

Registration No. 333-86105  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

AMENDMENT NO. 2  
TO  
FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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

Delaware 350 Main Street 13-3711775  
(State or Other Jurisdiction of Suite 307 (I.R.S. Employer  
Incorporation or Organization) Doylestown, Pennsylvania 18901 Identification Number)  
(Address, Including Zip Code and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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Steve H. Kanzer, C.P.A., Esq.  
Chairman of the Board  
350 Main Street  
Suite 307  
Doylestown, Pennsylvania 18901  
(215) 340-4699

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Copies to:  
Steven A. Fishman, Esq.  
Battle Fowler LLP  
75 East 55th Street  
New York, New York 10022  
(212) 856-7000  
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Approximate date of commencement of proposed sale to public: From time to time or at one time after the effective date of this registration statement as determined by market conditions.

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, 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. / /

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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 of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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(RED HERRING)  
The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where such offer or sale is not permitted.

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All of the shares of common stock covered by this prospectus are owned by the stockholders listed in the section of this prospectus called "Selling Stockholders" or are issuable on exercise of warrants owned by the selling stockholders. The selling stockholders may sell any or all of their shares from time to time. See "Plan of Distribution."

We will not receive any of the proceeds of sales by the selling stockholders. We have agreed to bear all expenses related to this offering, other than underwriting discounts and commissions and any transfer taxes on the shares of common stock being offered. The registration of the common stock covered by this Prospectus does not necessarily mean that any of the common stock will be offered or sold by the selling stockholders.

Our common stock is traded on the Nasdaq SmallCap Market under the symbol "DSCO."

The common stock offered hereby involves a high degree of risk. See "Risk Factors" beginning on page 4 for certain factors relevant to an investment in our common stock.

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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 September \_\_, 1999.

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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 carefully before you invest.

## COMPANY SUMMARY

We are a development stage pharmaceutical company that is focused on developing compounds intended for neonatal use in critical care hospital settings. We are also developing our lead product candidate for the treatment of acute respiratory distress syndrome and acute lung injury. Our two lead drug candidates are directed towards respiratory indications. We may seek to enter into collaborations with corporate partners for manufacturing and marketing of these drugs.

Our lead product is Surfaxin(R), a peptide (or small protein molecule) phospholipid formulation containing a proprietary, synthetic peptide called sinapultide. Surfaxin(R) is patterned after a human surfactant protein and is intended to be used for the treatment of several conditions characterized by insufficient surfactant. The lungs produce surfactant, a detergent-like substance consisting mainly of phospholipids (a derivative in which one of the fatty acids has been replaced by a phosphate). Lung surfactants lower the surface tension of the fluid normally present within the alveoli (air sacs). In the absence of sufficient surfactants, these air sacs tend to collapse. As a result, the lungs do not absorb sufficient oxygen. Surfaxin(R) is a synthetic or artificial surfactant designed to replace lung surfactant in patients suffering from a surfactant deficit. Replacement surfactants are currently approved only for treating respiratory distress syndrome in premature infants. Infants with this condition, as well as infants born with meconium (a component of the fetal bowel) in their lungs, which can lead to meconium aspiration syndrome, typically suffer from insufficient surfactant. This condition can lead to a life-threatening loss of pulmonary function. In addition, patients with acute respiratory distress syndrome and acute lung injury typically suffer from surfactant deficiency as well. Acute respiratory distress syndrome and acute lung injury can result from pneumonia, aspiration of gastric contents, trauma, smoke inhalation, head injury, and a variety of other events.

We are also developing SuperVent(TM) as a stable, aerosolized therapy for airway diseases such as cystic fibrosis and chronic bronchitis. These conditions are characterized by inflammation, injurious oxidation (a condition where atoms in tissue lose electrons, which can result in damage to the tissue) and excessive mucus. Cystic fibrosis is a progressive, lethal respiratory disease that afflicts approximately 23,000 patients in the United States and a comparable number in Europe. It is the most common lethal genetic disease among Caucasians. Because of this genetic defect, cystic fibrosis mucus is excessively viscous, as a result of which it does not flow and adheres to airway walls. This can lead to gradual destruction of the lungs of cystic fibrosis patients. The inability to clear mucus from the lungs can lead to blockage of the airways usually beginning in the smaller airways and alveoli. A new therapy that minimizes the complications of cystic fibrosis could have a major impact on the length and quality of life of its patients.

We are conducting clinical trials of Surfaxin(R) for treatment of Meconium aspiration syndrome and acute respiratory distress syndrome and acute lung injury and SuperVent(TM) for treatment of cystic fibrosis.

