Number of Shares of Common Stock Beneficially Owned	Percentage Beneficially Owned Before Offering	Number of Shares to be Offered for the Account of the Selling Stockholder	Number of Shares to be Owned after this Offering	Percentage to be Beneficially Owned after this Offering
Concordia Partners LP	363,776	45,977	409,753	*	275,862	133,891	*

Coralbasin & Co.	1,149,425	229,885	1,379,310	5.52	1,379,310	0	0
Coralrock & Co.	574,713	114,943	689,656	2.77	689,656	0	0
Gary B. Davis	60,977	9,195	70,172	*	55,172	15,000	*
Deutsche Bank AG, London Branch	229,885	45,977	275,862	1.11	275,862	0	0
Milton H. Dresner Revocable							
Living Trust	11,494	2,299	13,793	*	13,793	0	0
Boro Durakovic	13,793	2,759	16,552	*	16,552	0	0
First Investors Holding Co.	137,931	27,586	165,517	*	165,517	0	0
Jesup & Lamont Securities Corp.		164,911	164,911	*	164,911	0	0

Keys Foundation	306,808	45,977	352,785	1.42	275,862	76,923	*
Maria Molinsky	52,774	7,675	60,449	*	27,587	32,862	*
Tis Prager	42,175	6,897	49,072	*	41,380	7,692	*
Roseworth Group Limited	114,937	22,987	137,924	*	137,924	0	0
Wayne Saker	45,977	9,195	55,172	*	55,172	0	0
Shipman & Goodwin LLP Profit Sharing	11,500	2,300	13,800	*	13,800	0	0
Peter Stern	11,494	2,299	13,793	*	13,793	0	0
Ursus Capital LP	343,896	33,793	377,689	1.52	202,759	174,930	*
Ursus Offshore Ltd.	357,932	35,172	393,104	1.59	211,034	182,070	*
Valor Capitol Management, LP	392,950	64,368	457,318	1.84	386,207	71,111	*
Jacqueline Waterman	5,517	1,103	6,620	*	6,620	0	0
Bruno Widmer	22,989	4,598	27,587	*	27,587	0	0
William Wolff, MD	3,218	644	3,862	*	3,862	0	0

\* Less than 1%.

The information contained in this table reflects "beneficial" ownership of common stock within the meaning of Rule 13d-3 under the Exchange Act. On October 25, 2001, the Company had 24,752,112 shares of common stock outstanding. Beneficial ownership information reflected in the table includes shares issuable upon the exercise of outstanding warrants issued by the Company at their initial exercise prices.

Except as set forth below, none of the selling stockholders named in the preceding table has had any position, office or other material relationship with us or any of our affiliates within the past three years. Jesup & Lamont Securities Corp. ("Jesup & Lamont"), was the placement agent for our private placement that closed on October 1, 2001, through which all the selling stockholders bought the Shares that are being registered hereby. Jesup & Lamont's Shares represent shares of common stock that are issuable pursuant to the placement warrant issued to it for acting as our placement agent. Gary B. Davis, Peter Stern and Jacqueline Waterman are registered representatives of Jesup & Lamont.

#### PLAN OF DISTRIBUTION

The shares of common stock covered by this prospectus (the "Shares") are beneficially owned by the selling stockholders. The selling stockholders and any of their pledgees, assignees and successors-in-interest (hereinafter collectively referred to in this section as the "selling stockholders") may offer and sell, at one time or from time to time, some or all of the Shares. We have registered the Shares for sale by the selling stockholders so that the Shares will be freely tradeable by them. Registration of the Shares does not mean, however, that the Shares necessarily will be offered or sold. We will not receive any proceeds from any offering or sale by the selling stockholders of the Shares. We will pay all costs, expenses and fees in connection with the registration of the Shares. The selling stockholders will pay all brokerage commissions and similar selling expenses, if any, attributable to the sale of the Shares.

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

- in a block trade in which a broker-dealer will attempt to sell a block of Shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by that broker-dealer for its account pursuant to this prospectus;
- on markets where our common stock is traded or in an exchange distribution in accordance with the rules of the exchange;
- through broker-dealers, that may act as agents or principals;
- directly to one or more purchasers;
- through agents;
- in connection with the loan or pledge of Shares to a broker-dealer, and the sale of the Shares so loaned or the sale of the Shares so pledged upon a default;
- in connection with put or call option transactions, in hedge transactions and in settlement of other transactions in standardized or over-the-counter options;
- through short sales of the Shares by the selling stockholders or counterparties to those transactions, in privately negotiated transactions; or
- in any combination of the above. In addition, any of the Shares that qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus.

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

- purchases of the Shares by a broker-dealer as principal and resales of the Shares by the broker-dealer for its account pursuant to this prospectus;
- ordinary brokerage transactions; or
- transactions in which the broker-dealer solicits purchasers.

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

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

The selling stockholders are not restricted as to the price or prices at which they may sell their Shares. Sales of such 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, 233 Broadway, New York, New York 10279, and Citicorp Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661-2511. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference rooms. 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. 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 Commission, 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 listed below:

1. Our Annual Report on Form 10-KSB filed with the Commission on April 2, 2001, for the fiscal year ended December 31, 2000 (the "Annual Report");
2. Our Quarterly Reports (unaudited) on Form 10-QSB for the quarterly periods ending March 31, 2001 and June 30, 2001;
3. Our Form 8-K's filed with the Securities and Exchange Commission on October 5, 2001, May 7, 2001, and March 2, 2001; and
4. The description of our capital stock contained in our Form 8-A as filed with the Securities and Exchange Commission on July 13, 1995.

