WASHINGTON, D.C. 20549 FORM 10-KSB /X/ Annual Report under Section 13 or 15(d) of the Securities Exchange Act of 1934 (Fee required) For the fiscal year ended December 31, 1999 // Transition report under Section 13 or 15(d) of the Securities Exchange Act of 1934 (No fee required) For the transition period from to

U.S. SECURITIES AND EXCHANGE COMMISSION

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) 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:

Name of Each Exchange on Which Registered

None

Title of Each Class None

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

Common Stock, \$.001 par value	Class A Warrants	Class B Warrants
(Title of Class)	(Title of Class)	(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. \$178,000.

As of March 28, 2000, 14,051,805 shares of the registrant's common stock, par value \$0.001 per share, were outstanding (exclusive of shares of such common stock owned by each director and executive officer 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 28, 2000 was approximately \$120 million. The aggregate market value of all of the registrant's outstanding common stock (20,630,290 shares) and including shares of common stock held by each director and executive officer and each person who beneficially owns 10% or more of the outstanding shares of common stock of the registrant, was approximately \$176 million computed by reference to the closing price of such common equity on the Nasdaq SmallCap Market on March 28, 2000. Shares of common stock beneficially owned by each director and executive officer and each person who beneficially owned by each director and executive officer 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 the first two sentence of 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 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.

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 subsidiary, Acute Therapeutics, Inc. ("ATI"), (ii) all references to the Company's activities, results of operations and financial condition prior to November 25, 1997 relate to Discovery Laboratories, Inc., a former Delaware corporation ("Old Discovery"), a predecessor to the Company, insofar as business activities relating to the SuperVentTM, Surfaxin(R) and DSC-103 products described herein are concerned and (iii) all references to the Company's common stock, par value \$0.001 per share (the "Common Stock") are to the Company's common Stock after giving effect to a 1-for-3 reverse split of the Common Stock effected on November 25, 1997. 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 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 and Section 21E of the Securities Exchange Act of 1934, as amended, 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 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 prospectus.

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 and acute lung injury in adult patients. We believe we can use Surfaxin(R) to treat other respiratory conditions. These include asthma, chronic obstructive pulmonary disease, emphysema and cystic fibrosis. In addition, we believe we can use Surfaxin(R) to deliver drugs that are currently delivered by injection. These drugs include antibiotics, pulmonary vasodilators, brochodilators, steroids and proteins. We are also evaluating acquiring licenses to other drug candidates in the early stage of development for the treatment of respiratory 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 an artificial lung surfactant containing a peptide or small protein. We patterned Surfaxin(R) after a human surfactant protein. 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 respiratory distress syndrome in premature infants, meconium aspiration syndrome in full-term infants and respiratory distress syndrome and acute lung injury acute respiratory distress syndrome in adults. We have also begun developing Surfaxin(R) to treat other respiratory disorders.

Respiratory distress syndrome is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. Meconium aspiration syndrome is a similar condition, in which full-term infants are born with meconium in their lungs which depletes the natural surfactant in their lungs. Meconium is the baby's first bowel movement in the mother's womb. This condition can lead to meconium aspiration syndrome if the baby breathes in the meconium. Both of these conditions 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. This results in the need for mechanical ventilation and can be life-threatening. Acute respiratory distress syndrome can result from a variety of events. Some of these events are pneumonia, breathing in the contents of the stomach, trauma, smoke inhalation, near drowning and head injury.

The incidence of ARDS/ALI is approximately 240,000 patients per year in the United States. Respiratory distress syndrome affects 40,000 to 50,000 infants per year in the United States. Twenty to forty percent of infants with respiratory distress syndrome require extended mechanical ventilation and hospitalization. Meconium aspiration syndrome affects approximately 26,000 newborn infants per year in the United States.

Presently, the FDA has only approved replacement surfactants for treating respiratory distress syndrome in premature infants. These approved replacement surfactants come from pigs and

cows. Surfaxin(R) is a synthetic surfactant. As a result, we believe that we can manufacture Surfaxin(R) less expensively. In addition we believe that Surfaxin(R) might possess other pharmaceutical benefits not possessed by animal surfactants. The FDA has not approved replacement surfactants for treatment of meconium aspiration syndrome and acute respiratory distress syndrome. The FDA has granted meconium aspiration syndrome and acute respiratory distress syndrome fast track designation. 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 meconium aspiration syndrome.

We also intend to begin 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.

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

Cystic fibrosis is a progressive, lethal respiratory disease that afflicts approximately 23,000 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 conducting clinical trials of Surfaxin(R) for the treatment of respiratory distress syndrome, meconium aspiration syndrome and acute respiratory distress syndrome. In addition, we are conducting clinical trials of SuperVentTM for treatment of cystic fibrosis.

PRODUCTS AND TECHNOLOGIES UNDER DEVELOPMENT

#### SURFAXIN(R)

The Company's lead product is Surfaxin(R), a protein-phospholipid formulation containing the proprietary, synthetic peptide sinapultide, for the treatment of several conditions characterized by insufficient surfactant. Lung surfactants are protein-phospholipid complexes which 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 idiopathic respiratory distress syndrome in premature babies ("RDS"). Infants with this condition, as well as infants born with meconium (a component of the fetal bowel) in their lungs, which can lead to meconium aspiration syndrome ("MAS"), typically suffer from insufficient surfactant. This condition 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. If Surfaxin(R) can be formulated as an aerosol, it might have utility in other pulmonary disorders, such as asthma.

Surfaxin(R) is an aqueous suspension of lipids containing the novel synthetic peptide sinapultide. Surfaxin(R) was invented at The Scripps Research Institute ("Scripps"). Surfaxin(R) is patterned after human Surfactant Protein B, shown to have the greatest surfactant activity in humans. The product 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 RDS 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 RDS. 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 RDS 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 RDS IND to permit the initiation of a Phase 2 clinical trial of Surfaxin(R) to treat MAS on May 27, 1997 at Thomas Jefferson University Hospital in Philadelphia. 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. The trial intends to enroll 200 MAS patients. The Company is engaged in discussions with the FDA concerning a protocol for Phase 3 clinical trials for Surfaxin(R) for RDS. The Company intends to commence the Phase 3 clinical trial upon approval of the protocol on terms acceptable to the Company. The Company also commenced a pivotal Phase 2/3 clinical trial in ARDS/ALI in July 1998. This trial was stopped on January 27, 2000 due to the Company's cash position and so that a new Phase 2 ARDS/ALI trial could be commenced using a new, less viscous formulation of Surfaxin(R). A new Phase 2 trial is currently being planned, which the Company expects to commence following submission of a protocol and subsequent and the ARDS/ALI trial could be to the Company's cash position and so that a new Phase 2 ARDS/ALI trial could be commenced using a new, less viscous formulation of Surfaxin(R). A new Phase 2 trial is currently being planned, which the Company expects to commence follo

## SuperVent(TM)

The Company is developing SuperVent(TM) as a stable, aerosolized, multidimensional therapy for airway diseases such as cystic fibrosis ("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(TM)'s 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 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. Preliminary analysis of the data show that SuperVent(TM) decreased the amount of Interleukin 8 (IL-8) 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 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 is developing DSC-103 (formerly known as ST-630) for use in treating postmenopausal osteoporosis. Postmenopausal osteoporosis is a disease of postmenopausal women characterized by decreased bone mass which leads to reduced bone strength and an increased risk of fractures. DSC-103 is an analog of the active circulating vitamin D hormone, calcitricl, modified to increase its potency and lengthen its circulating half-life. As a class, vitamin D analogs are commonly used therapies in Europe and Japan for osteoporosis. In aggregate, this class of compounds is believed to generate several hundred million dollars in worldwide sales for osteoporosis.

Published studies have confirmed the efficacy of vitamin D analogs in increasing bone mass and decreasing fractures. Vitamin D analogs, however, have not been well accepted in the United States due to certain side effects in the compounds currently marketed. Specifically, prior studies of vitamin D analogs have been associated with hypercalcemia in a percentage of patients. Hypercalcemia is elevated calcium levels in the blood above a generally accepted range. No vitamin D analogs are currently marketed for osteoporosis in the United States.

In November 1997, the Company filed an IND with the FDA to initiate Phase 1 clinical studies of DSC-103 as a once-daily, orally administered drug for the treatment of postmenopausal osteoporosis in the United States. On December 5, 1997, the Company initiated an initial safety and dose-ranging study of DSC-103 in healthy normal volunteers and postmenopausal women either with or without osteoporosis at Covance Clinical Research Unit Inc. in Madison, Wisconsin. The Company completed that clinical study and determined that DSC-103 does not represent a risk of hypercalcemia at any dosage levels that may prove efficacious for treating postmenopausal osteoporosis. The Company has access to preclinical data generated by Sumitomo Pharmaceuticals and Taisho Pharmaceuticals with respect to DSC-103 pursuant to the terms of the licensing arrangements described herein.

Because DSC-103 does not meet the critical care focus of Discovery, it is the Company's intention to seek a pharmaceutical partner to further develop DSC-103 for metabolic bone diseases.

#### 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 consist of four issued United States patents and two pending United States applications. The four issued patents are United States 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 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 patent Rights consist of certain pending United States patent and compositions. The orthor Patent Rights consist of certain pending United States patent 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. A US patent covering use of all known surfactants (including Surfaxin(R)) as a lavage was recently issued to The Scripps Research Institute and licensed to Discovery Laboratories, Inc.

## CMHA License Agreement: SuperVent(TM) /Tyloxapol

The Company has obtained the core technology relating to SuperVent(TM) pursuant to a license agreement with the Charlotte-Mecklenberg Hospital Authority (the "CMHA License Agreement"). The CMHA License Agreement grants the Company an exclusive worldwide license under two issued United States patents (United States Patent No. 5,474,760 and United States 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 SuperVentTM, 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 SuperVentTM 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 means to deliver the active compound, there can be no assurance that any patent application covering this formulation will issue or that the compound will not prove similarly effective in lower concentrations which are not covered by any of the Company's patent applications.

#### WARF License Agreement: DSC-103

Pursuant to an agreement (the "WARF License Agreement") with the Wisconsin Alumni Research Foundation ("WARF"), the Company has an exclusive license within all countries in the Western hemisphere in the field of prevention, treatment, amelioration or cure of bone disease, under U.S. Patent No. 4,358,406 (the "DSC-103 Patent") covering the compound DSC-103 and U.S. Patent No. 5,571,802 (the "DSC-103 Use Patent") covering a method for treating postmenopausal osteoporosis. In addition, the Company has options to extend the exclusive license to the remaining countries of the world with the exception of Japan. The Company options expire on January 1, 2002.

The DSC-103 Patent will expire in July 2001, which the Company anticipates will be prior to receipt of any marketing approval for DSC-103 in the United States. The DSC-103 Use Patent, which expires in 2014, is limited to claims relating to a method of treating postmenopausal osteoporosis in humans having such disease with an effective dosage of DSC-103. These claims do not include claims relating to the use of DSC-103 to treat other metabolic bone disorders, such as age-related osteoporosis (which occurs in men and women) and renal osteodystrophy. At the Company's request, WARF filed an application to pursue additional claims relating to the use of DSC-103 to treat other metabolic bone diseases. However, there can be no assurance that any patent containing such additional claims will issue in the United States or elsewhere. United States and foreign patents covering certain processes relating to the manufacture of vitamin D analogs, which have been nonexclusively licensed to the Company under the WARF License Agreement, will expire on various dates up to 2005.

#### 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 to Scripps' Surfaxin(R) research efforts per annum. In March 2000, the Company and Scripps entered into an Agreement extending the term for one year commencing March 1, 2000 and for additional one year terms upon agreement of the parties. The Company will contribute \$247,731 per annum to Scripps' Surfaxin(R) research under the Agreement. The Company has an option to acquire an exclusive worldwide license to technology developed under the 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. The Company has not received any notice of development of 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 technology.

#### Collaboration Agreements

The Company entered into a sublicense agreement with Laboratorios del Dr. Esteve, S.A. ("Laboratorios Dr. Esteve") pursuant to which the Company granted to Laboratorios Dr. Esteve an exclusive license to market and sell Surfaxin(R) products in southern Europe (other than Italy), Central and South America and Mexico, with an option to acquire an exclusive license for Italy. In addition, the Company granted to Laboratorios Dr. Esteve a right of first negotiation with respect to other products developed by the Company for distribution and sale in the licensed territory. Under the sublicense agreement, the Company will be entitled to milestone payments upon achievement of certain milestones. In addition, the Company entered into a supply

agreement with Dr. Esteve pursuant to which Laboratorios Dr. 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 mav 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 ueveloped, of 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 infrience patents. 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.

THIRD PARTY SUPPLIERS; MANUFACTURING AND MARKETING

To be successful, the Company's products must be manufactured in commercial quantities under good manufacturing practice ("GMP") requirements set by the FDA at acceptable costs. The FDA periodically inspects manufacturing facilities in the United States in order to assure compliance with applicable GMP requirements. Foreign manufacturers also are inspected by the FDA if their drugs are marketed in the United States. Failure of the foreign or domestic suppliers of Discovery'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.

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). In addition, the Company has entered into an agreement with Taylor Pharmaceuticals, Inc. for the manufacture of Surfaxin(R) for use in the Company's planned clinical trials.

The active compound in SuperVent(TM) 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 with GMP standard manufacturing capabilities and there are few alternative non-GMP approved 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 proposed Phase 1/2 clinical trial of SuperVentTM, 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. In addition, the Company does not intend to enter into an agreement for supply of the formulated drug containing tyloxapol unless it plans to initiate a Phase 3 clinical trial of tyloxapol for the treatment of CF. There can be no assurance that 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 would be required to seek alternate manufacturing sources capable of producing tyloxapol and the formulated drug. There can be no assurance that 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 would have a material adverse effect on the Company's business, financial condition and results of operations.

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.

#### 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 Company's products under development.

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 RDS. CurosurfTM, marketed in Europe by Ares-Serono and Chiesi, and in the US by Dey Labs, is a porcine lung extract. ExosurfTM, marketed by Glaxo Wellcome, contains only phospholipids and synthetic organic detergents and no stabilizing protein peptides. SurvantaTM, which has been shown to be more effective than or ExosurfTM in clinical trials, is an extract of bovine lung that contains the cow version of Surfactant Protein B. Recently, Forest Laboratories has obtained marketing clearance from the FDA for its calf lung surfactant, InfasurfTM, for use in RDS. Although none of the four approved surfactants for RDS 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 RDS

Genentech has marketed PulmozymeTM in the United States and Canada as a CF therapy since early 1994. PulmozymeTM 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 yearly cost of PulmozymeTM treatment for an average patient is \$12,000. The Company believe that the high cost of this treatment may reduce its competitive profile as compared with SuperVent(TM).

There are numerous approved therapies for osteoporosis which will compete with DSC-103. Such therapies include estrogen, which is of proven benefit in treating osteoporosis in postmenopausal women, but is associated with significant adverse effects (including increased breast and uterine cancer risk); FosamaxTM (alendronate), a drug of the bisphosphonate class marketed by Merck; EvistaTM a selective estrogen receptor modulator marketed by Eli Lilly; and MiacalcinTM, a nasally administered calcitonin marketed by Sandoz Pharmaceuticals. In addition, there are a number of therapies in development for osteoporosis that potentially will compete with DSC-103.

## 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 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. Typically, clinical testing involves a three-phase process. 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 could have a material adverse effect on the Company's business, financial condition and results of operations.

During October 1998, the FDA granted the Company Fast Track approval status for the ARDS/ALI 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. The FDA Office of Orphan Products Development (the "OOPD")

has designated Surfaxin(R) as an orphan drug for the treatment of MAS and ARDS/ALI. During October 1998, the OOPD awarded Discovery a renewable Orphan Products Development Grant, ranging from \$194,390 for the first year to \$583,170 over three years, to finance the Company's MAS trial.

#### EMPLOYEES

The Company has 11 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.

#### 1998 Merger

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

#### 1997 Merger

On November 25, 1997, Old Discovery was merged (the "1997 Merger") with and into the Company. 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 (the "Reverse Split") of the outstanding 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. Accordingly, 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. We expect 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 which 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; -- that we will successfully market our proposed products.

If We Cannot Raise Additional Capital We Will Need to Discontinue Our Research and Development Activities. In Addition, Any Additional Financing Could Result in Dilution.

We will need substantial additional funding to conduct our research and product development activities and, if we are successful, to manufacture and market products. We intend to raise further funds through collaborative ventures entered into 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 provide assurance 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. If we fail to enter into collaborative ventures or to receive additional funding, we would have to scale back or discontinue our research and development operations. Furthermore, we could cease to qualify for listing of our securities on the Nasdaq SmallCap Market. See "We Face the Possibility of Delisting From the Nasdaq SmallCap Market."

If We Fail to Obtain Regulatory Approval to Commercially Manufacture or Sell Any of Our Products or If the FDA Delays Approval of Our Product Candidates, it Could Increase the Cost of Product Development or Ultimately Prevent or Delay Our Ability to Sell Our Products and Generate Revenues.

In order to sell our products that are under development, we must receive regulatory approvals for our products. The 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 agencies in other countries require an extensive regulatory approval process before we can market our product. This process includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation by the FDA that the manufacturer maintains good laboratory, clinical and manufacturing practices during testing and manufacturing. The process is lengthy, expensive and uncertain. It is also possible that we may not reach agreement with the FDA on the design of clinical studies necessary for approval. In addition, conditions imposed by the FDA on our clinical trials could significantly increase the time required for completion of clinical trials and the costs of conducting clinical trials. Clinical trials could significantly increase the time required for completion of clinical trials and the costs or more to complete.

The testing and approval processes require the expenditure of substantial resources. The FDA may not give us the requisite approvals for our products on a timely basis, if ever. The FDA

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. We may need to enter into additional collaboration agreements. Our success may depend upon obtaining 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 develop or commercialize successfully any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner.

Discoveries or Developments of New Technologies by Our Competitors or Others May Make Our Products less Competitive or Make Our Products Obsolete.

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. The research efforts of others may render our research and product development efforts obsolete. 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, personal and managerial resources than we have.

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. 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.

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 application 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 third parties may not provide any protection against competitors. In particular, our issued and pending patents relating to SuperVent(TM) cover high concentrations of tyloxapol. These patents could prove meaningless if low concentrations of tyloxapol are as effective as higher concentrations of tyloxapol in treating the indications which we are developing our SuperVent(TM) product to treat.

Patents Which Others Obtain 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. Accordingly, we cannot determine which inventions third parties claim in pending patent applications which 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. Tt 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. 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 Our 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 patent applications and maintaining 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 Our Employees Could Breach.

We require all employees to enter into confidentiality agreements that prohibit the disclosure of confidential information to third parties and require disclosure and assignment to us of rights to our employees' ideas, developments, discoveries and inventions while we employ them. In addition, we seek to obtain these types of agreements from our consultants, advisors and research collaborators. To the extent that consultants, key employees or other third parties apply technological information which they or other parties independently develop to any of our proposed 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. 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; or
  - that agreements we would 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.

If the Third Parties We Depend on for the Manufacture of Our Pharmaceutical Products Do Not Supply These Products in a Timely Manner, it May Delay or Impair Our Ability to Develop and Market Our Products.

We rely on outside manufacturers, including Taylor Pharmaceuticals, Inc., 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 products after marketing approval. We may also enter into arrangements with other manufacturers for the manufacture of material 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. In this event 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. 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 good manufacturing practice 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 good manufacturing practice requirements or other FDA regulatory requirements, it could adversely affect our ability to market our products.

We Do Not Have Marketing and Sales Experience, and Our Lack of That Experience Could Limit Our Ability to Generate Revenues from Future Product Sales.

We do not have marketing and sales experience or marketing or sales personnel. If we do not develop a marketing and sales force, then we will 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 Effect Our Ability to Develop and Market Our Products.

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

Our future success also will depend in part on the continued service of our key scientific and management personnel and our ability to identify, hire and retain additional personnel, including marketing and sales staff. We experience intense competition for qualified personnel.

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

Our Industry is Highly Competitive and We Have less Capital and Resources than Many of Our Competitors, and This May Give Them an Advantage in Developing and Marketing Products Similar to Ours.

Our industry is highly competitive. 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, marketing, financial, technological, personnel and managerial resources than we have. In addition, many of these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

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

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing products before us. If we commence commercial product sales, we will 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 uncompetitive. 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. Accordingly, 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 might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiation of other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, this insurance 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.

Healthcare Reform Measures and Reimbursement Procedures May Prevent Us from Obtaining an Adequate Level of Reimbursement for Our Products That in Turn Would Decrease Our Ability to Generate Revenues.

Efforts of governmental and third-party payers to contain or reduce the costs of health care through various means could affect the levels of revenues and profitability of pharmaceutical and biotechnology products and companies. For example, in some foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, there have been a number of federal and state proposals to implement similar government control. Pricing constraints on our products could negatively impact our revenues and profitability.

In the United States and elsewhere, successful commercialization of our products will depend in part on the availability of reimbursement to the consumer using our products from third-party health care payers such as government and private insurance plans. Third-party payors may not provide sufficient reimbursement to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Third-party health care payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services. If we succeed in bringing one or more products to market, and the government or third-party payers fail to provide adequate coverage or reimbursement rates for those products, it could reduce our product sales and product revenues.

Directors, Executive Officers, Principal Stockholders and Affiliated Entities Own a Significant Percentage of Our Capital Stock, and this Could Have an Effect on Actions by the Stockholders.

As of March 29, 2000, our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, approximately 32% of our outstanding voting securities. Accordingly, these stockholders have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

We Face the Possibility that Nasdaq May Delist our Common Stock from the NASDAQ SmallCap Market.

To meet the current listing requirements for Nasdaq to continue to list our securities on the Nasdaq SmallCap Market, we will have to maintain: (a)

- (1) at least \$2 million in net tangible assets or
- (2) \$35 million in market capitalization or
- (3) \$500,000 in net income (over two of the last
- (b) a public float of at least 500,000 shares valued at \$1 million or more and
- (c) a minimum bid price of \$1 and
- (d) at least 300 holders of our common stock and (e) at least two active market makers.

At December 31, 1999, we had \$3,108,000 in net tangible assets. The closing price of our common stock during the period from January 1, 1999 to March 28, 2000 ranged from \$1.00 to \$12.63 and the closing price of our common stock on March 28, 2000 was \$8.53.

If we are unable to satisfy the listing requirements, Nasdaq may delist our securities from the Nasdaq SmallCap Market. If any trading markets for our securities are available, investors could only trade in the over-the-counter securities are available, investors could only 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). Consequently, this would impair the liquidity of our securities. This could reduce the number of our securities investors could buy and sell and could result in delays in the timing of the transactions, reduction in securities analysts' and the news media's coverage of us and lower prices for our securities.

The "Penny Stock" Rules May Adversely Affect the Liquidity of Our Common Stock.

If Nasdaq delisted our securities from the Nasdaq SmallCap Market, Rule 15g-9 under the Exchange Act would apply. Rule 15g-9 imposes additional sales practice requirements on

broker-dealers that sell these types of securities to persons other than established customers and "accredited investors" (generally, individuals with net worth in excess of \$1,000,000 or annual incomes exceeding \$200,000, or \$300,000 together with their spouses). For transactions that this rule covers, a broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written consent to the transaction prior to sale. Consequently, the rule may adversely affect the ability of broker-dealers to sell our securities and may adversely affect the ability of stockholders to sell any of our securities in the secondary market.

The Commission has adopted regulations that define a "penny stock". Generally, a penny stock is an equity security that has a market price of less than \$5.00 per share. For any transaction involving a penny stock that is not exempt, the rules require that a broker-dealer deliver a disclosure schedule that the Commission has prepared relating to the penny stock market. The rule also requires the broker-dealer to disclose information about commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, rules require that the broker-dealers send monthly statements disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

These restrictions will not apply to our securities if the Nasdaq SmallCap Market continues to list our securities. If Nasdaq delists our securities and they become subject to the existing or proposed rules on penny stocks, it could severely adversely affect the market liquidity for our securities.

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 28, 2000, there were approximately 20,630,290 shares of common stock outstanding. In addition, as of March 28, 2000 up to 6,765,313 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.

We cannot predict the effect that the availability of these shares for sale will have on the market price of our common stock. Nevertheless, because holders may sell substantial amounts of our common stock in the public market, the market price of our common stock could drop as a result of sales of these securities or the perception that these types of sales may occur. These factors could also make it more difficult for us to raise funds through future offerings of securities.

Anti-takeover Provisions of Our Certificate of Incorporation and Delaware Law Could Delay Actual or Potential Changes of Control, Which Could Affect Stockholder Ability to Benefit From Market Fluctuations and Changes in Management.

Our Certificate of Incorporation and Delaware law contain provisions which 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 on 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. The possible issuance of preferred stock and the provisions of Delaware law could have the effect of discouraging others from making tender offers for our securities. As a consequence, they also may inhibit fluctuations in the market price of our common stock that otherwise could result from actual or rumored takeover attempts. Those provisions also may have the effect of preventing changes in our management.

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 is (215) 340-4699 and its facsimile number is (215) 340-3940.

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 1999.

## 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." In addition, the Company's units (consisting of Common Stock, Class A Warrants and Class B Warrants), Class A Warrants and Class B Warrants are approved for listing on the Nasdaq SmallCap Market. As of March 28, 2000, the number of stockholders of record of the Common Stock was approximately 128, and the number of beneficial owners of shares of the Common Stock was approximately 956. As of March 28, 2000, there were approximately 20,630,290 shares of Common Stock were issued and outstanding.

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

	Low	High
First Quarter 1998 Second Quarter 1998 Third Quarter 1998 Fourth Quarter 1998	4.00 2.00	9.00 5.38 4.38 4.88
First Quarter 1999 Second Quarter 1999 Third Quarter 1999 Fourth Quarter 1999	1.13 1.00	4.00 2.50 2.00 3.06

First Quarter 2000 (through March 28, 2000).....2.43 12.63

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.

#### 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 had incurred a cumulative net loss of approximately \$32.4 million as of December 31, 1999. 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 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 and that it will focus primarily on the conduct of clinical trials for Surfaxin(R) indications. The Company expects to expand 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. The Company anticipates the near term acquisition of equipment necessary to manufacture Surfaxin(R). The Company also anticipates the hiring of further personnel to augment the clinical development of Surfaxin(R). A pivotal Phase 2/3 clinical trial of Surfaxin(R) for the treatment of ARDS/ALI 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/ALI real could be commenced using a new, less viscous formulation of Surfaxin(R). A new Phase 2 trial is currently being planned, which we expect to commence following submission of a protocol

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 initiated a pivotal Phase 3 trial in MAS in January 2000. The trial intends to enroll 200 MAS patients. The Company is engaged in discussions with the FDA concerning a protocol for Phase 3 clinical trials for Surfaxin(R) for RDS. The Company intends to commence the Phase 3 clinical trial upon approval of the protocol on terms acceptable to the Company. Such trial, and any other clinical trials of the Company's products in development that have not yet commenced, will require the receipt of approvals by the United States Food and Drug Administration (the "FDA"). There can be no assurance as to the receipt or the timing of such approvals.

