U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-KSB

|X| Annual Report under Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2000

|_| Transition report under Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the transition period from to

Commission file number 0-26422

DISCOVERY LABORATORIES, INC.
(Name of Small Business Issuer in Its Charter)

DELAWARE	94-3171943
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

350 SOUTH MAIN STREET, SUITE 307, DOYLESTOWN, PENNSYLVANIA 18901
(Address of Principal Executive Offices Including Zip Code)

(215) 340-4699
(Issuer's Telephone Number, Including Area Code)

Securities registered under Section 12(b) of the Exchange Act:

Title of Each Class	Name of Each Exchange on Which Registered
None	None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, $.001 par value
(Title of Class)

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES X NO

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. |_|

State issuer's revenues for its most recent fiscal year. $741,000.

The aggregate market value of all of the registrant's outstanding common stock, par value $0.001 per share (20,871,794 shares, including shares of common stock held by each director and executive officer (as such term is defined in Rule 16a-1(f) of the Exchange Act) and each person who beneficially owns 10% or more of the outstanding shares of common stock) was approximately $68 million computed by reference to the closing price of such common equity on the Nasdaq SmallCap Market on March 26, 2001.

As of March 26, 2001, 13,880,563 shares of the registrant's common stock were outstanding (exclusive of shares of such common stock owned by each director and executive officer (as such term is defined in Rule 16a-1(f) of the Exchange Act) and each person who beneficially owns 10% or more of the outstanding shares of common stock). The aggregate market value of voting and non-voting common equity held by non-affiliates computed by using the closing price of such common equity on the Nasdaq SmallCap Market on March 26, 2001, was approximately $45 million. Shares of common stock beneficially owned by each director and executive officer (as such term is defined in Rule 16a-1(f) of the Exchange Act) and each person who beneficially owns 10% or more of the outstanding shares of common stock have been excluded from the calculations set forth in this paragraph in that such persons may be deemed affiliates of the registrant. This determination of affiliate status is not necessarily conclusive.

The information required by Items 9 through 12 of Part III is incorporated by reference to the Company's definitive proxy statement to be filed with the Commission within 120 days after the end of the Company's most recent fiscal year.

Transitional Small Business Disclosure Format: YES NO X

Unless the context otherwise requires, (i) all references to the "Company" include Discovery Laboratories, Inc. ("Discovery"), and its wholly-owned, presently inactive subsidiary, Acute Therapeutics, Inc. ("New ATI"), and (ii) all references to the Company's activities, results of operations and financial condition prior to November 25, 1997, insofar as business activities relating to the Surfaxin(R) and SuperVent(TM) products described herein are concerned, relate to Discovery Laboratories, Inc., a former Delaware corporation ("Old Discovery"), a predecessor to the Company. See Item 1 and Item 4 in this Annual Report on Form 10-KSB (this "Report").

FORWARD LOOKING STATEMENTS

The statements set forth under "Item 1 Description of Business" and elsewhere in this report, including, without limitation, in "Item 1 Description of Business, Important Factors Regarding the Company", which are not historical constitute "Forward Looking Statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 including statements regarding the expectations, beliefs, intentions or strategies for the future. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements 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 us; 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 "Item 1 Description of Business, Important Factors Regarding the Company", and in the documents incorporated by reference in this report.

We do not undertake to update any forward-looking statements.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

We are a development stage pharmaceutical company that focuses on developing compounds to treat respiratory diseases that affect the ability of the lungs to absorb oxygen. We are initially developing our lead product candidate, Surfaxin(R), for use by newborn infants to treat two respiratory conditions in critical care units of hospitals. We are also developing this lead product candidate for the treatment of acute respiratory distress syndrome in adult patients ("ARDS") and acute lung injury in adult patients ("ALI", ARDS and ALI are sometimes referred to herein collectively as "ARDS/ALI"). We believe 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 deliver drugs that are currently delivered orally or by injection. These drugs include antibiotics, pulmonary vasodilators, bronchodilators, steroids and proteins. We are also evaluating acquiring 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 manufacturing and marketing these drugs.

Our lead product is Surfaxin(R). Surfaxin(R) is a formulation of a humanized, synthetic lung surfactant containing a peptide that mimics a protein. We patterned Surfaxin(R) after human surfactant protein B. Surfactants are substances that are produced 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 in premature infants ("IRDS"), meconium aspiration syndrome in full-term infants ("MAS"), ARDS and ALI. We have also begun developing Surfaxin(R) to treat other respiratory disorders.

IRDS in premature infants 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 the baby's first bowel movement in the mother's womb. If the baby breathes in the meconium, it could lead to MAS. 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 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.

The incidence of ARDS/ALI ranges between approximately 150,000 and 240,000 patients per year in the United States with a fatality rate as high as 35-55%. IRDS in infants affects approximately 60,000 patients per year in the United States. Twenty to forty percent of premature infants with IRDS require extended mechanical ventilation and hospitalization. MAS affects approximately 22,000 to 26,000 newborn infants per year in the United States.

Presently, the FDA has only approved replacement surfactants for treating IRDS in premature infants. The most commonly used of these approved replacement surfactants come from pigs and cows and require relatively complex extractive manufacturing processes. Surfaxin(R) is a

humanized, synthetic surfactant modeled after the most active protein found in human surfactant. As a result, 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 surfactants such as its resistance to proteolytic degradation and no potential to transmit animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease").

The FDA has not approved replacement surfactants 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 the clinical trials nor does it mean that the regulatory requirements are less stringent. However, the FDA will review the New Drug Application for a drug granted fast track status within six months. The FDA has awarded us an orphan drug grant to support our development of Surfaxin(R) in MAS and has designated Surfaxin(R) as an orphan drug for the treatment of MAS, IRDS in babies and ARDS/ALI. In October 2000, The Company was 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 converting 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.

Our second compound under development is SuperVent(TM) (active compound, tyloxapol). We intend to use SuperVent(TM) to treat airway diseases such as cystic fibrosis and chronic bronchitis. We deliver SuperVent(TM) to patients using a nebulizer. A nebulizer is a device that turns liquid into mist, making it breathable. We anticipate using SuperVent(TM) for the treatment of lung conditions involving inflammation, excessive mucus and injurious oxidation. Injurious oxidation is a condition in which atoms in tissue lose electrons, which can result in damage to the tissue.

Cystic fibrosis is a progressive, lethal respiratory disease that afflicts approximately 28,000 patients in the United States and a comparable number in Europe. Cystic fibrosis is the most common lethal genetic disease among Caucasians. Because of this genetic defect, mucus accumulates and clogs the lungs, impairing breathing. 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 in the lungs. 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.

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 clinical trials for the treatment of IRDS in premature infants and expect to commence enrollment in these trials in the second quarter of 2001. In addition, we have initiated a Phase 2 clinical trial of Surfaxin(R) for the treatment of ARDS. The Company is also evaluating whether to conduct further clinical trials of SuperVent(TM) for treatment of cystic fibrosis ("CF") and is considering entering into suitable collaborative arrangements with a partner.

PRODUCTS AND TECHNOLOGIES UNDER DEVELOPMENT

SURFAXIN(R)

The Company's lead product is Surfaxin(R), a peptide-phospholipid formulation containing the proprietary, synthetic peptide, sinapultide, for the treatment of several conditions characterized by insufficient surfactant. Lung surfactants are protein-phospholipid complexes that coat the alveoli (air sacs) of the lungs. Lung surfactants lower surface tension in expiration and raise it during inspiration to prevent the collapse of alveoli. Replacement surfactants are currently approved only for treating IRDS in premature babies. Infants with IRDS, as well as infants born with meconium (a component of the fetal bowel) in their lungs, which can lead to MAS, typically suffer from insufficient surfactant. MAS can lead to a life-threatening loss of pulmonary function. Patients with ARDS/ALI, which can result from trauma, smoke inhalation, head injury, pneumonia and a variety of other events, typically suffer from surfactant deficiency as well. We are also evaluating Surfaxin(R) as an aerosol formulation that may have utility in other pulmonary disorders, such as asthma.

Surfaxin(R) is an aqueous suspension of lipids containing the novel synthetic peptide sinapultide and was invented at The Scripps Research Institute ("Scripps"). Surfaxin(R) is patterned after human surfactant protein B, shown to have the most activity of the human surfactant proteins. Surfaxin(R) was exclusively licensed by Scripps to Johnson & Johnson, Inc. ("J&J"), which, together with its wholly owned subsidiary, Ortho Pharmaceutical Corporation ("Ortho"), engaged in development activities with respect to sinapultide. The Company acquired the exclusive worldwide sublicense to the sinapultide technology from J&J and Ortho in October 1996.

In July 1992, an investigational new drug application ("IND") submitted by Scripps relating to the use of Surfaxin(R) to treat IRDS was approved by the United States Food and Drug Administration (the "FDA"). J&J subsequently completed a multi-center, Phase 2 clinical trial of Surfaxin(R) in 47 infants with IRDS. This trial demonstrated safety and efficacy. In September 1994, an IND was submitted by J&J relating to the use of Surfaxin(R) to treat ARDS and was subsequently approved by the FDA. Both the IRDS IND and the ARDS IND have been transferred to the Company. The Company subsequently received FDA approval to amend the approved ARDS IND and re-initiate Phase 1 clinical trials of Surfaxin(R) for the treatment of ARDS. The Company amended the existing IRDS IND to permit the initiation of a Phase 2 clinical trial of Surfaxin(R) to treat MAS on May 27, 1997. This trial was completed and results were announced on February 4, 1999. The Company initiated a pivotal Phase 3 trial in MAS in January 2000 and commenced enrollment in the trial in May 2000. The trial intends to enroll 200 MAS patients. In November 2000, the Company obtained FDA clearance for a 110 patient Phase 2 trial in ARDS. Pending the successful outcome of ongoing discussions with the FDA, the Company also intends to initiate two Phase 3 multinational clinical trials for Surfaxin(R) for IRDS during the second quarter of 2001. The IRDS Phase 3 trials will use Surfaxin(R) versus an active comparator that will be either totally synthetic or animal derived. The Phase 3 trials can be conducted at clinical sites located in North America, Europe and Latin America and the Company presently anticipates that such trials will not contain a placebo-controlled arm. Conditioned upon the successful outcome of such trials, the Company has committed to provide Surfaxin(R) to certain Latin American regions that participate in the studies at a significantly reduced cost for a period of 10 years following commercialization.

SuperVent(TM)

The Company is developing SuperVent(TM) as a stable, aerosolized, multidimensional therapy for airway diseases such as CF and chronic bronchitis, which are characterized by inflammation, injurious oxidation and excessive sputum. CF results from a genetic defect in the CFTR gene. The CFTR gene codes for a membrane protein responsible for the transport of chloride ions. Because of this genetic defect, CF mucus is excessively viscous and adherent to airway walls. Destruction of the lungs of CF patients occurs gradually as the inability to clear mucus from the lungs leads to blockage of the airways usually beginning in the smaller airways and alveoli. A new therapy, which minimizes the pulmonary complications of CF, would have a major impact on the length and quality of life of its patients.

SuperVent's(TM) active component is tyloxapol, a compound which has been safely used as an emulsifying agent in drug formulations by the United States pharmaceutical industry for over 40 years. Experimental research conducted by consultants to the Company indicates that tyloxapol may possess biological activities beyond its well-recognized emulsification properties. In vitro studies conducted by the inventors demonstrated that tyloxapol has three mechanisms of action: anti-inflammatory activity, anti-oxidant activity and mucoactive activity. This combination of pharmacological activities is not presently found in any single, safe, effective therapy for CF or chronic bronchitis in the United States.

The Company's clinical development plan for SuperVent(TM) is to focus first on CF. In September 1995, the FDA approved a physician-sponsored IND to begin a clinical trial of SuperVent(TM) for use in treating CF. The trial commenced on March 17, 1997, at the University of Utah Health Sciences Center and is designed to determine whether aerosolized SuperVent(TM) holds promise as a low toxicity, anti-inflammatory, anti-oxidant and mucolytic agent for the treatment of CF. Part A of such clinical trial was completed on March 31, 1998. The results from this clinical trial in normal healthy volunteers have indicated that the compound had no significant effects on any objective measure of safety (although coughing was noted by several subjects at the highest doses tested). The Company began a Phase 2a clinical trial of SuperVent(TM) for the treatment of CF on August 4, 1999. Analysis of the data show that SuperVent(TM) dramatically decreased the amount of Interleukin 8 (IL-8) and Interleukin 6 (IL-6) in the sputum of treated patients compared to controls. IL-8 is an important body chemical that causes the migration of inflammatory cells to the site of release. A reduction in a CF patient's IL-8 level could potentially result in an anti-inflammatory effect occurring in the lungs which may result in a clinical benefit for the patient. The Phase 2a clinical trial involved 8 patients and an additional Phase 2 trial will likely be required prior to commencement of a Phase 3 trial.

DSC-103

The Company has determined that DSC-103 does not meet its critical care focus and its license of DSC-103 has been terminated with the licensor, effective September 2000. Earlier in the year, in anticipation of such action, the Company terminated a related sublicense that had previously been granted for DSC-103.

LICENSING ARRANGEMENTS; PATENTS AND PROPRIETARY RIGHTS

J&J License Agreement: Surfaxin(R)

The Company has received an exclusive, worldwide sublicense from J&J (the "J&J License Agreement") to commercialize Surfaxin(R) for the diagnosis, prevention and treatment of disease.

The J&J License Agreement is a sublicense under certain patent rights previously licensed to J&J by Scripps (the "Scripps Patent Rights") and a license under certain other patent rights held by Ortho (the "Ortho Patent Rights"). The Scripps Patent Rights principally consist of four issued United States patents and two pending United States patent applications. The four issued patents are U.S. Patent No. 5,407,914; U.S. Patent No. 5,260,273; U.S. Patent No. 5,164,369; and U.S. Patent No. 6,013,619. These patents relate to humanized, synthetic pulmonary surfactants (including Surfaxin(R)), certain related polypeptides and a method of treating respiratory distress syndrome with these surfactants. The first of these patents will expire in 2009. The two pending United States applications relate to pulmonary surfactants, related polypeptides, liposomal surfactant compositions and methods of treating respiratory distress syndromes with these surfactants and compositions. The Ortho Patent Rights consist of certain pending United States patent applications which relate to methods of manufacturing certain peptides which may be used in the manufacture of Surfaxin(R). J&J is responsible for filing, prosecuting and maintaining the Ortho Patent Rights. In October 2000, the Company was issued European Patent No. 0350506 covering certain novel peptides and polypeptides related to the human surfactant SP18 monomer protein.