Discovery Laboratories was incorporated in Delaware on November 6, 1992 as Ansan, Inc. On November 25, 1997, Discovery Laboratories, Inc., a former Delaware corporation ("Old Discovery"), was merged with and into Discovery Laboratories, then known as Ansan. In connection with this merger in 1997, our name was changed to Discovery Laboratories, Inc. On June 16, 1998, Discovery Laboratories completed the acquisition of the then outstanding minority interest in Acute Therapeutics, Inc.

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.

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## RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the following risk factors together with all of the other information included or incorporated by reference in this prospectus before you decide to purchase shares of our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In this event, the trading price of our common stock could decline and you could lose part or all of your investment.

BECAUSE WE ARE A DEVELOPMENT STAGE COMPANY, WE MAY NOT BE ABLE TO DEVELOP AND MARKET OUR PRODUCTS, AND EVEN IF WE DO, WE MAY NOT GENERATE ENOUGH REVENUE TO BE PROFITABLE.

We are a development stage company. Therefore, you must evaluate us in light of the uncertainties and complexities present in a development stage pharmaceutical company. Our product candidates are in the research and development stage and, accordingly, we have not begun to market or generate revenues from the commercialization of any of these products. Our products under development will require significant time-consuming and costly research, development, preclinical studies, clinical testing, regulatory approval and significant additional investment prior to their commercialization. We may not be able to develop and commercialize our products. We cannot assure you that our products under development, if successfully developed, will generate sufficient or sustainable revenues to enable us to be profitable.

BECAUSE WE DO NOT YET HAVE PRODUCT REVENUES AND HAVE A HISTORY OF LOSSES, OUR FUTURE PROFITABILITY IS UNCERTAIN.

We are not currently generating any product revenues and we expect that we will not generate significant product revenues for the foreseeable future, if at all. As a development stage company engaged in conducting development and clinical testing activities, we expect to generate significant operating losses for the foreseeable future. We expect to incur significant increasing operating losses over the next several years. To achieve profitable operations, we, either alone or with others, must successfully develop and obtain regulatory approval for marketing our products. We cannot assure you that we will:

- enter into potentially necessary collaborative arrangements with third parties;
- successfully complete preclinical or clinical trials;
- obtain required regulatory approvals;
- successfully develop, manufacture and market product candidates; or
- generate additional revenues or profitability.

If we fail to achieve any of the above goals, we will continue to incur loss from operations and may not be able to continue our operations.

THE TYPES OF PRODUCTS WE ARE DEVELOPING ARE SUBJECT TO RISKS THAT ARE DIFFICULT TO FORESEE, AND OUR DEVELOPMENT EFFORTS MAY BE UNSUCCESSFUL.

Our development of products is subject to the risks of failure inherent in the development of new pharmaceutical products based on innovative or new technologies. During the development process, we could experience unforeseen problems that could delay us from completing the development of our products. We cannot assure you that:

- our research and development efforts will be successful;
- our proposed products will be commercially viable or successfully marketed.

IF WE ARE NOT ABLE TO RAISE ADDITIONAL CAPITAL WE WILL BE UNABLE TO CONTINUE OUR RESEARCH AND DEVELOPMENT ACTIVITIES. IN ADDITION, ANY ADDITIONAL FINANCING THAT MAY BE AVAILABLE COULD RESULT IN DILUTION.

Our existing working capital will not be sufficient to meet our needs and we may not be able to obtain adequate additional financing necessary to meet our working capital requirements. We will need substantial additional funding to conduct our research and product development activities and, if approved by the FDA or corresponding foreign regulatory authorities, to manufacture and market the products currently under development and any other products that we may develop in the future. We intend to seek to raise further funds through collaborative ventures entered into with potential corporate partners and additional debt or equity financings. We cannot provide assurance that these types of arrangements can be obtained. We have not entered into arrangements to obtain any additional financing. Any additional financing could be on unattractive terms or result in significant dilution of stockholders' interests. If we fail to enter into collaborative ventures or to receive additional funding, we would have to scale back or discontinue our research and development operations. Furthermore, we could ultimately cease to qualify for listing of our securities on the Nasdaq SmallCap Market. See "Possible Delisting From Nasdaq SmallCap Market; Market Illiquidity." If additional financing is not available, we will be required to modify our business development plans or reduce or cease certain or all of our operations.

IF WE FAIL TO OBTAIN REGULATORY APPROVAL TO COMMERCIALY MANUFACTURE OR SELL ANY OF OUR PRODUCTS OR IF APPROVAL IS DELAYED, IT COULD INCREASE THE COST OF PRODUCT DEVELOPMENT OR ULTIMATELY PREVENT OR DELAY OUR ABILITY TO SELL OUR PRODUCTS AND GENERATE REVENUES.