A Phase 1/2 clinical trial of SuperVent(TM) for the treatment of cystic fibrosis ("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. Preliminary analysis of the data show that SuperVent(TM) decreased the amount of Interleukin 8 (IL-8) 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.

On December 5, 1997 a Phase 1 clinical study of DSC-103 (formerly known as ST-630) as a once-daily, orally administered drug for the treatment of postmenopausal osteoporosis in the United States was initiated. Part B of such trial was commenced on April 2, 1998 and was successfully completed on June 29, 1998. It is the Company's present intention to seek to develop DSC-103 through a corporate partnering arrangement rather than directly.

The Company's expenses decreased from \$16,090,000 in 1998 to \$5,292,000 in 1999. The decrease resulted primarily from a write-off of acquired in-process research and development and supplies in 1998. In addition, the Company's research and development costs decreased from \$5,082,000 in 1998 to \$2,869,000 in 1999. This decrease resulted primarily from a slow-down in research and development due to the Company's cash position. As a result of the receipt of proceeds from the private placement completed in March, 2000, the Company expects to significantly increase its research and development and clinical trial efforts. As a result of the

decreases in expenses from 1998, the Company's total comprehensive net loss decreased from \$15,626,000 in 1998 to \$4,958,000 in 1999. In addition, due to the reduction in the total comprehensive net loss and the increase in the weighted average common shares outstanding during 1999, the Company's net loss per share decreased from \$4.02 in 1998 to \$0.66 in 1999.

#### Liquidity

At December 31, 1999, the Company had working capital of \$2.7 million. In March 2000, the Company completed a private placement pursuant to which it received net proceeds of approximately \$17.5 million. The Company believes its working capital after completion of the offering is sufficient to meet its planned research and development activities through the third quarter 2001. However, the Company will need additional financing from investors or collaborators to complete research and development of its product candidates.

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 a 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.

On July 29, 1999, the Company received \$2.45 million in gross proceeds when it completed a private offering of Units (the "Unit Offering"), at a per Unit price of \$500,000, consisting of (a) 413,223 shares of the Company's Common Stock, par value \$0.001 per share (the "Common Stock, and (b) an equal number of the Company's Class D Warrants, each of which entitles the holder thereof to purchase a 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. Paramount Capital, Inc. received options (the "Placement Options") to acquire 0.49 Units at a per Unit exercise price of \$550,000 as partial compensation for its services in connection with the 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 of \$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 Laboratorios Del Dr. Esteve, S.A. ("Laboratorios Dr. 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. Each of the Units consisted of (a) 76,923 shares of the Company's common stock and (b) a number of Class E warrants equal to 20% of the number of shares of common stock included in each 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 per share equal to \$7.63 per share. In addition, Paramount received cash fees of approximately \$1.32 million and options (the "Placement Options") to acquire 9,230 shares of common stock per Unit sold at an exercise price of \$8.113 per share as partial compensation for its services in connection with the offering.

The Company's working capital requirements will depend upon numerous factors, including, without limitation, 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.

PART III

The information required by Item 8 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, 1999, a report filed on March 29, 2000, and a report filed in October 1998, relating to publishing an interim report to shareholders.

## 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.

By:

Date: March 28, 2000

/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	
/s/ Evan Myrianthopoulos		March _, 2000
	Evan Myrianthopoulos Vice President, Finance	March _, 2000
/s/ Cynthia Davis	Cynthia Davis Controller (Principal Accounting Officer)	March _, 2000
/s/ Steve Kanzer	Steve H. Kanzer, C.P.A., Esq. Chairman of the Board	March _, 2000
/s/ Richard Power	Richard Power Director	March _, 2000
/s/ Marvin Rosenthale	Marvin Rosenthale	
	Director	March _, 2000
/s/ Mark Rogers	Mark C. Rogers, M.D. Director	March _, 2000
/s/ Herbert McDade, Jr.	Herbert McDade, Jr. Director	March _, 2000
/s/ M. Link	Max Link, Ph.D. Director	March _, 2000
/s/ David Naveh	David Naveh, Ph.D. Director	March _, 2000
/s/ Richard Sperber	Richard Sperber Director	March _, 2000

## EXHIBIT INDEX

## EXHIBIT NO.

## DESCRIPTION

- 2.1(3) Agreement and Plan of Merger dated as of March 5, 1998 among Discovery, ATI Acquisition Corp. and ATI.
- 2.2(4) Agreement and Plan of Reorganization and Merger, dated as of July 16, 1997, by and between Discovery and Old Discovery.
- 3.1(3) Restated Certificate of Incorporation of Discovery.
- 3.2 Amendment to Restated Certificate of Incorporation of Discovery.
- 3.3(8) Certificate of Designation of Series C Preferred Stock.
- 3.4(2) By-laws of Discovery.
- 3.5 Certificate of Ownership Merging ATI Acquisition Corp. into Discovery.
- 4.1(8) Form of Class C Warrant.
- 4.2(10) Form of Class D Warrant.
- 4.3(12) Form of Class E Warrant.
- 4.4 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(2) Warrant Agreement, dated as of August 8, 1995 among Discovery, Continental Stock Transfer & Trust Company and D.H. Blair Investment Banking Corp.
- 10.3(2) Form of Escrow Agreement by and between Discovery, Continental Stock Transfer & Trust Company and certain securityholders of Discovery.
- 10.4(2) Form of Indemnification Agreement.
- 10.5(3) Investor Rights Agreement dated March 20, 1996, between Old Discovery and RAQ, LLC.
- 10.6(3) Registration Rights Agreement dated October 28, 1996, between ATI, JJDC, and Scripps.
- 10.7(5)+ Inventory Transfer/Stock Purchase Agreement dated October 28, 1996, among ATI, Johnson & Johnson Development Corporation ("JJDC"), The R.W. Johnson Pharmaceutical Research Institute and Ortho.
- 10.8(5)+ Sublicense Agreement dated October 28, 1996 between ATI, Johnson & Johnson, Inc. and Ortho.
- 10.9(5)+ License Agreement between Discovery and The Charlotte-Mecklenburg Hospital Authority dated March 20, 1996.
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- 10.10+ Amendment of License Agreement between Discovery and The Charlotte-Mecklenburg Hospital Authority dated March 20, 1996.
- 10.11(5)+ License Agreement dated September 6, 1996, between Discovery and WARF, as amended on October 31, 1996.
- 10.12(2) Restated 1993 Stock Option Plan of Discovery.
- 10.13(2) 1995 Stock Option Plan of Discovery.
- 10.14(9) Amended and Restated 1998 Stock Incentive Plan of Discovery.
- 10.15(3) Management Agreement between Discovery Laboratories, Inc. and Acute Therapeutics, Inc. dated as of March 5, 1998.
- 10.16(3) Lease Agreement between Discovery and Newmark and Company Real Estate, Inc., dated May 29, 1997, for professional offices at 509 Madison Avenue, New York, New York.
- 10.17(8) Sublease dated as of August 25, 1998 among the Company, Milan Entertainment, Inc. and Entertainment Management Group, Inc.
- 10.18(8) Indenture of Lease dated as of July 1, 1998 between SLTI1, LLC and Acute Therapeutics, Inc.
- 10.19(8)+ Pharmaceutical Services Contract dated August 15, 1997 between McKesson BioServices and the Company, as amended.
- 10.20(8)+ Agreement dated as of August 16, 1998 between the Company and Pharmalytic, Inc.
- 10.21(8) Agreement dated November 25, 1998 between the Company and Brobeck, Phleger and Harrison, LLP
- 10.22(8) Letter Agreement dated September 15, 1998 between the Company and Lehman Brothers.
- 10.23(8) Letter Agreement dated November 18, 1998 between the Company and Charles Cochrane.
- 10.24(8) Letter Agreement dated January 4, 1999 between the Company and Yi, Tuan & Brunstein.
- 10.25(8)+ Development Agreement dated as of March 30, 1998 between ATI and Taylor Pharmaceuticals, Inc.
- 10.26(8) Registration Rights Agreement dated as of June 16, 1998 among the Company, Johnson & Johnson Development Corporation ("JJDC") and Scripps.
- 10.27(8) Stock Exchange Agreement dated as of June 16, 1998 between the Company and JJDC.
- 10.28(8) Letter of Agreement dated April 27, 1998 between the Company and Robinson, Leher, and Montgomery
- 10.29(8)+ Letter Agreement dated April 27, 1998 between the Company and KPMG Peat Marwick LLP, as amended.

- 10.30(8)+ Research Funding and Option Agreement dated October 28, 1996, between Scripps and ATI, as amended by letter agreement dated February 26, 1997.
- 10.31(8)+ Amendment No 1 to Research Funding and Option Agreement dated March 1, 1998.
- 10.32(5)+ Clinical Testing Agreement dated as of February 24, 1997 between Discovery and the University of Utah.
- 10.33(3)+ Clinical Development Services Agreement dated as of December 1, 1997 between Discovery and Covance Clinical Research Unit.
- 10.34(3)+ Supply Agreement between ATI and Polypeptides Laboratories, Inc., dated December 10, 1997, for the processing of peptides.
- 10.35(3) Letter Agreement between ATI and Lehman Brothers dated November 10, 1997.
- 10.36(8) Employment Agreement dated October 1, 1996 between ATI and Robert J. Capetola, Ph.D.
- 10.37(8) Employment Agreement between Discovery and Lisa Mastroianni, R.N., dated June 16, 1998
- 10.38(8) Employment Agreement between Discovery and Christopher J. Schaber, R.A.C., dated June 16, 1998
- 10.39(8) Employment Agreement dated as of June 16, 1998 between Discovery and Huei Tsai, Ph.D.
- 10.40(8) Employment Agreement dated as of June 16, 1998 between Discovery and Thomas E. Wiswell, M.D.
- 10.41(8) Employment Agreement dated as of June 16, 1998 between the Company and Evan Myrianthopoulos.
- 10.42(8) Employment Agreement dated as of June 16, 1998 between the Company and Cynthia Davis.
- 10.43(8) Form of Intellectual Property and Confidential Information Agreement.
- 10.44(5) Management Agreement dated June 1, 1996 by and between Discovery and Steve Kanzer.
- 10.45(5)+ Consulting Agreement dated December 9, 1996 between ATI and Dr. Charles Cochrane.
- 10.46(5)+ Consulting Agreement dated December 9, 1996 between ATI and Susan Revak.
- 10.47(5) Consulting Agreement dated October 28, 1996 between ATI and The Sage Group.
- 10.48(5) Amendment No. 1 to Letter Agreement dated as of April 30, 1998 to Consulting Agreement dated October 28, 1996 between ATI and The Sage Group.
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10.49(5) Letter amendment dated October 7, 1998 to Consulting Agreement dated October 28, 1996 between ATI and The Sage Group.

10.50(8) Form of Stock Purchase Agreement.

10.51(11) Notice of Grant of Stock Option.

- 10.52+ Sublicense Agreement between Discovery Laboratories, Inc. and Laboratories del Dr. Esteve S.A. dated October 26, 1999.
- 10.53+ Supply Agreement between Discovery Laboratories, Inc. and Laboratories del Dr. Esteve S.A. dated October 26, 1999.
- 10.54Securities Purchase Agreement between Discovery Laboratories, Inc. and Laboratorios P.E.N., S.A.<br/>dated October 26, 1999.
- 10.55+ Research Funding and Option Agreement dated March 1, 2000 between Discovery and Scripps.
- 16.1(7) Letter dated January 28, 1998 from Ernst & Young LLP to the Securities and Exchange Commission
- 21.1(3) Subsidiaries of Discovery.
- 23.1 Consent of Richard A. Eisner & Company, LLP
- 27.1 Financial Data Schedule.

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(1) Incorporated by reference to Discovery's Annual Report on Form 10-K-SB for the year ending December 31, 1995.

(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 Annual Report on Form 10-KSB for the year ending December 31, 1997.

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

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

(6) Incorporated by reference to Discovery's Proxy Statement on Schedule 14A dated May 6, 1998.

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

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

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

(10) Incorporated by reference to Discovery's Current Report on Form 8-K filed August 9, 1999.

- (11) Incorporated by reference to Discovery's Quarterly Report on Form 10-Q for the quarter ending September 30, 1999.
- (12) Incorporated by Reference to Discovery's Current Report on Form 8-K filed March 29, 2000.
- + Confidential treatment requested as to certain portions of these exhibits. Such portions have been redacted and filed separately with the Commission.

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

Contents

PageConsolidated Financial StatementsIndependent auditors' reportBalance sheet as of December 31, 1999Balance sheet as of December 31, 1999Statements of operations for the years ended December 31, 1999 and 1998 and the<br/>period from May 18, 1993 (inception) through December 31, 1999Statements of changes in stockholders' equity for the period from May 18, 1993 (inception)<br/>through December 31, 1999 and 1998 and the<br/>period from May 18, 1993 (inception) through December 31, 1999 and 1998 and the<br/>period from May 18, 1993 (inception) through December 31, 1999Statements of cash flows for the years ended December 31, 1999 and 1998 and the<br/>period from May 18, 1993 (inception) through December 31, 1999Kotes to financial statements

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

We have audited the accompanying consolidated balance sheet of Discovery Laboratories, Inc. and subsidiary (a development stage company) as of December 31, 1999, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 1999, and the period from May 18, 1993 (inception) through 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 audits.

We conducted our audits in accordance with generally accepted auditing standards. 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 provide a reasonable basis for our opinion.

In our opinion, the financial statements enumerated above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc. and subsidiary as of December 31, 1999 and the consolidated results of their operations and their consolidated cash flows for each of the years in the two-year period ended December 31, 1999, and the period from May 18, 1993 (inception) through December 31, 1999, in conformity with generally accepted accounting principles.

Richard A. Eisner & Company, LLP

New York, New York February 25, 2000

With respect to the last paragraph of Note A March 23, 2000

With respect to note F[3] March 1, 2000

With respect to the second paragraph of Note G March 14, 2000

With respect to the last paragraph of Note G March 3, 2000

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

Consolidated Balance Sheet December 31, 1999

ASSETS Current assets:

Cash and cash equivalents Inventory Prepaid expenses and other current assets	\$
Total current assets Property and equipment, net of depreciation Security deposits	4,188,000 426,000 18,000
	\$ 4,632,000
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable and accrued expenses Deferred revenue Capitalized lease - current	\$ 425,000 1,036,000 15,000
Total current liabilities	1,476,000
Capitalized lease - noncurrent	48,000
<pre>Commitments (Notes F and I) Stockholders' equity:     Preferred stock, \$.001 par value; 5,000,000 shares authorized:         Series B convertible; 1,530,756 shares issued and outstanding (liquidation preference         \$20,665,000)     Series C redeemable convertible; 2,039 shares issued and outstanding (liquidation         preference \$2,481,000) Common stock, \$.001 par value; 35,000,000 authorized; 9,689,240 shares issued     Treasury stock (2,000 shares of common stock at cost)     Additional paid-in capital     Unearned portion of compensatory stock options     Deficit accumulated during the development stage</pre>	2,000 2,481,000 10,000 (5,000) 33,749,000 (37,000) (33,092,000) 
	\$        4,632,000 ========

See notes to financial statements

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

Consolidated Statements of Operations

	Year Ended December 31, 1999 1998		2000
Interest income License fees Research grants	0.0	,000 \$ 394,000 ,000 ,000 27,000	<u> </u>
	334,	,000 421,000	1,673,000
Expenses: Write-off of acquired in-process research and development			
and supplies Research and development General and administrative	2,421,	,000 2,788,000	12,869,000           7,755,000
Interest		,000	
Total expenses	5,292,	,000 16,090,000	34,145,000
	(4,958,	,000) (15,669,000	0) (32,472,000)
Minority interest in net loss of subsidiary		24,000	
Net loss	(4,958,	,000) (15,645,000	0) (32,446,000)
Other comprehensive income: Unrealized gain on marketable securities available for sale		19,000	)
Total comprehensive loss	\$    (4,958, 	,000) \$ (15,626,000	0) \$ (32,446,000) == ================================
Net loss per share - basic and diluted (Note C[9])	\$(0.66) ======	\$(4.02) =====	
Weighted average number of common shares outstanding	7,545,000		

See notes to financial statements

# Consolidated Statements of Changes in Stockholders' Equity May 18, 1993 (Inception) Through December 31, 1999

						Prefer	red Stock	
	Common	Stock		y Stock	Serie			eries C
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of common shares, May 1993 Net loss	440,720							
Expenses paid on behalf of the Company								
Balance - December 31, 1993 Net loss	440,720	1,000						
Balance - December 31, 1994 Issuance of common shares, February 1995 Net loss Payment on stock subscriptions	440,720 143,016	1,000						
Expenses paid on behalf of the Company								
Balance - December 31, 1995 Issuance of common shares, March 1996 Issuance of private placement units August,	583,736 1,070,175	1,000 1,000						
October and November 1996 Issuance of common shares for cash and	856,138	1,000			2,200,256	\$ 2,000		
compensation, September 1996 Exercise of stock options, July and	82,502							
October 1996 Net loss	19,458							
Balance - December 31, 1996	2,612,009	3,000			2,200,256			
Private placement expenses	2,012,000	0,000			2,200,200	2,000		
Issuance of common shares pursuant to Ansan Merger Exercise of stock options, July, August and	546,433							
October 1997 Accumulated dividends on preferred stock	17,513							
Net loss								
Balance - December 31, 1997	3,175,955	3,000			2,200,256	2,000		
Issuance of common shares pursuant to ATI Merger Fair value of common stock issuable on exercise of ATI options Series C preferred stock issued	1,033,500	1,000						
pursuant to ATI Merger							2,039	\$ 2,039,000
Accrued dividends payable on Series C preferred stock at time of ATI Merger								238,000
Common stock issued in settlement of Series C preferred stock dividends	49,846							(204,000)
Exercise of stock options, July and December 1998 Series B preferred stock converted	131,676 685,103	1,000			(253,375)			
(carried forward)	5,076,080	5,000			1,946,881	2,000	2,039	2,073,000
						2,000		

	Stock Subscriptions Receivable	Additional Paid-in Capital	Unearned Portion of Compensatory Stock Options	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage
Issuance of common shares, May 1993 Net loss Expenses paid on behalf of the Company	\$ (2,000) 1,000	\$ 1,000			\$ (1,000)
Balance - December 31, 1993 Net loss	(1,000)	1,000			(1,000)

Balance - December 31, 1994 Issuance of common shares, February 1995	(1,000) (1,000)	1,000 1,000	(1,000)
Net loss Payment on stock subscriptions Expenses paid on behalf of the Company	2,000	18,000	(17,000)
Balance - December 31, 1995 Issuance of common shares, March 1996 Issuance of private placement units August,	0	20,000 5,000	(18,000)
October and November 1996 Issuance of common shares for cash and		18,933,000	
compensation, September 1996		42,000	
Exercise of stock options, July and October 1996 Net loss		7,000	(2,661,000)
Balance - December 31, 1996	Θ	19,007,000	(2,679,000)
Private placement expenses		(11,000)	
Issuance of common shares pursuant to Ansan Merger Exercise of stock options, July, August and		2,459,000	
August and October 1997 Accumulated dividends on preferred		9,000	(238,000)
stock Net loss			
Net 1055			(9,164,000)
Balance - December 31, 1997	0	21,464,000	(12,081,000)
Issuance of common shares pursuant to ATI Merger Fair value of common stock issuable on		5,037,000	
exercise of ATI options Series C preferred stock issued pursuant to ATI Merger		2,966,000	
Accrued dividends payable on Series C preferred stock at time of ATI			
Merger Common stock issued in settlement of Series C preferred stock dividends		204,000	
Exercise of stock options, July and December 1998		30,000	
Series B preferred stock converted		(1,000)	
(carried forward)	0	29,700,000	(12,081,000)

	Total
Issuance of common shares, May 1993 Net loss Expenses paid on behalf of the Company	\$ 0 (1,000) 1,000
Balance - December 31, 1993 Net loss	0 0
Balance - December 31, 1994 Issuance of common shares, February 1995	0 0
Net loss Payment on stock subscriptions Expenses paid on behalf of the Company	(17,000) 2,000 18,000
Balance - December 31, 1995 Issuance of common shares, March 1996 Issuance of private placement units August,	3,000 6,000
October and November 1996 Issuance of common shares for cash and compensation, September 1996 Exercise of stock options, July and	18,936,000 42,000
October 1996 Net loss	7,000 (2,661,000)
Balance - December 31, 1996	16,333,000
Private placement expenses Issuance of common shares pursuant to	(11,000)
Ansan Merger Exercise of stock options, July, August and	2,459,000
October 1997 Accumulated dividends on preferred	9,000 (238,000)
stock Net loss	(9,164,000)
Balance - December 31, 1997	9,388,000

Issuance of common shares pursuant to ATI Merger Fair value of common stock issuable on	5,038,000
exercise of ATI options Series C preferred stock issued	2,966,000
pursuant to ATI Merger	2,039,000
Accrued dividends payable on Series C preferred stock at time of ATI Merger	238,000
Common stock issued in settlement of Series C preferred stock dividends Exercise of stock options, July and	0
December 1998 Series B preferred stock converted	30,000 0
(carried forward)	19,699,000

See notes to financial statements

Consolidated Statements of Changes in Stockholders' Equity May 18, 1993 (Inception) Through December 31, 1999 (continued)

						Prefer	red Stock	
	Common Stock		Treasu	iry Stock	Seri	es B	Ser	ies C
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
(brought forward)	5,076,080	\$ 5,000			1,946,881	\$ 2,000	2,039	\$ 2,073,000
Noncash exercise of private placement warrants Dividends payable on Series C preferred stock Treasury stock acquired Treasury stock issued in payment for	8,372	(31,750)	\$ (90,0	100 )				204,000
services Unrealized gain on marketable securities available for sale Fair value of options granted Amortization of unearned portion of compensatory stock options Net loss		16,150	51,6	100				
Balance - December 31, 1998	5,084,452	5,000	(15,600)		1,946,881		2,039	2,277,000
Common stock and warrants in a private placement offering in March and April 1999	826,447	1,000		(39,000)		2,000		
Issuance of private placement units in July and August 1999 (net of offering costs) Exercise of stock options Common stock issued in connection with	2,024,792 119,732	2,000						
Series B preferred stock converted Treasury stock acquired	317,164 1,295,485	1,000 1,000	(2,000)	(5,000)	(416,125)			
Treasury stock issued in payment for services Common stock issued in payment for services Amortization of unearned portion of compensatory stock options	21,168		15,600	39,000				
Compensatory stock options granted Dividend payable on Series C preferred stock Unrealized loss on marketable securities available for sale Net loss								204,000
Balance - December 31, 1999	9,689,240 ======	\$10,000 ======	(2,000)	, ,	1,530,756 ======	\$ 2,000 ======	2,039 ======	\$ 2,481,000 ======
	Stock Subscription Receivable	Capit	F Lonal Co in Cal	Unearned ortion of mpensatory Stock Options	Accumula Other Comprehen Income	I sive De	Deficit ccumulated During the evelopment Stage	
(brought forward)	\$ 0	\$ 29,70					12,081,000	)
Noncash exercise of private placement warrants Dividends payable on Series C preferred stock Treasury stock acquired Treasury stock issued in payment for							(204,000	)
services Unrealized gain on marketable securities available for sale Fair value of options granted Amortization of unearned portion of compensatory stock options		14	12,000 \$	(142,000) 18,000	\$19,00	0		
Net loss						(1	15,645,000	)
Balance - December 31, 1998	Θ	29,84	12,000	(124,000)	19,00	0 (2	27,930,000	)
Common stock and warrants in a private placement offering in March and April 1999 Issuance of private placement units in July and		99	99,000					

August 1999 (net of offering costs) Exercise of stock options Common stock issued in connection with sublicense agreement		2,231,000 17,000 563,000			
Series B preferred stock converted Treasury stock acquired		(1,000)			
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 Compensatory stock options granted		37,000	124,000 (37,000)		
Dividend payable on Series C preferred stock		- <b>,</b>	(- , ,		(204,000)
Unrealized loss on marketable securities available for sale				(19,000)	
Net loss					(4,958,000)
Balance - December 31, 1999	\$0 ======	\$ 33,749,000 ======	\$ (37,000) =======	\$0 ======	\$(33,092,000) ======

	Total
(brought forward)	\$ 19,699,000
Noncash exercise of private placement warrants	Θ
Dividends payable on Series C preferred stock	Θ
Treasury stock acquired Treasury stock issued in payment for services	(90,000) 51,000
Unrealized gain on marketable securities available for sale Fair value of options granted Amortization of unearned portion of	19,000 0
compensatory stock options Net loss	18,000 (15,645,000)
Balance - December 31, 1998	4,052,000
Common stock and warrants in a private placement offering in March and April 1999 Issuance of private placement units in	1,000,000
July and August 1999 (net of offering costs) Exercise of stock options Common stock issued in connection with	2,233,000 17,000
sublicense agreement Series B preferred stock converted	564,000 0
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 Compensatory stock options granted Dividend payable on Series C preferred stock	124,000 0 0
Unrealized loss on marketable securities available for sale Net loss	(19,000) (4,958,000)
Balance - December 31, 1999	\$ 3,108,000 ======

See notes to financial statements

Consolidated Statements of Cash Flows

	-	Year Ended December 31,			(]	/ 18, 1993 Inception) Through Ecember 31
		1999		1998		1999
Cash flows from operating activities:						
cash ribws from operating activities.						
Net loss Adjustments to reconcile net loss to net cash used in operating activities:	\$	(4,958,000)	\$	(15,645,000)	\$	(32,401,000)
Write-off of acquired in-process research and development and supplies Write-off of licenses				8,220,000		13,508,000 683,000
Depreciation and amortization		87,000		65,000		216 000
Compensatory stock options		124,000		18,000		142,000
Expenses paid using treasury stock and common stock Changes in:		27,000		51,000		78,000
Prepaid expenses and other current assets		137,000		(13,000)		(35,000)
Accounts payable and accrued expenses Deferred revenue		(590,000) 1,036,000		523,000		247,000 1,036,000
Other assets		1,030,000		12,000		(18,000)
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		(4,137,000)		(6,769,000)		(16,645,000)
Cash flave from investing activities.						
Cash flows from investing activities: Purchase of property and equipment Proceeds from disposal of property and equipment				(235,000) 25,000		25,000
Acquisition of licenses Purchase of marketable securities		(1 000 000)		(142 000)		(711,000) (21,745,000)
Proceeds from sale or maturity of marketable securities		3,525,000		2,574,000		22,150,000
Net cash payments on merger				(142,000) 2,574,000 (216,000)		(1,670,000)
Net cash provided by (used in) investing activities		2,411,000		2,006,000		(2,497,000)
Cash flows from financing activities: Proceeds from issuance of securities, net of expenses		3,797,000		(90,000)		22,722,000
Purchase of treasury stock Principal payments under capital lease obligation		(5,000) (10,000)		(90,000)		(95,000) (10,000)
Collections on stock subscriptions and proceeds on exercise of stock		47.000		~~~~~		70,000
options		17,000		30,000		72,000
Net cash provided by (used in) financing activities		3,799,000		(60,000)		22,689,000
Net increase (decrease) in cash and cash equivalents		2,073,000		(4,823,000)		3,547,000
Cash and cash equivalents - beginning of period		1,474,000		6,297,000		
Cash and cash equivalents - end of period	\$	3,547,000	\$	1,474,000	\$	3,547,000
	===		===			
Supplementary disclosure of cash flows information:						
Interest paid	\$	2,000			\$	13,000
Noncash transactions:	۴	204 000	¢	204 000	¢	646 000
Accrued dividends on Series C preferred stock Series C preferred stock dividends paid using common stock	\$	204,000	\$ \$	204,000 204,000		646,000 204,000
Preferred stock issued for inventory			Ψ		գ \$	575,000
Equipment acquired through capitalized lease	\$	73,000			\$	73,000
Common stock and treasury stock issued in payment for services	\$	73,000			\$	73,000

See notes to financial statements

Notes to Financial Statements December 31, 1999

## NOTE A - 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 Company's common stock (the "Old ATI Exchange Ratio"), each share of Old ATI's Series B preferred stock and all outstanding options to purchase Old ATI common stock were assumed by the Company and are exercisable for shares of the Company's common stock on the basis of the Old ATI Exchange Ratio. Further, 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 Company's common stock subject to the achievement of certain corporate milestones. At December 31, 1999, the milestones had not been achieved and thereby the options for the 335,000 shares remain unvested. As these options vest, the Company will incur a charge at each vesting date for the exercise price of the options. In addition, pursuant to a management agreement entered into between the Company and Old ATI at the time the merger agreement were granted options to purchase 126,500 shares of fue Company's common stock.