U.S. Patent No. 6,013,619 was issued to Scripps and licensed to the Company and covers all known synthetic (including Surfaxin(R)), animal- or human-derived surfactants for use in any form of pulmonary lavage for respiratory distress syndromes. Pulmonary lavage techniques (using surfactant) include lavage via a bronchoscope in adults as well as direct pulmonary lung lavage via an endotracheal tube in newborn babies with MAS. The Company believes that the lavage technique may provide a clinical benefit to ARDS and MAS patients by decreasing the amount of infectious and inflammatory debris in the lungs, restoring the alveoli to a more normal state and possibly resulting in patients getting off mechanical ventilation sooner.

CMHA License Agreement: SuperVent(TM)/Tyloxapol

The Company has obtained the core technology relating to SuperVent(TM) pursuant to a license agreement (the "CMHA License Agreement") with the Charlotte-Mecklenberg Hospital Authority ("CMHA"). The CMHA License Agreement grants the Company an exclusive worldwide license under two issued United States patents (U.S. Patent No. 5,474,760 and U.S. Patent No. 5,512,270) and two pending United States patent applications held by CMHA, and any later-issued United States and any foreign patents based on or issuing from the issued patents and the pending patent applications. The issued United States patents expire in 2013. The United States patents cover methods of using tyloxapol, the active compound in SuperVent(TM), to treat cystic fibrosis and methods of treating diseases caused by oxidant species, such as myocardial infarction, stroke and ARDS. The two pending United States patent applications relate to the use of tyloxapol as an anti-inflammatory and anti-oxidant agent.

Tyloxapol, the active compound in SuperVent(TM), was the subject of an issued United States composition of matter patent which expired in 1965. The patents and patent applications licensed to the Company differ from the expired patent, inter alia, in that one patent application covers proprietary pharmaceutical formulations containing high concentrations of tyloxapol and the other patents and patent applications cover uses of tyloxapol to treat certain diseases. Although the Company believes that high concentration formulations of tyloxapol will represent the most practical and efficacious means to deliver the active compound, there can be no assurance that any patent covering this formulation will be issued or that the compound will not

prove similarly effective in lower concentrations which are not covered by any of the Company's patent applications. See "Important Factors Regarding the Company."

Scripps Agreement

The Company and Scripps were parties to a sponsored research agreement (the "Sponsored Research Agreement") that expired during February 1999 pursuant to which the Company contributed $460,000 per annum to Scripps' Surfaxin(R) research efforts. The Sponsored Research Agreement was for an initial term of two years with renewal provisions for additional one-year periods. In March 2000, the Company and Scripps entered into an agreement extending the term for one year and pursuant to such extension the Company contributed $463,000 to Scripps. The Company and Scripps are currently finalizing an agreement to extend the Sponsored Research Agreement for an additional year commencing March 1, 2001. In connection therewith, it is currently contemplated that the Company will contribute an additional $489,000 to Scripps' Surfaxin(R) research efforts commencing March 1, 2001. The Company has an option to acquire an exclusive worldwide license to technology developed under the Sponsored Research Agreement prior to its expiration, which it is required to exercise within 180 days from receipt of notice from Scripps of the development of such technology. Scripps will own all technology that it developed pursuant to work performed under the Sponsored Research Agreement. The Company has the right to receive 50% of the net royalty income received by Scripps for inventions jointly developed by the Company and Scripps to the extent the Company does not exercise its option with respect to such inventions.

Collaboration Agreements

The Company entered into a sublicense agreement with Laboratorios del Dr. Esteve, S.A. ("Esteve") pursuant to which the Company granted to Esteve an exclusive license to market and sell Surfaxin(R) products in southern Europe (with an option for Italy), Central and South America and Mexico. In addition, the Company granted to Esteve a right of first negotiation with respect to other products developed by the Company for distribution and sale in the licensed territories. Under the sublicense agreement, the Company has received, and subject to certain limitations will continue to receive, certain nonrefundable license fees and research and development expenditure reimbursements with respect to Surfaxin(R). In addition, the Company entered into a supply agreement with Esteve pursuant to which Esteve agreed to purchase all of its requirements (subject to certain limits) of the Surfaxin(R) products from the Company. The Company will receive a percentage of the sales price of the licensed products for the Surfaxin(R) products as the purchase price under the supply agreement.

Risk of Loss of Technology/Technological Uncertainty and Obsolescence

The Company must satisfy the terms and conditions set forth in the license agreements described above in order to retain its license rights thereunder, including but not limited to, diligent pursuit of product development and the timely payment of royalty fees (including, with respect to certain such agreements, minimum royalty payments), milestone payments and other amounts. If the Company fails to comply with such terms and conditions as set forth in such license agreements, its rights thereunder for individual product opportunities could be terminated.

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 regarding the breadth of claims allowed in biotechnology patents or the degree of protection afforded under

such patents. The Company's success will depend, in part, on its ability, and the ability of its licensor(s), to obtain protection for its products and technologies under United States and foreign patent laws, to preserve its trade secrets and to operate without infringing the proprietary rights of third parties. The Company has obtained rights to certain patents and patent applications and may, in the future, seek rights from third parties to additional patents and patent applications. There can be no assurance that patent applications relating to the Company's potential products which have been licensed to date, or that it may license from others in the future, will result in patents being issued, that any issued patents will afford adequate protection to the Company or not be challenged, invalidated, infringed or circumvented, or that any rights granted thereunder will afford additional competitive advantages to the Company. Furthermore, there can be no assurance that others have not independently developed, or will not independently develop, similar products and/or technologies, duplicate any of the Company's products or technologies, or, if patents are issued to, or licensed by, the Company, design around such patents. There also can be no assurance that the validity of any of the patents licensed to the Company would be upheld if challenged by others in litigation or that the Company's activities would not infringe patents owned by others. The Company could incur substantial costs in defending itself in suits brought against it or any of its licensors, or in suits in which the Company may assert, against others, patents in which the Company has rights. Should the Company's products or technologies be found to infringe patents issued to third parties, the manufacture, use and sale of the Company's products could be enjoined and the Company could be required to pay substantial damages. In addition, the Company may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of its products and technologies. No assurance can be given that any licenses required under any such patents or proprietary rights would be made available on terms acceptable to the Company, if at all.

The Company also relies on trade secrets and proprietary know-how. The Company requires all employees to enter into confidentiality agreements that prohibit the disclosure of confidential information to third parties and require disclosure and assignment to the Company of rights to their ideas, developments, discoveries and inventions. In addition, the Company seeks to obtain such agreements from its consultants, advisors and research collaborators; however, such agreements may not be possible where such persons are employed by universities or other academic institutions that require assignment of employee inventions to them. See "Important Factors Regarding the Company."

THIRD PARTY SUPPLIERS; MANUFACTURING AND MARKETING

To be successful, the Company's products must be manufactured in commercial quantities and at reasonable commercial cost under good manufacturing practice requirements set by the FDA ("GMP"). The FDA periodically inspects manufacturing facilities in the United States and abroad in order to assure compliance with the GMP requirements. Foreign manufacturers also are inspected by the FDA if their drugs are marketed in the United States or if they are serving as a contract supplier to a United States based company. Failure of the foreign or domestic suppliers of the Company's products or failure of the manufacturers of the Company's products to comply with GMP regulations or other FDA regulatory requirements would have a material adverse effect on the Company's business, financial condition and results of operations. The Company does not have any manufacturing capacity of its own but instead intends to rely on outside manufacturers to produce appropriate clinical grade material for its use in clinical studies for certain of its products. See "Important Factors Regarding the Company."

The Company has acquired from J&J experimental compounds, the sinapultide and manufacturing equipment needed to produce and meet its requirements for clinical supplies of Surfaxin(R). The Company has entered into an agreement with Akorn, Inc. (formerly, Taylor Pharmaceuticals, Inc.), for the manufacture of Surfaxin(R) for use in the Company's planned clinical trials. In addition, the Company is evaluating the purchase of additional manufacturing equipment for approximately $500,000 in anticipation of optimizing the commercial process for Surfaxin(R) and to allow scale up of the manufacturing process to meet expanded clinical and commercial needs. The Company has also embarked on a program of identifying backup suppliers of the Company's components and products.

The active compound in SuperVent(TM), tyloxapol, is presently manufactured for several third parties pursuant to GMP standards by an affiliate of Sanofi-Winthrop, Inc. ("Sanofi"), a multinational pharmaceutical company. Sanofi is the sole supplier of tyloxapol that presently meets GMP standards and there are few alternative sources of supply. Currently, the Company purchases bulk tyloxapol from Sanofi on an as-needed basis. Although Sanofi has sold a quantity of tyloxapol sufficient for the Company's contemplated Phase 2 clinical trial of SuperVent(TM), the Company does not have an agreement with Sanofi to supply any additional material, either in connection with a Phase 3 clinical trial or, following regulatory approval, for marketing purposes. There can be no assurance that the Company will be able to enter into a supply agreement with Sanofi or a supplier of the formulated drug on terms acceptable to the Company, if at all. In such case, the Company would be required to seek alternate manufacturing sources capable of producing tyloxapol and the formulated drug. There can be no assurance that the Company will be able to identify and contract with alternative manufacturers on terms acceptable to it, if at all. Any interruption in the supply of tyloxapol would have a material adverse effect on the Company's business, financial condition and results of operations. See "Important Factors Regarding the Company."

The Company may elect to market Surfaxin(R) and SuperVent(TM) directly or may, in the future, seek to enter into collaboration agreements to license these products, if they are successfully developed. The Company currently has no marketing and sales experience and no marketing or sales personnel. Unless a sales force is established, the Company will be dependent on corporate partners or other entities for the marketing and selling of its products. There can be no assurance that the Company will be able to enter into any satisfactory arrangements for the marketing and selling of its products. The inability of the Company to enter into such third party distribution, marketing and selling arrangements for its anticipated products could have a material adverse effect on the Company's business, financial condition and results of operations. See "Important Factors Regarding the Company."

COMPETITION

The Company is engaged in highly competitive fields of pharmaceutical research. Competition from numerous existing companies and others entering the fields in which the Company operates is intense and expected to increase. The Company expects to compete with, among others, conventional pharmaceutical companies. Most of these companies have substantially greater research and development, manufacturing, marketing, financial, technological, personnel and managerial resources than the Company. Acquisitions of competing companies by large pharmaceutical or health care companies could further enhance such competitors' financial, marketing and other resources. Moreover, competitors that are able to complete clinical trials,

obtain required regulatory approvals and commence commercial sales of their products before the Company could enjoy a significant competitive advantage. There are also existing therapies that may be expected to compete with the products the Company has under development. See "Important Factors Regarding the Company."

Presently, there are no approved drugs that are specifically indicated for MAS or ARDS/ALI. Current therapy consists of general supportive care and mechanical ventilation. Four products are specifically approved for the treatment of IRDS. Curosurf(TM), marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc., is a porcine lung extract. Exosurf(TM), marketed by GlaxoSmithKline, plc, contains only phospholipids and synthetic organic detergents and no stabilizing protein or peptides. Survanta(TM), which has been shown to be more effective than Exosurf(TM) in clinical trials, is an extract of bovine lung that contains the cow version of surfactant protein B. Forrest Laboratories, Inc., markets its calf lung surfactant, Infasurf(TM), for use in IRDS. Although none of the four approved surfactants for IRDS is approved for ARDS or ALI, which are significantly larger markets, there are a significant number of other potential therapies in development for the treatment of ARDS/ALI that are not surfactant related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin(R). The Company believes that synthetic surfactants such as Surfaxin(R) will be far less expensive to produce than the animal-derived products approved for the treatment of IRDS and will have no capability of transmitting the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease").

Genentech, Inc., has marketed Pulmozyme(TM) in the United States and Canada as a CF therapy since early 1994. Pulmozyme(TM) reduces the viscosity of CF mucus by cleaving the DNA released from destroyed inflammatory, epithelial and bacterial cells which collect in mucus and contribute to its abnormal viscosity and adherence. The approximate annual cost of Pulmozyme(TM) treatment for an average patient is $12,000. The Company believes that the high cost of this treatment may reduce its competitive profile as compared with SuperVent(TM).

GOVERNMENT REGULATION

The testing, manufacture, distribution, advertising and marketing of drug products are subject to extensive regulation by governmental authorities in the United States and other countries. Prior to marketing, any pharmaceutical products developed or licensed by the Company 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 efficacy and confirmation by the FDA that good laboratory, clinical and manufacturing practices were maintained during testing and manufacturing, can take many years, requires the expenditure of substantial resources and gives larger companies with greater financial resources a competitive advantage over the Company. The FDA review process can be lengthy and unpredictable, and the Company may encounter delays or rejections of its applications when submitted. If questions arise during the FDA review process, approval may take a significantly longer period of time. Generally, in order to gain FDA approval, a company first must conduct preclinical studies in a laboratory and in animal models to obtain preliminary information on a compound's efficacy and to identify any safety problems. The results of these studies are submitted as part of an IND application that the FDA must review before human clinical trials of an investigational drug can start.

Clinical trials are normally done in three phases and generally take two to five years or longer to complete. Phase 1 consists of testing the drug product in a small number of humans to determine preliminary safety and tolerable dose range. Phase 2 involves larger studies to evaluate the effectiveness of the drug product in humans having the disease or medical condition for which the product is indicated and to identify possible common adverse effects in a larger group of subjects. Phase 3 consists of additional controlled testing to establish clinical safety and effectiveness in an expanded patient population of geographically dispersed test sites, to evaluate the overall benefit-risk relationship for administering the product and to provide an adequate basis for product labeling.

After completion of clinical trials of a new drug product, FDA and foreign regulatory authority marketing approval must be obtained. A New Drug Application ("NDA") submitted to the FDA generally takes one to three years to obtain approval. If questions arise during the FDA review process, approval may take a significantly longer period of time. The testing and approval processes require substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. Even if regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. For marketing outside the United States, the Company also will be subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. None of the Company's products under development have been approved for marketing in the United States or elsewhere. No assurance can be given that the Company will be able to obtain regulatory approval for any such products under development. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested will delay or preclude the Company or its licensees or marketing partners from marketing their products, or limit the commercial use of the products, and thereby would have a material adverse effect on the Company's business, financial condition and results of operations. See "Important Factors Regarding the Company."