In order to sell our products that are under development, we must receive regulatory approvals for our products. The testing, manufacture, distribution, advertising and marketing of drug products are subject to extensive and rigorous regulation by governmental authorities in the United States and other countries. Prior to marketing, any pharmaceutical products developed or licensed by us must undergo an extensive regulatory approval process required by the FDA and by comparable agencies in other countries. This process, which includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation by the FDA that good laboratory, clinical and manufacturing practices were maintained during testing and manufacturing, is lengthy, expensive and uncertain. Clinical trials generally take two to five years or more to complete.

The testing and approval processes require the expenditure of substantial resources. We may not be able to obtain the requisite approvals for our products on a timely basis, if at all. Any required approvals, once obtained, may be withdrawn. 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, we may be restricted or delayed in the marketing of a product, forced to make product recalls or seizures or may be subject to other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. For marketing outside the United States, we also will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. None of our products under development has been approved for marketing in the United States or elsewhere. If we fail to obtain requisite governmental approvals or fail to obtain approvals of the scope requested of our business, we will be unable to market our products.

OUR STRATEGY IS TO ENTER INTO COLLABORATIVE AGREEMENTS WITH THIRD PARTIES WITH RESPECT TO OUR PRODUCTS AND WE HAVE NOT YET ENTERED INTO ANY OF THESE AGREEMENTS. IN ADDITION, 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 development and clinical testing of our products and for the manufacturing, marketing and commercialization of our products depends upon the formation of collaborative arrangements with pharmaceutical companies. We have not yet entered into any of these arrangements or agreements to date. Our success will depend upon obtaining partners. In addition, if we obtain partners, we will depend on their expertise and their dedication of sufficient resources to develop and commercialize certain of our proposed products. We may in the future grant to our collaborative partners, if any, rights to license and commercialize pharmaceutical products developed under these collaborative agreements. Those 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 collaborative partners fail to develop or commercialize successfully 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.

The market for biotechnology is characterized by rapidly changing technology and evolving industry standards. Our products under development are intended to treat diseases for which other technologies and proposed treatments are rapidly developing. The results of our research and product development efforts may be rendered obsolete by research efforts of others, including the efforts and activities of governments, major research facilities and large multinational corporations with greater research and development, manufacturing, marketing, financial, technological, personal and managerial resources than we have.

IF WE ARE UNABLE TO PROTECT OUR INTELLECTUAL PROPERTY, WE MAY BE UNABLE TO PREVENT OTHER COMPANIES FROM USING OUR TECHNOLOGY IN COMPETITIVE PRODUCTS. IF WE INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, WE MAY BE PREVENTED FROM DEVELOPING OR MARKETING OUR PRODUCTS.

IF WE ARE UNABLE TO OBTAIN PATENTS FOR OUR PRODUCTS OTHERS COULD COMMERCIALIZE EQUIVALENT 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 our licensors 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. To date, there has emerged no consistent policy at the United States Patent and Trademark Office regarding the breadth of claims allowed in biotechnology patents or the degree of protection afforded under these types of patents.

EVEN IF WE ARE ABLE TO OBTAIN PATENTS TO PROTECT OUR PRODUCTS, THOSE PATENTS MAY NOT BE BROAD ENOUGH TO KEEP OTHERS FROM COMPETING WITH US.

Various United States and foreign patents applications (including international applications filed under the Patent Cooperation Treaty) have been filed with respect to the products and technologies under our development and patents have been issued with respect to our products and technologies. These patents and patent applications have been licensed to us. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. Also, patent rights may not be sufficiently broad enough to provide us with proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents we own or license from third parties may not provide any protection against competitors. In particular, our issued and pending patents relating to SuperVent(TM) cover high concentrations of tyloxapol. These patents could prove meaningless if it were to be determined that low concentrations of tyloxapol are as effective as higher concentrations of tyloxapol in treating the indications for which we are seeking to develop our SuperVent(TM) product.

OUR ABILITY TO MARKET OUR PRODUCTS MAY BE LIMITED BY PATENTS OBTAINED BY OTHERS.

Our commercial success also depends significantly on our ability to operate without infringing the patents or violating the proprietary rights of others. A United States patent application is maintained under conditions of confidentiality while the application is pending. Accordingly, we will not be able to determine which inventions are

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claimed in pending patent applications filed by third parties. Litigation may be necessary to defend or enforce our patent and license rights or to determine the scope and validity of the proprietary rights of others. Defense and enforcement of patent claims can be expensive and time-consuming. Thus, even in those instances in which the outcome is favorable to us, these 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 may not be available from third parties. We may be required 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 OUR RIGHTS TO OUR PRODUCTS.