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

The historical consolidated financial position of the Company includes the accounts of Old 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	Ψ	3,030,000
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.

Notes to Financial Statements December 31, 1999

### NOTE A - THE COMPANY AND BASIS OF PRESENTATION (CONTINUED)

The following pro forma unaudited statement of operations gives effect to the Old ATI Merger as if it had occurred on January 1, 1998. A nonrecurring charge of \$8,220,000 for in-process research and development has not been considered in the pro forma result.

	December 31, 1998
Net loss	\$ (7,431,000)
Net loss per common share - basic and diluted	\$(1.70) ======
Weighted average number of common shares outstanding	4,370,000 =======

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The accompanying 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. All intercompany balances and transactions have been eliminated.

As reflected in the accompanying 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. On March 23, 2000, the Company received \$17,500,000 net proceeds from the sale of 37.74 units in a private placement. Each unit consists of 76,923 shares of common stock and Class E warrants to purchase an additional 15,385 shares of common stock at \$7.38 per share. In connection with this private placement, the placement agent, Paramount Capital, Inc. ("Paramount") received fees of \$1,321,000 and the Company agreed to issue to Paramount warrants to purchase 348,341 shares of common stock at \$8.113 per share. 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 B - RETROACTIVE ADJUSTMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

In October 1996, in conjunction with a licensing agreement with Johnson & Johnson, Inc.'s ("J&J") wholly owned subsidiary, Ortho Pharmaceuticals, Inc. (see Note F[1]), J&J contributed manufacturing equipment and raw material inventory in exchange for the Company's non-voting Series B preferred stock which had a liquidation preference of \$2,039,000. The equipment and inventory was charged to operations as acquired in-process research and development and supplies during the year ended December 31, 1996. However, certain of this raw material inventory, valued at approximately \$575,000, which was then located at the vendor, had an alternative future use. Such inventory could have been sold to other users and was in excess of the estimated quantity required for the Company's research and development purposes. The Company had arranged with the vendor to defer delivery of the product. Previously issued financial statements have been restated to reflect capitalizing such inventory effective December 31, 1996 and a corresponding reduction in deficit accumulated during the development stage.

Notes to Financial Statements December 31, 1999

### NOTE C - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

[1] Cash and cash equivalents:

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

[2] Marketable securities:

The investments are classified as available for sale, and are comprised of United States government obligations and shares in a mutual fund which invests in income producing securities. Investments are carried at fair or market value. Any appreciation/depreciation on these investments is recorded as a separate component of stockholders' equity until realized.

[3] 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 (a) term of the lease or (b) useful life of the improvements.

[4] Inventory:

Inventory is stated at the lower of cost or market and consists of raw materials.

[5] Licenses:

Through March 1997, licenses were capitalized and were being amortized on a straight-line basis over their respective terms of 15 to 17 years. Subsequently, the Company determined that since they will not pursue any alternative uses for the licenses, that all license costs would be written off as research and development costs.

[6] Research and development:

Research and development costs are charged to operations as incurred. Certain of the Company's research and development efforts are funded by a grant awarded to the Company by the Food and Drug Administration. Draw downs of the grant are included in research grant revenue. In 1999 and 1998, the amounts funded were approximately \$71,000 and \$27,000, respectively.

[7] Use of estimates:

The preparation of financial statements in conformity with generally accepted accounting principles 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.

[8] 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.

Notes to Financial Statements December 31, 1999

#### NOTE C - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### [9] 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. See Note H to the financial statements for further information.

[10] Net loss per share:

Net loss per 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 and common shares issuable for little or no cash consideration. Potential common shares not included in the calculation of net loss per share for the years ended December 31, 1999 and 1998, as the effect would be anti-dilutive, are as follows (Notes G and H):

Number of Potential Common Shares		
1999	1998	
4,766,000	6,061,000	
892,000	932,000	
405,000		
595,000	727,000	
569,000		
2,025,000		
	Common S 1999 4,766,000 892,000 405,000 595,000 569,000	

#### [11] Comprehensive income:

During 1998, the Company adopted Statement of Financial Accounting Standards No. 130 "Reporting Comprehensive Income", which establishes standards for reporting and display of comprehensive income and its components. Accordingly, the Company revised the format of its consolidated statements of operations to include total comprehensive income. The adoption of this statement had no effect on the Company's results of operations.

[12] Reclassifications:

Certain prior year amounts have been  $% \left( {{\mathcal{T}}_{{\rm{s}}}} \right)$  resentation.

Notes to Financial Statements December 31, 1999

#### NOTE D - PROPERTY AND EQUIPMENT

At December 31, 1999 property and equipment was comprised of the following:

Leasehold improvements Furniture Equipment	\$ 92,000 53,000 474,000
Less accumulated depreciation	619,000 193,000
	\$ 426,000 ======

Equipment includes property under a capitalized lease of \$73,000 and accumulated depreciation of \$3,000.

During 1998 and 1999, the Company paid an aggregate \$107,000 to the spouse of an officer for the acquisition of leasehold improvements.

#### NOTE E - INCOME TAXES

At December 31, 1999, the Company has available for federal income tax purposes net operating loss carryforwards of approximately \$28,000,000 expiring through 2019, that may be used to offset future taxable income. As a result of the ownership change pursuant to the Ansan Merger, use of Ansan's portion of the net operating loss carryforward of approximately \$9,500,000 at November 1997, is limited in accordance with Section 382 of the Internal Revenue Code. Pursuant to Section 382 of the Internal Revenue Code, the utilization of these carryforwards may become further limited based on certain ownership changes that may have occurred or may occur. The Company has research and development credit carryforwards of approximately \$671,000 which expire in 2019. Ansan's portion of these credits of approximately \$179,000 are also subject to a Section 383 limitation. There will be an annual amount available to offset future taxable income.

The principal difference between the deficit accumulated during the development stage for financial reporting purposes and the net operating loss carryforward for tax purposes is primarily due to the write-off of the acquired in-process research and development and supplies and certain research and development expenses which were not deducted for tax purposes. The Company has provided a valuation reserve against the full amount of the deferred tax asset of \$11,267,000 since realization of this benefit is not certain. The components of the deferred tax assets are net operating loss carryforwards of approximately \$10,246,000, research and development expenses of approximately \$350,000 and research and development credits of approximately \$671,000. The valuation reserve increased by approximately \$1,989,000 and \$1,924,000 for the years ended December 31, 1999 and 1998, respectively. The difference between the statutory federal income tax rate of 34% and the Company's effective tax rate of 0% is due to the increase in the valuation allowance.

NOTE F - LICENSE, SUBLICENSE AND RESEARCH FUNDING AGREEMENTS

[1] Concurrent with the Company's original investment in Old ATI, Johnson & Johnson, Inc. ("J&J "), Ortho Pharmaceuticals, Inc., a wholly owned subsidiary of 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

Notes to Financial Statements December 31, 1999

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

[1] (continued)

\$2,039,000 (the value of the preferred shares issued to J&J) and were charged to expense in full (see Note B). 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.

- [2] 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, not including 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:
  - (a) the Company was paid a nonrefundable license fee of \$375,000,
  - (b) the Company will be the exclusive supplier (except in certain events) of Surfaxin(R),
  - (c) Laboratorios Del Dr. Esteve S.A. agreed to conduct certain clinical trials in the above countries, however, costs as defined in the agreement, incurred on such clinical trials above an agreed upon amount, will be borne by the Company,
  - (d) Laboratorios Del Dr. Esteve S.A. paid \$375,000 in advance for Surfaxin(R)supplied for clinical trials described in (c) above,
  - (e) an affiliate of Laboratorios Del Dr. Esteve S.A. invested \$850,000 in the Company in exchange for common stock issued at a 50% premium over the ten day average closing price preceding the closing of this transaction. The Company has accounted for the premium as additional license fees amounting to \$286,000, and
  - (f) an option to an exclusive license for Italy for additional specified payments.

The Company has accounted for the license fees (including the premium paid for common stock) and advance payment for inventory as deferred revenue. Such deferred revenue will be recognized as revenue as it is earned.

- [3] 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. On March 1, 2000 the Company and Scripps entered into an agreement to extend the term for one year and provide for additional one year renewal options. Pursuant to this agreement, the Company will pay \$248,000 per year Scripps to fund Scripps' research efforts. The agreement provides for Scripps to 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 \$115,000 and \$460,000 in 1999 and 1998, respectively.
- [4] In 1996, the Company entered into a license agreement with the Charlotte-Mecklenburg Hospital Authority for the use of the active compound in SuperVent, a therapy which the Company is clinically testing. The Company paid a license issue fee of \$86,000 and has agreed to pay royalties on future sales and to pay future patent-related costs. The license expires upon expiration of the underlying patents.

Notes to Financial Statements December 31, 1999

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

[5] In 1996, the Company entered into a license agreement with the Wisconsin Alumni Research Foundation ("WARF") for the use of the patented compound DSC 103 (formerly ST-630) in the treatment of post-menopausal osteoporosis. The Company paid WARF an option fee of \$25,000 in June 1996 and a license issue fee of \$400,000 in October 1996 and is obligated to make future milestones payments aggregating \$3,095,000 and pay royalties on future sales. The license expires upon expiration of the underlying patents. The Company is currently seeking a development partner with respect to this compound.

In June 1999, the Company granted YuYu Industrial Company, Ltd. ("YuYu Industrial") of South Korea an exclusive license to use the DSC 103 and a nonexclusive license to manufacture the compound and ancillary compounds in South Korea. Under the agreement, YuYu Industrial paid the Company an up-front payment of \$68,000 including research and development fees, net of \$12,000 withheld for South Korean taxes, and agreed to make a subsequent milestone payment of \$50,000. YuYu Industrial also agreed to purchase specified minimum quantities of the drug compound for the first five years following the receipt of approval for marketing licensed products within South Korea. The Company is entitled to receive royalty payments for all product sales under the agreement.

#### NOTE G - STOCKHOLDERS' EQUITY

#### 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 and 19,458 shares of common stock of the Company). Preferred stockholders have 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 is 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 is in excess of 1,100,000 Series B shares outstanding.

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. Pursuant to the notice, all of the Series B shares were converted into 4,766,000 shares of common stock effective March 14, 2000.

The placement agent for the offering received approximately \$2,860,000 in cash plus warrants which pursuant to the merger give 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 are 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.

#### 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 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.

Notes to Financial Statements December 31, 1999

#### NOTE G - STOCKHOLDERS' EQUITY (CONTINUED)

1999 private placements: (continued)

In July 1999, the Company raised approximately \$2,233,000 (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 and 413,223 Class D warrants to purchase shares of common stock at an exercise price of \$1.33 per share. An aggregate of 2,024,792 shares of common stock and 2,024,792 Class D warrants were issued. The placement agent, Paramount Capital, Inc., received fees at 7% of the gross proceeds, reimbursement of certain expenses and an option to purchase 0.49 share of a unit at an exercise price of \$270,000. The Class D warrants are exercisable through August 2005.

### 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, one redeemable Class A warrant, and one Class B warrant. Each Class A warrant entitles the holder to purchase one share of common stock and one Class B warrant at an exercise price of \$19.50 per share. Each Class B warrant entitles the holder to purchase one share of common stock an exercise price of \$26.25 per share.

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 shares (including 115,491 shares held by the Company pending cancellation pursuant to the Ansan Merger (Note A)) and options to purchase 12,086 shares of common stock into escrow (the "Escrow Shares" and "Escrow Options", respectively). The Escrow Shares and Escrow Options are not transferable or assignable; however, the Escrow Shares may be voted. Holders of Escrow Options may exercise their options prior to their release from escrow; however, the shares issuable upon any such exercise will continue to be held in escrow. The Escrow Shares and Escrow Options will be released from escrow if, and only if, certain earnings or market price criteria have been met. If the conditions are not met by March 31, 2000, the Escrow Shares and Escrow Options will be cancelled and contributed to the Company's capital.

The release of Escrow Shares and Escrow Options held by employees, officers, directors, consultants and their relatives will be deemed compensatory. Accordingly, the Company will recognize as compensation expense, during the period in which the earnings or market price targets are met, a one-time charge to reflect the then fair market value of the shares released from escrow. Such charges could substantially reduce the Company's net income or increase the net loss. The amount of compensation expense recognized by the Company will not affect the total stockholders' equity.

#### Common shares reserved for issuance:

As of December 31, 1999, the Company has reserved shares of common stock for issuance upon conversion of preferred stock and exercise of options as follows:

<ul> <li>Series B preferred stock</li> <li>Series C preferred stock</li> <li>Stock option plan</li> </ul>	4,766,000 892,000 2,459,000
<pre>(iv) Placement agent warrants:</pre>	
Conversion of preferred stock	685,000
Common stock	76,000
Option	405,000
(v) Class A warrants	736,000
(vi) Class B warrants	1,234,000
(vii) Class C warrants	569,000
(viii) Class D warrants	2,025,000
(ix) Underwriter's option	173,000

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Notes to Financial Statements December 31, 1999

## NOTE G - STOCKHOLDERS' EQUITY (CONTINUED)

Treasury stock/common stock issued for services:

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

During 1999 and 1998, the Company acquired 2,000 and 31,750 shares of common stock for approximately \$5,000 and \$90,000, respectively. In 1998, the Company issued 16,150 of such shares (market value on date of issue \$51,000) in settlement of \$51,000 of services rendered and in 1999 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 is 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 are redeemable at liquidation value upon the occurrence of certain events. The liquidation value is payable at the option of the Company in either cash or shares of common stock. Series C stockholders are entitled to dividends of 10% per annum to be paid only upon liquidation or redemption.

On March 3, 2000,  $\ J\&J$  elected to convert their Series C preferred stock shares into 398,186 shares of common stock.

#### NOTE H - STOCK OPTIONS

Ansan's 1993 Stock Option Plan which was 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 options, nonstatutory stock options and options granted to 10% stockholders of the Company or 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. 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 Company's common stock (Note A).

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 Company's common stock 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 Company's common stock 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. The maximum number of shares of common stock initially reserved for issuance over the term of the plan shall not exceed 2,200,959.

Notes to Financial Statements December 31, 1999

# NOTE H - STOCK OPTIONS (CONTINUED)

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, 1999 and 1998 would have been approximately \$5,622,000 or \$0.74 per share and \$16,371,000 or \$4.20 per share, respectively. The weighted average fair value of the options granted are estimated at \$2.46 and \$2.63 per share, respectively, for the years ended December 31, 1999 and 1998, on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions: dividend yield 0%, volatility of 91% and 40%, risk-free interest rate of 4.86% for 1999 and 5.53% for 1998, and expected life of ten years.

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

	Year Ended December 31,							
	1999			1998				
	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	1,886,062	\$2.23	8.73 years	\$0.18 - \$4.50	371,993	\$1.67	
Options granted Options exercised Options forfeited Options expired ATI options	0.81 - 4.44 0.0026 - 0.51 0.08 - 4.44 4.19	1,108,893 (119,768) (297,888) (118,459)	2.18 0.11 3.56 4.19		0.19 - 4.87 0.0026 - 2.66	1,027,400 (131,676)	4.18 0.23	
assumed					0.0026 - 0.32	618,345	0.43	
Options outstanding at end of year	\$0.0026 - \$4.87	2,458,840 ======	2.42	8.50 years	\$0.0026 - \$4.87	1,886,062 ======	2.23	8.73 years
Options exercisable at end of year	\$0.0026-	1,235,604 ======	2.27	7.93 years	\$0.0026 - \$4.87	1,512,062 ======	2.28	8.76 years
	\$4.87							

Included in the options outstanding at December 31, 1999 are options to purchase 912,893 shares of the Company's common stock (at exercise prices ranging from \$1.38 to \$4.44) granted during 1998 and 1999 which vest upon the Company achieving specified milestones. Through December 31, 1999, the milestones were not reached and the options remain unvested. On vesting, the Company will incur a charge amounting to the excess, if any, of the market price over the exercise price.

# NOTE I - COMMITMENTS

[1] At December 31, 1999, the Company had employment agreements with six officers providing for an aggregate annual salary of \$853,000. The agreements expire on various dates through June 2002 and provide for the issuance of annual and milestone bonuses and the granting of options on the Company's attaining certain milestones.

Notes to Financial Statements December 31, 1999

# NOTE I - COMMITMENTS (CONTINUED)

[2] 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. Future minimum annual rents for this lease is as follows:

2000	\$ 148,000
2001	151,000
2002	157,000
2003	162,000
2004	167,000
2005	114,000

\$ 899,000 ======

The Company also leases additional office space pursuant to a three year lease entered into in May 1997. Such office space is currently being subleased at substantially the same terms and for the remaining period of the Company's commitment.

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

2000 2001 2002 2003	\$ 20,000 20,000 20,000 12,000
Less interest included	72,000 9,000
	\$ 63,000 =======

Total net rent expense for the years ended December 31, 1999 and 1998 was approximately 144,000 and 175,000, respectively.

Exhibit 3.2

STATE OF DELAWARE SECRETARY OF STATE DIVISION OF CORPORATIONS FILED 04:00 PM 07/21/1999 991300911 - 2315242

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 "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

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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

STATE OF DELAWARE CERTIFICATE OF OWNERSHIP

#### SUBSIDIARY INTO PARENT Section 253

#### CERTIFICATE OF OWNERSHIP MERGING

# ATI ACQUISITION CORP.

INTO

#### DISCOVERY LABORATORIES, INC.

# Pursuant to Section 253 of the General Corporation Law of the State of Delaware

Discovery Laboratories, Inc., a corporation originally incorporated under the name of Ansan, Inc. on the 6th day of November, 1992 and subsequently changed to Discovery Laboratories, Inc. on the 25th day of November, 1997 (the "Corporation"), pursuant to the provisions of the General Corporation Law of the State of Delaware:

DOES HEREBY CERTIFY that the Corporation owns 100% of the outstanding shares of each class of stock of ATI Acquisition Corp., a corporation originally incorporated under the name of Acute Therapeutics, Inc. on the 11th day of September, 1996, and amended its name to ATI Acquisition Corp. on the 16th day of June, 1998, pursuant to the provisions of the General Corporation Law of the State of Delaware ("ATI") and that the Corporation, by a resolution of its Board of Directors duly adopted at a meeting held on the 16th day of February, 1999, determined to and did merge ATI into itself, which resolution is as follows:

WHEREAS the Corporation lawfully owns 100% of the outstanding shares of each class of stock of ATI, a corporation organized and existing under the laws of the State of Delaware; and

WHEREAS in the judgment of this Board of Directors it is desirable for business reasons to merge ATI into the Corporation and to be possessed of all the estate, property, rights, and privileges of ATI;

NOW THEREFORE, upon motion duly made, seconded and carried, it was unanimously

RESOLVED, that such merger be effected by transferring all the assets and related liabilities of ATI into the Corporation; and

FURTHER RESOLVED, that an authorized officer of the Corporation be and is hereby directed to make and execute a certificate of ownership setting forth a copy of resolution to so merge and assume ATI's liabilities and obligations, the date of adoption thereof, and to file the same in the office of the Secretary of the State of Delaware; and

FURTHER RESOLVED, that the officers of the Corporation be, and they hereby are, authorized, empowered, and directed to do and perform all such further acts and things, to execute and deliver in the name of the Corporation, and where necessary or appropriate, to file with the appropriate governmental authorities, all such further certificates, instruments, or other documents, as in their judgment shall be necessary or advisable in order to effectuate such merger, the intent and purposes of the foregoing resolutions, and any or all of the transactions contemplated therein.

IN WITNESS WHEREOF, Discovery Laboratories, Inc., for the purpose of merging ATI into Discovery Laboratories, Inc. under the laws of the State of Delaware, has caused this Certificate of Ownership to be executed in its corporate name this \_\_\_\_ day of October, A.D. 1999.

By: /s/Robert J. Capetola Authorized Officer Name: Robert J. Capetola Title:

### [FORM]

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NEITHER SUCH SECURITIES NOR THE SECURITIES ISSUABLE UPON EXERCISE HEREOF NOR THE SECURITIES ISSUABLE UPON EXERCISE THEREOF HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED OR ANY STATE SECURITIES LAW. SUCH SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR UNLESS SUCH SALE OR TRANSFER IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

DISCOVERY LABORATORIES, INC.

Unit Purchase Option for the Purchase of Units Consisting of Shares of Common Stock and Warrants

No.\_\_\_\_ Option Units

FOR VALUE RECEIVED, Discovery Laboratories, Inc., a Delaware corporation (the "Company"), hereby certifies that \_\_\_\_\_\_\_\_, or his/her assigns, is entitled to purchase from the Company, at any time or from time to time commencing on December 28, 1999 and prior to 5:00 P.M., New York City time, on December 28, 2004, up to \_\_\_\_\_\_Units, each Unit consisting of (a) one share of Common Stock of the Company, par value \$.001 per share, (the "Common Stock"), and (b) one warrant (the "Class D Warrants") exercisable at any time prior to July 27, 2004, for the purchase of one share of Common Stock at a per share exercise price of \$1.33, for an aggregate Unit purchase price of \$\_\_\_\_\_ (computed on the basis of \$1.331 per Unit). (Hereinafter, (i) said Units are referred to as the "Units", (ii) said Class D Warrants are referred to as the "Warrants", (iii) the Common Stock included in the Units and purchasable upon exercise of the Warrants, is referred to as the "Common Stock", (iv) the shares of any capital stock purchasable hereunder or under any other Option in lieu of Common Stock) are referred to as the "Common Shares", (v) the shares of Common Stock purchasable upon exercise of the Warrants hereunder or under any other Option referred to as the "Warrant Shares", (vi) the shares of Common Stock purchasable upon exercise of the Warrants hereunder or under any other Option in lieu of Common Stock) are referred to as the "Sommon Shares", (vi) the shares of Common Stock purchasable upon exercise of the Warrants hereunder or under any other Option are referred to as the "Warrant Shares", (vi) the aggregate Option Price", (vii) the price payable (initially \$1.331 per Unit, subject to adjustment) for each of the Units, hereunder is referred to as the "Per Unit Price", (viii) this Option, all similar Options issued on the date hereof and all warrants hereafter

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issued in exchange or substitution for this Option or such similar Options are referred to as the "Options" and (ix) the holder of this Option is referred to as the "Holder" and the holder of this Option and all other Options are referred to as the "Holders" and Holders of more than fifty percent (50%) of the outstanding Options are referred to as the "Majority of the Holders." The Aggregate Option Price is not subject to adjustment. The Per Unit Price is subject to adjustment as hereinafter provided; in the event of any such adjustment, the number of Common Shares or Warrant Shares, as the case may be, deliverable upon exercise of this Option shall be adjusted in accordance with paragraph 3(i) below.

This Option, together with options of like tenor, constituting in the aggregate Options to purchase \_\_\_\_\_ Units, was originally issued pursuant to a placement agency agreement between the Company and Paramount Capital, Inc., as placement agent (the "Placement Agent") in connection with a private placement (the "Offering") of 4.9 Units (the "Offering Units"), each Offering Unit consisting of Common Stock and Class D Warrants for which the Placement Agent.