During October 1998, the FDA granted the Company fast track approval status for the ARDS and MAS indications. Fast track status facilitates the development and expedites the review of new drugs intended for treatment of life-threatening conditions for which there is presently no medical option by providing for the FDA's review of the NDA for a drug granted such fast track status within six months following filing of the application. The FDA Office of Orphan Products Development (the "OOPD") has designated Surfaxin(R) as an orphan drug for the treatment of MAS, IRDS and ARDS. In October 2000, the Company was awarded a $1 million Fast-Track Small Business Innovative Research (SBIR) grant by the National Institutes of Health to develop Surfaxin(R) for ARDS. In October 1998, the OOPD awarded the Company a renewable Orphan Products Development Grant, ranging from $194,390 for the first year to $583,170 over three or more years, to finance the Company's MAS trial.

EMPLOYEES

The Company has approximately 36 full-time employees. The Company's future success depends in significant part upon the continued service of its key scientific personnel and executive officers and its continuing ability to attract and retain highly qualified scientific and

managerial personnel. Competition for such personnel is intense and there can be no assurance that the Company can retain its key employees or that it can attract, assimilate or retain other highly qualified technical and managerial personnel in the future. See "Important Factors Regarding the Company."

1998 Merger

On June 16, 1998, Discovery completed the acquisition of the then outstanding minority interest in Acute Therapeutics, Inc., a Delaware corporation ("Old ATI"), through the merger of a transitory subsidiary of Discovery with and into Old ATI (the "1998 Merger"). Upon consummation of the 1998 Merger, (i) Dr. Capetola became the Chief Executive Officer of the Company, (ii) the other members of Old ATI's management team prior to the 1998 Merger assumed executive positions with the Company comparable to their prior positions with Old ATI and (iii) the Board of Directors of the Company was reconstituted.

1997 Merger

On November 25, 1997, Old Discovery was merged with and into the Company (the "1997 Merger"). Pursuant to the 1997 Merger, the name of the Company was changed from Ansan Pharmaceuticals, Inc., to Discovery Laboratories, Inc. Immediately following the consummation of the 1997 Merger, the Company effected a 1-for-3 reverse split of its outstanding common stock, par value $0.001 per share (the "Common Stock").

IMPORTANT FACTORS REGARDING THE COMPANY

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.

Our development of 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 our products. As a result, we may terminate development of these 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 available resources will be adequate to satisfy our capital needs through the first 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.

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 Nasdaq SmallCap Market. See "Important Factors Regarding the Company--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 our products. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products. The FDA and comparable foreign agencies require an extensive regulatory approval process before we can market our product. 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, 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 Unites 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 product 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. For marketing 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, it could prevent us from marketing 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. 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 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. 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 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 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, 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 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

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 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. In addition, if we find a replacement manufacturer 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 determine 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 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 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 that expires on December 31, 2005. We also have employment agreements with other key personnel with termination dates in 2001 and 2002. We do not maintain key-man life insurance. 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.

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 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 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, this 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, 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 March 26, 2001, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 33% 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."

For the 12-month period ended December 31, 2000, the price of our Common Stock has ranged from $2.44 to $12.63. We expect the price of our Common Stock to remain volatile and a more active market may never develop. The Company's Common Stock is listed for quotation on the Nasdaq SmallCap Market. The average daily trading volume in the Company's Common Stock varies significantly. For the 12-month period beginning January 1, 2000, through December 31, 2000, the average daily trading volume in our Common Stock was approximately 139,000 shares and the average number of transactions per day was approximately 150. 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.

In addition, we cannot assure investors that we will be able to continue to adhere to the strict listing criteria for the Nasdaq SmallCap Market. If the Common Stock were no longer listed on Nasdaq, 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 NASD's OTC Bulletin Board(R). 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, 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 March 26, 2001, there were 20,871,794 shares of Common Stock outstanding. In addition, as of March 26, 2001, up to 5,256,463 shares of Common Stock were issuable on exercise of outstanding options and warrants.

Holders of our stock options and warrants are likely to exercise them, if ever, at a time when we otherwise could obtain a price for the sale of our securities that is higher than the exercise price per security of the options or warrants. This exercise, or the possibility of this exercise, may impede our efforts to obtain additional financing through the sale of additional securities or make this financing more costly, and may reduce the price of our Common Stock.

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 shareholders. Our Board of Directors has the authority to fix and determine the relative rights

and preferences of preferred shares. Our Board of Directors also has 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 payments before dividends are distributed to the 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 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.

ITEM 2. DESCRIPTION OF PROPERTY.

The Company currently has its executive offices at 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901. The Company's telephone number of its executive offices is (215) 340-4699 and its facsimile number is (215) 340-3940. In November 2000, the Company established a satellite office in the United Kingdom to manage and oversee its European clinical research programs. In addition, the Company maintains offices in New York City where it conducts certain investor relations and legal functions.

In September 2000, the Company decided not to pursue its planned occupation of a building adjacent to its Doylestown, Pennsylvania headquarters that was previously purchased in early-August 2000 and originally intended to house the Company's expanded clinical research activities. As a lower cost alternative, the Company amended its existing lease agreement in September 2000 to include an additional approximately 4,000 square feet of space immediately adjacent to its offices. The Company sold the adjacent building on October 30, 2000, for approximately $565,000 in cash. After taking into account transaction costs, the proceeds from the sale of the building approximated its purchase price.

ITEM 3. LEGAL PROCEEDINGS.

The Company is not aware of any pending or threatened legal actions other than disputes arising in the ordinary course of its business that would not, if determined adversely to the Company, have a material adverse effect on the Company.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY-HOLDERS.

No matters were submitted to a vote of securityholders during the fourth quarter of 2000.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

The Common Stock is traded on the Nasdaq SmallCap Market under the symbol "DSCO." As of March 26, 2001, the number of stockholders of record of the Common Stock was approximately 161, and the number of beneficial owners of shares of the Common Stock was approximately 4,178. As of March 26, 2001, there were approximately 20,871,794 shares of Common Stock issued and outstanding.

The following table sets forth the quarterly price ranges of the Common Stock for the periods indicated, as reported by Nasdaq.

	Low	High
First Quarter 1999	$1.88	$4.00
Second Quarter 1999	$1.13	$2.50
Third Quarter 1999	$1.00	$2.00
Fourth Quarter 1999	$1.31	$3.06
First Quarter 2000	$2.44	$12.63
Second Quarter 2000	$2.75	$7.69
Third Quarter 2000	$3.88	$7.63
Fourth Quarter 2000	$3.03	$7.44
First Quarter 2001 (through March 26, 2001)	$2.72	$5.91

The Company has not paid dividends on the Common Stock. It is anticipated that the Company will not pay dividends on the Common Stock in the foreseeable future.

In May 2000, the Company's units (consisting of Common Stock, Class A Warrants and Class B Warrants) which were trading under the symbol "DSCOU" were delisted from trading because there were too few remaining holders of those units. By that time, most unit holders had already exercised their units for the underlying shares of Common Stock, Class A Warrants and Class B Warrants. On August 8, 2000, all Class A Warrants and Class B Warrants expired by their terms.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF OPERATIONS

The following discussion reflects the historical results of Old Discovery as the 1997 Merger was accounted for as a reverse acquisition with Old Discovery as the acquiror for financial reporting purposes.

Plan of Operations

Since its inception, the Company has concentrated its efforts and resources on the development and commercialization of pharmaceutical products and technologies. The Company has been unprofitable since its founding and has incurred a cumulative deficit of approximately $44 million through December 31, 2000. The Company expects to incur significantly increasing operating losses over the next several years, primarily due to the expansion of its research and development programs, including clinical trials for some or all of its existing products and

technologies and other products and technologies that it may acquire or develop. The Company's ability to achieve profitability depends upon, among other things, its ability to discover and develop products, obtain regulatory approval for its proposed products and enter into agreements for product development, manufacturing and commercialization. None of the Company's products currently generates revenues and the Company does not expect to achieve revenues for the foreseeable future. Moreover, there can be no assurance that the Company will ever achieve significant revenues or profitable operations from the sale of any of its products or technologies.

The Company is currently engaged in the development and commercialization of drugs for critical care that are intended to be used primarily in a hospital setting. The Company anticipates that during the next 12 months it will conduct substantial research and development of its products under development. The Company expects to continue the expansion of its research and development activities as a result of its receipt of approximately $17.5 million of net proceeds from its offering completed in March 2000. In continuation of its expanded research and development efforts, the Company anticipates the near term acquisition of approximately $500,000 of equipment in order to optimize the commercial process for Surfaxin(R) and to scale up the manufacturing process to meet expanded clinical and commercial needs. During 2000, the Company hired additional personnel, including four members of senior management, due to the expansion of its clinical development efforts regarding Surfaxin(R).

It is anticipated that the primary focus of the Company's research and development activities will be the several clinical trials for Surfaxin(R) indications and the evaluation of the feasibility of a Phase 2b trial for SuperVent(TM). A pivotal Phase 2/3 clinical trial of Surfaxin(R) for the treatment of ARDS was commenced on July 14, 1998. This trial was intended to enroll approximately 540 patients and be conducted at up to 43 clinical sites nationwide. This trial was stopped on January 27, 2000, due to the Company's cash position and so that a new Phase 2 ARDS trial could be commenced using a less viscous formulation of Surfaxin(R) that was developed at that time. The Company initiated a new Phase 2 trial in ARDS in March 2001.

A Phase 2a clinical trial of Surfaxin(R) for the treatment of MAS was commenced on May 27, 1997. This trial was completed and results were announced on February 4, 1999. The Company commenced enrollment of a pivotal Phase 3 trial in MAS in May of 2000. The Phase 3 trial intends to enroll 200 MAS patients. In November 2000, the Company initiated a Phase 2b clinical trial of Surfaxin(R) for the treatment of ARDS. This trial is designed in two parts -- Part A is a dose ranging study and Part B will consist of select doses identified in Part A. A total of 110 patients are expected to be enrolled in the study. Pending the successful outcome of ongoing discussions with the FDA, the Company intends to initiate two Phase 3 multinational clinical trials of Surfaxin(R) for IRDS during the second quarter of 2001. The IRDS Phase 3 trials will use Surfaxin(R) versus an active comparator that will be either totally synthetic or animal derived. The Phase 3 trials can be conducted at clinical sites located in North America, Europe and Latin America and the Company presently anticipates that the trials will not contain a placebo-controlled arm. Conditioned upon the successful outcome of the Phase 3 trials, the Company has committed to provide Surfaxin(R) to certain Latin American regions that participate in the studies at a significantly reduced cost for a period of ten years following commercialization.

A Phase 1/2 clinical trial of SuperVent(TM) for the treatment of CF was commenced on March 17, 1997. Part A of such clinical trial was completed on March 31, 1998. The Company began a

Phase 2a clinical trial of SuperVent(TM) for the treatment of CF on August 4, 1999. Analysis of the data show that SuperVent(TM) decreased the amount of Interleukin 8 (IL-8) and Interleukin 6 (IL-6) in the sputum of treated patients compared to controls. IL-8 is an important body chemical that causes the migration of inflammatory cells to the site of release. The Company believes that the reduction in IL-8 could potentially lead to a decreased inflammatory response in the lungs that may be clinically beneficial to CF patients.

The Company's expenses increased from $5,292,000 in 1999 to $12,644,000 in 2000. The increase was primarily due to an increase in the Company's research and development activities and a non-cash compensation charge of $2,515,000 recorded as a result of the grant of options and the vesting of certain milestone-based employee stock options (including 250,000 milestone options whose vesting was accelerated by the Board of Directors). As a result of the increases in expenses from 1999, the Company's net loss increased from $4,958,000 in 1999 to $10,861,000 in 2000. In addition, the increase in the total comprehensive net loss offset by the increase in the weighted average common shares outstanding during 2000 resulted in a decrease in the Company's net loss per share from $0.66 in 1999 to $0.58 in 2000.

Liquidity

As of December 31, 2000, the Company had working capital of approximately $16.6 million primarily due to its private placement completed in March 2000 in which it received net proceeds of approximately $17.5 million. The Company believes its current working capital is sufficient to meet its planned research and development activities through the first quarter of 2002. However, the Company will need additional financing from investors or collaborators to complete research and development and commercialization of its current product candidates.

Historically, the Company's working capital has been provided from the proceeds of private financings. On April 7, 1999 (the "April 1999 Financing"), the Company completed a private placement of shares of Common Stock and a newly created class of warrants of the Company (the "Class C Warrants") for an aggregate purchase price of $1,000,000. Investors in the April 1999 Financing received, in the aggregate, 826,447 shares of Common Stock at an adjusted purchase price of $1.21 and 569,026 Class C Warrants, each of which is exercisable for the purchase of one share of Common Stock for an exercise price of $2.15 at any time prior to the seventh anniversary of the issuance of such warrant. As of March 26, 2001, 56,907 of the Class C Warrants remain unexercised.

On July 29, 1999, the Company received approximately $2.2 million in net proceeds when it completed a private offering of units (the "1999 Unit Offering"), at a per Unit price of $500,000 (the "1999 Units"), each 1999 Unit consisting of (a) 413,223 shares of Common Stock and (b) an equal number of the Company's Class D Warrants, each of which entitled the holder thereof to purchase one share of Common Stock at any time prior to the close of business on July 27, 2004, at a per share purchase price equal to $1.33. As of March 26, 2001, all of the Class D Warrants had been exercised by the holders thereof. Paramount Capital, Inc. ("Paramount"), received options (the "1999 Placement Options") to acquire 0.49 1999 Units at a per 1999 Unit exercise price equal to $550,000 as partial compensation for its services in connection with the 1999 Unit Offering.

Pursuant to an agreement entered into on October 28, 1999, the Company issued 317,164 shares of Common Stock to Laboratorios P.E.N., S.A., at a price equal to $2.68 per share (based on a 50% premium over the average closing price for the 10 days prior to the closing date) for

aggregate proceeds of $850,000. The shares of Common Stock were issued to Laboratorios P.E.N., S.A. in connection with the sublicense agreement with Esteve described under "Item 1. Description of Business".