We depend on licensing arrangements to maintain rights to our products under development, and we will be required to make certain payments and satisfy certain performance obligations in order to maintain those licensing arrangements. Pursuant to our licensing agreements, we are responsible for the cost of filing and prosecuting patent applications and maintaining issued patents. 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.

We require all employees to enter into confidentiality agreements that prohibit the disclosure of confidential information to third parties and require disclosure and assignment to us of rights to our employees' ideas, developments, discoveries and inventions while so employed. In addition, we seek to obtain these types of agreements from our consultants, advisors and research collaborators. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this type of information that may not be resolved in our favor. In addition, we will rely on trade secrets and proprietary know-how that we will seek to protect in part by confidentiality agreements with its employees, consultants, advisors or others. We cannot assure you that:

- these agreements will not be breached;
- we would obtain adequate remedies for this type of breach; or
- our trade secrets or proprietary know-how will not otherwise become known or be independently developed by competitors.

IF THE THIRD PARTIES WE DEPEND ON FOR THE MANUFACTURE OF OUR PHARMACEUTICAL PRODUCTS DO NOT SUPPLY THESE PRODUCTS IN A TIMELY MANNER, IT MAY DELAY OR IMPAIR OUR ABILITY TO DEVELOP AND MARKET OUR PRODUCTS.

We will be required to rely on outside manufacturers, including Taylor Pharmaceuticals, Inc., to produce appropriate clinical grade material that meets standards for use in clinical studies for certain of our products. We may also enter into arrangements with other manufacturers for the manufacture of material for use in clinical testing.

Our outside manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our product candidates. If one of our outside manufacturers fails to deliver the required quantities of our product candidates for clinical use on a timely basis and at commercially reasonable prices, and we fail to find a replacement manufacturer or develop our own manufacturing capabilities, it could delay or impair our ability to obtain regulatory approval for our products.

In addition, our third-party manufacturers are required to register manufacturing facilities with the FDA and foreign regulatory authorities. The facilities will then be subject to inspections confirming compliance with good manufacturing practice requirements established with the FDA or corresponding foreign regulations. If our third-party foreign or domestic suppliers or manufacturers of our products fail to comply with good manufacturing practice requirements or other FDA regulatory requirements, our products may not be marketable.

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WE DO NOT HAVE MARKETING AND SALES EXPERIENCE, AND OUR LACK OF THAT 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 be dependent on entering into arrangements with corporate partners or other entities for the marketing and sale of our products. We may not be successful in entering into any satisfactory third-party arrangements for the marketing and sale of our products. In addition, we may not successfully develop marketing and sales experience and personnel or we may not have sufficient resources to do so. If we fail to establish successful marketing and sales capabilities or fail to enter into successful distribution, marketing and selling arrangements with third parties for our anticipated products, our business, financial condition and results of operations will be materially adversely affected.

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 EFFECT OUR ABILITY TO DEVELOP AND MARKET OUR PRODUCTS.

We are highly dependent upon the principal members of our management team, especially Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. We have an employment agreement with Dr. Capetola which expires on June 15, 2002. We also have employment agreements with other key personnel with termination dates expiring in 2001. We do not maintain key main life insurance. The loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals.

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.

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 be more established than we are, making it difficult for us to compete for key personnel.

WE ARE IN AN INDUSTRY CHARACTERIZED BY INTENSE COMPETITION AND WE HAVE LESS CAPITAL AND RESOURCES THAN MANY OF OUR COMPETITORS, AND THIS MAY GIVE THEM AN ADVANTAGE IN DEVELOPING AND MARKETING PRODUCTS SIMILAR TO OURS.

We are engaged in a highly competitive industry. Competition from numerous existing companies and potential new entities is intense and expected to increase. Many of these companies have substantially greater research and development, 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 approval or commercializing products before us. If we commence commercial product sales, we will be competing against companies with greater marketing and manufacturing capabilities, areas in which, as yet, we have limited or no experience. In addition, developments by competitors may render our product candidates obsolete or competitive. 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

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and licensing arrangements to collect royalties for use of technology that they have developed, some of which may be directly competitive with the technologies to be developed by us. These institutions will also compete with us in recruiting highly qualified scientific personnel. It is expected that therapeutic developments in the areas in which we will be active may occur at a rapid rate and that competition will intensify as advances in this field are made. Accordingly, we will be required to continue to devote substantial resources and efforts to research and development activities.

IF WE BECOME SUBJECT TO PRODUCT LIABILITY CLAIMS, IT MAY RESULT IN REDUCED DEMAND FOR OUR PRODUCTS OR DAMAGES THAT EXCEED OUR INSURANCE COVERAGE.