1. Exercise of Option.

(a) This Option may be exercised, in whole at any time or in part from time to time, commencing on December 28, 1999 and prior to 5:00 P.M., New York City time, on December 28, 2004 by the Holder:

(i) by the surrender of this Option (with the subscription form at the end hereof duly executed) at the address set forth in Subsection 9(a) hereof, together with proper payment of the Aggregate Option Price, or the proportionate part thereof if this Option is exercised in part, with payment for the number of Units made by certified or official bank check payable to the order of the Company; or

(ii) by the surrender of this Option (with the cashless exercise form at the end hereof duly executed) (a "Cashless Exercise") at the address set forth in Subsection 9(a) hereof. The exchange of the Option shall take place on the date specified in the Cashless Exercise Form or, if later, the date the Cashless Exercise Form is surrendered to the Company (the "Exchange Date"). Such presentation and surrender shall be deemed a waiver of the Holder's obligation to pay the Aggregate Option Price, or the proportionate part thereof if this Option is exercised in part. In the event of a Cashless Exercise this Option shall represent the right to subscribe for and acquire the number of Units (rounded to the next highest integer) equal to (x) the number of Units specified by the Holder in his/her Cashless Exercise Form (the "Total Number") (such number not to exceed the maximum number of Units subject to this Option, as may be adjusted from time to time) less (y) the number of Units equal to the quotient obtained by dividing (A) the product of the Total Number and the existing Per Unit Price by (B) the Market Price Per Unit. "Market Price Per Unit" shall mean first, if there is a trading market as indicated in Subsection (A) below for the Units, such Market Price Per Unit and if there is no such trading market in the Units, then Market Price Per Unit shall equal the sum of the aggregate Market Price of all shares of Common

Stock (on per share basis, the "Market Price Per Share of Common Stock") and Warrants (on a per warrant basis, the "Market Price Per Warrant") which comprise a Unit, with the meanings indicated in Subsections (B) through (F) below:

(A) If the Units are listed on a national securities exchange or listed or admitted to unlisted trading privileges on such exchange or listed for trading on the Nasdaq National Market or the Nasdaq Smallcap Market, the Market Price Per Unit shall be the average of the last reported sale prices (or if no last sale, the last quoted ask price) of the Units on such exchange or market for the five trading days immediately preceding the Exchange Date; or

(B) If the Common Stock or Warrants, as the case may be, are listed on a national securities exchange or admitted to unlisted trading privileges on such exchange or listed for trading on the Nasdaq National Market or the Nasdaq Smallcap Market, the Market Price Per Share of Common Stock, or Market Price Per Warrant, respectively, shall be the average of the last reported sale prices (or if no last sale, the last quoted ask price) of the Common Stock or Warrants, respectively, on such exchange or market for the five trading days immediately preceding the Exchange Date; or

(C) If the Common Stock or Warrants, as the case may be, are not so listed or admitted to unlisted trading privileges, the Market Price Per Share of Common Stock, or Market Price Per Warrant, respectively, shall be the last reported sale price (or if no last sale, the last quoted ask price) of the Common Stock or Warrants in the over-the-counter market as reported by the National Quotation Bureau or similar organization or in the Pink Sheets for the trading day immediately preceding the Exchange Date; or

(D) If the Common Stock is not so listed or admitted to unlisted trading privileges and the sale price is (or if no last sale, the last quoted ask price) not so reported, the Market Price Per Share of Common Stock shall be the fair market value as determined by agreement between the Board of Directors of the Company and a Majority of the Holders; or

(E) If neither clause (B) nor (C) applies to the Warrants, then the Market Price Per Warrant shall be an amount equal to the difference between (i) the Market Price Per Share of Common Stock which may be received upon the exercise of the Warrants, as determined in paragraphs (B), (C) and (D) above, and (ii) the per share exercise price of the Warrants then in effect.

(F) If the Company and the Majority of the Holders are unable to reach agreement on any valuation matter, such valuation shall be submitted to and determined by a nationally recognized independent investment bank selected by the Board of Directors of the Company and the Majority of the Holders (or, if such selection cannot be agreed upon promptly, or in any event within ten days, then such valuation shall be made by a nationally recognized independent investment banking firm selected by the American Arbitration Association in New York City in accordance with its rules), the costs of which valuation shall be paid for by the Company.

(b) If this Option is exercised in part, the Holder is entitled to receive a new Option covering the Units, which have not been exercised and setting forth the proportionate part of the Aggregate Option Price applicable to such Units. Upon surrender of this Option, the Company will (i) issue a certificate or certificates in the name of the Holder for the largest number of whole shares of the Common Stock and Warrants to which the Holder shall be entitled and, if this Option is exercised in whole, in lieu of any fractional shares of the Common Stock or Warrants to which the Holder shall be entitled, pay to the Holder cash in an amount equal to the fair value of such fractional shares (determined in such reasonable manner as the Board of Directors of the Company shall determine), and (ii) deliver the other securities and properties receivable upon the exercise of this Option, or the proportionate part thereof if this Option is exercised in part, pursuant to the provisions of this Option.

(c) This Option shall be exercisable only for Units consisting of Warrants and Common Shares at the then applicable Per Unit Price (including any adjustment pursuant to Section 3 below).

(d) Notwithstanding anything to the contrary contained in the Warrants, the following provisions shall apply in connection with the exercise of the Warrants issuable upon exercise of this Option by the Holder:

(i) if all outstanding Warrants are redeemed by the Company pursuant to Section 7 thereof or have been exercised prior to the exercise of this Option, the Holder shall be entitled to receive the Common Stock otherwise issuable upon exercise of the Warrants underlying this option (or the portion of this Option exercised) by giving written notice of exercise of such Warrants simultaneously with exercise of this Option, which notice shall specify whether the Warrants are being such exercised for a cash payment or by cashless exercise and the number shares of Common Stock as to which such Warrants are being exercised, and if the exercise of such Warrants. If all of the outstanding Warrants have been redeemed pursuant to Section 7 thereof or have been exercise the Warrants issuable upon exercise hereof simultaneously with exercise of this Option, then the Holder on exercise of this Option shall only receive the number of shares of the Common Stock included in the Units issuable on exercise of this Option (or the portion of this Option exercise) and shall not be issued any Warrants.

(ii) Notwithstanding anything to the contrary contained in the Warrants, the Holder may exercise the Warrants by cashless exercise by using the same formula as set forth for exercise of this Option by cashless exercise in Section 1(a)(ii) of this Option (except that, for this purpose, any reference to the Warrants or the Market Price Per Warrant in Section 1(a)(ii) shall be inapplicable).

2. Reservation of Warrant Shares and Common Shares; Listing. The Company agrees that, prior to the expiration of this Option, the Company will at all times (a) have authorized and in reserve, and will keep available, solely for issuance and delivery upon the exercise of this Option, the Units, the Warrants and the Common Shares underlying such Units and other securities and properties as from time to time shall be receivable upon the exercise of this Option, free and clear of all restrictions on sale or transfer, other than under Federal or state securities laws, and free and clear of all preemptive rights and rights of first refusal and (b) have authorized and in reserve, and will keep available, solely for issuance or delivery upon exercise of the Warrants, the shares of Common Stock, the Warrant Shares and the Common Shares and other securities and properties as from time to time shall be receivable upon such exercise, free and clear of all restrictions on sale or transfer, other than under Federal or state securities laws, and free and clear of all preemptive rights and rights of first refusal; and (c) if the Company is listed or hereafter lists its Common Stock on any national securities exchange, the Nasdaq National Market or the Nasdaq Smallcap Market, use its best efforts to keep the Common Shares authorized for listing on such exchange upon notice of issuance.

#### 3. Protection Against Dilution.

(a) The anti-dilution provisions of the Warrants shall protect the Holder from dilution of the purchase rights represented by the Warrants (it being understood for this purpose that the Holder shall be deemed to own the Warrants commencing on December 28, 1999); provided, however, that notwithstanding anything to the contrary contained in the Warrants, if all of the Warrants have been redeemed or exercised prior to exercise of this Option, the Holder shall not be entitled to any adjustment in the Per Share Warrant Price pursuant to Section 3(c) of the Warrants as a result of any issuances subsequent to the date of the redemption of the Warrants pursuant to Section 7 of the Warrants. In addition, the following anti-dilution provisions shall protect the Holder from dilution resulting from the issuance of Common Stock and other securities:

(i) If the Company shall issue or distribute to the holders of shares of Common Stock evidence of its indebtedness, any other securities of the Company or any cash, property or other assets (excluding a subdivision, combination or reclassification, or dividend or distribution payable in shares of Common Stock, referred to in Subsection 3(a)(ii), and also excluding cash dividends or cash distributions paid out of net profits legally available therefor in the full amount thereof (any such non-excluded event being herein called a "Common Stock Special Dividend")), the Per Unit Price shall be adjusted by multiplying the Per Unit Price then in effect by a fraction, (A) the numerator of which shall be (x) the then current

Market Price Per Share of Common Stock in effect on the record date of such issuance or distribution less (y) the fair market value (as determined in good faith by the Company's Board of Directors) of the evidence of indebtedness, cash, securities or property, or other assets issued or distributed in such Common Stock Special Dividend applicable to one share of Common Stock and (B) the denominator of which shall be the then current Market Price Per Share of Common Stock in effect on the record date of such issuance or distribution. An adjustment made pursuant to this Subsection 3(a)(i) shall become effective immediately after the record date of any such Common Stock Special Dividend.

(ii) If the Company shall (A) pay a dividend or make a distribution on its capital stock in shares of Common Stock, (B) subdivide its outstanding shares of Common Stock into a greater number of shares, (C) combine its outstanding shares of Common Stock into a smaller number of shares or (D) issue by reclassification of its Common Stock any shares of capital stock of the Company, the Per Unit Price shall be adjusted by multiplying the Per Unit Price by a fraction, the numerator of which shall be the number of Common Shares which this Option was exercisable for prior to such action and the denominator of which shall be the number of Common Shares which a Holder would have owned immediately following such action had such Option been exercised immediately prior to the record or effective date therefor. An adjustment made pursuant to this Subsection 3(a)(ii) shall become effective immediately after the record date in the case of a dividend or distribution and shall become effective immediately after the record subdivision, combination or reclassification.

(b) No adjustment in the Per Unit Price shall be required unless such adjustment would require an increase or decrease of at least \$0.05 per Unit; provided, however, that any adjustments which by reason of this Section 3(b) are not required to be made shall be carried forward and taken into account in any subsequent adjustment; provided, further, however, that adjustments shall be required and made in accordance with the provisions of this Section 3 (other than this Subsection 3(b)) not later than such time as may be required in order to preserve the tax-free nature of a distribution to the Holder of this Option. All calculations under this Section 3 shall be made to the nearest cent or to the nearest 1/100th of a share, as the case may be. Anything in this Section 3 to the contrary notwithstanding, the Company shall be entitled to make such reductions in the Per Unit Price, in addition to those required by this Section 3, as it in its discretion shall deem to be advisable in order that any stock dividend, subdivision of shares or distribution of rights to purchase stock or securities convertible or exchangeable for stock hereafter made by the Company to its stockholders shall not be taxable.

(c) Whenever the Per Unit Price is adjusted as provided in this Section 3 and upon any modification of the rights of a Holder of Options in accordance with this Section 3, the Company shall promptly prepare a brief statement of the facts requiring such adjustment or modification and the manner of computing the same and cause copies of such certificate to be mailed to the Holders of the Options. The Company may, but shall not be obligated to unless requested by the Holders of

more than fifty percent (50%) of the outstanding Options, obtain, at its expense, a certificate of a firm of independent public accountants of recognized standing selected by the Board of Directors (who may be the regular auditors of the Company) setting forth the Per Unit Price and the number of Warrants, Warrant Shares or Common Shares, as the case may be, after such adjustment or the effect of such modification, a brief statement of the facts requiring such adjustment or modification and the manner of computing the same and cause copies of such certificate to be mailed to the Holders of the Options.

(d) If the Board of Directors of the Company shall declare any dividend or other distribution with respect to the Common Stock other than a cash distribution out of earned surplus, the Company shall mail notice thereof to the Holders of the Options not less than 10 days prior to the record date fixed for determining stockholders entitled to participate in such dividend or other distribution.

(e) In case of any capital reorganization or reclassification, or any consolidation or merger to which the Company is a party other than a merger or consolidation in which the Company is the continuing corporation, or in case of any sale or conveyance to another entity of the property of the Company as an entirety or substantially as a entirety, or in the case of any statutory exchange of securities with another corporation (including any exchange effected in connection with a merger of a third corporation into the Company), the Holder of this Option shall have the right thereafter to receive on the exercise of this Option the kind and amount of securities, cash or other property which the Holder would have owned or have been entitled to receive immediately after such reorganization, reclassification, consolidation, merger, statutory exchange, sale or conveyance had this Option been exercised immediately prior to the effective date of such reorganization, reclassification, consolidation, merger, statutory exchange, sale or conveyance and in any such case, if necessary, appropriate adjustment shall be made in the application of the provisions set forth in this Section 3 with respect to the rights and interests thereafter of the Holder of this Option to the end that the provisions set forth in this Section 3 shall thereafter correspondingly be made applicable, as nearly as may reasonably be, in relation to any shares of stock or other securities or property thereafter deliverable on the exercise of this Option. The above provisions of this Subsection 3(e) shall similarly apply to successive reorganizations, reclassifications, consolidations, meraers, statutorv exchanges, sales or conveyances. The Company shall require the issuer of any shares of stock or other securities or property thereafter deliverable on the exercise of this Option to be responsible for all of the agreements and obligations of the Company hereunder. Notice of any such reorganization, reclassification, consolidation, merger, statutory exchange, sale or conveyance and of said provisions so proposed to be made, shall be mailed to the Holders of the Options not less than 30 days prior to such event. A sale of all or substantially all of the assets of the Company for a consideration consisting primarily of securities shall be deemed a consolidation or merger for the foregoing purposes.

(f) If, as a result of an adjustment made pursuant to this Section 3, the Holder of any Option thereafter surrendered for exercise shall become entitled to receive shares of two or more classes of capital stock or shares of Common Stock and other capital stock of the Company, the Board of Directors (whose determination shall be conclusive and shall be described in a written

notice to the Holder of any Option promptly after such adjustment) shall determine the allocation of the adjusted Per Unit Price between or among shares or such classes of capital stock or shares of Common Stock and other capital stock.

(g) Upon the expiration of any rights, options, warrants or conversion privileges, if such shall not have been exercised, the number of Units purchasable upon exercise of this Option, to the extent this Option has not then been exercised, shall, upon such expiration, be readjusted and shall thereafter be such as they would have been had they been originally adjusted (or had the original adjustment not been required, as the case may be) on the basis of (i) the fact that Common Stock, if any, actually issued or sold upon the exercise of such rights, options, warrants or conversion privileges, and (ii) the fact that such shares of Common Stock, if any, were issued or sold for the consideration actually received by the Company upon such exercise plus the consideration, if any, actually received by the Company for the issuance, sale or grant of all such rights, options, warrants or conversion privileges whether or not exercised; provided, however, that no such readjustment shall have the effect of decreasing the number of Units purchasable upon exercise of this Option by an amount in excess of the amount of the adjustment initially made in respect of the issuance, sale or grant of such rights, options, warrants or conversion privileges.

(h) Whenever the Per Unit Price payable upon exercise of each Option is adjusted pursuant to this Section 3, (i) the number of shares of Common Stock included in a Unit shall simultaneously be adjusted by multiplying the number of shares of Common Stock included in a Unit immediately prior to such adjustment by the Per Unit Price in effect immediately prior to such adjustment and dividing the product so obtained by the Per Unit Price, as adjusted and (ii) the number of shares of Common Stock or other securities issuable upon exercise of the Warrants included in the Units and the exercise price payable for each of the Warrant Shares (initially \$0.50 per Warrant Share, subject to adjustment) pursuant to the Warrant terms shall be adjusted in accordance with the terms of the Warrant Agreement applicable to holders of such Warrants.

(i) In case any event shall occur as to which the other provisions of this Section 3 are not strictly applicable but as to which the failure to make any adjustment would not fairly protect the purchase rights represented by this Option in accordance with the essential intent and principles hereof then, in each such case, the Board of Directors of the Company shall in good faith determine the adjustment, if any, on a basis consistent with the essential intent and principles established herein, necessary to preserve the purchase rights represented by the Options. Upon such determination, the Company will promptly mail a copy thereof to the Holder of this Warrant and shall make the adjustments described therein.

4. Fully Paid Stock; Taxes. The Company agrees that the shares of theCommon Stock represented by each and every certificate for Common Shares delivered on the exercise of this Option and the shares of Common Stock delivered upon the exercise of the Warrants, shall at the time of such delivery, be validly issued and outstanding, fully paid and nonassessable, and not subject to preemptive rights or rights of first refusal, and the Company will take all such actions as may be necessary to assure that the par value or stated value, if any, per share of the Common Stock is at all times equal to or less than the then Per Unit Price. The Company further

covenants and agrees that it will pay, when due and payable, any and all Federal and state stamp, original issue or similar taxes which may be payable in respect of the issue of any Warrant Share, Common Share or any certificate thereof to the extent required because of the issuance by the Company of such security.

# 5. Registration Under Securities Act of 1933.

(a) The Holder shall, with respect to the Common Shares only, have the right to participate in the registration rights granted to holders of Registrable Securities pursuant to Section 5 of the subscription agreements (the "Subscription Agreements") between such holders and the Company that were entered into at the time of the initial sale of the Units. By acceptance of this Option, the Holder agrees to comply with the provisions in Section 5 of the Subscription Agreement to same extent as if he/she were a party thereto.

(b) Until all Common Shares and Warrant Shares have been sold under a Registration Statement or pursuant to Rule 144 under the Act, the Company shall use its reasonable best efforts to file with the Securities and Exchange Commission all current reports and the information as may be necessary to enable the Holder to effect sales of his/her shares in reliance upon Rule 144 promulgated under the Act.

#### 6. Investment Intent; Limited Transferability.

(a) The Holder represents, by accepting this Option, that he/she understands that this Option and any securities obtainable upon exercise of this Option have not been registered for sale under Federal or state securities laws and are being offered and sold to the Holder pursuant to one or more exemptions from the registration requirements of such securities laws. In the absence of an effective registration of such securities or an exemption therefrom, any certificates for such securities shall bear the legend set forth on the first page hereof. The Holder understands that he/she must bear the economic risk of his/her investment in this Option and any securities obtainable upon exercise of this Option for an indefinite period of time, as this Option and such securities have not been registered under Federal or state securities laws and therefore cannot be sold unless subsequently registered under such laws, unless an exemption from such registration is available.

(b) The Holder, by his acceptance of his/her Option, represents to the Company that he/she is acquiring this Option and will acquire any securities obtainable upon exercise of this Option for his/her own account for investment and not with a view to, or for sale in connection with, any distribution thereof in violation of the Act. The Holder agrees that this Option and any such securities will not be sold or otherwise transferred unless (i) a registration statement with respect to such transfer is effective under the Act and any applicable state securities laws or (ii) such sale or transfer is made pursuant to one or more exemptions from the Act.

(c) This Option may not be sold, transferred, assigned or hypothecated for six months from the date hereof except (i) to any firm or corporation that succeeds to all or substantially all of the business of Paramount Capital, Inc., (ii) to any of the officers, employees, associates or affiliated

companies of Paramount Capital, Inc., or of any such successor firm, (iii) to any NASD member participating in the Offering or any officer or employee of any such NASD member or (iv) in the case of an individual, pursuant to such individual's last will and testament or the laws of descent and distribution, and is so transferable only upon the books of the Company which it shall cause to be maintained for such purpose. The Company may treat the registered Holder of this Option as he/she appears on the Company's books at any time as the Holder for all purposes. The Company shall permit any Holder of an Option or his/her duly authorized attorney, upon written request during ordinary business hours, to inspect and copy or make extracts from its books showing the registered holders of Options. All Options issued upon the transfer or assignment of this Option will be identical to those of the Holder.

7. Loss, etc., of Option. Upon receipt of evidence satisfactory to the Company of the loss, theft, destruction or mutilation of this Option, and of indemnity reasonably satisfactory to the Company, if lost, stolen or destroyed, and upon surrender and cancellation of this Option, if mutilated, the Company shall execute and deliver to the Holder a new Option of like date, tenor and denomination.

8. Option Holder Not Stockholder. This Option does not confer upon the Holder any right to vote or to consent to or receive notice as a stockholder of the Company, as such, in respect of any matters whatsoever, or any other rights or liabilities as a stockholder, prior to the exercise hereof; this Option does, however, confer certain rights and require certain notices to Holders as set forth herein.

9. Communication. No notice or other communication under this Option shall be effective unless, but any notice or other communication shall be effective and shall be deemed to have been given if, the same is in writing and is mailed by first-class mail, postage prepaid, addressed to:

(a) the Company at Discovery Laboratories, Inc., 3359 Durham Road, Doylestown, Pennsylvania, 18901, Attn: Vice President, Finance or such other address as the Company has designated in writing to the Holder, or

(b) the Holder at c/o Paramount Capital, Inc., 787 Seventh Avenue, New York, NY 10019 or other such address as the Holder has designated in writing to the Company.

10. Headings. The headings of this Option have been inserted as a matter of convenience and shall not affect the construction hereof.

11. Applicable Law. This Option shall be governed by and construed inaccordance with the law of the State of New York without giving effect to the principles of conflicts of law thereof.

12. Amendment, Waiver, etc. Except as expressly provided herein, neither this Option nor any term hereof may be amended, waived, discharged or terminated other than by a written instrument signed by the party against whom enforcement of any such amendment, waiver, discharge or termination is sought; provided, however, that any provisions hereof may be amended, waived, discharged or terminated upon the written consent of the Company and the then current Majority of the Holders of the Options only.

IN WITNESS WHEREOF, the Company has caused this Option to be signed by its Vice President, Finance and attested by its Secretary this \_\_\_\_ day of February, 2000.

DISCOVERY LABORATORIES, INC.

By: Name: Robert J. Capetola Title: President and Chief Executive Officer

ATTEST:

Secretary

# SUBSCRIPTION

The undersigned, \_\_\_\_\_\_, pursuant to the provisions of the foregoing Option, hereby agrees to subscribe for and purchase \_\_\_\_\_\_ Units of Discovery Laboratories, Inc., each Unit consisting of Common Stock, \$.001 par value, and Class D Warrants to purchase share(s) of Common Stock, covered by said Option, and makes payment therefor in full at the price per share provided by said Option. The undersigned hereby confirms the representations and warranties made by him/her in the Option.

Dated:\_\_\_\_\_

# Signature:

#### Address:

# CASHLESS EXERCISE

The undersigned \_\_\_\_\_\_, pursuant to the provisions of the foregoing Option, hereby elects to exchange his/her Option for \_\_\_\_\_ Units, each Unit consisting of Common Stock, \$.001 par value, and Class D Warrants to purchase \_\_\_\_\_\_ share(s) of Common Stock, pursuant to the cashless exercise provisions of the Option. The undersigned hereby confirms the representations and warranties made by him/her in the Option.

Dated:\_\_\_\_

#### Signature:

# Address:

# ASSIGNMENT

FOR VALUE RECEIVED \_\_\_\_\_\_ hereby sells, assigns and transfers unto \_\_\_\_\_\_ the foregoing Option and all rights evidenced thereby, and does irrevocably constitute and appoint \_\_\_\_\_\_, attorney, to transfer said Option on the books of Discovery Laboratories, Inc.

Dated:\_\_\_\_

Signature:

Address:

#### PARTIAL ASSIGNMENT -----

transfers unto \_\_\_\_\_\_\_\_ the right to purchase \_\_\_\_\_\_ Units of Discovery Laboratories, Inc., each Unit consisting of Common Stock, \$.001 par value, and Class D Warrants to purchase \_\_\_\_\_\_\_ share(s) of Common Stock, covered by the foregoing Option, and a proportionate part of said Option and the rights evidenced thereby, and does irrevocably constitute and appoint \_\_\_\_\_\_\_, attorney, to transfer that part of said Option on the books of Discovery Laboratories, Inc.

Dated:\_\_\_

Signature:

Address:

Exhibit 10.10

Certain portions have been omitted pursuant to a request for confidentiality and such omitted portions have been separately filed with the Commission.

[DISCOVERY LABORATORIES, INC. LETTERHEAD]

March 7, 2000

VIA FEDEX

Charlotte-Mecklenburg Hospital Authority P.O. Box 32861 Charlotte, North Carolina 28232-2861

Attention: Dr. James G. Martin Cannon Research Center 1542 Garden Terrace Drive Charlotte, North Carolina 28203

Dear Dr. Martin:

Reference is herein made to the License Agreement dated as of March 20, 1996 by and between The Charlotte-Mecklenburg Hospital Authority and Discovery Laboratories, Inc., as successor-in-interest to Triad Pharmaceuticals and as amended by an Amendment Letter dated July 18, 1996 and as further amended by an Amendment Letter dated August 8, 1996 and as further amended by an Amendment Letter dated December 9, 1996 (collectively, the "License Agreement").

 $$\ensuremath{\mathsf{Licensor}}$  and  $$\ensuremath{\mathsf{Licensee}}$$  hereby agree to further amend the  $$\ensuremath{\mathsf{License}}$$  Agreement as follows:

1. Section 3.4 is hereby amended and restated as follows:

"In the event[\*\*\*], then Licensee shall on [\*\*\*] pay to Licensor a nonrefundable, one-time, additional license fee in the amount of [\*\*\*] to maintain its rights under this Agreement for one additional year. On each subsequent anniversary of [\*\*\*] thereafter, if [\*\*\*], then Licensee will pay an additional [\*\*\*] for each further annual extension of the License Agreement. Licensee's failure to pay any such additional license fee shall constitute a material breach or default for purposes of the termination provisions of Paragraph 7.3."

[\*\*\*] Confidential treatment requested.

935262.1

2. Section 4.1.5 is hereby amended and restated as follows:

"Within thirty (30) days following [\*\*\*], Licensee shall pay Licensor a nonrefundable, one time, license fee in the amount of [\*\*\*]."

Except as expressly provided for in this Amendment, the terms of the License Agreement shall continue in full force and effect without modification and amendment, including without limitation, Section 4.1.4. If the terms set forth above are acceptable to you, please acknowledge your consent in the space provided below and return one executed original to us.

Very truly yours,

DISCOVERY LABORATORIES, INC.

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

Name: Robert J. Capetola, Ph.D. Title: President/CEO

Consented and agreed to this 9th day of March, 2000

CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY

By:/s/ James G. Martin, Ph.D.

Name: James G. Martin, Ph.D.

Title: Vice President, Research Chairman, Research Development Board, Cannon Research Center

#### Exhibit 10.52

# Certain portions have been omitted pursuant to a request for confidentiality and such omitted portions have been separately filed with the Commission.

\_\_\_\_\_

#### SUBLICENSE AGREEMENT

between

DISCOVERY LABORATORIES, INC.

and

LABORATORIOS DEL DR. ESTEVE S.A.

Concerning Sinapultide (Lucinactant)

#### October 26th, 1999

\_\_\_\_\_

935292.1

#### SUBLICENSE AGREEMENT

THIS SUBLICENSE AGREEMENT (this "Agreement") is made as of October 26th, 1999 (the "Effective Date"), between DISCOVERY LABORATORIES, INC. ("Licensor"), a Delaware corporation, and LABORATORIOS DEL DR. ESTEVE S.A., a company organized and existing under the laws of Spain ("Licensee").

WHEREAS, Licensor has the exclusive worldwide right, under a license from Johnson & Johnson, to sublicense certain technology, including certain technology relating to synthetic pulmonary surfactant peptides and proteins, one of which is known as sinapultide;

WHEREAS, Licensor owns certain technology and patent rights relating to synthetic pulmonary surfactant formulations; and

WHEREAS, Licensee desires to acquire a license to the Licensed Products in the Licensed Territory (in each case as defined below) and Licensor is willing to grant such license to Licensee for the purpose of commercializing the Licensed Products for the treatment of certain respiratory distress syndromes;

NOW, THEREFORE, in consideration of the promises and the performance of the covenants herein contained, the parties agree as follows:

### ARTICLE 1

#### DEFINITIONS

For the purposes of this Agreement, the following terms shall have the following meanings:

"Affiliate/s" of a Person shall mean any Person which directly or indirectly Controls, is Controlled by or is under common Control with such Person.