On March 22, 2000, the Company received approximately $17.5 million in net proceeds in a private offering of units at a per unit price of $500,000 (the "2000 Units"). Each of the 2000 Units consisted of (a) 76,923 shares of Common Stock and (b) a number of Class E Warrants equal to 20% of the number of shares of Common Stock included in each 2000 Unit, each of which entitles the holder to purchase one share of Common Stock at any time prior to the close of business on March 21, 2005, at an exercise price equal to $7.38 per share. In addition, the placement agent, Paramount, received cash fees of approximately $1.32 million and options (the "2000 Placement Options") to acquire 9,230 shares of Common Stock per 2000 Unit sold, at an exercise price equal to $8.113 per share, as partial compensation for its services in connection with the 2000 Offering.

The Company's working capital requirements will depend upon numerous factors, including, without limitation, the progress of the Company's research and development programs, preclinical and clinical testing, timing and cost of obtaining regulatory approvals, levels of resources that the Company devotes to the development of manufacturing and marketing capabilities, technological advances, status of competitors and the ability of the Company to establish collaborative arrangements with other organizations.

ITEM 7. FINANCIAL STATEMENTS.

See Index to Consolidated Financial Statements on Page F-1.

ITEM 8. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.

Not Applicable

PART III

The information required by Items 9 through 12 of Part III is incorporated by reference to the Company's definitive proxy statement to be filed with the Commission within 120 days after the end of the Company's fiscal year.

ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits

Exhibits are listed on the Index to Exhibits at the end of this Report. The exhibits required by Item 601 of Regulation S-B, listed on such Index in response to this Item, are incorporated herein by reference.

(b) Reports on Form 8-K

One report on Form 8-K was filed by the Company during the three months ended December 31, 2000. A current report was filed on December 22, 2000, as amended on January 9, 2001, reporting the engagement of Ernst & Young LLP as the Company's new independent accountants to audit the Company's consolidated financial statements and the dismissal of the Company's prior accountants, Richard A. Eisner & Co., LLP, in connection therewith.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

DISCOVERY LABORATORIES, INC.

Date: March 29, 2001 By: /s/ Robert J. Capetola

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

In accordance with the Exchange Act, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Name & Title	Date
/s/ Robert J. Capetola	Robert J. Capetola, Ph.D. Chief Executive Officer	March 29, 2001
/s/ Deni Zodda	Deni Zodda, Ph.D. Principal Financial Officer	March 29, 2001
/s/ Cynthia Davis	Cynthia Davis Controller (Principal Accounting Officer)	March 29, 2001
/s/ Herbert McDade, Jr.	Herbert McDade, Jr. Chairman of the Board of Directors	March 29, 2001
/s/ Richard Power	Richard Power Director	March 29, 2001
/s/ Marvin Rosenthale	Marvin Rosenthale Director	March 29, 2001
/s/ Mark C. Rogers	Mark C. Rogers, M.D. Director	March 29, 2001
/s/ Max Link	Max Link, Ph.D. Director	March 29, 2001

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
2.1(1)	Agreement and Plan of Merger dated as of March 5, 1998, among Discovery, ATI Acquisition Corp. and Old ATI.
2.2(3)	Agreement and Plan of Reorganization and Merger, dated as of July 16, 1997, by and between Discovery and Old Discovery.
3.1(1)	Restated Certificate of Incorporation of Discovery.
3.2	Amendment to Restated Certificate of Incorporation of Discovery.
3.3(2)	By-laws of Discovery.
3.4(10)	Certificate of Ownership Merging ATI Acquisition Corp., into Discovery.
4.1(6)	Form of Class C Warrant.
4.2(9)	Form of Class E Warrant.
4.3(10)	Unit Purchase Option issued to Paramount Capital, Inc., in connection with the March 1999 private placement.
10.1	Reference is made to Exhibits 2.1 and 2.2.
10.2(1)	Investor Rights Agreement, dated as of March 20, 1996, between Old Discovery and RAQ, LLC.
10.3(1)	Registration Rights Agreement, dated as of October 28, 1996, between ATI, Johnson & Johnson Development Corporation ("JJDC"), and Scripps.
10.4(4)+	Sublicense Agreement, dated as of October 28, 1996, between ATI, Johnson & Johnson, Inc., and Ortho.
10.5(4)+	License Agreement, between Discovery and The Charlotte-Mecklenburg Hospital Authority dated as of March 20, 1996.
10.6(10)+	Amendment of License Agreement between Discovery and The Charlotte-Mecklenburg Hospital Authority, dated as of March 20, 1996.
10.7(2)	Restated 1993 Stock Option Plan of Discovery.
10.8(2)	1995 Stock Option Plan of Discovery.
10.9(7)	Amended and Restated 1998 Stock Incentive Plan of Discovery.
10.10(1)	Management Agreement between Discovery Laboratories, Inc., and Acute Therapeutics, Inc., dated as of March 5, 1998.
10.11(6)	Indenture of Lease, dated as of July 1, 1998, between SLTI1, LLC and Acute Therapeutics, Inc.

10.12	Amendment, dated as of September 15, 2000, to the Indenture of Lease dated as of July 1, 1998, between SLTI1, LLC and Discovery.
10.13(6)	Letter Agreement, dated as of January 4, 1999, between Discovery and Yi, Tuan & Brunstein.
10.14(6)	Registration Rights Agreement, dated as of June 16, 1998, among Discovery, JJDC and Scripps.
10.15(6)	Stock Exchange Agreement, dated as of June 16, 1998, between Discovery and JJDC.
10.16	Employment Agreement, dated January 1, 2001, between Discovery and Robert J. Capetola, Ph.D.
10.17(6)	Employment Agreement, dated as of June 16, 1998, between Discovery and Christopher J. Schaber.
10.18(6)	Employment Agreement, dated as of June 16, 1998, between Discovery and Huei Tsai, Ph.D.
10.19(6)	Employment Agreement, dated as of June 16, 1998, between Discovery and Cynthia Davis.
10.20(6)	Form of Intellectual Property and Confidential Information Agreement.
10.21(6)	Form of Stock Purchase Agreement.
10.22(8)	Notice of Grant of Stock Option.
10.23(10)+	Sublicense Agreement between Discovery Laboratories, Inc., and Laboratories del Dr. Esteve S.A., dated as of October 26, 1999.
10.24(10)+	Supply Agreement between Discovery Laboratories, Inc., and Laboratories del Dr. Esteve S.A., dated as of October 26, 1999.
10.25(10)	Securities Purchase Agreement between Discovery Laboratories, Inc., and Laboratorios P.E.N., S.A., dated October 26, 1999.
10.26(10)+	Research Funding and Option Agreement, dated as of March 1, 2000, between Discovery and Scripps.
16.1(5)	Letter dated as of January 28, 1998, from Ernst & Young LLP to the Securities and Exchange Commission.
16.2(11)	Letter dated January 9, 2001, from Richard A. Eisner & Company, LLP, to the Securities and Exchange Commission.
21.1(1)	Subsidiaries of Discovery.
23.1	Consent of Richard A. Eisner & Company, LLP.
23.2	Consent of Ernst & Young LLP.

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

(2) Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 33-92-886).

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

(4) Incorporated by reference to Discovery's Registration Statement on Form SB-2 (File No. 333-19375).

(5) Incorporated by reference to Discovery's Current Report on form 8-K/A dated January 16, 1998.

(6) Incorporated by reference to Discovery's Annual Report on Form 10-K for the year ending December 31, 1998.

(7) Incorporated by reference to Discovery's Proxy Statement on Schedule 14A filed June 1, 1999.

(8) Incorporated by reference to Discovery's Quarterly Report on Form 10-Q for the quarter ending September 30, 1999.

(9) Incorporated by Reference to Discovery's Current Report on Form 8-K filed March 29, 2000.

(10) Incorporated by reference to Discovery's Annual Report on Form 10-K for the year ending December 31, 1999.

(11) Incorporated by Reference to Discovery's Amended Current Report on Form 8-K/A filed January 9, 2001.

+ Confidential treatment requested as to certain portions of these exhibits. Such portions have been redacted and filed separately with the Commission.

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

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REPORT OF INDEPENDENT AUDITORS

Board of Directors and Stockholders
Discovery Laboratories, Inc.
Doylestown, Pennsylvania

We have audited the accompanying consolidated balance sheet of Discovery Laboratories, Inc. (a development stage enterprise) as of December 31, 2000, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and for the period May 18, 1993 (inception) through December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The consolidated financial statements for the period May 18, 1993 (inception) through December 31, 1999 include total revenues and net loss of $1,673,000 and $32,446,000, respectively. Our opinion on the consolidated statements of operations, stockholders' equity, and cash flows for the period May 18, 1993 (inception) through December 31, 2000, insofar as it relates to amounts for prior periods through December 31, 1999, is based solely on the report of other auditors.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits and the report of other auditors provide a reasonable basis for our opinion.

In our opinion, based on our audit and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc., at December 31, 2000, and the consolidated results of its operations and its cash flows for the year then ended and the period from May 18, 1993 (inception) through December 31, 2000, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 27, 2001

REPORT OF INDEPENDENT AUDITORS

Board of Directors and Stockholders
Discovery Laboratories, Inc.
Doylestown, Pennsylvania

We have audited the accompanying consolidated statement of operations, changes in stockholders' equity and cash flows of Discovery Laboratories, Inc. (a development stage company) for the year ended December 31, 1999. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements enumerated above present fairly, in all material respects, the consolidated results of operations and consolidated cash flows of Discovery Laboratories, Inc. for the year ended December 31, 1999, in conformity with accounting principles generally accepted in the United States of America.

/s/ Richard A. Eisner & Company, LLP

New York, New York
February 25, 2000

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Consolidated Balance Sheet
December 31, 2000

ASSETS	
Current assets:	
Cash and cash equivalents	$ 7,281,000
Available-for-sale marketable securities	11,587,000
Prepaid expenses and other current assets	149,000
Total current assets	19,017,000
Property and equipment, net of depreciation	697,000
Security deposits	3,000
	$ 19,717,000
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities:	
Accounts payable and accrued expenses	$ 2,382,000
Capitalized lease - current	17,000
Total current liabilities	2,399,000
Deferred revenue	851,000
Capitalized lease	31,000
Total liabilities	3,281,000
Stockholders' equity:	
Common stock, $.001 par value; 35,000,000 authorized; 20,871,112 shares issued	21,000
Additional paid-in capital	60,891,000
Unearned portion of compensatory stock options	(347,000)
Deficit accumulated during the development stage	(43,989,000)
Treasury stock (26,743 shares of common stock at cost)	(213,000)
Accumulated other comprehensive income	73,000
	16,436,000
	$ 19,717,000

See notes to financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Consolidated Statements of Operations

	Year Ended December 31,		May 18, 1993 (Inception) Through December 31,
	2000	1999	2000
Revenues:			
Interest, dividends, and realized gains	$ 1,042,000	$ 156,000	$ 2,510,000
Research and development collaborative contracts	741,000	178,000	946,000
	1,783,000	334,000	3,456,000
Expenses:			
Write-off of acquired in-process research and development and supplies	--	--	13,508,000
Research and development	7,356,000	2,869,000	20,225,000
General and administrative	2,768,000	2,296,000	10,381,000
Compensatory stock options	2,515,000	125,000	2,657,000
Interest	5,000	2,000	18,000
Total expenses	12,644,000	5,292,000	46,789,000
	(10,861,000)	(4,958,000)	(43,333,000)
Minority interest in net loss of subsidiary	--	--	26,000
Net loss	$(10,861,000)	$ (4,958,000)	$(43,307,000)
Net loss per common share	$ (0.58)	$ (0.66)	
Weighted average number of common shares outstanding	18,806,000	7,545,000	

See notes to financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Consolidated Statements of Changes in Stockholders' Equity
May 18, 1993 (Inception) Through December 31, 2000

	Common Stock		Treasury Stock		Preferred Stock Series B	
	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of common shares, May 1993	440,720	$1,000				
Issuance of common shares, February 1995	143,016					
Expenses paid on behalf of the Company, 1993						
Payment on stock subscriptions, 1995						
Expenses paid on behalf of the Company, 1995						
Issuance of common shares, March 1996	1,070,175	1,000				
Issuance of private placement units August, October and November 1996	856,138	1,000			2,200,256	$2,000
Issuance of common shares for cash and Compensation, September 1996	82,502					
Exercise of stock options, July and October 1996	19,458					
Private placement expenses, 1997						
Issuance of common shares pursuant to Ansan Merger, November 1997	546,433					
Exercise of stock options, July, August and October 1997	17,513					
Accumulated dividends on preferred stock, 1997						
Issuance of common shares pursuant to ATI Merger, June 1998	1,033,500	1,000				
Fair value of common stock issuable on Exercise of ATI options, 1998						
Series C preferred stock issued pursuant to ATI Merger, June 1998						
Accrued dividends payable on Series C Preferred stock at time of ATI Merger, 1998						
Common stock issued in settlement of Series C preferred stock dividends, 1998	49,846					
Exercise of stock options, July and December 1998	131,676					
Series B preferred stock converted, 1998	685,103	1,000			(253,375)	
Noncash exercise of private placement warrants, 1998	8,372					
Dividends payable on Series C preferred stock, 1998						
Treasury stock acquired, 1998			(31,750)	$(90,000)		
Treasury stock issued in payment for services, 1998			16,150	51,000		
Unrealized gain on marketable securities Available for sale, 1998						
Fair value of options granted, 1998						
Amortization of unearned portion of Compensatory stock options, 1998						
Net loss, Inception through 12/31/98						
Balance - December 31, 1998 (carried forward)	5,084,452	5,000	(15,600)	(39,000)	1,946,881	2,000