In addition, all documents filed with the Securities and Exchange Commission by Discovery pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this prospectus and prior to the termination of this offering shall be deemed to be incorporated by reference into this prospectus and to be a part of this prospectus from the date of the filing of such

documents. You may request a copy of these filings, at no cost, by writing or telephoning us at the following address: Discovery Laboratories, Inc., 350 South Main Street, Suite 307, Doylestown,

Pennsylvania 18901, Attention: Cynthia Davis. Telephone requests may be directed to (215) 340-4699, extension 112. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

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

#### EXPERTS

The consolidated financial statements of Discovery Laboratories, Inc., and subsidiary (collectively, "Discovery") as of December 31, 2000, and for the year then ended, and for the period from May 18, 1993 (inception), through December 31, 2000, included in Discovery's Annual Report (Form 10-KSB), have been incorporated by reference in this registration statement in reliance on the report of Ernst & Young LLP, independent auditors, appearing therein. In addition, the consolidated financial statements of Discovery for the year ended December 31, 1999, included in such Annual Report (Form 10-KSB), have been incorporated by reference in this Registration Statement in reliance on the report of Richard A. Eisner & Company, LLP, independent auditors, appearing therein. Such reports have been given upon the authority of the respective independent auditors reporting thereon as experts in accounting and auditing.

#### LEGAL MATTERS

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

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

4,440,222 SHARES

DISCOVERY LABORATORIES, INC.

COMMON STOCK

November [\_\_\_], 2001



## 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 Commission registration fee.

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

## ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

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

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

We have entered into indemnification agreements with certain of our executive officers containing provisions that may require us, among other things, to indemnify such officers 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 such officer's or director's duty of loyalty to us for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for actions leading to improper personal benefit to the officer or director and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provisions also do not affect an officer's or director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

## ITEM 16. EXHIBITS

EXHIBIT NO.	DESCRIPTION
5.1	Opinion of Dickstein Shapiro Morin & Oshinsky, LLP, legal counsel.
23.1	Consent of Richard A. Eisner & Company, LLP, predecessor independent auditors.
23.2	Consent of Ernst & Young LLP, independent auditors.
23.3	Consent of Dickstein Shapiro Morin & Oshinsky, LLP, legal counsel (included in Exhibit 5.1).
24.1	Powers of Attorney (contained on signature pages of this Registration Statement on this Form S-3).

## ITEM 17. UNDERTAKINGS

We, the undersigned Registrant (the "Registrant") hereby undertake:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to the Registrant Statement to:
  - (i) Include any prospectus required by Section 10(a)(3) of the Securities Act;
  - (ii) Reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) that individually or in the aggregate represent a fundamental change in the information set forth in the Registration Statement; and
  - (iii) Include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement

or any material change to such information in the Registration Statement;

II-1

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

- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

SIGNATURES

Pursuant to the requirement of the Securities Act 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 1st day of November, 2001.

DISCOVERY LABORATORIES, INC.  
(Registrant)

By: /s/ Robert J. Capetola, Ph.D.  
-----

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, Ph.D. -----	Robert J. Capetola, Ph.D. Chief Executive Officer	November 1, 2001
/s/ Deni M. Zodda, Ph.D. -----	Deni M. Zodda, Ph.D. Principal Financial Officer	November 1, 2001
/s/ Cynthia Davis -----	Cynthia Davis Controller (Principal Accounting Officer)	November 1, 2001
/s/ Herbert McDade, Jr. -----	Herbert McDade, Jr. Chairman of the Board of Directors	November 1, 2001
/s/ Max Link -----	Max Link, Ph.D. Director	November 1, 2001
/s/ Richard Power -----	Richard Power Director	November 1, 2001

Dickstein Shapiro Morin & Oshinsky LLP  
 1177 Avenue of the Americas, 41st Floor  
 New York, NY 10036-2714  
 Tel: (212) 835-1400  
 Fax: (212) 997-9880

November 1, 2001

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 "Act"), on October 31, 2001, for the registration under the Act of up to 4,440,222 shares (the "Shares") of the Company's common stock, par value \$0.001 per share (the "Common Stock"), comprised of 3,562,759 shares of Common Stock which are issued and are outstanding (the "Shares"), 712,552 shares (the "Class F Warrant Shares") of Common Stock which are issuable upon the exercise of certain Class F warrants of the Company (the "Class F Warrants") and 164,911 shares (the "Placement Warrant Shares") of Common Stock which are issuable upon the exercise of certain Placement Warrants of the Company (the "Placement Warrants"). The Shares are to be offered for resale on a delayed or continuous basis pursuant to Rule 415 promulgated under the Securities Act by certain selling stockholders of the Company named in the Registration Statement (the "Selling Stockholders").

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

2

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

INDEPENDENT AUDITORS' CONSENT

We consent to the reference to our firm under the caption "Experts" in the Registration Statement on Form S-3 and related Prospectus of Discovery Laboratories, Inc. for the registration of 4,440,222 shares of its common stock and to the incorporation by reference therein of our report dated February 25, 2000, with respect to the consolidated financial statements for the year ended December 31, 1999 included in its annual report on Form 10-KSB for the year ended December 31, 2000, filed with the Securities and Exchange Commission.

Richard A. Eisner & Company, LLP

New York, New York  
October 25, 2001



Consent of Independent Auditors

We consent to reference to our firm under the caption "Experts" in the Registration Statement (Form S-3 to be filed on or about October 31, 2001) and related prospectus of Discovery Laboratories, Inc. for the registration of 4,440,222 shares of its common stock and to the incorporation by reference therein of our report dated March 27, 2001, with respect to the consolidated financial statements of Discovery Laboratories, Inc. included in its Annual Report (Form 10-KSB) for the year ended December 31, 2000, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
October 25, 2001