"ARDS/ALI Indication" shall mean the use of Licensed Products for the treatment of acute respiratory distress syndrome or acute lung injury.

"Control" shall mean direct or indirect beneficial ownership of at least 50% of the voting stock of a Person having outstanding voting securities, or a 50% or greater interest in the income of a Person not having outstanding securities, or, in either case, the power to direct or cause the direction of the management or policies of such Person.

"Development" shall refer to all activities relating to formulation, process development, manufacturing scale-up, quality assurance/quality control, clinical studies and regulatory affairs in connection with a Licensed Product. "Development Costs" shall mean Direct Development Costs and Indirect Development Costs.

"Direct Development Costs" shall mean all direct costs incurred in connection with the Development of a Licensed Product in the Field. Direct Development Costs shall include but are not limited to the cost of studies (including post-approval studies) on the pharmacokinetic, metabolic or clinical aspects of a Licensed Product conducted internally or by individual investigators or consultants (such as contract research organizations) necessary for the purpose of obtaining and/or maintaining approval of a Licensed Product in the Field by a governmental entity in a country of the Licensed Territory (including without limitation related hospital grants), and costs for preparing, submitting, reviewing or developing data or information for the purpose of submission to a governmental entity to obtain and/or maintain approval of a Licensed Product in the Field in a country of the Licensed Territory.

"EMEA" shall mean the European Medicines Evaluation Agency.

"FDA" shall mean the United States Food and Drug Administration.

"Field" shall mean the use of Licensed Products for the ARDS/ALI Indication and the Neonatal Indications [\*\*\*].

"Indication" shall mean any ARDS/ALI Indication or Neonatal Indication  $[^{\star\star\star}].$ 

"Indirect Development Costs" shall mean all indirect costs incurred in connection with the Development of a Licensed Product in the Field, including without limitation, general and administrative expenses, allocable overhead, and compensation, benefits and travel and other employee-related expenses.

"Initial Period" shall mean, on a country by country basis, the period comprehended between the Effective Date until the latest of the following dates:

(i) the expiration of the last Patent Rights containing a Valid Claim covering a Licensed Product in such country; or

(ii) the fifteenth (15th) anniversary of the first commercial sale of a Licensed Product in such country.

"IRDS Indication" shall mean the use of Licensed Products for the treatment of infant (idiopathic) respiratory distress syndrome.

[\*\*\*] Confidential treatment requested.

"Licensed Know-how" shall mean all know-how, data, information or technology arising before or during the course of this agreement which are proprietary to the Licensor and/or with respect to which Licensor has the power and right to grant the licenses provided for herein and which relate to the development or therapeutic use of Licensed Products.

"Licensed Methods" shall mean the methods for treating respiratory distress syndromes that are covered by one or more claims of [\*\*\*], and all corresponding national patents and patent applications, European Patent Convention filings and applications and filings and applications under similar administrative international conventions, together with any divisional, continuation, continuation-in-part, substitution, reissue, extension, registration, confirmation, reexamination, renewal, supplementary protection certificate or other application based thereon.

"Licensee Proprietary Information" shall mean any scientific and technical information or data developed, possessed or acquired by Licensee relating to Licensed Products, Patent Rights or Licensed Know-how which Licensee is free to disclose other than such information that is within or enters the public domain.

"Licensed Products" shall mean, with respect to each Indication, (i) the Surfaxin(R) Product and/or (ii) if any Replacement Product has been identified by the Committee pursuant to Section 5.8 with respect to such Indication, the most recently identified Replacement Product with respect to such Indication.

"Licensed Rights" shall mean collectively the Patent Rights, the Licensed Methods, the Trademarks and the Licensed Know-how.

"Licensed Territory" shall mean Spain, Andorra, Portugal, Greece, Central and South America, with an option for Italy as established in Section 2.2.

"Marketing Regulatory Approvals" shall mean all permissions and applications for such permissions from the regulatory and/or governmental health authorities in the Licensed Territory which are necessary for the importation of the Licensed Products and their marketing, use, distribution and sale in the Licensed Territory, including, where applicable, the Pricing Approvals.

"MAS Indication" shall mean the use of Licensed Products for the treatment of meconium aspiration syndrome.

"Neonatal Indications" shall mean the IRDS Indication and the MAS Indication.  $% \left[ {\left[ {{\rm{MAS}} \right]_{\rm{AS}}} \right]$ 

"NDA" shall mean a New Drug Application or Product License Application filed with the United States Food and Drug Administration under 21 USC 355(b) (FDCA

Section 505(b)) or its equivalent filed with the EMEA or with any country within the Licensed Territory for purposes of mutual recognition by the other countries within the Licensed Territory.

"Original License" shall mean the Sublicense Agreement dated as of October 28, 1996 between the Original Licensor and Licensor.

"Original Licensor" shall mean Johnson & Johnson.

"Patent Rights" shall mean (i) the patents and patent applications in Schedule I hereto, (ii) and any other patents or patent applications covering the surfactant pharmaceutical compositions referenced in the patents and patent applications in Schedule I or their use or administration owned by Licensor or under which Licensor has the right, at any time while this Agreement is in effect, to license to Licensee and (iii) with respect to the foregoing letters patent and patent applications, all corresponding national patents and patent applications, Patent Cooperation Treaty and European Patent Convention filings and applications and filings and applications under similar administrative international conventions, together with any divisional, continuation, continuation-in-part, substitution, reissue, extension, supplementary protection certificate or other application based thereon. Notwithstanding the foregoing, "Patent Rights" shall not include any patents or patent applications, filings, or applications under any treaty, or any divisional, continuation, continuation-in-part, substitution, reissue, extension, supplementary protection certificate or other application relating in whole or in part to the use or administration of any of the surfactant pharmaceutical compositions on Schedule I or any Licensed Product, alone or together with other active or inactive components, outside the Field.

"Person" shall mean any natural person, corporation, limited liability company, unincorporated association, partnership, joint venture or other entity.

"Phase 2 Clinical Trial" shall mean a controlled study in humans of the potential efficacy and safety of a Licensed Product which is prospectively designed to demonstrate activity of a given dose/s of a Licensed Product in a particular indication.

"Phase 3 Clinical Trial" shall mean a controlled study in humans with a Licensed Product which is prospectively designed to demonstrate statistically any possible difference in efficacy or equivalence and/or safety in comparison with an approved drug, if there is an approved drug and standard of care, if there is no approved drug.

"Pricing Approvals" shall mean approvals by the regulatory and/or governmental health authorities in the Licensed Territory defining the prices of the Licensed Products and reimbursement conditions for the sale thereof.

"Product Failure" shall mean, with respect to the Surfaxin(R) Product or any Replacement Product, the earlier to occur of (i) a determination by the applicable regulatory

authority in (or having jurisdiction over) any country of the Licensed Territory that the Surfaxin(R) Product or such Replacement Product may not be commercialized for an Indication, or that further clinical trials of the Surfaxin(R) Product or such Replacement Product should not be conducted for an Indication or (ii) a determination by the Committee (as defined in Section 5.4) that the continued development of the Surfaxin(R) Product or such Replacement Product for an Indication is not economically feasible or is unlikely to result in the receipt of Marketing Regulatory Approvals within time frames and in markets that will permit Licensor and Licensee to achieve the anticipated benefits of this Agreement.

"Replacement Product" shall mean [\*\*\*].

"Scripps Patent Rights" shall mean the Patent Rights identified in part (a) of Schedule I.

"Securities Purchase Agreement" shall mean the Securities Purchase Agreement dated as of October 26th, 1999 between Licensor, as the seller and Licensee's Affiliate Laboratorios P.E.N., S.A. as the purchaser.

"Surfaxin(R)Product" shall mean, in each jurisdiction [\*\*\*].

"Trademark" shall mean Surfaxin(R) and such other trademarks owned by Licensor that are selected by the Committee (as defined in Section 5.4) for use within the Licensed Territory in connection with one or more Licensed Products.

"Valid Claim" shall mean a claim of an unexpired patent within the Patent Rights which has matured into an issued patent or a claim being prosecuted in a pending application within the Patent Rights. In each case a claim shall be presumed to be valid unless and until it has been held to be invalid by a final, unappealable judgement of a court of competent jurisdiction.

#### ARTICLE 2

#### GRANT

Section 2.1. Grant of License. Licensor hereby grants to Licensee, and Licensee hereby accepts from Licensor, upon the terms and conditions herein specified, an exclusive license under the Patent Rights, the Licensed Know-how and the Trademark to import, use and sell Licensed Products under the Trademark, and to practice Licensed Methods, in the Licensed Territory in the Field. Licensor hereby agrees that it shall not grant

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any other licenses to exploit the Licensed Rights, the Licensed Products or the Replacement Products in the Licensed Territory to any third party (including, without limitation, its Affiliates) during the term of this Agreement. The license granted hereunder does not include any right or license of Licensee to make or have made Licensed Products, all such right and license, together with the right to sublicense, being hereby retained by Licensor. The license granted under this Article 2 shall be subject to the terms and conditions of this Agreement and the following terms:

 (a) The rights of the Original Licensor of the Scripps Patent Rights to use the Scripps Patent Rights for educational and research purposes;

(b) To the extent applicable, the rights of the United States Government pursuant to 35 U.S.C. 202 et seq. and 37 C.F.R. 401.1 et seq. (the "U.S. Government Interest") which may have arisen or resulted from federal funding of research relating to the Scripps Patent Rights, including the non-exclusive right of the United States Government to practice the inventions covered by the Scripps Patent Rights; and

(c) The reserved right of Licensor, to use the Licensed Rights for research and development purposes and, to the extent permitted by Section 6.2, for publication purposes subject to approval by Licensee.

Licensee shall have no right to sublicense or otherwise share its rights hereunder with any other Person other than (i) Affiliates of Licensee (provided that such Affiliates shall acknowledge in writing that they have read this Agreement and that they agree to be bound by the applicable terms herein contained, and provided further that Licensee shall not be relieved of any of its obligations under this Agreement thereby), as provided for in Section 14.9, and (ii) third parties pursuant to a sublicense or distribution agreement complying with Section 2.4.

Section 2.2 Option for Italy. Subject to the conditions set forth hereinafter, Licensee shall have an option right (the "Option Right") to include Italy in the Licensed Territory. The Option Right shall be exercised by Licensee not later than sixty (60) days (the "Option Period") after [\*\*\*].

In the event that Licensee desires to exercise the Option Right, it shall prior or upon the expiration of the Option Period so notify Licensor in writing. Should Licensee fail to exercise its Option Right within the Option Period or should Licensee notify Licensor at any time during the Option Period by written notice of its intention not to exercise the Option Right, then Licensor shall be no longer under any obligation towards Licensee for the country of Italy.

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In the event that Licensee exercises its Option Right, the country of Italy shall be covered by the terms of this Agreement (provided, however, that Section 4.1 (a) shall not apply) and Licensee shall pay to Licensor the following License Fees in consideration thereof:

(a) [\*\*\*] within ten (10) business days of receipt of Licensor's invoice issued upon first grant of final Marketing Regulatory Approval for the MAS Indication in Italy.

(b) [\*\*\*].

(c) [\*\*\*] within ten (10) business days of receipt of Licensor's invoice issued upon first grant of final Marketing Regulatory Approval for the ARDS/ALI Indication in Italy.

Moreover, Licensee shall, within 90 (ninety) days of exercising its Option Right, purchase from Licensor shares of Licensor's common stock for a total price of Seven Hundred Fifty Thousand Dollar (\$750,000) at a fifty percent (50%) premium to the average market value of Licensor's shares in the ten (10) days period immediately preceding the date of acquisition.

Section 2.3. No Active Sales Outside Licensed Territory. Licensee shall neither directly nor indirectly carry out any active sales of the Licensed Products outside the Licensed Territory and it shall not advertise the Licensed Products or maintain branches for the distribution of the Licensed Products outside the Licensed Territory.

Section 2.4. Sublicense Agreements. Licensee shall be entitled to sublicense its rights and obligations under this Agreement in any country of the Licensed Territory other than [\*\*\*], provided that (i) any such sublicense agreement shall be under terms no less stringent than the ones contained in this Agreement and (ii) Licensee hereby warrants and represents that any such sublicensee will comply with all applicable terms of this Agreement.

Section 2.5. Consideration for Licensed Products. Licensee shall not accept as consideration for the sale or transfer of Licensed Products any consideration other than cash except as consented to by Licensor following agreement between Licensor and Licensee on the methodology for valuing such non-cash consideration.

Section 2.6. Right of First Negotiation on New Products. In the event that, during a period of [\*\*\*] Licensor owns or controls the rights to distribute, market and sell a product other than the Licensed Products in the Licensed Territory which reaches or has reached [\*\*\*], Licensor shall promptly so notify Licensee in writing and shall provide Licensee with information on such product as is reasonably necessary for Licensee's evaluation of interest. Upon receipt of such notice and information, Licensee shall have a

period of sixty (60) days to deliver to Licensor a written notice of its interest in distributing, marketing and selling such product in the Licensed Territory. If Licensee does not deliver such notice to Licensor within such period, Licensor shall thereafter have no further obligation to Licensee with respect to such product. If Licensee delivers to Licensor a notice confirming its interest in such product, for sixty (60) days following Licensor's receipt of Licensee's notice, the parties shall engage in exclusive, good-faith negotiations for the terms upon which Licensor would appoint Licensee as the licensee of such product in the Licensed Territory which shall be consistent insofar as reasonably possible, with the terms of this Agreement. If the parties have failed to reach agreement on such terms by the end of such sixty day period, Licensor shall thereafter have no further obligations to Licensee with respect to such product; provided, however, that Licensor will not enter into any agreement relating to the distribution, marketing and sale of the same product in the Licensed Territory with a third party on terms which, taken as a whole, are more favorable to such third party than those last offered in writing by Licensor to Licensee for such product.

#### ARTICLE 3

#### GRANT BACK

In consideration for Licensor (i) making the Licensed Know-how (including any improvements thereto) available to Licensee on a continuing basis for the duration of this Agreement and (ii) procuring, and making available to Licensee the benefit of, equivalent grants from Licensor's other licensees of Patent Rights outside the Licensed Territory, Licensee hereby grants to Licensor and such other licensees a royalty-free, nonexclusive license outside the Licensed Territory, with the right to grant sublicenses, under any and all inventions (whether patentable or not) hereafter during the term of this Agreement, developed, possessed or acquired by Licensee related to the Licensed Products, Patent Rights, Licensed Know-how or Licensed Methods; provided that Licensee is not legally restricted or prevented from granting such rights in connection with the relevant invention. Licensee shall provide Licensor with a written enabling disclosure of each invention (such as a patent application or internal docket reference) unambiguously identifying it as an invention governed by this Article 3 prior to filing a patent application or taking any other action disclosing or potentially disclosing the same to third parties.

Licensee shall promptly disclose all Licensee Proprietary Information to Licensor and, subject to the execution of confidentiality undertakings comparable to those set forth in Article 6, to Licensor's other licensees of Patent Rights outside the Licensed Territory on a continuing basis during the term of this Agreement. Licensee hereby grants to Licensor and such licensees a royalty-free nonexclusive license, with the right to grant sublicenses, to use the Licensee Proprietary Information. Licensee shall not disclose any Licensee Proprietary Information under circumstances that would reasonably be expected to result in the loss of the protectible status of any Licensee Proprietary Information without the prior written consent of Licensor, which consent shall not be unreasonably withheld.

# ARTICLE 4

# CONSIDERATION

Section 4.1. License Fee. (a) Licensee agrees to pay to Licensor a non-refundable license fee of Three Hundred Seventy Five Thousand Dollars (\$375,000.00) within ten (10) business days of receipt of Licensor's invoice issued on or after the Effective Date, subject to paragraph (b) below.

(b) Any and all taxes that are levied on license fees accruing under this Agreement in a country in which provision is made in the law or by regulation for withholding may be deducted by the payor from such royalties and paid to the proper taxing authority and evidence of such payment shall be secured and sent to Licensor within 1 month of such payment. The parties shall do all such lawful acts and things and sign all such lawful deeds and documents as either party may reasonably request from the other party to enable Licensee, its Affiliates and/or sublicensees to take advantage of any applicable legal provision or any double taxation treaties with the object of paying the sums due to Licensor hereunder without withholding any tax.

(c) The balance of any amounts which remain unpaid more than 30 days after they are due to Licensor hereunder shall accrue interest until paid at an annual rate 2% over the United States Clearing Bank Base Lending Rate or the maximum amount allowed under applicable law. However, in no event shall this interest provision be construed as a grant of permission for any payment delays.

Section 4.2 Supply Agreement. Concurrently with the execution of this Agreement, Licensor and Licensee shall enter into a supply agreement for Licensed Products (the "Supply Agreement").

Section 4.3 Location of Payment. The amounts provided for by this Article 4 shall be paid to Licensor by swift transfer to the bank account designated by Licensor.

### ARTICLE 5

### CLINICAL TRIALS, REGULATORY APPROVALS AND MARKETING

Section 5.1 Submission for Regulatory Approvals (a) Subject to the completion of requisite clinical investigations, Licensor shall prepare and submit to the regulatory authorities in the Licensed Territory applications for Marketing Regulatory

Approvals as soon as practicable and shall use its diligent efforts to obtain and maintain all Marketing Regulatory Approvals that are obtained by Licensor for the term of this Agreement, all at the cost and expense of Licensor. When filing for Marketing Regulatory Approvals, Licensor shall designate Licensee or such Licensee's Affiliates or sublicensees designated by Licensee as its distributors or local representatives for the Licensed Products in the Licensed Territory. Licensor shall, upon the granting of each Marketing Regulatory Approval obtained by Licensor, promptly supply Licensee with a copy of such approval.

> (b) Subject to receipt of the Marketing Regulatory Approvals, Licensee shall prepare and submit to the regulatory authorities in the Licensed Territory applications for Pricing Approvals as soon as practicable and shall use its diligent efforts to obtain and maintain all Pricing Approvals that are obtained by Licensee for the term of this Agreement, all at the cost and expense of Licensee. Licensee shall, upon the granting of each Pricing Approval obtained by Licensee shall further be responsible for achieving insertion of Licensed Products into hospital formularies.

Section 5.2 Access of Licensee to Marketing Regulatory Approvals. Licensor shall, in connection with any Marketing Regulatory Approval obtained by it in the Licensed Territory, grant Licensee an irrevocable right of access and reference thereto and shall effect such notifications to regulatory authorities as shall be reasonably necessary to accomplish the foregoing. To the extent Marketing Regulatory Approvals are transferred to Licensee, Licensee shall maintain such Marketing Regulatory Approvals at its cost and expense. Licensor shall assist Licensee in maintaining such Marketing Regulatory Approvals including supplying to Licensee any information in connection therewith which Licensor is free to disclose.

Section 5.3 Conduct of Clinical Investigations (a) Subject to paragraph (b) below, Licensor shall at its own cost and expense conduct all preclinical and clinical trials necessary for obtaining the Marketing Regulatory Approvals in the Licensed Territory.

(b) Licensee shall be responsible for conducting the following clinical trials with the Surfaxin(R)Product in the Licensed Territory:

(i) a Phase 3 Clinical Trial in IRDS [\*\*\*]; and

(ii) a Phase 2 Clinical Trial in ARDS/ALI with [\*\*\*].

Such clinical trials shall be conducted at Licensee's cost and expense, provided that the applicable Licensed Product to be used during all such trials shall be provided by Licensor to Licensee for an amount equal to Three Hundred Seventy Five Thousand Dollars (\$375,000.00) which amount shall be payable upon execution and delivery of this Agreement and is inclusive of any custom duties associated with

[\*\*\*] Confidential treatment requested.

the importation of such Licensed Product in Spain (which shall be reimbursed by Discovery to Esteve in due course), and provided further, notwithstanding anything herein to the contrary, the direct and indirect costs incurred by Licensee under this Section 5.3(b), but not including the costs for the purchase of the Licensed Product, shall not exceed[\*\*\*]. Any costs and expenses in excess of such amount shall be for Licensor's account. The protocols of any clinical trials conducted by Licensee shall be reviewed and approved by Licensor, who shall not unreasonably withhold or delay its approval.

(c) Licensor warrants that any clinical trials carried out by it with respect to the Licensed Products shall be conducted in accordance with FDA good clinical practice and Licensee warrants that all clinical trials carried out by it with respect to the Licensed Products shall be conducted in accordance with the European Union good clinical practice. Licensor and Licensee shall keep each other fully informed on the progress of all clinical trials and shall promptly provide the other with copies of all submissions to regulatory authorities in connection therewith, all significant communications received from such regulatory authorities and reasonably detailed descriptions (in English) of all meetings with and verbal communications with such regulatory authorities which are of significance. Each of Licensor and Licensee shall use its best efforts to complete all clinical trials for which it is responsible within the parameters established by the Committee (as such term is defined in Section 5.4).

Section 5.4 Oversight Committee. (a) Licensee and Licensor shall jointly form an oversight committee (the "Committee") for the purposes of developing and assisting with the implementation of the clinical trials within the Licensed Territory.

> (b) The Committee shall be comprised of four members, two members to be executives appointed by, and to be representatives of, each of Licensee and Licensor. The Committee shall be chaired by a designee of Licensor. In the event of any deadlock or other inability of the Committee to reach a determination with respect to any matter within the authority of the Committee, the issue shall be referred to the respective Chief Executive Officers or General Managers of each party who shall use their best endeavours to agree in good faith to a resolution of the dispute within thirty (30) days of their receipt of notice as to such dispute. If they are unable to resolve the dispute within such thirty (30) day period, it shall be referred to the decision of an external expert suitably qualified to resolve such dispute which is mutually acceptable to both parties, whose decision shall be final. In resolving the dispute, the appointed expert shall take into account clinical development practices and procedures common in the pharmaceutical industry.

> (c) The initial members of the Committee shall be designated by the parties hereto not later than 30 days after the Effective Date. Upon resignation

[\*\*\*] Confidential treatment requested.

by or removal of any member of the Committee, Licensee or Licensor, as appropriate, shall have the sole right to appoint a successor.

(d) The Committee shall meet within thirty (30) days after the Effective Date and thereafter at least every six months until grant of Marketing Regulatory Approvals and Pricing Approvals for Licensed Products [\*\*\*]. The location of such meetings shall alternate between Doylestown, Pennsylvania, United States and Barcelona, Spain unless otherwise agreed to by Licensor and Licensee. The Committee may also meet by means of a telephone or video conference call with the consent of each of Licenser.

(e) Licensee and Licensor shall use reasonable efforts to cause their representatives to attend the meetings of the Committee. If a representative of either of the parties hereto is unable to attend a meeting, such party may designate an alternate to attend such meeting in place of the absent representative. In addition, each party may, with the consent of the other party, invite consultants or scientific advisors to attend meetings of the Committee.

(f) The Committee will report to Licensor and Licensee annually with a written comprehensive report on the execution of the clinical trials.

Section 5.5 Commencement of Marketing. Licensee shall consummate its first commercial sale of each Licensed Product in each country of the Licensed Territory within ninety (90) days after obtaining Pricing Approval (or if Pricing Approval is not applicable, within ninety (90) days of Marketing Regulatory Approval in such country); provided, however, that if Licensee has failed to meet such deadlines in any country because of reasons beyond the control of Licensee, Licensor and Licensee shall discuss in good faith a new deadline for such country. In the event Licensee does not consummate a sale within such period, Licensor may notify Licensee of a default under this Section 5.5 and, in the event such default is not cured within thirty (30) days from such notice of default, Licensor shall have the right to terminate the license granted to Licensee hereunder with respect to such Licensed Product in such country.

Section 5.6. Commencement of Marketing; Post-Commencement Trials. Licensee shall be responsible for conducting, at its own cost and expense such post-marketing clinical trials and research and development activities as Licensee deems useful or necessary to promote the sale of Licensed Products in the Licensed Territory provided that the protocol shall be approved in accordance with Section 5.3(b) in advance of its commencement. Licensor and Licensee shall monitor and supervise the conduct thereof following commencement.

Section 5.7. Standard of Diligence. (a) Licensee shall use commercially reasonable efforts to commercialize the Licensed Products in the Licensed Territory throughout the term of this Agreement in accordance with all applicable legal and regulatory requirements, including promoting the Licensed Products by accepted promotional practices consistent with those used (i) by Licensee in connection with the promotion of its other products and (ii) in the critical care pharmaceutical industry generally.

(b) From and after the date that an NDA with respect to any Licensed Product is filed with the EMEA or the applicable regulatory authority in the Licensed Territory, Licensee shall provide Licensor regularly with summary reports on its plans for launch of Licensed Products in the countries within the Licensed Territory that are member countries of the European Union (in the case of the EMEA) or the countries in Central and South America and of the anticipated commercial potential therefor in such countries.

Section 5.8. Product Failure. In the case of a Product Failure with respect to an Indication in any country, the Committee shall seek to identify a single Replacement Product for development by Licensee and Licensor for such Indication in the country or countries in which such Product Failure occurred. In the event a Replacement Product has not been identified for development in writing by the Committee within one year of such Product Failure, either party shall have the right to terminate this Agreement with respect to such Indication in such country or countries within 30 days following expiration of such one-year period by written notice to the other party. The Committee shall prepare a written development plan with respect to each Replacement Product that has been identified for development by the Committee as promptly as practicable following its identification, which shall include provisions for the funding of Development Costs with respect to such Replacement Product by Licensor, Licensee and other Licensor's licensees in countries outside the Licensed Territory where Licensor or its licensees intend to commercialize such Replacement Product. In the event the Committee has not reached agreement upon such development plan, including the funding of Development Costs, within 90 days after identification of a Replacement Product for development hereunder, then either party shall have the right to terminate this Agreement with respect to such Indication in such country or countries by written notice to the other within the 30 days following expiration of such 90-day period; provided, however, than in such event, Licensor shall not enter into any agreement relating to the development, distribution, marketing and sale of the same product in the Licensed Territory with a third party on terms which, taken as a whole, are more favorable to such third party than those last offered in writing by Licensor for such product.

Section 5.9. Medico-Marketing Plan. Licensee shall submit to Licensor a medico-marketing plan for the Licensed Products (the "Development Plan") as soon as possible, but in any event no later than ninety (90) days prior to the planned launch date in each country of the Licensed Territory, such plan to be updated by Licensee before the end of each calendar year.

Section 5.10. Reports. Licensee shall, as promptly as practicable, submit written reports to Licensor as follows:

(a) quarterly statements showing the amount of sales of Licensed Products in terms of units and currency of the Licensed Territory; and

(b) annual statements by no later than February 28 of each year detailing the medico-marketing activities carried out by Licensee during the previous calendar year.