	Preferred Stock Series C		Stock Subscriptions Receivable	Additional Paid-in Capital	Unearned Portion of Compensatory Stock Options	Accumulated Other Comprehensive Income (loss)
	Shares	Amount				
Issuance of common shares, May 1993			$(2,000)	$ 1,000		
Issuance of common shares, February 1995			(1,000)	1,000		
Expenses paid on behalf of the Company, 1993			1,000			
Payment on stock subscriptions, 1995			2,000			
Expenses paid on behalf of the Company, 1995				18,000		
Issuance of common shares, March 1996				5,000		
Issuance of private placement units August, October and November 1996				18,933,000		
Issuance of common shares for cash and Compensation, September 1996				42,000		
Exercise of stock options, July and October 1996				7,000		
Private placement expenses, 1997				(11,000)		
Issuance of common shares pursuant to Ansan Merger, November 1997				2,459,000		
Exercise of stock options, July, August						

and October 1997				9,000		
Accumulated dividends on preferred stock, 1997						
Issuance of common shares pursuant to ATI Merger, June 1998				5,037,000		
Fair value of common stock issuable on Exercise of ATI options, 1998				2,966,000		
Series C preferred stock issued pursuant to ATI Merger, June 1998	2,039	$2,039,000				
Accrued dividends payable on Series C Preferred stock at time of ATI Merger, 1998		238,000				
Common stock issued in settlement of Series C preferred stock dividends, 1998		(204,000)		204,000		
Exercise of stock options, July and December 1998				30,000		
Series B preferred stock converted, 1998				(1,000)		
Noncash exercise of private placement warrants, 1998						
Dividends payable on Series C preferred stock, 1998		204,000				
Treasury stock acquired, 1998						
Treasury stock issued in payment for services, 1998						
Unrealized gain on marketable securities Available for sale, 1998						$19,000
Fair value of options granted, 1998				142,000	$(142,000)	
Amortization of unearned portion of Compensatory stock options, 1998					18,000	
Net loss, Inception through 12/31/98						
Balance - December 31, 1998 (carried forward)	2,039	2,277,000	--	29,842,000	(124,000)	19,000

	Deficit Accumulated During the Development Stage	Total
Issuance of common shares, May 1993	$	--
Issuance of common shares, February 1995		--
Expenses paid on behalf of the Company, 1993		1,000
Payment on stock subscriptions, 1995		2,000
Expenses paid on behalf of the Company, 1995		18,000
Issuance of common shares, March 1996		6,000
Issuance of private placement units August, October and November 1996		18,936,000
Issuance of common shares for cash and Compensation, September 1996		42,000
Exercise of stock options, July and October 1996		7,000
Private placement expenses, 1997		(11,000)
Issuance of common shares pursuant to Ansan Merger, November 1997		2,459,000
Exercise of stock options, July, August and October 1997		9,000
Accumulated dividends on preferred stock, 1997	(238,000)	(238,000)
Issuance of common shares pursuant to ATI Merger, June 1998		5,038,000
Fair value of common stock issuable on Exercise of ATI options, 1998		2,966,000
Series C preferred stock issued pursuant to ATI Merger, June 1998		2,039,000
Accrued dividends payable on Series C Preferred stock at time of ATI Merger, 1998		238,000
Common stock issued in settlement of Series C preferred stock dividends, 1998		--
Exercise of stock options, July and December 1998		30,000
Series B preferred stock converted, 1998		--
Noncash exercise of private placement warrants, 1998		--
Dividends payable on Series C preferred stock, 1998	(204,000)	--
Treasury stock acquired, 1998		(90,000)
Treasury stock issued in payment for services, 1998		51,000
Unrealized gain on marketable securities Available for sale, 1998		19,000
Fair value of options granted, 1998		--
Amortization of unearned portion of Compensatory stock options, 1998		18,000
Net loss, Inception through 12/31/98	$(27,488,000)	(27,488,000)
Balance - December 31, 1998 (carried forward)	(27,930,000)	4,052,000

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Consolidated Statements of Changes in Stockholders' Equity
May 18, 1993 (Inception) Through December 31, 2000
(continued)

	Common Stock		Treasury Stock		Preferred Stock Series B	
	Shares	Amount	Shares	Amount	Shares	Amount
(brought forward)						
Balance - December 31, 1998	5,084,452	5,000	(15,600)	(39,000)	1,946,881	2,000
Comprehensive loss:						
Net loss						
Other comprehensive loss - unrealized loss on marketable securities available-for-sale						
Total comprehensive loss						
Common stock and warrants in a private placement offering in March and April 1999	826,447	1,000				
Issuance of private placement units in July and August 1999 (net of offering costs)	2,024,792	2,000				
Exercise of stock options	119,732					
Common stock issued in connection with sublicense agreement	317,164	1,000				
Series B preferred stock converted	1,295,485	1,000			(416,125)	
Treasury stock acquired			(2,000)	(5,000)		
Treasury stock issued in payment for services			15,600	39,000		
Common stock issued in payment for services	21,168					
Amortization of unearned portion of Compensatory stock options						
Compensatory stock options granted						
Dividend payable on Series C preferred stock						
Balance - December 31, 1999	9,689,240	$10,000	(2,000)	$ (5,000)	1,530,756	$ 2,000
Comprehensive loss:						
Net loss						
Other comprehensive income - unrealized gain on marketable securities available-for-sale						
Total comprehensive loss						
Exercise of stock options	532,059		(31,743)	(245,000)		
Common placement warrant conversions	18,232					
Preferred placement warrant conversions	18,511					
Exercise of Class C & D warrant conversions	2,536,911	3,000				
Series B preferred stock conversions	4,765,631	5,000			(1,530,756)	(2,000)
Treasury stock issued in payment for services			7,000	37,000		
Common stock issued in payment for services	9,496					
Compensation charge on vesting of options and warrants						
Compensatory stock options and warrants granted						
Dividends payable on Series C stock						
Series C preferred stock conversions	398,186					
Issuance of private placement units	2,902,846	3,000				
Balance - December 31, 2000	20,871,112	$21,000	(26,743)	$(213,000)	--	$ --

	Preferred Stock Series C		Stock Subscriptions Receivable	Additional Paid-in Capital	Unearned Portion of Compensatory Stock Options	Accumulated Other Comprehensive Income (loss)
	Shares	Amount				
(brought forward)						
Balance - December 31, 1998	2,039	2,277,000	--	29,842,000	(124,000)	19,000
Comprehensive loss:						
Net loss						
Other comprehensive loss - unrealized loss on marketable securities available-for-sale						(19,000)

Total comprehensive loss						
Common stock and warrants in a private placement offering in March and April 1999				999,000		
Issuance of private placement units in July and August 1999 (net of offering costs)				2,231,000		
Exercise of stock options				17,000		
Common stock issued in connection with sublicense agreement				563,000		
Series B preferred stock converted				(1,000)		
Treasury stock acquired						
Treasury stock issued in payment for services				14,000		
Common stock issued in payment for services				47,000		
Amortization of unearned portion of Compensatory stock options					124,000	
Compensatory stock options granted				37,000	(37,000)	
Dividend payable on Series C preferred stock		204,000				
Balance - December 31, 1999	2,039	$ 2,481,000	$ --	$33,749,000	$ (37,000)	$ --
Comprehensive loss:						
Net loss						
Other comprehensive income - unrealized gain on marketable securities available-for-sale						73,000
Total comprehensive loss						
Exercise of stock options				524,000		
Common placement warrant conversions						
Preferred placement warrant conversions						
Exercise of Class C & D warrant conversions				3,792,000		
Series B preferred stock conversions				(3,000)		
Treasury stock issued in payment for services						
Common stock issued in payment for services				47,000		
Compensation charge on vesting of options and warrants				2,330,000		
Compensatory stock options and warrants granted				495,000	(310,000)	
Dividends payable on Series C stock		36,000				
Series C preferred stock conversions	(2,039)	(2,517,000)		2,517,000		
Issuance of private placement units				17,440,000		
Balance - December 31, 2000	--	$ --	$ --	$60,891,000	$(347,000)	$73,000

	Deficit Accumulated During the Development Stage	Total
(brought forward)		
Balance - December 31, 1998	(27,930,000)	4,052,000
Comprehensive loss:		
Net loss	(4,958,000)	(4,958,000)
Other comprehensive loss - unrealized loss on marketable securities available-for-sale		(19,000)
Total comprehensive loss		(4,977,000)
Common stock and warrants in a private placement offering in March and April 1999		1,000,000
Issuance of private placement units in July and August 1999 (net of offering costs)		2,233,000
Exercise of stock options		17,000
Common stock issued in connection with sublicense agreement		564,000
Series B preferred stock converted		--
Treasury stock acquired		(5,000)
Treasury stock issued in payment for services		53,000
Common stock issued in payment for services		47,000
Amortization of unearned portion of Compensatory stock options		124,000
Compensatory stock options granted		--
Dividend payable on Series C preferred stock	(204,000)	--
Balance - December 31, 1999	$(33,092,000)	$ 3,108,000
Comprehensive loss:		
Net loss	(10,861,000)	(10,861,000)
Other comprehensive income - unrealized gain on marketable securities		

available-for-sale		73,000
Total comprehensive loss		(10,788,000)
Exercise of stock options		279,000
Common placement warrant conversions		--
Preferred placement warrant conversions		--
Exercise of Class C & D warrant conversions		3,795,000
Series B preferred stock conversions		--
Treasury stock issued in payment for services		37,000
Common stock issued in payment for services		47,000
Compensation charge on vesting of options and warrants		2,330,000
Compensatory stock options and warrants granted		185,000
Dividends payable on Series C stock	(36,000)	--
Series C preferred stock conversions		--
Issuance of private placement units		17,443,000
Balance - December 31, 2000	$(43,989,000)	$ 16,436,000

See notes to financial statements

DISCOVERY LABORATORIES, INC. AND SUBSIDIARY
(a development stage company)

Consolidated Statements of Cash Flows

	Year Ended December 31,		May 18, 1993 (Inception) Through, December 31,
	2000	1999	2000
Cash flows from operating activities:			
Net loss	$(10,861,000)	$ (4,958,000)	$(43,307,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Write-off of acquired in-process research and development and supplies	--	--	13,508,000
Write-off of licenses	--	--	683,000
Depreciation and amortization	123,000	87,000	339,000
Compensatory stock options	2,515,000	124,000	2,657,000
Expenses paid using treasury stock and common stock	84,000	27,000	162,000
Loss on sale of property	4,000	--	4,000
Changes in:			
Prepaid expenses, inventory and other current assets	492,000	137,000	457,000
Accounts payable and accrued expenses	1,957,000	(590,000)	2,249,000
Other assets	15,000	--	(3,000)
Proceeds from R&D collaborative contracts	605,000	1,036,000	1,641,000
Amortization of deferred revenue	(790,000)	--	(790,000)
Expenses paid on behalf of company	--	--	18,000
Employee stock compensation	--	--	42,000
Reduction of research and development supplies	--	--	(161,000)
Net cash used in operating activities	(5,856,000)	(4,137,000)	(22,501,000)
Cash flows from investing activities:			
Purchase of property and equipment	(948,000)	(114,000)	(1,494,000)
Proceeds from sale of property and equipment	550,000	--	575,000
Acquisition of licenses	--	--	(711,000)
Purchase of marketable securities	(11,514,000)	(1,000,000)	(33,259,000)
Proceeds from sale or maturity of marketable securities	--	3,525,000	22,150,000
Net cash payments on merger	--	--	(1,670,000)
Net cash (used in) provided by investing activities	(11,912,000)	2,411,000	(14,409,000)
Cash flows from financing activities:			
Proceeds from issuance of securities, net of expenses	21,517,000	3,814,000	44,311,000
Purchase of treasury stock	--	(5,000)	(95,000)
Principal payments under capital lease obligation	(15,000)	(10,000)	(25,000)
Net cash provided by financing activities	21,502,000	3,799,000	44,191,000
Net increase in cash and cash equivalents	3,734,000	2,073,000	7,281,000
Cash and cash equivalents - beginning of period	3,547,000	1,474,000	--
Cash and cash equivalents - end of period	$ 7,281,000	$ 3,547,000	$ 7,281,000
Supplementary disclosure of cash flows information:			
Interest paid	$ 5,000	$ 2,000	$ 18,000
Noncash transactions:			
Accrued dividends on Series C preferred stock	$ 36,000	$ 204,000	$ 682,000
Series C preferred stock dividends paid using common stock	$ --	$ --	$ 204,000
Preferred stock issued for inventory	$ --	$ --	$ 575,000
Equipment acquired through capitalized lease	$ --	$ 73,000	$ 73,000
Unrealized gain (loss) on marketable securities	$ 73,000	$ (19,000)	$ 73,000

See notes to financial statements

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION

Discovery Laboratories, Inc. (the "Company"), formerly known as Ansan Pharmaceuticals, Inc. ("Ansan"), was incorporated in Delaware on November 6, 1992 and was formed to license and develop pharmaceutical products to treat a variety of human diseases. In November 1997, Ansan merged (the "Ansan Merger") with Discovery Laboratories, Inc., a former Delaware corporation ("Old Discovery"), and was the surviving corporate entity. Subsequent to the Ansan Merger, Ansan changed its name to Discovery Laboratories, Inc. The Ansan Merger was accounted for as a reverse acquisition with Old Discovery as the acquirer for financial reporting purposes since Old Discovery's stockholders owned approximately 92% of the merged entity on a diluted basis. The consolidated financial statements include the accounts of Ansan from November 25, 1997 (the date of acquisition).

Acute Therapeutics, Inc. ("Old ATI"), was formed in October 1996 upon the Company's investment of $7,500,000 in exchange for 600,000 shares of Old ATI's Series A preferred stock, then representing 75% of the voting securities of Old ATI. In June 1998, ATI Acquisition Corp., a wholly owned subsidiary of the Company, merged with and into Old ATI with Old ATI being the surviving entity (the "Old ATI Merger"). Pursuant to the Old ATI Merger, each outstanding share of Old ATI's common stock was exchanged for 3.90 shares of the Common stock of the Company (the "Old ATI Exchange Ratio"), each share of Old ATI's Series B preferred stock was converted into one share of the Company's Series C preferred stock and all outstanding options to purchase Old ATI common stock were assumed by the Company and are exercisable for shares of the Common stock of the Company on the basis of the Old ATI Exchange Ratio.

In October 1999, Old ATI was merged with and into the Company. Also in October 1999, the Company created a new wholly owned subsidiary, which is currently inactive, called Acute Therapeutics, Inc. ("New ATI").

The value of the common stock of the Company issued to Old ATI's common stockholders plus the assumption of the outstanding Old ATI options and merger related costs has been attributed to in-process research and development upon management's evaluation and has been recorded as an expense upon acquisition.

The cost of the Old ATI Merger is as follows:

Common stock issued to Old ATI stockholders (1,033,500 shares at fair value)*	$ 5,038,000
Fair value of common stock issuable on exercise of options to purchase Old ATI common stock net of exercise proceeds	2,966,000
Transaction costs	216,000
	$ 8,220,000

* No discount from market value was recognized in determining the fair value of the common stock issued. The lack of a discount had no effect on financial position.

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Old ATI (through the date of its merger into the Company) and New ATI (from October 1999). All intercompany balances and transactions have been eliminated.