If we successfully develop any products, the marketing and use of our products, through third-party arrangements or otherwise, whether for commercial applications or during clinical trials, 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. We presently carry product liability insurance relating to our clinical trials of SuperVent(TM) and our clinical trials of Surfaxin(R) in treating acute respiratory distress syndrome and acute lung injury and Meconium aspiration syndrome. However, this insurance coverage might not be sufficient to fully cover any potential claims. We may be required to obtain additional product liability insurance coverage prior to initiation of other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, this insurance can be expensive and difficult to obtain. We cannot provide assurance that adequate insurance will be available in the future at an acceptable cost, if at all. Any product liability claim, even one that was not in excess of our insurance coverage or one that was ultimately determined to be meritless, could have a material adverse effect on our business, financial condition and results of operations.

HEALTHCARE REFORM MEASURES AND REIMBURSEMENT PROCEDURES MAY PREVENT US FROM OBTAINING AN ADEQUATE LEVEL OF REIMBURSEMENT FOR OUR PRODUCTS THAT IN TURN WOULD DECREASE OUR ABILITY TO GENERATE REVENUES.

The levels of revenues and profitability of pharmaceutical and/or biotechnology products and companies may be affected by efforts of governmental and third-party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, there have been a number of federal and state proposals to implement similar government control. Pricing constraints on our products could have a material adverse effect on our business.

In the United States and elsewhere, successful commercialization of our products will depend in part on the availability of reimbursement to the consumer using our products from third-party health care payers such as government and private insurance plans. 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 product development. Third-party health care payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services. If we succeed in bringing one or more products to market, and the government or third-party payers fail to provide adequate coverage or reimbursement rates for those products, we may not be able to sell our products on a competitive basis. If we are not able to sell our products on a competitive basis, our business, financial condition and results of operations will be materially adversely affected.

DIRECTORS, EXECUTIVE OFFICERS, PRINCIPAL STOCKHOLDERS AND AFFILIATED ENTITIES OWN A SIGNIFICANT PERCENTAGE OF OUR CAPITAL STOCK, AND THIS COULD HAVE AN EFFECT ON CERTAIN DECISIONS.

As of August 13, 1999, our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 34% of our outstanding voting securities, assuming conversion of convertible securities. Accordingly, these stockholders 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. Such a concentration of ownership may have the effect of delaying or preventing a change in control, including transactions in which stockholders might otherwise recover a premium for their shares over their current market prices.

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WE FACE THE POSSIBILITY OF BEING DELISTED FROM THE NASDAQ SMALLCAP MARKET.

To meet the current Nasdaq listing requirements for our securities to continue to be listed on the Nasdaq SmallCap Market, we will have to maintain (a) (1) at least \$2 million in net tangible assets, (2) \$35 million in market capitalization or (3) \$500,000 in net income (over two of the last three years), (b) a public float of at least 500,000 shares valued at \$1 million or more and (c) a minimum bid price of \$1. In addition, our common stock will have to be held by at least 300 holders and will have to have at least two active market makers. For purposes of determining compliance with the public float requirement, shares of stock held by officers, directors and 10% or greater stockholders are excluded. At June 30, 1999, we had \$2,090,000 in net tangible assets. In addition, we received net proceeds of approximately \$2.45 million in a private placement completed in July 1999. The closing price of our common stock during the period from January 1, 1999 to September 27, 1999 ranged from \$1.00 to \$4.00 and the Closing Price of our common stock on September 27, 1999 was \$1.44. We will need to raise additional capital in order to continue to meet the listing requirements.

If we are unable to satisfy the NASD's listing maintenance requirements, our securities may be delisted from the Nasdaq SmallCap Market. In this type of event, trading, if any, in our securities would thereafter be conducted in the over-the-counter market in the Pink Sheets(R), a quotation medium operated by the National Quotation Bureau, LLC, or on the NASD's OTC Bulletin Board(R). Consequently, the liquidity of our securities could be impaired, not only in the number of securities that could be bought and sold, but also through delays in the timing of the transactions, reduction in securities analysts' and the news media's coverage of us and lower prices for our securities than might otherwise be attained.

THE "PENNY STOCK" RULES MAY ADVERSELY AFFECT THE LIQUIDITY FOR OUR COMMON STOCK.

If our securities were to be delisted from the Nasdaq SmallCap Market, they could become subject to Rule 15g-9 under the Exchange Act, which imposes additional sales practice requirements on broker-dealers that sell these types securities to persons other than established customers and "accredited investors" (generally, individuals with net worth in excess of \$1,000,000 or annual incomes exceeding \$200,000, or \$300,000 together with their spouses). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to sale. Consequently, the rule may adversely affect the ability of broker-dealers to sell our securities and may adversely affect the ability of stockholders to sell any of the securities acquired hereby in the secondary market.