Section 5.11. Promotional Material. Licensor shall supply Licensee with samples of all training aids and literature used by Licensor and its Affiliates and distributors and sublicensees thereof for training their sales representatives and samples of all promotional and sales material used by Licensor or its Affiliates and distributors and sublicensees thereof for the Licensed Products.

Section 5.12. Promotional Claims. All technical and scientific information and therapeutic claims referred to by Licensee in promotional advertisements, promotional literature, sales aids, training aids and literature and the like with respect to each Licensed Product shall be consistent with any Marketing Regulatory Approval and the information and claims made by Licensor with respect thereto insofar as the latter are consistent with Marketing Regulatory Approvals or permitted practices in the Licensed Territory.

Section 5.13. Samples of Licensee's Promotional Material. Licensee shall supply Licensor with samples of product labeling, packages and/or cartons and the like and of all advertisements, promotional literature, sales aids, training material for salesmen, used by Licensee in connection with the promotion and sale of the Licensed Products.

Section 5.14. Adverse Event Reporting. The Parties shall establish a procedure for the handling of adverse events as soon as is practicable after the Effective Date, which procedure shall be in conformance with all applicable laws, rules and regulations. Each Party shall advise the other, by telephone or facsimile, within twenty-four (24) hours after it becomes aware of any serious adverse event arising in connection with the use of any Licensed Products and shall include the following information: a description of the patient, the Licensed Product, the reporting source and a description of the event and/or such other information as may be required by the relevant regulatory authorities in the Licensed Territory at the time the serious adverse event shall provide the other with a written report delivered by confirmed facsimile of any reported serious adverse event stating the full facts known to it, including but not limited to such information as may be required by the relevant regulatory at the time the serious adverse event shall provide the other with a written report delivered by confirmed facsimile of any reported serious adverse event stating the full facts known to it, including but not limited to such information as may be required by the relevant regulatory authorities in the Licensed Territory at the time the serious adverse event shall provide the other with a written report delivered by confirmed faces and the serious adverse event stating the full facts known to it, including but not limited to such information as may be required by the relevant regulatory authorities in the Licensed Territory at the time the serious adverse event shall provide the other with a more protect.

#### ARTICLE 6

# TRANSFER OF LICENSED KNOW-HOW; CONFIDENTIALITY; PUBLICATION

Section 6.1. Transfer of Licensed Know-How. Promptly after the Effective Date and from time to time as it becomes available during the term of this Agreement, Licensor shall provide Licensee with the Licensed Know-How.

Section 6.2. Confidentiality. Any information disclosed by either party, its Affiliates or permitted licensees to the other party hereunder shall be safeguarded by the recipient, shall not be disclosed to third parties and shall be made available only to recipient's employees, Affiliates, licensees for the Licensed Products or independent contractors who agree to equivalent conditions and who have a need to know the information for the purposes specified under this Agreement. Subject to the license granted under Article 2, all confidential information shall remain the property of and, subject to Sections 7.7 and 7.8, shall be returned to the disclosing party within thirty (30) days of termination of this Agreement. These mutual obligations of confidentiality shall apply during and for a period of ten years after the term of this Agreement, but such obligations shall not apply to any information that:

(a) is or hereafter becomes generally available to the public other than by reason of any default with respect to a confidentiality obligation under this Agreement; or

(b) was already known to the recipient as evidenced by prior written documents in its possession; or

(c) is disclosed to the recipient by a third party who is not in default of any confidentiality obligation to the disclosing party hereunder; or

(d) is developed by or on behalf of the receiving party, without reliance on confidential information received hereunder; or

(e) is provided to third parties under appropriate terms and conditions including confidentiality provisions equivalent to those in this Agreement for development purposes including, without limitation, consulting, manufacturing development, manufacturing, external testing and marketing trials with respect to the products covered by this Agreement; or

(f) is used with the consent of the disclosing party (which consent shall not be reasonably withheld) in applications for patents or copyrights under the terms of this Agreement; or

(g) has been approved in writing for publication by each of

(h) is required to be disclosed in compliance with applicable laws or regulations in connection with the manufacture or sale of products covered by this Agreement; or

(i) is otherwise required to be disclosed in compliance with applicable laws or regulations or order by a court or other regulatory body having competent jurisdiction; or

(j) is product-related information which is reasonably required to be disclosed in connection with marketing of products covered by this Agreement.

Section 6.3. Procedures for Obtaining Permission for Disclosure. In the event that either party (the "Disclosing Party") desires to publish or disclose, by written, oral or other presentation, any confidential information or other information regarding the Licensed Rights, the Disclosing Party shall notify the other party (the "Nondisclosing Party") in accordance with Section 14.2 at least sixty (60) days before any written or other publication or disclosure. The Disclosing Party shall include with such notice a description of any proposed oral presentation or, in any proposed written or other disclosure, a current draft of such proposed disclosure or abstract. The Nondisclosing Party may, no later than thirty (30) days following the receipt of such notice, notify the Disclosing Party that the Nondisclosing Party will not consent to such disclosure of confidential information. If the Disclosing Party does not receive any such objection to the proposed disclosure of confidential information or other information regarding the Licensed Rights within such 30-day period, the Disclosing Party shall be free to make such disclosure in substantially the manner and form proposed at the time notice was given to the Nondisclosing Party.

## ARTICLE 7

#### TERMINATION

Section 7.1. Term. Unless otherwise terminated by operation of law or by acts of the parties in accordance with the provisions of this Agreement, this Agreement shall be in force from the Effective Date and shall remain in effect with respect to each Licensed Product in each country of the Licensed Territory for the duration of the Initial Period. Upon expiry of the Initial Period with respect to any country in the Licensed Territory, the license granted under Section 2.1 shall become fully paid up in such country, except that Licensee shall pay Licensor a royalty equal to one percent of Licensed Product sales for continued use by Licensee of the Trademark and Licensed Know-how. In addition the parties agree that in such event Licensee the capability of manufacturing the Licensed Products and such know-how shall be delivered to Licensee in such a way as to communicate it to Licensee promptly, effectively and economically.

Section 7.2. Termination by Licensor for Breach. Upon any material breach of or default under this Agreement by Licensee, Licensor may terminate this Agreement upon ninety (90) days written notice to Licensee. Said notice shall become effective at the end of said period, unless during said period Licensee shall cure such breach or default or shall take reasonable steps to cure the same.

Section 7.3. Termination by Licensee. Licensee may terminate this Agreement on sixty (60) days advance written notice to Licensor for any reason, whereupon Licensee shall not be obligated to make any further payments to Licensor other than those payments accruing prior to such termination or pursuant to Section 7.9.

Section 7.4. Termination Upon Bankruptcy Event. If (i) Licensee files a petition in bankruptcy or for the appointment of a receiver or trustee, (ii) Licensee proposes a written agreement of composition or extension of its debts or makes an assignment for the benefit of its creditors, or (iii) an involuntary petition against Licensee is filed in any insolvency proceeding and such petition is not dismissed within sixty (60) days after filing, Licensor may immediately terminate this Agreement.

Section 7.5. No Automatic Termination upon Licensor's Bankruptcy. If (i) Licensor files a petition in bankruptcy or for the appointment of a receiver or trustee; (ii) Licensor proposes a written agreement of composition or extension of its debts or makes an assignment for the benefit of its creditors; or (iii) an involuntary petition against Licensor is filed in any insolvency proceeding and such petition is not dismissed within sixty (60) days after filing, Licensee shall have the option to either:

(a) Immediately terminate this Agreement; or

(b) Continue to market the Licensed Products under the Licensed Know-How, Patent Rights, Marketing Regulatory Approvals and the Trademark, in which case the license granted hereunder to Licensee pursuant to Section 2.1 shall become a license to "make, have made, import, use, offer to sell and sell Licensed Products", provided that such license to make or have made Licensed Products shall be nonexclusive and that Licensor shall be entitled to a royalty in an amount equal to the sum of (i) [\*\*\*] and (ii) [\*\*\*] of such Licensed Product sales. Licensee shall be solely responsible for payment of the third party royalty obligations under such circumstances; provided, however, that any royalties to be paid under this sub-section 7.5 (b) shall be due only to the extent that Licensee's cost of the Licensed Product in finished, packaged and labelled form, quality controlled and ready for resale

to the ultimate customer plus the royalties hereinabove established shall not exceed the Transfer Price established in Section 2.2 of the Supply Agreement. In addition the parties agree that in such event the intellectual property delivered to Licensee shall include all know-how necessary or useful to give Licensee the capability of manufacturing the Licensed Products and such know-how shall be delivered to Licensee in such a way as to communicate it to Licensee promptly, effectively and economically.

Section 7.6. Termination With Respect to Competitive Activities. During the term of this Agreement, in the event Licensee acquires a surfactant product suitable for use in treating any ARDS/ALI Indication or Neonatal Indication (including through off-label use) (a "Competitive Product"), or in the event Licensee becomes an Affiliate of a Person whose product line includes a Competitive Product, Licensee shall notify the other party thereof within thirty (30) days of such acquisition or Affiliation and of its intention to either (a) divest such Competitive Product or Affiliation or (b) terminate this Agreement and the Supply Agreement. Any such termination shall be effective sixty (60) days after such notice becomes effective in accordance with Section 14.2. Alternatively, Licensee may notify Licensor that it intends to retain such Competitive Product in its portfolio but does not wish to terminate this Agreement, in which event Licensor shall, within ninety (90) days of such notice, advise Licensee of its intent to terminate this Agreement (which termination shall be effective thirty (30) days after such notice) or acquiescence in Licensee's desire to so retain such Competitive Product. Failing Licensor's notification within such ninety day term, it shall be understood that Licensor agrees to the marketing by Licensee of such Competitive Product and Licensor shall not be entitled thereafter to terminate this Agreement for such reason.

Section 7.7. Reversion. Upon termination of this Agreement for any reason, other than expiry of the Initial Period or under Section 7.8, all rights granted to Licensee hereunder shall revert to Licensor and Licensee undertakes:

(a) to deliver to Licensor all copies of any Licensed Know-how in its possession,

(b) not to use the Licensed Know-how as long as it has to be kept confidential under Article 6 hereof;

(c) to transfer to Licensor, at Licensor's request, a single copy of all Licensee Proprietary Information and, at Licensor's expense, all health regulatory approvals and regulatory filings relating to Licensed Products in Licensee's possession;

(d) to the extent requested by Licensor, to transfer to Licensor or its designee responsibility for and control of ongoing Licensed Products development work, including control over contracts with third parties for such work,

where permissible in accordance with such contracts, in an expeditious and orderly manner with the costs for such work to be assumed by Licensor or its designee as of the date of such transfer; and

> (e) to the extent requested by Licensor, to transfer to Licensor or its designee all inventory of Licensed Products and materials and equipment for manufacture of Licensed Products at a price equal to Licensee's fully amortized standard cost.

Section 7.8. Effect of Certain Terminations. In the event Licensee terminates this Agreement or the Supply Agreement by reason of a material unremedied breach of the same by Licensor [\*\*\*], Licensee shall have the right (without prejudice to Licensee's other rights and remedies at law or under this Agreement, including the right to specific performance hereof by Licensor) to (a) manufacture or procure the supply of Licensed Products from a third party supplier acceptable to Licensee and (b) continue to use, the Licensed Know-How, Patent Rights, Marketing Regulatory Approvals and Trademark on the terms (other than compensation terms) provided herein in exchange for payment of a royalty in an amount equal to the sum of (i) [\*\*\*] and (ii) [\*\*\*] cost of the Licensed Products in finished, packaged and labelled form, quality controlled and ready for resale to the ultimate customer plus the royalties hereinabove established shall not exceed the Transfer Price established in Section 2.2 of the Supply Agreement and only during the Initial Period, after which the royalty to be paid by Licensee shall be reduced to one percent, as established in Section 7.1. In addition the parties agree that in such event Licensor shall deliver to Licensee all know-how necessary or useful to give Licensee the capability of manufacturing the Licensed Products and such know-how shall be delivered to Licensee in such a way as to communicate it to Licensee promptly, effectively and economically.

Section 7.9. Survival. Upon any termination of this Agreement, Articles 3 (except in the event of termination by Licensee under Section 7.8), 6, 9, 10 and 11 and Sections 7.7 through 7.10, shall survive such termination and continue in force and effect to the extent necessary to effectuate such provisions.

Section 7.10. Disposition. Upon termination of this Agreement, other than by expiration of the Initial Period or by Licensee under Section 7.8, subject to Sections 7.4 and 7.7, Licensee shall have no right under the Patent Rights to import, use or sell Licensed Products, except that Licensee shall have the right for one hundred twenty (120) days following termination to dispose of Licensed Products on hand and complete any existing contracts requiring rights under the Patent Rights which can be completed within the one hundred twenty (120) days.

# ARTICLE 8

### INFRINGEMENT

Section 8.1. Notice. (a) In the event that Licensee believes that there is an infringement of the Licensed Rights by a third party hereto selling material quantities of products in the Licensed Territory in competition with Licensee's sale of Licensed Products hereunder, Licensee shall promptly provide Licensor with written notice that such infringement is occurring. In the event that Licensee believes that such infringement is to Licensee's substantial detriment, Licensee shall provide Licensor with reasonable evidence of the infringement.

> (b) Licensor shall have the right, at Licensor's sole expense (subject to Section 8.5(a)), to bring suit against the infringer for infringement of the Licensed Rights. However, if after six (6) months from the date of receipt of evidence of infringement from Licensee, Licensor has not initiated suit against the infringer, Licensee shall have the right, at Licensee's sole expense (subject to Section 8.5(b)), to bring such suit provided that the Original Licensor has consented to Licensee bringing such suit. Licensor shall make its best efforts to obtain the Original Licensor's consent in favor of Licensee.

Section 8.2. Assistance. In the event either party hereto shall initiate or carry on legal proceedings to enforce the Licensed Rights against an alleged infringer, as provided herein, the other party hereto shall render reasonable assistance to and cooperate with the party initiating or carrying on such proceedings.

Section 8.3. Legal Proceedings. In the event that either party shall institute legal proceedings to enforce the Licensed Rights, it shall have sole control of such suit and the other party shall be entitled to be represented in any such suit by counsel of its choosing, at its sole expense.

Section 8.4. Discontinuance. Neither party hereto shall discontinue or settle any such proceedings brought by it without obtaining the concurrence of the other party if such action would impose any obligations on such other party or affect the exercise of the rights granted hereunder to such other party (which concurrence shall not be unreasonably withheld).

Section 8.5. Recoveries. All damages, settlements and awards made or obtained in connection with any suit or other legal proceeding under this Article 8 shall be distributed as follows:

(a) If Licensor initiated the suit and prosecuted it to its conclusion, Licensor shall be entitled to retain the balance of any damages, settlements

and awards, provided that Licensee may elect (within thirty (30) days of initiation of such suit) to fund up to twenty-five percent (25%) of Licensor's litigation costs and to share in the same proportion of net recoveries.

(b) If the Licensee initiated the suit and prosecuted it to its conclusion, Licensee shall be entitled to retain the balance of any damages, settlements and awards; provided that Licensor may elect (within thirty (30) days of initiation of such suit) to fund up to twenty-five percent (25%) of Licensee's litigation costs and to share in the same proportion of net recoveries received by Licensee.

#### ARTICLE 9

## NON-USE OF NAMES

Section 9.1. Non-Use. Subject to the licenses expressly granted hereunder with respect to the Trademark, nothing contained in this Agreement shall be construed as granting to Licensor or Licensee any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of the other (including contraction, abbreviation or simulation of any of the foregoing) without the prior, written consent of the other.

Section 9.2. Relationship. Nothing herein shall be deemed to establish a relationship of principal and agent between Licensor and Licensee, nor any of their agents or employees for any purpose whatsoever. This Agreement shall not be construed as constituting Licensor and Licensee as partners, or as creating any other form of legal association or arrangement which would impose liability upon one party for the act or failure to act of the other party.

#### ARTICLE 10

#### REPRESENTATIONS AND WARRANTIES

Section 10.1 Representations of Licensor. Licensor represents and warrants to Licensee that:

(a) Subject to Section 2.1, it has the right to grant the license granted under this Agreement and that it has full power and authority to execute, deliver and perform this Agreement, the Supply Agreement, the Securities Purchase Agreement and the obligations hereunder and thereunder.

(b) Subject to Section 2.1, to Licensor's knowledge, there are no claims or potential claims by any third parties (other than the Original Licensor



and Scripps) to an ownership interest in the Licensed Rights licensed to Licensee under this Agreement.

(c) Licensor has obtained any required third-party consents under contracts to which Licensor or any of its Affiliates is a party to Licensor's entry into this Agreement, the Supply Agreement and the Securities Purchase Agreement and the performance of its obligations hereunder and thereunder.

(d) To Licensor's knowledge, based solely on a review of the records of the United States Patent and Trademark Office and the corresponding offices in countries other than the United States, the patents listed on Schedule I are subsisting.

(e) No third party has served on Licensor or any of its Affiliates any claim, lawsuit, charge, complaint or other action alleging that the Licensed Rights are invalid or unenforceable or that the Licensed Rights infringe any patent or other proprietary or property rights of any third parties or advised Licensor or any of its Affiliates in writing that it intends to pursue any such claim, lawsuit, charge, complaint or other action. Licensor has not, prior to the date hereof, entered into any compulsory license with a third party with respect to the Patent Rights.

(f) The rights of the Original Licensor and of any subsequent licensor (excluding the Licensor) of the Scripps Patent Rights do not prevent the grant of the license made hereunder nor do such rights permit any such person to sell (directly or indirectly) or license for sale surfactant pharmaceutical preparations based on or embodying the Patent Rights in the Licensed Territory or enable such person to demand any indemnity, royalty or compensation of whatever nature from Licensee as a result of Licensee's sales of Licensed Products in the Licensed Territory in accordance with the terms of this Agreement.

(g) Licensor is not in breach of any of its obligations under the Original License as of the date hereof.

(h) All of Licensor's employees having access to any confidential information with respect to the Licensed Rights are subject to written confidentiality obligations with respect to the disclosure of such information.

(i) Prior to the execution of this Agreement it has disclosed to Licensee all material information pertaining to the Licensed Products and the Patent Rights reasonably relevant to Licensee in order to assess its interest in entering into this Agreement, and that no material information pertaining to the Licensed Products and the Patent Rights actually known to Licensor as of the Effective Date regarding the foregoing has been withheld from Licensee by Licensor.

Section 10.2. Mutual Representation. Each party hereby warrants that the execution, delivery and performance of this Agreement, the Supply Agreement and the Securities Purchase Agreement has been duly approved and authorized by all necessary corporate actions of both parties; does not require any shareholder approval which has not been obtained or the approval and consent of any trustee or the holders of any indebtedness of either party; does not contravene any law, regulation rules or order binding on either party, and does not contravene the provisions of or constitute a default under any indenture, mortgage contract or other agreement or instrument to which either party is a signatory.

Section 10.3. Validity. Subject to the foregoing provisions of this Article 10, nothing in this Agreement shall be construed as a representation or a warranty by Licensor that any process practiced or anything imported, used or sold under any license granted under this Agreement is or will be free from infringement of patents of third parties.

Section 10.4. No Consequential Damages. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES RESULTING FROM EXERCISE OF THIS LICENSE OR SALE OR USE OF LICENSED PRODUCTS OR LICENSED KNOW-HOW.

### ARTICLE 11

### INDEMNIFICATION

Section 11.1. Indemnification by Licensee. Subject to Section 10.4 and to the extent not covered by Licensor's indemnity under Section 11.2, Licensee agrees to indemnify and hold harmless Licensor and its Affiliates and their respective officers, directors, employees and agents from and against any and all claims, damages and liabilities, including reasonable attorneys fees and expenses, asserted by third parties, both government and private (collectively, "Claims"), arising from Licensee's or its Affiliates' or sublicensees' import, use, offer to sell or sale of Licensed Products pursuant to this Agreement, including without limitation any claim for breach of warranty, negligence or strict liability with respect to any Licensed Product.

Section 11.2. Indemnification by Licensor. Subject to Section 10.4, Licensor agrees to indemnify and hold harmless Licensee, its Affiliates and sublicensees and their respective officers, directors, employees and agents from and against any and all Claims arising from (a) any infringement of any patent or other intellectual property interest in the Licensed Territory by any Person other than the parties to this Agreement relating to the Licensed Products; (b) any breach by Licensor of its representations and warranties set forth in this Agreement; (c) any negligent act or omission of Licensor and (d) any intrinsic or manufacturing defect of the Licensed Products existing when the Licensed Products are placed by Licensor in the custody of the carrier for transport to Licensee . This Section shall apply to the Supply Agreement. In the event of any contradiction between the Supply Agreement and any of the terms contained in this Sublicense Agreement, the terms of this Agreement shall prevail.

Section 11.3. Insurance. Licensor and Licensee shall maintain during the term of this Agreement insurance policies covering their respective obligations under this Article 11, issued by reputable insurance companies under ordinary terms and conditions in the pharmaceutical industry and will prove the existence thereof to the other party if so requested.

#### ARTICLE 12

#### TRADEMARK MATTERS; PATENT MARKING

Section 12.1. Trademarks Used in Connection With Licensed Products. (a) Licensed Products shall be marketed under the Trademark. Licensee admits the validity of the Trademark and agrees that it shall not challenge the same in the Licensed Territory or elsewhere.

> (b) Licensor shall be responsible, at its own cost and expense, to register, maintain and renew registrations of the Trademark in the Licensed Territory, to the extent that it is necessary for the purposes of obtaining Marketing Regulatory Approval and for the marketing of the Licensed Products in the Licensed Territory. Licensee agrees not to take any actions (including without limitation effecting any trademark registrations) inconsistent with the foregoing and not to register anywhere in the world any trademark confusingly similar to Surfaxin(R) or any derivative thereof.

> (c) Licensee agrees to take such actions as may be reasonably requested by Licensor to assist Licensor to register, maintain or renew any Trademark at the sole cost and expense of Licensor.

Section 12.2. Patent Marking. Licensee shall mark all Licensed Products made, used, or sold under the terms of this Agreement, or their containers, in accordance with the applicable patent marking laws.

#### ARTICLE 13

#### PATENT PROSECUTION AND MAINTENANCE

Section 13.1. Maintenance of Patent Rights. Licensor has obtained certain commitments from the licensor (the "Original Licensor") of the Scripps Patent Rights and the patent rights listed in Section (b) of Schedule I (collectively, the "Third Party Patent Rights")

that the Original Licensor will maintain the Third Party Patent Rights or, in the event that the Original Licensor does not do so, that Licensor shall be given the right to do so. Licensor undertakes to enforce its rights with respect to maintenance of the Third Party Patent Rights against the Original Licensor and, to the extent Licensor succeeds to the maintenance of the Third Party Patent Rights, to use all commercially reasonable efforts to do so. Licensor further undertakes to maintain the Patent Rights owned by Licensor. Licensor shall provide Licensee with copies of all written materials received by Licensor from the Original Licensor, the Original Licensor's or Licensor's counsel, or any governmental agency or instrumentality relating to prosecution and/or maintenance of Patent Rights and shall afford Licensee the opportunity to review and comment upon any filings to be made with respect to the Patent Rights (in the case of the Third Party Patent Rights, to the same extent Licensor is entitled to do so).

Section 13.2. Cooperation By Parties. Licensor and Licensee agree to cooperate in order to avoid loss of any rights which may be available to Licensor or the Original Licensor under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of Member States of the European Community and other similar measures in any country. Without limiting the foregoing, Licensee agrees to timely supply Licensor with all information reasonably requested by Licensor to file or have filed (or to permit the Original Licensor to file or have filed) an application for patent term extension within the 60-day period following U.S. NDA approval. The same shall apply with respect to the approval by health regulatory authorities in a country of the European Community or approval by the appropriate authorities in any other country in the Licensed Territory.

#### ARTICLE 14

#### GENERAL

Section 14.1. Entire Agreement. This Agreement, including the Schedules and Exhibits hereto, constitutes the entire agreement and understanding between the parties as to the subject matter hereof. All prior negotiations, representations, agreements, contracts, offers and earlier understandings of whatsoever kind, whether written or oral between Licensor and Licensee in respect of the subject matter of this Agreement, are superseded by, merged into, extinguished by and completely expressed by this Agreement. No aspect, part or wording of this Agreement may be modified except by mutual agreement between the Licensor and Licensee taking the form of an instrument in writing signed and dated by duly authorized representatives of both Licensor and Licensee.

Section 14.2. Notices. Any notice or communication or permitted to be given by this Agreement shall be given by post-paid, first class, registered or certified mail or by reputable courier service addressed to:

In the case of Licensor: Discovery Laboratories, Inc. 350 South Main Street, Suite 307 Doylestown, Pennsylvania 18901 Attention: Robert J. Capetola, Ph.D.

Chief Executive Officer

With a copy to:

Han-Hsien Tuan, Esq. Yi Tuan & Brunstein 350 Fifth Avenue, Suite 5411 New York, New York 10118

In the case of Licensee: Laboratorios del Dr. Esteve, S.A. Av. Mare de Deu de Montserrat, 221 08041 Barcelona (Spain) Attention: Director, International

Such addresses may be altered by notice so given. If no time limit is specified for a notice required or permitted to be given by this Agreement, the time limit therefor shall be 10 full business days, not including the day of mailing. Notice shall be considered made as of the date of deposit with the appropriate post office or courier service.

Section 14.3. Governing Laws and Dispute Resolution. (a) This Agreement and its effect are subject and shall be construed and enforced in accordance with the laws of the State of New York, United States, except as to any issue which depends upon the validity, scope or enforceability of any patent within the Patent Rights, which issue shall be determined in accordance with the applicable patent laws of the country of such patent.

> (b) Any controversy or claim arising out of or relating to this Agreement, or the breach, termination or validity thereof which cannot be settled within three (3) months of it having arisen shall be submitted to the respective President or General Manager of each Party and if, within thirty (30) days or such other period as may be agreed upon between the Parties following such reference, the dispute remains unresolved, it shall be settled on application by either Party by arbitration conducted in the English language, in Stockholm (Sweden) in accordance with the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said rules. The parties expressly agree to abide the award rendered. This provision shall not prevent either party from addressing any competent court or tribunal in order to seek for interim measures.

Section 14.4. Conflicts. Nothing in this Agreement shall be construed so as to require the commission of any act contrary to law, and whenever there is any conflict

between any provision of this Agreement or concerning the legal right of the parties to contract and any statute, law, ordinance or treaty, the latter shall prevail, but in such event the affected provisions of this Agreement shall be curtailed and limited only to the extent necessary to bring it within the applicable legal requirements.