As reflected in the accompanying consolidated financial statements, since inception, the Company has incurred substantial losses from operations. As a result of the start-up nature of its business, the Company can expect to continue incurring substantial operating losses for at least the next several years and significant additional financing will be required. Continuation of the Company is dependent on its ability to obtain additional financing and, ultimately, on its ability to achieve profitable operations. There is no assurance, however, that such financing will be available or that the Company's efforts will ultimately be successful.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and cash equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents.

Available-for-sale marketable securities

The investments are classified as available for sale, and are comprised of commercial paper and shares in mutual funds, which invest in income producing securities. Investments are carried at fair market value. Realized gains are computed using the average cost of securities sold. Any appreciation/depreciation on these investments is recorded as other comprehensive income in the statements of changes in stockholders' equity until realized.

Property and equipment

Furniture and equipment is recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets (five to seven years). Leasehold improvements are amortized over the lower of the (a) term of the lease or (b) useful life of the improvements.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Long-lived assets

In accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," the Company records impairment losses on long-lived assets used in operations, including intangible assets, when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. No such losses have been recorded.

Research and development

Research and development costs are charged to operations as incurred.

Revenue recognition - research and development collaborative agreements

The Company received nonrefundable fees from companies under license, sublicense and research funding agreements (See Note 6). The Company initially records such funds as deferred revenue and recognizes research and development collaborative contract revenue when the amounts are earned, which occurs over a number of years as the Company performs research and development activities.

Additionally, the Company has been awarded grants from certain third party organizations to help fund research for the drugs that the Company is attempting to bring to full commercial use. Once research and development expenditures qualifying under the grant are incurred, grant reports are periodically completed and submitted to the granting agency for review. If approved, the granting agency will then remit payment to the Company. Such amounts are recorded as revenue upon receipt.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Stock-based compensation

The Company adopted Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"). The provisions of SFAS No. 123 allow companies to either expense the estimated fair value of employee stock options or to continue to follow the intrinsic value method set forth in Accounting Principles Board Opinion 25, "Accounting for Stock Issued to Employees" ("APB 25") but disclose the pro forma effects on net income (loss) had the fair value of the options been expensed. The Company has elected to continue to apply APB 25 in accounting for its employee stock option incentive plans and to provide the required SFAS No. 123 disclosures - see Note 8.

Net loss per common share

Net loss per common share is computed pursuant to the provisions of Statement of Financial Accounting Standards No. 128, "Earnings per Share", and is based on the weighted average number of common shares outstanding for the periods. Potential common shares not included in the calculation of net loss per share for the years ended December 31, 2000 and 1999, as the effect would be anti-dilutive, are as follows:

	Number of Potential Common Shares	
	2000	1999
Series B convertible preferred stock	--	4,766,000
Series C convertible preferred stock	--	892,000
Placement agent's option to acquire 0.49 unit	405,000	405,000
Stock options	1,653,000	595,000
Class C warrants	57,000	569,000
Class D warrants	--	2,025,000
Placement agent's common warrants (@ $0.64)	56,000	56,000
Series B preferred warrants (@ $3.53)	655,000	--
Other warrants	65,000	--

Reclassifications

Certain prior year amounts have been reclassified to conform to the 2000 presentation.

NOTE 3 - INVESTMENTS

The following is a summary of available-for-sale marketable securities at December 31, 2000:

Cost	$ 11,514,000
Gross Unrealized Gain	240,000
Gross Unrealized Loss	(167,000)
Estimated Fair Value	$ 11,587,000

NOTE 4 - PROPERTY AND EQUIPMENT

At December 31, 2000, property and equipment was comprised of the following:

Leasehold improvements	$ 140,000
Furniture	141,000
Equipment	732,000
	1,013,000
Less accumulated depreciation	316,000
	$ 697,000

The equipment balance includes $73,000 of property under a capital lease. The related accumulated depreciation was $13,000 at December 31, 2000.

NOTE 5 - INCOME TAXES

Since its inception, the Company has never recorded a provision or benefit for Federal and state income taxes.

The reconciliation of the income tax benefit computed at the Federal statutory rates to the Company's recorded tax benefit for the years ended December 31, 2000 and 1999 is as follows:

	2000	1999
Income tax benefit, statutory rates	$ 3,652,000	$ 1,685,000
State taxes on income, net of Federal benefit	836,000	43,000
Research and development tax credit	85,000	136,000
Other	(95,000)	125,000
Income tax benefit	$ 4,478,000	$ 1,989,000
Valuation allowance	(4,478,000)	(1,989,000)
Income tax benefit	--	--

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities are as follows at December 31, 2000:

Long-term deferred tax assets:	
Net operating loss carryforwards (Federal and state)	$14,771,000
Research and development tax credits	660,000
Capitalized research and development	363,000
Total gross long-term deferred tax assets	15,794,000
Long-term deferred tax liabilities:	
Property and equipment	(49,000)
Net deferred tax assets	15,745,000
Less: valuation allowance	(15,745,000)
	$ --

The difference between the deficit accumulated during the development stage for financial reporting purposes and the net operating loss carryforwards for tax purposes is primarily due to the write-off of the acquired in-process research and development and supplies, which were not deducted for tax purposes. The Company was in a net deferred tax asset position at December 31, 2000 (before the consideration of a valuation allowance). Due to the

NOTE 5 - INCOME TAXES (CONTINUED)

fact that the Company is in the development stage, management believes it is prudent at this time to fully reserve the net deferred tax asset.

At December 31, 2000, the Company had available carryforward net operating losses (for Federal tax purposes) of approximately $36,400,000 and a research and development tax credit carryforward of $660,000. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 and continuing through 2020. Additionally, at December 31, 2000, the Company had available carryforward losses of approximately $23,964,000 for state tax purposes. As a result of the Ansan Merger, the utilization of $9,700,000 of the Federal net operating loss carryforwards is subject to annual limitations in accordance with Section 382 of the Internal Revenue Code. Certain state carryforward net operating losses are also subject to annual limitations.

NOTE 6 - LICENSE, SUBLICENSE AND RESEARCH FUNDING AGREEMENTS

Concurrent with the Company's original investment in Old ATI, Ortho Pharmaceuticals, Inc., a wholly owned subsidiary of Johnson & Johnson, Inc. ("J&J "), and Old ATI entered into an agreement (the "J&J License Agreement") granting an exclusive license of the Surfaxin(R) technology to Old ATI in exchange for certain license fees ($200,000 of which was paid in November 1996), milestone payments aggregating $2,750,000, royalties and 40,000 shares of Old ATI common stock. J&J contributed its Surfaxin(R) raw material inventory and manufacturing equipment to Old ATI in exchange for 2,039 (originally 2,200) shares of nonvoting Series B preferred stock of Old ATI having a $2,039,000 (originally $2,200,000) liquidation preference and a $100 per share cumulative annual dividend. The inventory and equipment were valued at $2,039,000 (the value of the preferred shares issued to J&J). At December 31, 2000, based primarily on the Company's contemplated use of such inventory and equipment in connection with its proposed clinical trials for acute respiratory distress syndrome and idiopathic respiratory distress syndrome, the full amount of the inventory and equipment has been charged to research and development expense. The Scripps Research Institute ("Scripps") received 40,000 shares of common stock of Old ATI in exchange for its consent to the J&J License Agreement.

In October 1999, the Company granted an exclusive license to Laboratorios Del Dr. Esteve S.A. to commercialize and sell Surfaxin(R) within Central and South America, Mexico and certain Southern European countries (with an option to include Italy). The license expires, on a country by country basis, on the later of the expiration of the underlying patents or the fifteenth anniversary from the first commercial sale of Surfaxin(R) within each country. Certain additional terms of the agreement are:

- the Company was paid a nonrefundable license fee of $375,000;
- the Company will be the exclusive supplier (except in certain events) of Surfaxin(R);
- Laboratorios Del Dr. Esteve S.A. agreed to reimburse certain research and development expenditures borne by the Company in conducting certain clinical trials in the above countries. However, costs as defined in the license agreement, incurred in connection with such clinical trials in excess of an agreed upon amount, will not be reimbursed;
- Laboratorios Del Dr. Esteve S.A. paid $375,000 in advance for Surfaxin(R)supplied for clinical trials described above;
- an affiliate of Laboratorios Del Dr. Esteve S.A. invested $850,000 in the Company in exchange for common stock of the Company issued at a 50% premium over the ten day average closing price preceding the closing of the investment. The Company has accounted for the premium as additional license fees amounting to $286,000; and
- an option to an exclusive license for Italy for additional specified payments.

NOTE 6 - LICENSE, SUBLICENSE AND RESEARCH FUNDING AGREEMENTS (CONTINUED)

The Company has accounted for the license fees (including the premium paid for common stock), the reimbursement of research and development expenditures and advance payment for Surfaxin(R) to be used in clinical trials as deferred revenue. Such deferred revenue will be recognized as it is earned.

In 1996, Old ATI entered into a research funding and option agreement with Scripps to provide certain funding of research activities. The agreement was for an initial term of two years with renewal provisions for additional one-year periods. The Company and Scripps are currently finalizing an agreement to extend the term for one year. Pursuant to this agreement, the Company will pay $489,000 per year to fund Scripps' research efforts. The agreement provides that Scripps shall grant an option to the Company to acquire an exclusive license for the application of technology developed from the research program. Pursuant to the agreement, payments to Scripps were $468,000 and $115,000 in 2000 and 1999, respectively.

In 1996, the Company entered into a license agreement with the Charlotte-Mecklenburg Hospital Authority (Charlotte-Mecklenberg) for the use of the active compound in SuperVent(TM), a therapy which the Company is clinically testing. The Company paid a license issue fee of $86,000 and has agreed to pay amounts based on the achievement of certain milestones, royalties on future sales and future patent-related costs. If the Company meets all milestones as defined the agreement, payments paid to Charlotte-Mecklenburg will aggregate $850,000. The license expires upon expiration of the underlying patents.

NOTE 7 - STOCKHOLDERS' EQUITY

2000 private placement

In March 2000, the Company received approximately $17,500,000 in net proceeds from the sale of 37.74 units in a private placement offering. Each unit consisted of 76,923 shares of common stock of the Company and Class E warrants to purchase additional 15,385 shares of common stock of the Company at $7.38 per share. The Class E warrants of the Company are exercisable through March 2005. In connection with this private placement, the placement agent, Paramount Capital, Inc. ("Paramount"), received fees of approximately $1,321,000 and the Company agreed to issue to Paramount warrants to purchase 348,341 shares of common stock of the Company at $8.113 per share.

1999 private placements

During March and April 1999 the Company raised $1.0 million in a private placement offering of 826,447 shares of common stock and 569,026 Class C warrants to purchase common stock of the Company at an exercise price of $2.15 per share (after adjustment to the issue price in accordance with the terms of the offering). The Class C warrants are exercisable through April 2006. As of December 31, 2000, approximately 512,000 Class C warrants have been exercised.

In July 1999, the Company raised approximately $2,231,000 (net of offering costs of approximately $217,000) in a private placement offering of units. Each unit was sold for $500,000 and consisted of 413,223 shares of common stock of the Company and 413,223 Class D warrants to purchase shares of common stock of the Company at an exercise price of $1.33 per share. An aggregate of 2,024,792 shares of common stock of the Company and 2,024,792 Class D warrants were issued. The Class D warrants were exercisable through July 2004. As of December 31, 2000, all of the Class D warrants have been exercised. The placement agent, Paramount, received fees of 7% of the gross proceeds, reimbursement of certain expenses and an option to purchase 0.49 units at a per unit exercise price of $550,000.

NOTE 7 - STOCKHOLDERS' EQUITY (CONTINUED)

1996 private placement

In 1996, in a private placement offering, Old Discovery sold approximately 44 units (each unit consisting of securities converted in the Ansan Merger into 50,000 shares of Series B convertible preferred stock of the Company and 19,458 shares of common stock of the Company). Preferred stockholders had voting rights based upon the number of shares of common stock issuable upon conversion of the preferred shares. Pursuant to the terms of the offering, on December 1, 1998, the conversion rate was adjusted whereby each share of preferred stock is convertible at the option of the holders into 3.11 shares of common stock of the Company. Net proceeds from the private placement approximated $19,000,000. The Company was restricted from declaring dividends or distributions on its common stock without the approval of the holders of at least 66.67% of the outstanding Series B shares as long as there was in excess of 1,100,000 Series B shares outstanding.

The placement agent for the offering received approximately $2,860,000 in cash plus warrants which, pursuant to the merger gave the holders thereof the right to acquire 220,026 shares of Series B preferred stock (which as a result of the conversion of the Series B preferred stock were convertible into 685,000 shares of common stock) at a price of $11 per share, through November 8, 2006, and to acquire 85,625 shares of common stock at a price of $0.64 per share through November 8, 2006. The warrants contain certain anti-dilution provisions and may be exercised on a "net exercise" basis pursuant to a provision that does not require the payment of any cash to the Company.

In February 2000, the Company gave notice to its Series B convertible preferred stockholders of its intention to convert all outstanding shares of Series B preferred stock into common stock of the Company. Pursuant to the notice, all of the Series B shares were converted into 4,766,000 shares of common stock of the Company effective March 14, 2000.

Unit offering

In August 1995, Ansan issued an aggregate of 498,333 units (including 65,000 units pursuant to the underwriter's overallotment option) at $15.00 per unit in an initial public offering (the "Offering"). Each unit consisted of one share of common stock of the Company, one redeemable Class A warrant, and one Class B warrant. Each Class A warrant entitles the holder to purchase one share of common stock of the Company and one Class B warrant at an exercise price of $19.50 per share. Each Class B warrant entitled the holder to purchase one share of common stock of the Company an exercise price of $26.25 per share. All Class A and Class B Warrants remaining unexercised at August 2000 expired by their terms.

In connection with the Offering, the holders of the Ansan's common stock and options to purchase common stock placed, on a pro rata basis, 121,246 common shares (including 115,491 shares held by the Company pending cancellation pursuant to the Ansan Merger (Note 1)) and options to purchase 12,086 shares of common stock into escrow (the "Escrow Shares" and "Escrow Options", respectively). Certain contractual conditions necessary for the release of these escrow shares and escrow options were not met by March 31, 2000, and the Escrow Shares and Escrow Options were cancelled pursuant to their terms.