The Commission has adopted regulations that define a "penny stock" to be an equity security that has a market price (as therein defined) less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule prepared by the Commission relating to the penny stock market. Disclosure is also required to be made about commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, monthly statements are required to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

These restrictions will not apply to our securities if our securities continue to be listed on the Nasdaq SmallCap Market and have certain price and volume information provided on a current and continuing basis or meet certain minimum net tangible assets or average revenue criteria. Our securities may not qualify for exemption from these restrictions. In any event, even if our securities continue to be exempt from these restrictions, we would remain subject to Section 15(b)(6) of the Exchange Act, which gives the Commission the authority to prohibit any person who is engaged in unlawful conduct while participating in a distribution of a penny stock from associating with a broker-dealer or participating in a distribution of a penny stock, if the Commission finds that these restrictions would be in the public interest. If our securities were subject to the existing or proposed rules on penny stocks, the market liquidity for our securities could be severely adversely affected.

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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 August 10, 1999, in addition to approximately 9,064,881 shares of common stock, we could be required to issue up to 10,951,289 shares of Common Stock if outstanding options, warrant and preferred stock are converted into Common Stock. In addition, shares of Series C preferred stock would be convertible into approximately 1,775,821 shares of common stock based on the market price of the common stock as of June 1, 1999.

Our stock options and warrants are likely to be exercised, if at all, 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.

No prediction can be made as to the effect, if any, that the availability of these shares for sale will have on the market price of our common stock. Nevertheless, because substantial amounts of our common stock may be sold in the public market, subject, in some cases, to compliance with Rule 144 under the Securities Act, the market price of our common stock could drop as a result of sales of these securities or the perception that these types of sales may occur. These factors could also make it more difficult for us to raise funds through future offerings of securities.

WE ARE SUBJECT TO ANTITAKEOVER PROVISIONS OF OUR CERTIFICATE OF INCORPORATION AND DELAWARE LAW.

Certain provisions of our Certificate of Incorporation and Delaware law 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 shareholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue these shares, 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 coupons before dividends would be declared to holders of common stock and the right to the redemption of these 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 subject to certain 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 certain conditions are met. 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 Delaware law could have the effect of discouraging others from making tender offers for our securities and, as a consequence, they also may inhibit fluctuations in the market price of our common stock that otherwise could result from actual or rumored takeover attempts. Those provisions also may have the effect of preventing changes in our management.

OUR BUSINESS COULD BE AFFECTED BY THE YEAR 2000 ISSUE.

The Year 2000 Issue is the result of computer programs being written using two digits rather than four to define the applicable year. Any computer programs or hardware that have date-sensitive software or embedded chips may recognize a date using "00" as the year 1900 rather than the year 2000.

In terms of our internal operations, we do not use equipment with embedded chip technology that is date sensitive. We expect that the systems to be affected by the Year 2000 date change include the database, networking and accounting software licensed by us. We expect to incur out-of-pocket costs related to making inquiries of, and receiving confirmations from, third parties of no more than \$10,000.

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If our computer systems or the computer systems of any of our suppliers, customers or other third parties are not Year 2000 compliant or if those systems are unable to recover from system interruptions that may result from the Year 2000 date change, our business could be materially adversely affected.

#### FORWARD-LOOKING STATEMENTS

This prospectus may contain 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. Forward-looking statements are subject to risks and uncertainties. Those risks and uncertainties may cause our actual results, performance or achievements to be materially different from what is expressed or implied by the forward-looking statements. Forward-looking statements are based on assumptions and describe our future plans, strategies and expectations. Forward-looking statements are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend" or "project" or comparable terminology.

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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 certain 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 7,192,870 shares of common stock, including 2,759,189 shares of common stock issuable upon the exercise of outstanding warrants issued by Discovery Laboratories. The selling stockholders may offer all or part of the shares of common stock covered by this prospectus. Information with respect to shares owned beneficially after the offering assumes the sale of all of the shares offered and no other purchases or sales of common stock. The common stock offered by this prospectus may be offered from time to time by the selling stockholders named below.