Section 14.5. Registration. Licensee shall take all reasonable and necessary steps to register this Agreement in any country where such is required to permit the transfer of funds and/or payment of royalties to Licensor hereunder or is otherwise required by the government or law of such country to effectuate or carry out this Agreement. Notwithstanding anything contained herein, Licensee shall not be relieved of any of its obligations under this Agreement by any failure to register this Agreement in any country, and, specifically, Licensee shall not be relieved of its obligation to make any payment due to Licensor hereunder at Licensor's address specified in Article 14.2 hereof, where such payment is blocked due to any failure to register this Agreement.

Section 14.6. Headings. As used in this Agreement, singular includes the plural and plural includes the singular, wherever so required by the context. The headings appearing at the beginning of the numbered Articles and Sections hereof have been inserted for convenience only and do not constitute a part of this Agreement.

Section 14.7. Agency. Nothing herein shall be deemed to create an agency, joint venture or partnership between the parties hereto.

Section 14.8. Force Majeure. Notwithstanding any other provisions of this Agreement, neither of the parties hereto shall be liable in damages for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its control including but not limited to acts of God, governmental restrictions, wars, or insurrections, strikes, floods, work stoppages and/or lack of materials; provided, however, that the party suffering such delay or default shall notify the other party in writing of the reasons for the delay or default. If such reasons for delay or default continuously exist for six (6) months, this Agreement may be terminated by either party.

Section 14.9. Assignment. Neither party shall assign this Agreement without the prior written consent of the other party, provided, however, that Licensee may assign some or all of its rights and obligations hereunder to the following Affiliates: Laboratorios P.E.N., S.A. (Spain), Esteve Farma, Lda. (Portugal), Provesan S.A. (Switzerland) and to any other Affiliate which Licensee may establish in the Licensed Territory. Licensee hereby warrants and represents that such Affiliates will comply with all applicable terms of this Agreement, and guarantees such Affiliates' performance hereunder.

Section 14.10. Successors and Assigns. Subject to Section 14.9, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of Licensor and Licensee respectively.

Section 14.11. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Section 14.12. Announcements. Neither Party shall make any public announcement or press release regarding the content or signature of this Agreement without the other Party's prior written consent other than as may be required by law or any stock exchange rules. If such public announcement or press release is required by law or any stock exchange rules the Parties shall use their reasonable endeavours to agree to the text and content thereof prior to making such public announcement or press release.

[THE REMAINDER OF THIS PAGE LEFT INTENTIONALLY BLANK]

IN WITNESS WHEREOF, the parties hereto have hereunto set their hands and duly executed this Agreement on the date(s) indicated below, to be effective the day and year first above written.

DISCOVERY LABORATORIES, INC. /s/ Robert J. Capetola By: Robert J. Capetola, Ph. D. President and CEO 26th October 1999 Name: Title: Date: LABORATORIOS DEL DR. ESTEVE, S.A. /s/ Dr. J. Esteve By: Dr. J. Esteve Name: Title: President Date: 26th October 1999

SCHEDULE I

[\*\*\*]

# VIA FACSIMILE & HAND DELIVERED

Laboratorios del Dr. Esteve, S.A. Av. Mare de Deu de Montserrat, 221 08041 Barcelone (Spain)

Attention: Director, International

Re: Sublicense of Surfaxin from Discovery Laboratories, Inc. to Laboratorios del Dr. Esteve, S.A.

Dear Director:

Reference is herein made to the Sublicense Agreement dated October 27, 1999 (the "Agreement") between Discovery Laboratories, Inc. and Laboratorios del Dr. Esteve, S.A.

You have requested and we hereby acknowledge that Mexico is included in the definition of "Licensed Territory" in Article 1, "Definitions," page 4 of the Agreement.

 $\ensuremath{\text{Please}}$  return one countersigned copy to us and one to our attorneys, Yi Tuan & Brunstein. Thank you for your attention.

Very truly yours,

DISCOVERY LABORATORIES, INC.

By:	/s/Robert J. Capetola
Name:	Robert J. Capetola, Ph.D.
Title:	President

ACKNOWLEDGED AND AGREED TO: LABORATORIOS DEL DR. ESTEVE, S.A.

By: /s/ Dr. J. Esteve

Name: /Dr. J. Esteve

Title: President

Certain portions have been omitted pursuant to a request for confidentiality and such omitted portions have been separately filed with the Commission.

#### SUPPLY AGREEMENT

Supply Agreement dated as of October 26th, 1999 by and between DISCOVERY LABORATORIES, INC. ("Seller") and LABORATORIOS DEL DR. ESTEVE, S.A., a company organized and existing under the laws of Spain ("Buyer").

WHEREAS, Seller is engaged in clinical studies of surfactant pharmaceutical preparations for the treatment of acute respiratory distress syndrome ("ARDS"), acute lung injury ("ALI"), infant respiratory distress syndrome ("IRDS") and meconium aspiration syndrome ("MAS"); and

WHEREAS, Seller and Buyer are parties to a Sublicense Agreement dated as of October 26th, 1999 (the "Sublicense Agreement") pursuant to which Buyer has agreed to purchase from Seller, and Seller has agreed to supply to Buyer, Licensed Products (such term and other capitalized terms used and not otherwise defined herein having the meanings assigned to them in the Sublicense Agreement) from Seller.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants set forth below, Seller and Buyer mutually agree as follows:

## ARTICLE I

#### -----

# DEFINITIONS

As used in this Agreement, the following terms shall have the following meanings:

"Affiliate/s" of a Person shall mean any Person which directly or indirectly Controls, is Controlled by or is under common Control with such Person.

"Business Day" shall mean any day on which banking institutions are open or authorized to be open in the Commonwealth of Pennsylvania.

"Current Good Manufacturing Practices" or "cGMP" shall mean (i) with respect to the United States, the good manufacturing practices required by the FDA and set forth in the Federal Food, Drugs and Cosmetics Act or FDA regulations,

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policies or guidelines in effect at a particular time for the manufacture, testing and quality control of pharmaceutical materials and (ii) with respect to any other country, the standards for the manufacture and testing of pharmaceutical materials that are imposed by any regulatory authority having jurisdiction.

"Control" shall mean direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of a Person having outstanding voting securities, or a fifty percent (50%) or greater interest in the income of a Person not having outstanding securities, or, in either case, the power to direct or cause the direction of the management or policies of such Person.

"EMEA" shall mean the European Medicines Evaluation Agency.

"Ex Factory Price" shall mean Licensee or its Affiliate's selling price for each Licensed Product in Spain (officially called "PVL" or "Precio Venta Laboratorio") as such price is authorized from time to time by the Spanish regulatory authorities and set forth in the Spanish Pricing Approval.

"FDA" shall mean the United States Food and Drug Administration.

"Facility" means an Owned Facility or a Contract Facility (in each case as defined in Section 3.1).

"First Commercial Sale" shall mean the first commercial sale by Buyer, its Affiliates or sublicensees of any Licensed Product following final EMEA or other regulatory approval required to market such Licensed Product commercially in the Licensed Territory for use in humans.

"Person" shall mean any natural person, corporation, limited liability company, unincorporated association, partnership, joint venture or other entity.

"Specifications" shall mean the Licensed Product specifications approved by the EMEA and the other regulatory authorities having

jurisdiction in the Licensed Territory, as the same may be amended from time to time in accordance with applicable regulatory procedures.

"Transfer Price" shall mean the price for each Licensed Product established in accordance with Section 2.2.

ARTICLE II

PURCHASE AND SALE OF PRODUCTS

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Section 2.1. Purchase and Sale; Delivery; Acceptance or Rejection.

(a) Seller agrees to sell to Buyer such quantities of Licensed Products, manufactured in conformity with cGMP and meeting the Specifications, as Buyer may order in accordance with the terms and conditions of this Agreement. Subject to the provisions of Sections 3.4 and 7.2 hereof, so long as this Agreement shall remain in effect, Buyer agrees, for itself and its Affiliates and sublicensees, to satisfy solely through the purchase of Licensed Products from Seller under this Agreement 100% of Buyer's and its Affiliates' and sublicensees' requirements for Licensed Products.

(b) Purchase orders issued by Buyer to Seller with respect to purchases of Licensed Products shall be subject to, and governed exclusively by, the terms of this Agreement. Buyer agrees not to issue to Seller any purchase order containing terms different from those set forth herein and further agrees that no shipment of Licensed Product by Seller in accordance with a nonconforming purchase order shall be deemed to be acceptance of any terms of such purchase order conflicting with the terms of this Agreement except to the extent such conflicting terms are initialed by Seller with the words "change accepted" written thereon by Seller. Except as aforesaid, this Agreement shall override all other conflicting terms of purchase and/or sale contained in any purchase and/or sale document generated by Seller or Buyer.

(c) All Licensed Products sold to Buyer hereunder shall be delivered [\*\*\*], subject to paragraph (d) below. [\*\*\*] shall assist [\*\*\*] in arranging transportation in the manner specified by[\*\*\*], in accordance with applicable regulatory requirements, to any destinations specified in writing from time to time by Buyer; provided that all costs and expenses relating to such transportation and delivery (including without limitation customs, duties, taxes, insurance premiums and all expenses relating to validation of temperature-controlled shipment conditions) shall be at [\*\*\*]expense.

(d) Seller will include with each shipment copies of all applicable quality and testing records, which shall be in a form acceptable for any applicable EMEA or other regulatory submission in the Licensed Territory. Product shipments for sale by Buyer in the European countries of the Licensed Territory shall originate from a [\*\*\*] and shall be accompanied by a certificate of analysis made in such [\*\*\*]. Seller shall certify in writing, to Buyer's reasonable satisfaction, that each delivery of Licensed Product was produced and tested in compliance with (i) the Specifications, (ii) cGMP requirements and (iii) all applicable regulatory documents.

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(e) Buyer may reject any portion of any shipment of Licensed Product which does not conform with the Specifications. In order to reject a shipment, Buyer must (i) give notice to Seller of Buyer's intent to reject the shipment within 30 days of receipt together with a detailed written indication of the reasons for such possible rejection, and (ii) as promptly as reasonably possible thereafter, but in any event within an additional thirty (30) days, provide Seller with notice of final rejection and the full basis therefor. After notice of intent to reject is given, Buyer shall cooperate with Seller in determining whether rejection is necessary or justified. If such notices of intent to reject and final rejection are not timely received, Buyer shall be deemed to have accepted such delivery of Licensed Product and to have waived all claims for non-conformity with the Specifications, damage, defect or shortage, other than claims for latent defects not capable of discovery by Buyer upon physical examination. In the event of latent defects not capable of discovery by Buyer upon physical examination, Buyer shall inform Seller within fifteen (15) days of discovering any such defect. Buyer shall be entitled to a refund of the purchase price (together with insurance, freight charges and, where applicable, custom duties) of properly rejected Licensed Products at the time they are ultimately rejected, provided that if Seller disputes the rejection, refund shall be made, if at all, at the time the dispute is finally resolved. Seller shall notify Buyer as promptly as reasonably possible (but in any event no later than thirty (30) days after receipt of Buyer's final rejection notice) whether it accepts Buyer's basis for any rejection. In the event Seller disputes Buyer's rejection, the parties will select a mutually agreeable independent third party laboratory which shall determine whether the rejected Licensed Products meet the applicable Specifications and shall confirm or dissent from Buyer's rejection of Licensed Products. If the parties are unable to agree on a laboratory firm within thirty (30) days after receipt of Buyer's final rejection notice, the laboratory shall be appointed by computer generation of a random number, with an even number signifying Seller's right to designate the laboratory and an odd number designating Buyer's right to designate the laboratory. If the independent tester confirms Buyer's rejection, Seller will pay the fees of the tester, and if the tester dissents from Buyer's rejection, Buyer will pay the fees.

(f) Whether or not Seller accepts Buyer's basis for rejection, promptly on receipt of a notice of rejection, Seller shall use its commercially reasonable efforts, at Buyer's request, to provide replacement Licensed Product, which shall be purchased by Buyer as provided in this Agreement as soon as reasonably practicable.

(g) Unless Seller requests the return to it of a rejected batch within 60 days of receipt of Buyer's notice of rejection, Buyer shall, at Seller's cost, destroy such batch promptly and provide Seller with certification

of such destruction. Buyer shall, upon receipt of Seller's request for return, promptly dispatch said batch to Seller, at Seller's cost.

(h) No change to the Specifications shall be effective unless the same shall be required or permitted by any regulatory agency having jurisdiction over any country in the Licensed Territory, Buyer or the Licensed Products (and if not required, shall be agreed to in writing by Buyer and Seller). Seller shall give Buyer advance notice of any change to the Specifications required by a regulatory agency.

2.2 Price; Method of Payment.

(a) Buyer shall purchase Licensed Products from Seller hereunder at the applicable Transfer Price. The Transfer Price for each unit of Licensed Product shall equal [\*\*\*], subject to paragraph (d) below.

(b) Seller shall invoice Buyer for each shipment of Licensed Products delivered by Seller to Buyer, its Affiliates or sublicensees at the Transfer Price converted into U.S. dollar at the exchange rate of the last Business Day of the calendar month immediately preceding the month when the Licensed Product is shipped to Licensee, as quoted by the Wall Street Journal.

(c) Buyer shall pay Seller's invoices in U.S. Dollar not later than ninety (90) days following the date of the applicable invoice by wire transfer to the bank account designated by Seller.

(d) In the event that the Transfer Price of any Licensed Product represents more than [\*\*\*], Licensor and Licensee shall, at Licensee's request, hold good faith discussions in order to adjust the Transfer Price with respect to Licensed Product sales in such country.

(e) All payments under this Section 2.2 shall be free of all withholdings of any nature whatsoever (including, without limitation, withholding taxes, monetary transfer fees, or similar taxes and charges), and in the event any withholding is required, Buyer shall pay the same together with such additional amount as is required so that each such payment shall be, under any circumstances and in any event, in the amount as set forth or referred to herein.

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[\*\*\*] Confidential treatment requested.

# ARTICLE III

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# PRODUCTION OF PRODUCTS

#### Section 3.1. Manufacturing of Licensed Products.

(a) Until such time, if any, as a Seller-owned manufacturing facility (an "Owned Facility") is qualified for the manufacture of Licensed Products sold to Buyer hereunder, Seller shall manufacture or have manufactured the Licensed Products sold to Buyer hereunder at a contract manufacturing facility (a "Contract Facility") [\*\*\*]. Commencing sixty (60) days prior to the First Commercial Sale of any Licensed Product in a country of the Licensed Territory (provided that such date of First Commercial Sale has been communicated to Seller [\*\*\*] Seller shall maintain at least one alternate production site for Licensed Products sold to Buyer hereunder, which alternate production site, if a Contract Facility, shall [\*\*\*]. Seller's obligation to maintain an alternate manufacturing facility may also be satisfied through a sublicensing arrangement complying with Section 3.2.

(b) Seller shall be responsible for obtaining and maintaining all necessary licenses, registrations, authorizations and approvals (other than such licenses, registrations, authorizations and approvals that are required to be obtained or made by an owner or operator of a Contract Facility) which are necessary to manufacture, handle, store, label, package, transport and ship Licensed Products under CGMP conditions and in accordance with other regulatory requirements.

(c) Seller shall provide Buyer with copies of any correspondence sent from Seller to governmental entities relating to the manufacturing, handling, storage, labeling, packaging, transportation or shipment of Licensed Products at the time such correspondence is sent by Seller, purged of Seller proprietary and/or confidential information and trade secrets. Seller shall provide Buyer with copies of any comments, responses, notices or other correspondence received by Seller from any governmental entity relating to the foregoing matters within fifteen (15) days of receipt of such correspondence by Seller, purged of any Seller proprietary information and/or trade secrets.

(d) Seller shall furnish to Buyer (i) promptly, but in any event within fifteen (15) days after receipt, a summary of any report or correspondence issued by a governmental entity (or a third party authorized by

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[\*\*\*] Confidential treatment requested.

a governmental entity) in connection with a visit or inquiry relating to any Owned Facility or, to the extent Seller is provided with such information, any Contract Facility, including but not limited to, any FDA Form 483 or warning letter and (ii) not later than fifteen (15) days after the time Seller provides such to a governmental entity, summaries of any and all proposed responses or explanations relating thereto (each, a "Proposed Response"), in each case purged of trade secrets or other confidential or proprietary information of Seller. After the filing of a response with the appropriate governmental entity, Seller will notify Buyer of any further oral and/or written contacts with a governmental entity (or a third party authorized by a governmental entity) relating to the manufacturing, handling, storage, labeling, packaging, transportation or shipment of Licensed Products.

(e) If requested in writing by Buyer, Seller shall permit Buyer to inspect, once per year, during normal business hours and hours during which Seller is manufacturing Licensed Products, Seller's Facilities and manufacturing records to the extent Buyer deems it reasonably necessary to enable Buyer to verify compliance with any statutory or regulatory requirements to which Buyer is subject and which are applicable to the manufacture and/or packaging of Licensed Products. Notwithstanding the foregoing, Buyer shall have the right to inspect Seller's Facilities and manufacturing records at any time, in the event that there is a quality or regulatory problem with any Licensed Product. If, as a result of any such inspection, Buyer concludes that Seller is not in compliance with any regulatory obligations or requirements applicable to Buyer, Buyer shall so notify Seller in writing, specifying such areas of noncompliance in reasonable detail and Seller shall remedy the problems identified.

(f) Seller agrees to use all reasonable efforts to promptly rectify or resolve any deficiencies noted by a governmental entity (or third party authorized by a governmental entity) in a report or correspondence issued to Seller with respect to an Owned Facility or a Contract Facility.

#### Section 3.2. Subcontracting.

It is understood and agreed that Seller shall have the right in connection with its performance hereunder to contract with such third parties as Seller deems advisable to manufacture Licensed Products, provided that (i) manufacture and/or quality control by any such third party has been authorised by the competent regulatory authorities in the Licensed Territory, (ii) Seller shall provide Buyer with not less than fifteen (15) days' advance notice of its intent to contract with any third party and shall identify such third party to Buyer, (iii) Buyer may audit Seller's contractor's qualifications and (iv) Seller shall remain fully liable for its performance hereunder to the same extent as if such contractor had not been engaged.

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For so long as the Sublicense Agreement remains in effect with respect to any country in the Licensed Territory, until such time as Buyer has a fully paid-up license in such country in accordance with the terms of the Sublicense Agreement, Seller shall supply Licensed Products only to Buyer for distribution within such country.

#### Section 3.4. Alternate Sources of Supply.

In the event Seller is unable to supply conforming Licensed Products sufficient to meet Buyer's firm orders made consistent with Section 4.1, Buyer shall have the immediate right to manufacture and package Licensed Product with a supplier other than Seller (a "Back-Up Supplier"). Such right shall continue until Seller notifies Buyer that Seller is able to supply all Licensed Products required by Buyer as provided herein, in which case Buyer shall recommence sourcing Licensed Products from Seller once any outstanding orders from a Back-Up Supplier have been satisfied (provided that Buyer shall not at any time enter into binding commitments for the purchase of quantities of Licensed Products from any Back-Up Supplier exceeding Buyer's requirements for Licensed Products during the three-month period commencing with the date of the latest such commitment). Seller shall be entitled to receive a royalty in an amount equal to the sum of [\*\*\*] and (ii) [\*\*\*] of such Licensed Product sales; but only to the extent that Buyer's cost of the Licensed Product in finished, packaged, labelled and quality controlled form ready for resale to the ultimate customer plus the royalties hereinabove established shall not exceed the [\*\*\*]. Buyer may elect to act as Back-Up Supplier or, at its election, have a third party supplier of Buyer's choice (and reasonably acceptable to Seller) act as Back-Up Supplier. Seller shall cooperate fully with Buyer and any separate Back-Up Supplier, and shall use commercially reasonable best efforts to enable the Back-Up Supplier to qualify and validate the Back-Up Supplier's facilities and to manufacture and package Licensed Products. Seller shall give the Back-Up Supplier prompt and unrestricted access to, or, if requested, Seller shall immediately provide to the Back-Up Supplier, all technical information necessary for the Back-Up Supplier to manufacture Licensed Products during the period permitted hereby. Any disclosure or use of technical information will be subject to the confidentiality restrictions set forth in Article 6 of the Sublicense Agreement. The Back-Up Supplier shall have the right to observe the operation of any laboratory and manufacturing and/or packaging facility of Seller (subject to Buyer obligations of confidentiality to third parties), and to have a reasonable number of employees or other representatives of Seller visit the Back-Up Suppliers' facilities, at Buyer's option and in accordance with a mutually agreed timetable, to demonstrate and explain any of the technical information and the manufacturing and packaging processes for the

[\*\*\*] Confidential treatment requested.

Licensed Products. Seller shall reasonably cooperate with Buyer and Back-Up Supplier to obtain any regulatory approval in the Licensed Territory as may be required for the manufacture of Licensed Products by the Back-Up Supplier.

Section 3.5. Allocation in the Event of Shortage.

If for any reason Seller experiences a shortage of materials required to manufacture Licensed Products and Seller is therefore unable to supply Buyer with the full quantity of Licensed Products ordered by it and accepted by Seller, Buyer shall be entitled to receive that quantity of Licensed Products which bears the same proportion to the total quantity of available Licensed Products as the quantity of Licensed Products purchased by Buyer from Seller in the 12 months preceding the supply shortage (or a shorter period if Buyer has started purchasing Licensed Products less than 12 months before the shortage occurs) bears to all purchases of orders from Seller from all customers (including Buyer) for Licensed Products during such period.

## ARTICLE IV

## QUANTITY FORECASTS; ORDERS

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#### Section 4.1. Forecasts.

(a) In order to assist Seller in planning its production, commencing sixty (60) days prior to the calendar month in which the First Commercial Sale of Licensed Products takes place in any country in the Licensed Territory, Buyer shall provide Seller with [\*\*\*] rolling forecast of the quantities of such Licensed Product required by Buyer, by month, for the following [\*\*\*]. The first [\*\*\*] of such projections shall constitute a binding commitment to order the quantity of such Licensed Product forecast for such period, provided that with respect to the first [\*\*\*] provided that the portion of such forecast relating to such country is separately stated and is so indicated. Projections for months [\*\*\*] shall be made in good faith and shall constitute Buyer's best estimates of future orders, but shall not be binding on Buyer. Updated [\*\*\*] forecasts will be provided at the beginning of each succeeding calendar month for the [\*\*\*]. Buyer's forecast shall also describe anticipated regulatory modifications to any English language version of Licensed Product labeling proposed by Seller. Seller shall, no later than fifteen (15) Business Days after receipt of each suck forecast, notify Buyer in writing of any prospective problems of which Seller is aware of that might prevent Seller from meeting Buyer's forecast order quantities or estimated delivery dates.

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[\*\*\*] Confidential treatment requested.

(b) Buyer shall provide Seller with its firm purchase orders for Licensed Product in accordance with the lead-times and batch size increments to be specified by Seller in writing as soon as reasonably practicable but in any event before Buyer places its first order for Licensed Products, such lead-times and batch sizes to be applicable during the term of this Agreement unless otherwise agreed in writing by the parties. Notwithstanding the foregoing, Buyer shall have the right, up to the date of manufacture, to issue binding change orders to increase or decrease such purchase orders with the consent of Seller, which shall not be unreasonably withheld so long as Buyer agrees to compensate Seller for any damages suffered by Seller as a consequence of such change order (including damages attributable to loss of allocable overhead recoupment, but excluding loss of profit), provided that Seller shall advise Buyer before carrying out any change order of Seller's estimated increased cost of doing so. Buyer agrees to accept partial shipments of Licensed Products should, for any reason, it become necessary to ship in advance of order completion, provided that Seller shall (i) give advance written notice to Buyer of such shipment and (ii) bear any additional cost to Buyer of receiving Licensed Products in partial shipments. Seller shall make all commercially reasonable efforts to comply with any revisions to purchase order requirements consistent with the provisions of Section 4.1(a) and this Section 4.1(b). Seller, within ten (10) Business Days after the date that a purchase order is issued to it, shall acknowledge receipt of Buyer's order and confirm in writing that the order can be supplied. For purposes hereof, a purchase order will be deemed issued on the earlier of (i) the date that Seller receives the purchase order via mail and (ii) the date of receipt of the telecopied purchase order.

Section 4.2. Purchase Order Contents.

(a) Each purchase order shall specify the quantity, concentration and container size of Licensed Product ordered and the required delivery date. Seller shall use reasonable commercial efforts to deliver each shipment of Licensed Product within five (5) days of the delivery date specified in Buyer's purchase order relating thereto (provided that in no event shall such date be less than 30 days after the date the purchase order is issued, unless otherwise consented to by Buyer) using carriers mutually agreeable to Buyer and Seller. Seller shall use commercially reasonable efforts to accommodate "Rush" orders from Buyer.

(b) When all appropriate validation and quality control release criteria for a particular shipment of Licensed Product have been met (the "Release Date"), Seller shall notify Buyer in writing of the expected delivery dates (including details of destination, date and time) to enable delivery and receipt to be coordinated. Title and risk of loss to Licensed Products shall

pass to Buyer upon delivery of Licensed Products by Seller to the carrier.

Section 4.3. Packaging.

(a) Licensed Products shall be delivered to Buyer as finished goods in final packaged and labelled form, quality controlled in accordance with Section 2.1 (d) and ready for resale to the ultimate customer and in accordance with the packaging requirements set forth in the Marketing Regulatory Approvals.

(b) Buyer shall distribute all Licensed Products as packaged by Seller in accordance with Section 4.3(a). In no event shall any Licensed Products be repackaged or reconfigured by Buyer without Seller's prior written consent.

## Section 4.4. Labelling.

With respect to each country in the Licensed Territory, prior to distribution of a Licensed Product, Buyer shall provide Seller with evidence of the regulatory approval of labelling specifications for such Licensed Product in such country and any variations required by the applicable regulatory agency. All such materials shall be provided to Seller together with an English translation by a translator reasonably acceptable to Seller. Seller shall distribute Licensed Products bearing only labelling supplied or approved by Buyer and in accordance with such regulatory requirements.

# ARTICLE V

#### CERTAIN OBLIGATIONS OF BUYER

Buyer agrees to ascertain and comply with all applicable laws and regulations and standards of industry or professional conduct in connection with the use, distribution or promotion of the Licensed Products, including without limitation, those applicable to product claims, labelling, approvals, registrations and notifications, and also to obtain Seller's prior written consent to all claims, labels, instructions, packaging or the like, which consent shall not be unreasonably withheld.

Buyer agrees to use commercially reasonable efforts, at its sole expense, to obtain and maintain any applicable approvals, registrations, notifications or the like (other than any NDA or its equivalent for which Seller shall be responsible to the extent provided in the Sublicense Agreement) with regard to marketing, using, selling, labeling or otherwise promoting or making claims regarding the Licensed Products or

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their uses or reimbursement therefor in the Licensed Territory other than those for which Seller is responsible pursuant to the Sublicense Agreement. Seller will reasonably cooperate with Buyer in such efforts. Buyer shall not file any such application or document without Seller's prior written consent, which shall not be unreasonably withheld. To the extent permitted by law, all approvals, registrations, notifications and the like (and all documents, applications and information related thereto) and all rights thereunder or thereto shall be for the sole benefit of and shall be solely owned by and in the name of Seller. Buyer will provide Seller with any information regarding the foregoing that Seller may request (with English translations).