NOTE 7 - STOCKHOLDERS' EQUITY (CONTINUED)

Common shares reserved for issuance

As of December 31, 2000, the Company has reserved shares of common stock for issuance upon exercise of options and warrants as follows:

(i)	Stock option plan	3,162,000
(ii)	Placement agent:	
	Common stock options	56,000
	Preferred B warrants	655,000
	Unit options	405,000
	Common stock	348,000
(iii)	Class C warrants	57,000
(iv)	Class E warrants	581,000
(v)	Other warrants	65,000

Treasury stock/common stock issued for services

During 1998, the Company's Board of Directors approved a stock repurchase program wherein the Company could buy its own shares from the open market and use such shares to settle indebtedness. Such shares are accounted for as treasury stock.

During 2000, the Company acquired 31,743 shares of common stock of the Company in exchange for option conversions, having a value of $245,000 and issued 7,000 shares of treasury stock in satisfaction of services rendered. In addition, during 2000, the Company issued 9,496 shares of common stock of the Company in lieu of cash payments for services and rent.

During 1999, the Company acquired 2,000 shares of common stock of the Company for approximately $5,000 and issued 15,600 shares of treasury stock in settlement of $39,000 of indebtedness. The fair market value of the 15,600 shares of treasury stock on the date it was issued in 1999 was approximately $53,000 and the difference was charged to expense and credited to paid-in-capital.

Series C preferred stock

The Company's Series C redeemable convertible preferred stock was convertible at the option of the holder into common stock at a conversion price equal to the market price of the common stock, as defined. Such shares were redeemable at liquidation value upon the occurrence of certain events. The liquidation value was payable at the option of the Company in either cash or shares of common stock. Series C stockholders were entitled to dividends of 10% per annum to be paid only upon liquidation or redemption.

On March 3, 2000, the sole shareholder, J&J, elected to convert their Series C preferred stock shares into 398,186 shares of common stock of the Company.

NOTE 8 - STOCK OPTIONS

Ansan's 1993 Stock Option Plan as amended and restated (the "1993 Plan"), provided that incentive stock options may be granted to employees, and nonstatutory stock options may be granted to employees, directors, consultants and affiliates. In May 1995, Ansan adopted the 1995 Stock Option Plan (the "1995 Plan"). No further options will be granted under the 1993 Plan or 1995 Plan.

Options granted under the 1993 Plan and 1995 Plan expire no later than ten years from the date of grant, except when the grantee is a 10% stockholder of the Company or an affiliate company, in which case the maximum term is five years from the date of grant. The exercise price shall be at least 100%, 85% and 110% of the fair value of the stock subject to the option on the grant date, as determined by the Board of Directors, for incentive stock

NOTE 8 - STOCK OPTIONS (CONTINUED)

options, nonstatutory stock options and options granted to 10% stockholders of the Company or an affiliate company, respectively. Options granted under the 1993 Plan are exercisable immediately upon grant, however, the shares issuable upon exercise of the options are subject to repurchase by the Company at the exercise price paid per share. Such repurchase rights lapse as the shares vest over a period of five years from the date of grant.

On consummation of the Ansan Merger, the Company assumed Old Discovery's outstanding options which were exchanged at the Ansan Exchange Ratio for options to purchase the Common stock of the Company - see Note 1.

In March 1998, the Company adopted its 1998 Stock Incentive Plan which includes three equity programs (the "1998 Plan"). Under the Discretionary Option Grant Program, options to acquire shares of the Common stock of the Company may be granted to eligible persons who are employees, nonemployee directors, consultants and other independent advisors. Pursuant to the Stock Issuance Program, such eligible persons may be issued shares of the Common stock of the Company directly, and under the Automatic Option Grant Program, eligible directors will automatically receive option grants at periodic intervals at an exercise price equal to 60% of fair market value per share on the date of the grant. On June 16, 2000, the 1998 Stock Incentive Plan was amended to increase the maximum number of shares of common stock reserved for issuance over the term of the plan from 2,200,959 to 3,000,000.

The pro forma effects of applying SFAS No. 123 and the stock options activity shown below are those of the 1998 Plan, Old Discovery's 1996 Stock Option/Stock Issuance Plan through the date of the Ansan Merger and the 1993 Plan and 1995 Plan after the Ansan Merger as the Ansan Merger was accounted for as a reverse acquisition.

The Company applies APB 25 in accounting for stock options and, accordingly, recognizes compensation expense for the difference between the fair value of the underlying common stock and the exercise price of the option at the date of grant. The effect of applying SFAS No. 123 on pro forma net loss is not necessarily representative of the effects on reported net income or loss for future years due to, among other things, (i) the vesting period of the stock options and (ii) the fair value of additional stock options in future years. Had compensation cost for the Company's stock option plans been determined based upon the fair value of the options at the grant date of awards under the plans consistent with the methodology prescribed under SFAS No. 123, the Company's net loss for each of the years ended December 31, 2000 and 1999 would have been approximately $14,092,000 or $0.75 per share and $5,622,000 or $0.74 per share, respectively. The weighted average fair value of the options granted are estimated at $3.40 and $2.46 per share, respectively, for the years ended December 31, 2000 and 1999, on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions: dividend yield 0%, volatility of 130% and 91%, respectively, risk-free interest rate of 6% and 4.86%, respectively and expected life of three and a half years.

Additional information with respect to the stock option activity is summarized as follows:

	Year Ended December 31,							
	2000				1999			
	Price Per Share	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Price Per Share	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Options outstanding at Beginning of year	$0.0026 - $4.87	2,475,752	$2.27	7.93 years	$0.0026 - $4.87	1,886,064	$2.23	8.73 years
Options granted	1.66 - 7.00	1,147,000	4.36		0.81 - 4.44	1,108,893	2.18	
Options exercised	0.08 - 4.44	(528,158)	0.98		0.0026 - 0.51	(119,732)	0.11	
Options forfeited	0.32	(39,000)	0.32		0.08 - 4.44	(297,888)	3.56	
Options expired	--	--	--		4.19	(101,585)	4.19	
Options outstanding at end of year	$0.0026 - $7.00	3,055,594	$3.39	8.33 years	$0.0026 - $4.87	2,475,752	$2.42	8.50 years
Options exercisable at end of year	$0.0026 - $7.00	3,055,594	$3.39	8.33 years	$0.0026 - $4.87	2,436,752	2.27	7.93 years

NOTE 8 - STOCK OPTIONS (CONTINUED)

Currently, all outstanding options are immediately exercisable. Any unvested options are subject to repurchase by the Company at the exercise price paid per share.

In accordance with the employment agreements entered into with the Company in connection with the Old ATI Merger, Old ATI management was granted, in the aggregate, options to purchase (i) 338,500 shares of the Common stock of the Company, subject to vesting and (ii) 335,000 shares of the Common stock of the Company subject to the achievement of certain corporate milestones. In April 2000, the milestones related to 154,510 options had been achieved and the related options vested.

In September 1999, management was granted, in the aggregate, options to purchase 500,000 shares of the Common stock of the Company subject to the achievement of certain corporate milestones. In January 2000, 50% of the milestones related to 250,000 options had been achieved and the related options vested. In September 2000, the Board of Directors of the Company accelerated the remaining 50% of the 250,000 milestone options.

In connection with milestones being achieved, the Company incurred non-cash compensation charges amounting to $2,515,000 and $125,000, in 2000 and 1999, respectively, representing the excess of the fair value over the exercise price of the options granted.

Included in the options outstanding at December 31, 2000, are options to purchase 141,600 shares of the Common stock of the Company (at an exercise price of $4.44) granted during 1998 which vest upon the Company achieving specified milestones. On vesting, the Company will incur a charge amounting to the excess, if any, of the fair value over the exercise price. In addition, pursuant to a management agreement entered into between the Company and Old ATI at the time the merger agreement relating to the Old ATI Merger was executed, the members of Old ATI management were granted options to purchase 126,500 shares of the Common stock of the Company.

NOTE 9 - COMMITMENTS

At December 31, 2000, the Company had employment agreements with seven officers providing for an aggregate annual salary of $1,324,000. The agreements expire on various dates through December 2005 and provide for the issuance of annual and milestone bonuses. In addition, the Company had employment agreements with three additional employees providing for an aggregate annual salary of $204,000. The agreements expire on various dates through January 2002 and provide for the issuance of annual bonuses and the granting of options based on management recommendation. In March 2001, the Board of Directors of the Company agreed to renew employment contracts with certain officers, which were due to expire in June 2001, under essentially the same terms.

In July 1998, the Company entered into a seven-year lease agreement to lease office and laboratory space in premises owned by a Company officer/stockholder. In September 2000, the lease agreement was amended to include additional space. Future minimum annual rents for this lease is as follows:

2001	$ 198,000
2002	205,000
2003	212,000
2004	219,000
2005	111,000
	$ 945,000

NOTE 9 - COMMITMENTS (continued)

In June 2000, the Company entered into a lease agreement to lease office space in premises from a law firm that has previously provided legal services to the Company. Future minimum annual rents for this lease is $7,000 through June 2001. Total net rent expense for the years ended December 31, 2000 and 1999 was approximately $181,000 and $144,000, respectively.

In September 1999, the Company entered into a four-year lease agreement to lease laboratory equipment, which is being accounted for as a capital lease. Future minimum lease payments for this lease are as follows:

2001	$ 20,000
2002	20,000
2003	13,000
	53,000
Less interest included	5,000
	$ 48,000

NOTE 10 - RELATED PARTY TRANSACTIONS

The Company currently leases office and laboratory space in premises owned by a Company officer/stockholder. Lease payments made to this party for the years ended December 31, 2000 and 1999 were approximately $170,000 and $142,100, respectively.

The Company, from time to time, engages the spouse of an officer to perform miscellaneous repairs and maintenance and improvements of office and laboratory space. Payments made to this party for the years ended December 31, 2000 and 1999 were approximately $77,900 and $29,300, respectively.

In May 2000, the Company entered into an agreement with Clinical Data Management, Inc. (CDM), to perform duties associated with processing data for clinical trials. CDM is wholly owned by the spouse of the Company's President and Chief Executive Officer. Payments made to CDM and its owner, including payments made prior to the agreement, for the years ended December 31, 2000 and 1999 were approximately $110,700 and $24,500, respectively.

Exhibit 3.2

CERTIFICATE OF AMENDMENT
TO THE RESTATED CERTIFICATE OF INCORPORATION
OF DISCOVERY LABORATORIES, INC.

Pursuant to Section 242 of the
General Corporation Law of the State of Delaware

Discovery Laboratories, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), DOES HEREBY CERTIFY, that the Restated Certificate of Incorporation of the Corporation filed with the Secretary of State of the State of Delaware is hereby amended as follows:

1. The name of the Corporation is Discovery Laboratories, Inc.

2. The original Certificate of Incorporation of the Corporation was filed under the name Ansan, Inc. with the Secretary of State of the State of Delaware on November 6, 1992.

3. Paragraph A. of Article FOURTH of the Restated Certificate of Incorporation is hereby amended in its entirety to read as follows:

A. Authorization.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is 40,000,000 consisting of 35,000,000 shares of common stock, par value $.001 per share (the "Common Stock"), and 5,000,000 shares of preferred stock, par value $.001 per share (the "Preferred Stock").

The Board of Directors may divide the Preferred Stock into any number of series, fix the designation and number of shares of each such series, and determine or change the designation, relative rights, preferences, and limitations of any series of Preferred Stock. The Board of Directors (within the limits and restrictions of any resolutions adopted by it originally fixing the number of any shares of any series of Preferred Stock) may increase or decrease the number of shares initially fixed for any series, but no such decrease shall reduce the number below the number of shares then outstanding and shares duly reserved for issuance.

4. The foregoing amendment was duly adopted in accordance with Section 228 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, Discovery Laboratories, Inc. has caused this Certificate of Amendment to be signed this 15th day of July, 1999.

DISCOVERY LABORATORIES, INC.

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

Name: Robert J. Capetola, Ph.D.
Title: Chief Executive Officer

Exhibit 10.12

ADDENDUM 1 TO LEASE
September 15, 2000

This Addendum is attached to and made part of the lease dated July 1, 1998, by and between SLT1 L.L.C. (landlord) and ACUTE THERAPEUTICS, Inc. (tenant)(the "Lease").

I. LEASED PREMISES

Begining on September 16, 2000 , the description of the leased premises is hereby amended to include all 13,667 square feet of the entire building owned by SLT1 L.L.C.

II. TERM

The term for the Lease (including the additional premises provided for in Section I) shall commence on the 16th day of September 16, 2000 and end at the close of business on the 31st day of August 2005.

III. RENT

Base Rent: Fourteen dollars and twenty five cents ($14.25) per square foot per year ratably due on the first day of each calendar month begining on September 16, 2000. Additional rent and increasing minimum rent per square foot per year shall be as set forth in the lease.

Except as amended herein, the remaining terms and conditions of the Lease shall remain in full force and effect.

Tenant: Discovery Laboratories, Inc. (formerly Acute Therapeutics, Inc.)

By: /s/ Robert J. Capetola

Robert Capetola, President/CEO

Landlord: SLT1 L.L.C.

By: Huei Tsai

Huei Tsai

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") shall be effective as of January 1, 2001, by and between DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Company"), and ROBERT J. CAPETOLA, PH.D. ("Executive").

WHEREAS, the Company and Executive desire that Executive be employed by the Company and that the terms and conditions of such employment be hereby defined.

NOW, THEREFORE, in consideration of the employment of Executive by the Company, the Company and Executive hereby agree as follows:

1. Terms of the Agreement. The Company shall employ Executive and Executive shall accept employment for a period of four (4) years commencing on January 1, 2001 (the "Commencement Date") and continuing until December 31, 2005, subject, however, to prior termination as hereinafter provided in Section 5 (such term is hereinafter referred to as the "Employment Period").

2. Executive's Duties and Obligations.

a. Duties. Executive shall serve as the Company's President and Chief Executive Officer. Executive shall be responsible for overall management of the Company and all duties customarily associated with his title including, without limitation, activities regarding (i) day-to-day operational affairs; (ii) the development and commercialization of the Company's products; (iii) proposed strategic alliances, joint ventures and other potential collaborations; and (iv) all other appropriate functions for the Company. All of the operating managers of the Company shall report to Executive. Executive shall at all times report to, and shall be subject to the policies established by, the Board of Directors of the Company (the "Board") and any executive committee thereof (the "Executive Committee"). The Company agrees that, at all times during the Employment Period, it will nominate Executive for election to the Board. Executive hereby agrees to immediately resign from any Board position held by him at the expiration or termination of the Employment Period.

b. Location of Employment. Executive's principal place of business shall be at the Company's headquarters to be located within thirty (30) miles of Doylestown, Pennsylvania; provided, that Executive acknowledges and agrees that the performance by Executive of his duties shall require frequent travel including, without limitation, overseas travel from time to time.

c. Proprietary Information and Inventions Agreement. Executive shall execute the Company's standard form of Intellectual Property and Confidential Information Agreement (the "Confidentiality Agreement") a copy of which is attached to this Agreement as

Exhibit A. Executive shall comply at all times with the terms and conditions of the Confidentiality Agreement and all other reasonable policies of the Company governing its confidential and proprietary information.