| Name   | Number of Shares of Common Stock, not including Warrants, Beneficially Owned | Number of Shares Represented by Warrants Beneficially Owned | Total Number of Shares of Common Stock Beneficially Owned + | Percentage Beneficially Owned Before Offering | Number of Shares to be Offered for the Account of the Selling Stockholder | Number of Shares to be Owned after this Offering | Percentage to be Beneficially Owned after this Offering |
|--|--|---|---|---|---|--|---|
| Moonlight International, Ltd.....            | 165,289  | 165,289   | 330,578   | 4.9%  | 330,578   | 0  | *   |
| Dr. Tis Prager.....                          | 41,322   | 41,322  | 82,644  | 1.2%  | 82,644  | 0  | *   |
| Keys Foundation.....                         | 165,289  | 165,289   | 330,578   | 4.9%  | 330,578   | 0  | *   |
| Finsbury Worldwide Pharmaceutical Trust..... | 826,446  | 826,446   | 1,652,892   | 20.0%   | 1,652,892   | 0  | *   |
| Caduceus Capital II, L.P.....                | 165,289  | 165,289   | 330,578   | 4.9%  | 330,578   | 0  | *   |
| Winchester Global Trust Company Ltd.....     | 661,157  | 661,157   | 1,322,314   | 16.7%   | 1,322,314   | 0  | *   |
| Windward Venture Partners                    | 83,645   | 56,903  | 139,548   | 2.0%  | 139,548   | 0  | *   |
| Benjamin Bollag.....                         | 61,693   | 42,677  | 104,370   | 1.5%  | 104,370   | 0  | *   |
| Michael Bollag.....                          | 61,693   | 42,677  | 104,370   | 1.5%  | 104,370   | 0  | *   |
| Concordia Partners L.P.....                  | 310,954  | 56,903  | 367,857   | 4.6%  | 139,548   | 175,117  | 2.6%  |
| Aries Domestic Fund, L.P.....                | 385,576  | 117,529   | 503,105   | 7.4%  | 230,253   | 272,852  | 4.1%  |
| The Aries Master Fund                        | 907,012  | 274,237   | 1,181,249   | 17.0%   | 537,258   | 643,991  | 9.7%  |
| 126736 Canada, Inc.....                      | 378,358  | 28,451  | 69,773  | 1.0%  | 69,773  | 0  | 3.4%  |
| CPC Offshore Equity Fund I LTD.....          | 41,322   | 0   | 69,773  | 1.0%  | 69,773  | 0  | *   |
| Johnson & Johnson Inc.....                   | 205,846  | 0   | 205,846   | 3.0%  | 205,846   | 0  | *   |
| Paramount Capital Inc.....                   | 0  | 404,958   | 404,958   | 5.0%  | 404,958   | 0  | *   |
| Brobeck, Phleger & Harrison LLP              | 14,000   | 0   | 14,000  | 0.21%   | 14,000  | 0  | *   |
| Yi, Tuan & Brunstein.....                    | 4,850  | 0   | 4,850   | 0.07%   | 4,850   | 0  | *   |
| Scripps Research Institute.....              | 117,500  | 0   | 117,000   | 1.7%  | 117,000   | 0  | *   |
| RAQ, LLC                                     | 1,001,739  | 0   | 1,001,739   | 15.2%   | 1,001,739   | 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 August 13, 1999, Discovery Laboratories had 9,064,889 shares of common stock outstanding. Beneficial ownership information reflected in the table includes shares issuable upon the exercise of outstanding warrants issued by Discovery Laboratories.

## PLAN OF DISTRIBUTION

The shares of common stock covered by this prospectus are owned by the selling stockholders. As used in the rest of this section of the prospectus, the term "selling stockholders" includes the named selling stockholders and any of their pledgees, donees, transferees or other successors in interest selling shares received from a named selling stockholder after the date of this prospectus. The selling stockholders may offer and sell, 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 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.

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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.

#### 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, 7 World Trade Center, 13th Floor, New York, New York 10048, 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 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 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 and any filings we make with the Securities and Exchange Commission after the date of this prospectus under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934:

1. Our Annual Report on Form 10-KSB and 10-KSB/A for the year ended December 31, 1998;
2. Our Quarterly Reports on Form 10-Q-SB and Form 10-QSB/A for the quarter ended March 31, 1999;
3. Our Quarterly Report on Form 10Q-SB for the quarter ended June 30, 1999;
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; and

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5. Our current report on Form 8-K as filed with the Securities and Exchange Commission on August 9, 1999.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address: Discovery Laboratories, Inc., 305 South Main Street, Doylestown, Pennsylvania 18901, Attention: Cynthia Davis. Telephone requests may be directed to (215) 340-4699. Exhibits to the documents will not be sent, unless those exhibits have specifically been incorporated by reference in this prospectus.

This prospectus is part of a registration statement we filed with the 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 as of December 31, 1998 and each of the years in the two-year period ended December 31, 1998 and the period from May 18, 1993 (inception) through December 31, 1998 incorporated by reference in this registration statement have been audited by Richard A. Eisner & Company, LLP ("RAE"), independent auditors, as stated in their reports appearing therein. These financial statements have been so included in reliance on the reports of RAE given on their authority as experts in accounting and auditing.

#### LEGAL MATTERS

The validity of the shares of common stock offered hereby has been passed upon for us by Battle Fowler LLP, New York, New York.

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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 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.

7,192,870 SHARES

DISCOVERY LABORATORIES, INC.