3. Devotion of Time to Company's Business

a. Full-Time Efforts. During his employment with the Company, Executive shall devote substantially all of his time, attention and efforts to the proper performance of his implicit and explicit duties and obligations hereunder to the reasonable satisfaction of the Company.

b. No Other Employment. During his employment with the Company, Executive shall not, except as otherwise provided herein, directly or indirectly, render any services of a commercial or professional nature to any other person or organization, whether for compensation or otherwise, without the prior written consent of the Executive Committee or the Board.

c. Non-Competition During and After Employment. During the Employment Period and for fifteen (15) months from the date of the termination of Executive's employment hereunder (the "Termination Date"), Executive shall not, directly or indirectly, without the prior written consent of the Company, either as an employee, employer, consultant, agent, principal, partner, stockholder, corporate officer, director, or in any other individual or representative capacity (X) compete with the Company in the business of developing or commercializing pulmonary surfactants, cystic fibrosis treatments or any other category of compounds which forms the basis of the Company's products or products under development, or (Y) solicit, encourage, induce or endeavor to entice away from the Company, or otherwise interfere with the relationship of the Company with, any person who is employed or engaged by the Company as an employee, consultant or independent contractor or who was so employed or engaged at any time during the preceding six (6) months; provided, that nothing herein shall prevent Executive from engaging in discussions regarding employment, or employing, any such employee, consultant or independent contractor (i) if such person shall voluntarily initiate such discussions without any such solicitation, encouragement, enticement or inducement prior thereto on the part of Executive or (ii) if such discussions shall be held as a result of or employment be the result of the response by any such person to a written employment advertisement placed in a publication of general circulation, general solicitation conducted by executive search firms, employment agencies or other general employment services, not directed specifically at any such employee, consultant or independent contractor.

d. In the event that Executive breaches any provisions of Section 3(c) or of the Confidentiality Agreement or there is a threatened breach thereof, then, in addition to any other rights which the Company may have, the Company shall be entitled, without the posting of a bond or other security, to injunctive relief to enforce the restrictions contained therein. In the event that an actual proceeding is brought in equity to enforce the provisions of Section 3(c) or the Confidentiality Agreement, Executive shall not urge as a defense that there is

an adequate remedy at law nor shall the Company be prevented from seeking any other remedies which may be available.

e. To the extent that the restrictions imposed by Section 3(c) are interpreted by any court to be unreasonable in geographic and/or temporal scope, such restrictions shall be deemed automatically reduced to the extent necessary to coincide with the maximum geographic and/or temporal restrictions deemed by such court not to be unreasonable.

4. Compensation and Benefits.

a. Base Compensation. During the Employment Period, the Company shall pay to Executive (i) base annual compensation ("Base Salary") of Two Hundred Seventy Five Thousand ($275,000), payable in accordance with the Company's regular payroll practices and less all required withholdings and (ii) additional compensation, if any, and benefits as hereinafter set forth in this Section 4. Base Salary shall be reviewed at least annually for the purposes of determining increases, if any, based on Executive's performance, the performance of the Company, inflation, the then prevailing salary scales for comparable positions and other relevant factors; provided, however, that such Base Salary shall be increased annually (effective as of January 1, 2001) during the Employment Period by a minimum of 5% per year, and provided further, that any increase in Base Salary in excess of such 5% increase shall be solely within the discretion of the Company.

b. Bonuses. During the Employment Period, Executive shall:

(1) be entitled to a minimum year-end bonus equal to 20% of Base Salary for such year and, further, shall be eligible for such additional year-end bonus, which may be paid in either cash or equity, or both, as is awarded solely at the discretion of the Compensation Committee of the Board, provided, that the Company shall be under no obligation whatsoever to pay such discretionary year-end bonus for any year;

(2) incentive bonus, which may be paid in either cash or equity, or both, as is determined at the discretion of the Compensation Committee of the Board and in the amounts contemplated by and as otherwise set forth in the Management Agreement dated March __, 1998, upon the achievement of each of the following milestones (which bonuses, if any, will be paid only once for the attainment of each of the milestones): (i) the successful completion of Phase II studies for any Portfolio Compound, (ii) the successful completion of Phase III studies of any Portfolio Compound, and (iii) receipt of marketing approval in the United States for any Portfolio Compound.

c. Benefits. During the Employment Period, Executive shall be entitled to participate in all employee benefit plans, programs and arrangements made available generally to the Company's senior executives or to its employees on substantially the same basis that such benefits are provided to such executives or employees (including, without limitation profit-sharing, savings and other retirement plans (e.g., a 401(k) plan) or programs, medical, dental, hospitalization, vision, short-term and long-term disability and life insurance plans or

programs, accidental death and dismemberment protection, travel accident insurance, and any other employee welfare benefit plans or programs that may be sponsored by the Company from time to time, including any plans or programs that supplement the above-listed types of plans or programs, whether funded or unfounded); provided, however, that nothing in this Agreement shall be construed to require the Company to establish or maintain any such plans, programs or arrangements. Anything contained herein to the contrary notwithstanding, throughout the Employment Period, Executive shall be entitled to receive (i) term life insurance on behalf of Executive's named beneficiaries in the amount of $2,000,000 and (ii) long-term disability insurance (subject to a combined annual premium cap of $15,000 for the first year of the Employment Period, which cap shall be increased by 5% for each successive full year of the Employment Period), each at no cost to the Executive, except the Company shall have no liability whatsoever for any taxes (whether based on income or otherwise) imposed upon or incurred by Executive in connection with any such life or disability insurance.

d. Vacations. During the Employment Period, Executive shall be entitled to 20 days paid vacation per year, to be earned ratably throughout the year, 5 days of which may be carried over from year to year (provided, that in no event shall the aggregate number of such vacation days carried over to any succeeding year exceed 10 days).

e. Reimbursement of Business Expenses. Executive is authorized to incur reasonable expenses in carrying out his duties and responsibilities under this Agreement and the Company shall reimburse him for all such expenses, in accordance with reasonable policies of the Company.

f. Company Leased Automobile: In connection with Executive's employment hereunder, Executive shall be entitled to the use of a suitable automobile (to be determined in the good faith discretion of Executive) (the "Company Car") which shall be leased on Executive's behalf by the Company or, in the Company's sole discretion, the costs therefor shall be reimbursed to Executive. The annual total costs incurred by the Company in connection with the Company Car (including, without limitation, lease payments, insurance, maintenance and repairs, any governmental and regulatory fees (but excluding any amounts Executive may receive as reimbursement for gasoline, parking and tolls incurred in connection with his service to the Company) shall not exceed $10,000. Executive acknowledges and agrees that the Company Car shall be for Executive's exclusive use primarily with respect to Company business. At Executive's sole expense, Executive shall maintain a current United States driving license and shall immediately inform the Company's Controller if such license is revoked or suspended. Upon any such revocation or suspension, Executive will immediately forfeit any and all entitlement to the Company Car. Executive hereby agrees to at all times comply with the Company's written policies regarding Company automobiles and shall have full responsibility for any fines incurred for motoring offenses in respect of the Company Car whether such fines are incurred in his personal use or in connection with Company activities.

5. Termination of Employment.

a. Termination for Good Cause. The Company may terminate Executive's employment at any time for Good Cause, as such term is hereinafter defined. For the purposes of this Agreement, "Good Cause" means Executive's gross misconduct; Executive's gross neglect of duties; Executive's commission of any act involving moral turpitude; Executive's material breach of this Agreement or the Confidentiality Agreement; any act or omission of Executive involving fraud or embezzlement against the Company; Executive's appropriation of any property or proprietary information of the Company resulting, in either case, in substantial harm to the Company; or Executive's conviction of a felony. Executive shall have fifteen (15) days after receipt of written notice from the Company to cure any conduct constituting Good Cause hereunder; provided, however, that such fifteen (15) day period shall not apply if the Company reasonably determines that such conduct is not capable of being cured. If terminated for Good Cause in accordance with the provisions of this Section 5(a), Executive shall be entitled to any unpaid compensation accrued through the last day of Executive's employment, a lump sum payment in respect of all accrued but unused vacation days (provided, that in no event shall the aggregate number of such accrued vacation days exceed 10 days) at his Base Salary in effect on the date such vacation was earned, payment of any other amounts owing to Executive but not yet paid and shall not be entitled to receive any other compensation or benefits from the Company whatsoever (except as and to the extent the continuation of certain benefits is required by law).

b. Termination without Good Cause. The Company may terminate Executive's employment at any time without Good Cause. If (i) Executive's employment is terminated by the Company without Good Cause or (ii) Executive resigns for Good Reason (as hereinafter defined).

(1) Executive shall be entitled to the amounts set forth in Section 5(a); and

(2) Executive shall be entitled to receive a lump-sum severance payment equal to fifteen (15) months of his Base Salary in effect on the date of his termination, payable within 10 business days of the Termination Date and less all required withholdings.

(3) For purposes hereof, "Good Reason" shall mean a resignation by Executive, upon at least 30 days prior written notice to the Company, following the occurrence of any of the following events without Executive's consent, unless the circumstances giving rise thereof have been cured by the Company within such 30-day notice period: (X) an involuntary reduction of 20% or greater in his then current Base Salary, (Y) a material diminution in Executive's title or duties or the assignment to him of duties that materially impair his ability to perform the duties normally assigned to a president and chief executive officer of a corporation the size and nature of the Company, or (Z) the failure of the Company, upon the request of the Executive, to obtain the assumption in writing of its obligation to perform this Agreement by any successor to all or substantially all of the assets of the Company within 45 days after a merger, consolidation, sale or similar transaction.

c. Death or Disability. This Agreement shall terminate if Executive dies or is Disabled as herein defined. For the purposes of this Agreement, "Disabled" shall mean a mental or physical condition that renders Executive substantially incapable of performing his duties and obligations under this Agreement, after taking into account provisions for reasonable accommodation, as determined by a medical doctor (such doctor to be mutually determined in good faith by the parties) for three (3) or more consecutive months or for a total of six (6) months during any twelve (12) consecutive months; provided, that during such period the Company shall give Executive at least thirty (30) days' written notice that it considers the time period for disability to be running. If this Agreement is terminated under this Section 5(c), Executive, his heirs, legal representatives or his estate shall be entitled to any unpaid amounts set forth in Section 5(a) but shall not be entitled to any severance benefits.

d. Termination by Executive. Executive shall give the Company 30 days prior notice before he voluntarily resigns his employment with the Company. In the event of Executive's voluntary resignation (other than for Good Reason), Executive shall be entitled to any unpaid amounts set forth in Section 5(a) but shall not be entitled to any severance benefits.

e. Lock-up Period. Executive shall not directly or indirectly, sell, offer, contract to sell, transfer the economic risk of ownership, make any short sale, pledge or otherwise dispose of any shares of Common Stock issued or issuable upon the exercise of options, or any securities convertible to or exchangeable or exercisable for such options, granted to Executive for a one-year lock up period following any termination of Executive's employment by (i) the Company for Good Cause or (ii) Executive, to the extent any such termination constitutes a breach of this Agreement.

6. Miscellaneous.

a. Governing Law. This Agreement shall be interpreted, construed, governed and enforced according to the laws of the Commonwealth of Pennsylvania as applied to agreements among Pennsylvania residents entered into and to be performed entirely within Pennsylvania without regard to the application of choice of law rules.

b. Amendments. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the parties hereto.

c. Severability. If one or more provisions of this Agreement are held to be invalid or unenforceable under applicable law, such provisions shall be construed, if possible, so as to be enforceable under applicable law, or such provisions shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

d. Successors and Assigns. The rights and obligations of the Company under this Agreement shall inure to the benefit of and shall be binding upon the successors and assigns of the Company. Executive shall not be entitled to assign any of his rights or obligations under this Agreement.

e. Notices. All notices required or permitted under this Agreement shall be in writing and shall be deemed effective upon personal delivery, on the date of scheduled delivery by a nationally recognized overnight service or two (2) days after deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed to the other party at the address shown below such party's signature, or at such other address or addresses as either party shall designate to the other in accordance with this Section 6(e).

f. Entire Agreement. This Agreement, including the exhibits attached hereto, constitutes the entire agreement between the parties with respect to the employment of Executive.

g. Survivorship. The rights and obligations of Executive and the Company hereunder shall survive any termination of Executive's employment to the extent necessary to the intended preservation of such rights and obligations.

h. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute one document.

IN WITNESS THEREOF, the parties have executed this Agreement as of the date set forth above.

DISCOVERY LABORATORIES, INC.

/s/ David L. Lopez

By: David L. Lopez, CPA, Esq.
Its: Vice President and General Counsel

Address: 350 South Main Street, Suite 307
Doylestown, PA 18901

EXECUTIVE,

/s/ Robert J. Capetola, Ph.D.

Address: 6097 Hidden Valley Drive
Doylestown, PA 18901

Exhibit 23.1

INDEPENDENT AUDITORS' CONSENT

We consent to the incorporation by reference in the Registration Statement on Form S-8 pertaining to Discovery Laboratories, Inc. Amended and Restated 1998 Stock Incentive Plan of our report dated February 25, 2000, on our audit of the consolidated financial statements for the year ended December 31, 1999 which report is included in the annual report on Form 10-KSB for the year ended December 31, 2000.

/s/ Richard A. Eisner & Company, LLP

New York, New York
March 29, 2001

Exhibit 23.2

Consent of Independent Auditors

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-55900) pertaining to the Discovery Laboratories, Inc. Amended and Restated 1998 Stock Incentive Plan and in the Registration Statements (Form S-3 No. 333-35206 and Form S-3 No. 333-86105) pertaining to the registration of shares of common stock of our report dated March 27, 2001, with respect to the consolidated financial statements of Discovery Laboratories, Inc. included in the Annual Report (Form 10-KSB) for the year ended December 31, 2000.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 27, 2001