COMMON STOCK

SEPTEMBER \_\_, 1999

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## 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 the Registrant 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.....            | \$1,769  |
| Accounting fees and expenses.....    | 4,500    |
| Legal fees and expenses.....         | 22,000   |
| Miscellaneous fees and expenses..... | 1,731    |
|                                      | -----    |
| Total.....                           | \$30,000 |
|                                      | =====    |

## Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation law empowers a Delaware corporation to indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed legal action, suit or proceedings, whether civil, criminal, administrative or investigative (other than action by or in the right of such corporation), by reason of the fact that such person was an officer or director of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such officer or director acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation's best interests and, for criminal proceedings, had no reasonable cause to believe his conduct was illegal. A Delaware corporation may indemnify officers and directors in an action by or in the right of the corporation under the same conditions, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation in the performance of his duty. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses which such officer or director actually and reasonably incurred.

In accordance with Delaware law, our restated certificate of incorporation contains a provision to limit the personal liability of our directors for violations of their fiduciary duty as a director. This provision eliminates each director's liability to us or our stockholders for monetary damages except (i) for any breach of each director's duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation law providing for liability of directors for unlawful payment of dividends or unlawful stock purchases or redemptions or (iv) for any transaction from which a director derived an improper personal benefit. The effect of this provision is to eliminate the personal liability of directors for monetary damages for actions involving a breach of their fiduciary duty of care, including any such actions involving gross negligence.

Item 16. Exhibits

| EXHIBIT NO. | DESCRIPTION   |
|-------------|---|
| 2.1*        | Agreement and Plan of Merger dated as of March 5, 1998 among Discovery, ATI Acquisition Corp. and ATI.                  |
| 2.2**       | Agreement and Plan of Reorganization and Merger, dated as of July 16, 1997, by and between Discovery and Old Discovery. |
| 5.1+        | Opinion of Battle Fowler LLP regarding the legality of the securities being registered.                                 |
| 16.1***     | Letter dated January 28, 1998 from Ernst & Young LLP to the Securities and Exchange Commission.                         |
| 23.1+       | Consent of Richard A. Eisner & Company, LLP.  |
| 24.1+       | Powers of Attorney.   |

\* Incorporated by reference to Discovery's Annual Report on Form 10-KSB for the year ending December 31, 1997.

\*\* Incorporated by reference to Discovery's Registration Statement on Form S-4 (File No. 333-34337).

\*\*\* Incorporated by reference to Discovery's Current Report on Form 8-K/A dated January 16, 1998.

+ Previously Filed.

Item 17. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to the Registrant Statement:
  - (i) To include any prospectus required by Section 10(a) (3) of the Securities Act;
  - (ii) To 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) To 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;

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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.
- (4) That, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this amendment to its Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of New York, New York, on the 28th day of September, 1999.

DISCOVERY LABORATORIES, INC.  
(Registrant)

By: /s/ Robert Capetola, PH.D

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

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

| Signature<br>-----  | Title<br>-----                               | Date<br>-----      |
|---|--|--------------------|
| /s/ Robert J. Capetola, Ph.D.<br>-----<br>Robert J. Capetola, Ph.D. | Chief Executive Officer                      | September 30, 1999 |
| *<br>-----<br>Evan Myrianthopoulos                                  | Vice President, Finance                      | September 30, 1999 |
| *<br>-----<br>Cynthia Davis   | Controller<br>(Principal Accounting Officer) | September 30, 1999 |
| *<br>-----<br>Steve H. Kanzer, C.P.A., Esq.                         | Chairman of the Board                        | September 30, 1999 |
| *<br>-----<br>Richard Power   | Director                                     | September 30, 1999 |
| *<br>-----<br>Marvin Rosenthale                                     | Director                                     | September 30, 1999 |
| *<br>-----<br>Mark C. Rogers, M.D.                                  | Director                                     | September 30, 1999 |
| *<br>-----<br>Herbert McDade, Jr.                                   | Director                                     | September 30, 1999 |
| *<br>-----<br>Max Link, Ph.D.                                       | Director                                     | September 30, 1999 |
| *<br>-----<br>David Naveh, Ph.D.                                    | Director                                     | September 30, 1999 |
| *<br>-----<br>Richard Sperber                                       | Director                                     | September 30, 1999 |

-----  
Robert J. Capetola  
\* As Attorney-in-fact

EXHIBIT INDEX

EXHIBIT NO.      DESCRIPTION  
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- \*          Incorporated by reference to Discovery's Annual Report on Form 10-KSB for the year ending December 31, 1997.
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  - \*\*\*        Incorporated by reference to Discovery's Current Report on Form 8-K/A dated January 16, 1998.
  - +          Previously filed.