# ARTICLE VI

# REGULATORY MATTERS

Section 6.1. Information Regarding Regulatory Approvals. Seller shall promptly advise Buyer, at Buyer's request, in matters pertaining to U.S. regulatory requirements relating to Seller's activities hereunder. Seller shall also provide to Buyer reasonable advance notice of any regulatory submission containing information or data provided by Buyer to Seller which Seller intends to disclose to regulatory agencies under this Agreement.

Section 6.2. Quality Control Program; Additional Testing Programs. Seller shall maintain a quality control program consistent with cGMP, as required by the FDA and/or any other governmental entity in the Licensed Territory, with respect to Seller's manufacture of Licensed Products hereunder. In addition, Seller will perform such additional testing programs, and provide Buyer with documentation arising from such testing programs, as may be agreed to by Buyer and Seller or required by any applicable regulatory authority.

Section 6.3. Retention of Samples. Seller shall retain as samples such quantities of Licensed Products from each batch of Licensed Product as Buyer shall reasonably request. Retained samples shall be maintained in a suitable storage facility for one year past the product's expiration date. All such samples shall be available for inspection and testing by Buyer at reasonable times and upon reasonable notice.

Section 6.4. Recalls. Buyer shall notify Seller promptly if any Licensed Product is the subject of a recall, market withdrawal or correction within the Licensed Territory (a "Recall"), and Buyer and/or its designee shall have sole responsibility for the handling and disposition of such Recall. Buyer and/or its designee shall bear the costs of all Recalls of Licensed Products except to the extent that such Recall shall have been the result of Seller's breach of any of the warranties set

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forth in this Agreement or the Sublicense Agreement, in which case Seller will promptly reimburse Buyer to such extent for actual, direct costs sustained as a result of the Recall. In the event that Seller disputes Buyer's determination that the fault is due to Seller and/or to its agent, the Parties will select a mutually agreeable outside consulting firm which will be instructed to review the applicable information and data and to confirm or dissent from Buyer's determination. If the consulting firm confirms Buyer's determination, Seller will pay the fees of such consulting firm. If the consulting firm dissents from Buyer's determination, Buyer will pay the fees of such consulting firm. Buyer and/or its designee shall maintain records of all sales of Licensed Products and customers sufficient to adequately administer a Recall, market withdrawal or correction for a period of three years after termination or expiration of this Agreement. Except as required by law, Buyer and/or its designee shall serve as the sole point of contact with the applicable governmental entity concerning any Recall within the Licensed Territory with respect to Licensed Products and Seller shall serve as the sole point of contact with the FDA with respect to any Recall. In the event that Seller is required to communicate with the FDA with respect to Recall of Licensed Products, Seller shall within one Business Day notify Buyer of such communication.

ARTICLE VII

TERMINATION; RIGHTS AND OBLIGATIONS UPON

TERMINATION

Section 7.1. Term. This Agreement shall commence on the date hereof and shall continue in effect with respect to each Licensed Product in each country in the Licensed Territory for so long as the Sublicense Agreement remains in effect with respect to such Licensed Product in such country and Buyer does not have a paid-up license thereunder with respect to such Licensed Product in such country.

Section 7.2. Termination for Default. If either party materially defaults in the performance of any material agreement, condition or covenant of this Agreement or the Sublicense Agreement [\*\*\*] after receipt by the defaulting party of a notice thereof from the other party, the party not in default may terminate this Agreement.

Section 7.3. Rights and Obligations on Expiration or Termination. Except to the extent expressly provided to the contrary, the following provisions shall survive the termination of this Agreement: Sections 6.3 and 6.4 and Articles VIII through X. Any rights of Seller to payments accrued through termination as well as obligations of the parties under firm orders for purchase and delivery of Licensed Products at the time of such termination shall remain in effect, except that in the case

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of termination under Section 7.2, the terminating party may elect whether obligations under firm orders will remain in effect and except that Seller will have no obligation with respect to delivery dates more than three months after termination.

# ARTICLE VIII

# WARRANTIES; REPLACEMENT OF PRODUCTS; INSURANCE

Section 8.1. Warranties. Seller warrants to Buyer for itself and on behalf of its subcontractors and agents who assume any of Seller's obligations hereunder that (i) when shipped to Buyer by Seller, the Licensed Products will conform to the Specifications, as then in effect, and will not be (A) adulterated or misbranded within the meaning of the Food, Drugs & Cosmetic Act or (B) be an article which may not, under the provisions of the Food, Drugs & Cosmetic Act, be introduced into interstate commerce, (ii) any Facility used by Seller will remain in compliance with cGMP at all times during the term of this Agreement and (iii) Seller shall obtain and maintain all necessary permits, registrations and licenses necessary to carry out its obligations pursuant to this Agreement. The foregoing warranties are the only warranties made by Seller with respect to the Licensed Products delivered hereunder, and may only be modified or amended by a written instrument signed by a duly authorized officer of Seller and duly authorized officer of Buyer. THE EXPRESS WARRANTIES CONTAINED IN THIS ARTICLE 8 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTIBILITY OR FITNESS FOR A PARTICULAR USE.

Section 8.2. Replacement of Licensed Products. Any Licensed Products delivered to Buyer by Seller which do not conform to the Specifications and are properly rejected as set forth in Article 2, or which are otherwise not in compliance with the warranties made in Section 8.1 or in the Sublicense Agreement, shall be replaced, or Buyer's account may be credited, at Buyer's election. The remedy of replacement or credit shall not be available if and to the extent that such nonconformance was caused by Buyer's misuse, unauthorized modification, neglect, improper testing or improper storage, including without limitation storage at inappropriate temperatures, transportation, use beyond any dating provided, by accident, fire or other hazard. THE EXPRESS OBLIGATIONS STATED IN THIS SECTION 8.2 AND IN SECTIONS 2.1 AND 8.3 ARE IN LIEU OF ALL OTHER LIABILITIES OR OBLIGATIONS OF SELLER FOR DAMAGES, INCLUDING BUT NOT LIMITED TO DIRECT OR CONSEQUENTIAL DAMAGES, ARISING OUT OF OR IN CONNECTION WITH THE DELIVERY, USE OR PERFORMANCE OF THE PRODUCTS.

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#### Section 8.3. Insurance.

Buyer and Seller shall maintain during the term of this Agreement products liability insurance policies, covering their respective obligations under this Agreement, issued by reputable insurance companies under ordinary terms and conditions in the pharmaceutical industry and will prove the existence thereof to the other party if so requested.

#### ARTICLE IX

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# MISCELLANEOUS

Section 9.1. Entire Agreement This Agreement, including the Schedules and Exhibits hereto, constitutes the entire agreement and understanding between the parties as to the subject matter hereof. All prior negotiations, representations, agreements, contracts, offers and earlier understandings of whatsoever kind, whether written or oral between Seller and Buyer in respect of the subject matter of this Agreement, are superseded by, merged into, extinguished by and completely expressed by this Agreement. No aspect, part or wording of this Agreement may be modified except by mutual agreement between the Seller and Buyer taking the form of an instrument in writing signed and dated by duly authorized representatives of both Seller and Buyer. The representations and warranties made by Seller in the Sublicense Agreement are incorporated herein by reference, provided that no breach of such representations and warranties shall be the basis for a termination of this Agreement unless the Sublicense Agreement is terminated simultaneously.

Section 9.2. Notices Any notice or communication or permitted to be given by this Agreement shall be given by post-paid, first class, registered or certified mail or reputable courier service addressed to:

> In the case of Seller: Discovery Laboratories, Inc. 350 South Main Street, Suite 307 Doylestown, Pennsylvania 18901 Attention: Robert J. Capetola, Ph.D. Chief Executive Officer

> > With a copy to:

Yi Tuan & Brunstein The Empire State Building 350 Fifth Avenue, Suite 5411 New York, New York 10118 Attention: Han-Hsien Tuan

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In the case of Buyer:	Laboratorios del Dr. Esteve, S.A. Av. Mare de Deu de Montserrat, 221
	08041 Barcelona (Spain)
	Attention: Director, International

Such addresses may be altered by notice so given. If no time limit is specified for a notice required or permitted to be given by this Agreement, the time limit therefor shall be 10 full Business Days, not including the day of mailing. Notice shall be considered made as of the date of deposit with the appropriate Post Office or courier service.

Section 9.3. Governing Laws and Dispute Resolution.

(a) This Agreement and its effect are subject and shall be construed and enforced in accordance with the laws of the State of New York, United States, except as to any issue which depends upon the validity, scope or enforceability of any patent within the Patent Rights, which issue shall be determined in accordance with the applicable patent laws of the country of such patent.

(b) Any controversy or claim arising out of or relating to this Agreement, or the breach, termination or validity thereof which cannot be settled within three (3) months of it having arisen shall be submitted to the respective President or General Manager of each Party and if, within thirty (30) days or such other period as may be agreed upon between the Parties following such reference, the dispute remains unresolved, it shall be settled on application by either Party by arbitration conducted in the English language, in Stockholm (Sweden) in accordance with the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said rules. The parties expressly agree to abide the award rendered. This provision shall not prevent either party from addressing any competent court or tribunal in order to seek for interim measures.

Section 9.4. Conflicts. Nothing in this Agreement shall be construed so as require the commission of any act contrary to law, and whenever there is any between any provision of this Agreement or concerning the legal right the parties to contract and any statute, law, ordinance or treaty, the latter prevail, but in such event the affected provisions of this Agreement shall curtailed and limited only to the extent necessary to bring it within the applicable legal requirements.

Section 9.5. Registration. Buyer shall take all reasonable and necessary steps to register this Agreement in any country where such is required to



permit the transfer of funds and/or payment of royalties to Seller hereunder or is otherwise required by the government or law of such country to effectuate or carry out this Agreement. Notwithstanding anything contained herein but subject to Section 9.4 hereof, Buyer shall not be relieved of any of its obligations under this Agreement by any failure to register this Agreement in any country, and, specifically, Buyer shall not be relieved of its obligation to make any payment due to Seller hereunder at Seller's address specified in Section 9.2 hereof, where such payment is blocked due to any failure to register this Agreement.

Section 9.6. Headings. As used in this Agreement, singular includes the plural and plural includes the singular, wherever so required by the context. The headings appearing at the beginning of the numbered Articles and Sections hereof have been inserted for convenience only and do not constitute a part of this Agreement.

Section 9.7. Agency. Nothing herein shall be deemed to create an agency, joint venture or partnership between the parties hereto.

Section 9.8. Force Majeure. Notwithstanding any other provisions of this Agreement, neither of the parties hereto shall be liable in damages for any delay or default in performing hereunder if such delay or default is caused by conditions beyond its control including but not limited to acts of God, governmental restrictions, wars, or insurrections, strikes, floods, work stoppages and/or lack of materials; provided, however, that the party suffering such delay or default shall notify the other party in writing of the reasons for the delay or default. If such reasons for delay or default continuous exist for six (6) months, this Agreement may be terminated by either party.

Section 9.9. Assignment. Neither party shall assign this Agreement without the prior written consent of the other party, provided, however, that Buyer may assign some or all of its rights and obligations hereunder to the following Affiliates: Laboratorios P.E.N., S.A. (Spain), Esteve Farma, Lda. (Portugal), Provesan S.A. (Switzerland) and to any other Affiliate which Buyer may establish in the Licensed Territory. Buyer hereby warrants and represents that such Affiliates will comply with all applicable terms of this Agreement, and guarantees such Affiliates' performance hereunder.

Section 9.10. Successors and Assigns. Subject to Section 9.9, this Agreement shall be binding upon and inure to the benefit of the permitted successors or permitted assigns of Seller and Buyer respectively.

Section 9.11. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

# ARTICLE X

# BASIS OF BARGAIN

EACH PARTY RECOGNIZES AND AGREES THAT THE WARRANTY DISCLAIMERS AND LIABILITY AND REMEDY LIMITATIONS IN THIS AGREEMENT ARE MATERIAL, BARGAINED FOR BASES OF THIS AGREEMENT AND THAT THEY HAVE BEEN TAKEN INTO ACCOUNT AND REFLECTED IN DETERMINING THE CONSIDERATION TO BE GIVEN BY EACH PARTY UNDER THIS AGREEMENT AND IN THE DECISION BY EACH PARTY TO ENTER INTO THIS AGREEMENT.

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DISCOVERY LABORATORIES, INC.

By:	/s/ Robert J. Capetola,
Name:	Robert J.Capetola, Ph.D.
Title:	President & CEO

LABORATORIOS DEL DR. ESTEVE, S.A.

By:	/s/ Dr. J. Esteve
Name:	Dr. J. Esteve
Title:	President

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#### SECURITIES PURCHASE AGREEMENT

SECURITIES PURCHASE AGREEMENT dated as of October 26th , 1999, between LABORATORIOS P.E.N., S.A., a corporation organized under the laws of Spain (the "Purchaser"), and DISCOVERY LABORATORIES, INC., a Delaware corporation (the "Seller").

WHEREAS, Seller wishes to sell to Purchaser and Purchaser wishes to purchase from Seller, upon the terms and subject to the conditions of this Agreement, certain shares of common stock of Seller, par value \$0.001 per share ("Common Stock"), upon the terms and subject to the conditions set forth in this Agreement;

WHEREAS, Seller and Purchaser are entering into this Agreement in contemplation of Seller and Purchaser's affiliate Laboratorios del Dr. Esteve, S.A. entering into that certain Sublicense Agreement dated as of October 26th , 1999 (the "Sublicense Agreement") relating to Seller's Surfaxin(R) product; and

WHEREAS, Seller and Purchaser are executing and delivering this Agreement in accordance with and in reliance upon the exemption from securities registration afforded, inter alia, by Regulation D as promulgated by the United States Securities and Exchange Commission (the "SEC") under the Securities Act of 1933, as amended (the "1933 Act"), and/or Section 4(2) of the 1933 Act.

NOW, THEREFORE, in consideration of the premises and the respective agreements hereinafter set forth, the parties hereto agree as follows:

#### ARTICLE I

#### PURCHASE AND SALE

Section 1.01. Purchase and Sale. Upon the terms and subject to the conditions set forth in this Agreement, Seller agrees to sell to Purchaser, and Purchaser agrees to purchase from Seller, on the Closing Date (as defined below) [this amount will be fixed at closing by the following equation: the quotient of (a) the Purchase Price and (b) a fifty percent (50%) premium to the average closing price of the Seller's stock for the ten (10) days preceding the Closing] shares of Common Stock (the "Shares"). In consideration of the sale and transfer to Purchaser of the Shares, Purchaser shall pay to Seller on the Closing Date, by wire transfer of immediately available funds, an aggregate purchase price of approximately Eight Hundred Fifty Thousand Dollars (\$850,000) (the "Purchase Price").

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Section 1.02. The Closing. The acquisition by Purchaser of the Shares (the "Closing") shall occur within 5 (five) business days of the date of execution of this Agreement, subject to satisfaction or waiver of the conditions set forth in Articles V and VI, at the offices of Yi Tuan & Brunstein, The Empire State Building, 350 Fifth Avenue, Suite 5411, New York, New York or at such other time and place as the Seller and the Purchaser may agree.

Section 1.03. Further Assurances. From and after the Closing, upon written request from and at the expense of Purchaser, Seller shall execute, acknowledge and deliver all such further acts, assurances, deeds, assignments, transfers, conveyances and other instruments and papers as may be reasonably required to sell, assign, transfer, convey and deliver the Shares to Purchaser.

#### ARTICLE II

#### REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Purchaser, acknowledging that such representations and warranties are made by Seller with the intent that they be relied upon by Purchaser in determining whether to invest in the Shares as follows:

Section 2.01. Organization and Qualification of Seller. The Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has the requisite corporate power to own its properties and to carry on its business as now being conducted. The Seller is duly qualified as a foreign corporation to do business and is in good standing in each jurisdiction where the nature of the business conducted or property owned by it makes such qualification necessary, other than those jurisdictions in which the failure to so qualify would not have a material adverse effect on the business, operations or condition (financial or otherwise) of Seller. The Seller has registered certain of its Common Stock pursuant to Section 12 of the 1934 Act, and such Common Stock is listed and traded on The NASDAQ SmallCap Market.

Section 2.02. Authority. Seller has the requisite power and authority to execute and deliver this Agreement and the other agreements and instruments to be executed and delivered by Seller pursuant hereto and to consummate the transactions contemplated hereby and thereby. All corporate acts and other proceedings required to be taken by or on the part of Seller to authorize such execution, delivery and consummation have been duly and properly taken .

Section 2.03. Enforceability. This Agreement has been duly executed and

delivered by Seller and constitutes, and such other agreements and instruments when duly executed and delivered by Seller will constitute, legal, valid and binding obligations of Seller enforceable against Seller in accordance with their respective terms, subject as to enforceability to general principles of equity and to bankruptcy, insolvency, moratorium, and other similar laws affecting the enforcement of creditors' rights generally. No approval, authorization, consent or other order or action of or filing with any court, administrative agency or other governmental body in the United States of America or any foreign government is required for the execution and delivery by Seller of this Agreement and the execution and delivery by Seller of such other agreements and instruments or the consummation by Seller of the transactions contemplated hereby or thereby.

Section 2.04. Capitalization; Status of the Shares. (a) As of the date hereof, the authorized capital stock of Seller consists of 35,000,000 shares of Common Stock, par value \$0.001 per share, and 5,000,000 shares of Preferred Stock, par value \$0.001 per share, of which 2,420,282 are designated Series B Convertible Preferred Stock of Seller (the "Series B Preferred Stock") and 2,039 are designated Series C Convertible Preferred Stock of Seller (the "Series C Preferred Stock"). As of the date hereof, (i) 9,064,889 shares of Common Stock were issued and outstanding, (ii) 1,617,505 shares of Series B Preferred Stock were issued and outstanding and are convertible into 5,035,706 shares of Common Stock, (iii) 2,039 shares of Series C Preferred Stock were issued and outstanding and are convertible into shares of Common Stock having an aggregate market value of \$2,467,190, (iv) 2,000 shares of Common Stock are held in the treasury of Seller, (v) 2,154,428 shares of Common Stock are reserved for issuance upon exercise of outstanding options issued under (A) Seller's 1998 Stock Incentive Plan, Seller's 1995 Stock Option Plan and Seller's 1993 Stock Option Plan (the "Option Plans") and (B) stock option plans of certain corporate predecessors of Seller, (vi) an aggregate of 2,297 shares of Common Stock are reserved for issuance under stock options granted by Seller outside the Option Plans, (vii) an aggregate of 2,593,818 shares of Common Stock are reserved for issuance under outstanding investor warrants, (viii) 684,997 shares of Common Stock are reserved for issuance upon conversion of the 220,026 shares of Series B Preferred Stock upon the exercise of outstanding warrants, and (ix) 173,333 shares of Common Stock are reserved for issuance upon exercise of Seller's outstanding unit purchase option (including warrants issuable upon the exercise of such unit purchase option). All of the outstanding shares of Common Stock have been duly authorized and validly issued and are fully paid and nonassessable and free of preemptive rights.

> (b) The Shares, upon such issuance, will be validly issued, fully paid and nonassessable shares of Common Stock. Except as described in the Reports (as hereinafter defined) or as set forth in this Agreement, there are no preemptive rights or other rights to subscribe for or to purchase, or any restrictions upon the voting or transfer of, any shares of Common Stock, pursuant to Seller's Certificate of Incorporation or Bylaws or any agreement or other instrument to which Seller is a party. The sale of the Shares as contemplated in this Agreement does not give rise to any rights, other than those which have been waived for or relating to the registration of any shares of Common Stock (other than as provided in Article 4 of this Agreement). The Shares are not subject to any voting trust agreement or other contract, agreement, arrangement, commitment or understanding, including any such

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agreement, arrangement, commitment or understanding restricting or otherwise relating to the voting, dividend rights or disposition of the Shares other than this Agreement.

Section 2.05. SEC Filings. Seller has duly and timely filed with the SEC all reports (the "Reports") required by the Securities Exchange Act of 1934 (the "1934 Act"). None of the Reports contained, at the time they were filed, any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements made therein in light of the circumstances under which they were made, not misleading. The financial statements (including the related notes) of Seller included in the Reports present fairly the financial position of Seller as of the dates indicated and its results of operations for the period specified therein. All such financial statements have been prepared in accordance with United States generally accepted accounting principles on a basis consistently applied. Seller will timely make in the future all required filings with the SEC.

Section 2.06. Absence of Certain Changes. Since December 31, 1998, there has been no material adverse change in the business, properties, operations, condition (financial or otherwise), or results of operations of Seller, except as disclosed in Seller's SEC filings and except for uses of cash in the course of Seller's business and corresponding decreases in stockholders' equity.

Section 2.07. No Conflicts. Seller is not in violation of its Certificate of Incorporation or Bylaws or in default in the performance of any material obligation contained in any material agreement, indenture or other instrument. The performance by Seller of its obligations under this Agreement and the consummation of the transactions herein contemplated will not conflict with or result in a breach of the Certificate of Incorporation or Bylaws of Seller, or any material agreement, indenture or other instrument to which Seller is a party or by which it is bound, or any law, rule, administrative regulation or decree of any court or governmental authority having jurisdiction over Seller or its properties, or result in the creation or imposition of any material lien, charge, claim or encumbrance upon any property or asset of Seller under any such agreement, indenture or other instrument. Except as required by the Act and applicable state securities or blue sky laws, no consent, approval, authorization or order of any court or governmental authority is required in connection with the consummation of the transactions contemplated by this Agreement. The rights granted to the Purchaser hereunder do not in any way conflict with and do not violate any rights granted to the other holders of Seller's securities or debt instruments.

Section 2.08. Properties. Except as otherwise stated in the Reports, (A) Seller has good marketable title (in fee simple, in the case of real property), free and clear of all liens and encumbrances, to all of the material real and personal property described in the Report as being owned by it, except for any liens and encumbrances which are not material in the aggregate and do not materially interfere with the conduct of the business of Seller, and (B) has valid leases to the material real property described in the Report as under lease to it with such exceptions as do not materially interfere with the conduct of the business of Seller.

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Section 2.09. Disputes. Except as set forth in the Reports, there are no actions, suits or proceedings pending before or by any court or governmental agency or authority, or any arbitrator, which seek to restrain or prohibit the consummation of the transactions contemplated hereby or which might reasonably be expected to result in any material adverse change in the condition (financial or other), business or results of operations of Seller and, to Seller's knowledge, no such action, suit or proceeding is being threatened.

Section 2.10. Compliance with Laws. Seller is not in violation of any law, ordinance, governmental rule or regulation or court degree to which it may be subject and Seller has not failed to obtain any license, permit, franchise or other governmental authorization necessary to the ownership of its property or to the conduct of its business as conducted on the date hereof, which violation or failure to obtain is likely to have a material adverse effect on the condition (financial or other), business or results of operations of Seller.

#### ARTICLE III

#### REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to Seller, acknowledging that such representations and warranties are made by Purchaser with the intent that they be relied upon by Seller in determining whether to sell the Shares, as follows:

Section 3.01. Organization. Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization.

Section 3.02. Authority. Purchaser has the full corporate power and authority to execute and deliver this Agreement and the other agreements and instruments to be executed and delivered by Purchaser pursuant hereto and to consummate the transactions contemplated hereby and thereby. All corporate acts and other proceedings required to be taken by or on the part of Purchaser to authorize such execution, delivery and consummation have been duly and properly taken.

Section 3.03. Enforceability. This Agreement has been duly executed and delivered by Purchaser and constitutes, and such other agreements and instruments when duly executed and delivered by Purchaser will constitute, legal, valid and binding obligations of Purchaser enforceable against Purchaser in accordance with their respective terms, subject as to enforceability to general principles of equity and to bankruptcy, insolvency, moratorium, and other similar laws affecting the enforcement of creditors' rights generally. No approval, authorization, consent or other order or action of or filing with any court, administrative agency or other governmental body in the United States of America or any foreign government is required for the execution and delivery by Purchaser of this Agreement and the execution and delivery by Purchaser of such other agreements and instruments or the

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consummation by Purchaser of the transactions contemplated hereby or thereby.

Section 3.04. Securities Act of 1933. (a) The Shares are being acquired by Purchaser for its own account, for investment purposes only and not with a view to any public distribution thereof, and Purchaser will not offer to sell or otherwise dispose of the Shares in violation of the registration requirements of the 1933 Act.

(b) The Purchaser has received and carefully reviewed copies of (i) Seller's Annual Report on Form 10-KSB for the year ended December 31, 1998 (including without limitation the section thereof entitled "Important Considerations Regarding Forward-Looking Statements"), (ii) Seller's Quarterly Report on Form 10-QSB for the quarter ended June 30, 1999 and (iii) all current reports on Form 8-K filed since the date of the Seller's Form 10-QSB for the quarter ended June 30, 1999. Purchaser has also been afforded the opportunity to ask questions of and receive answers from duly authorized officers or other representatives of Seller and has received any additional information regarding Seller which Purchaser has requested.

(c) The Purchaser's consent to this Agreement was not obtained by means of any form of general solicitation or general advertising, and in connection therewith Purchaser did not: (A) receive or review any advertisement, article, notice or other communication published in a newspaper or magazine or similar media or broadcast over television or radio whether closed circuit, or generally available; or (B) attend any seminar meeting or industry investor conference whose attendees were invited by any general solicitation or general advertising.

(d) The Purchaser is an accredited investor within the meaning of Rule 501 under the 1933 Act, and Purchaser was not formed for the purpose of receiving the Shares. The Purchaser, either by reason of Purchaser's business or financial experience or the business or financial experience of Purchaser's purchaser representative (within the meaning of Rule 501 under the 1933 Act), which Purchaser representative, if any, is unaffiliated with and is not compensated by Seller or any affiliate of Seller, directly or indirectly, has the capacity to protect Purchaser's interests in connection with the transactions contemplated by this Agreement.

(e) The Purchaser recognizes that its purchase of the securities contemplated herein involves a high degree of risk in that (i) an investment in Seller is highly speculative and (ii) Purchaser could sustain the loss of Purchaser's entire investment.

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#### ARTICLE IV

#### FURTHER COVENANTS AND AGREEMENTS

Section 4.01. Certificates; Restrictive Legend; Stop Transfer Instructions. Upon the Closing Date, Seller shall deliver to Purchaser one certificate representing the Shares, duly executed by or on behalf of Seller. Purchaser acknowledges and agrees that the Shares shall bear a restrictive legend in substantially the following form:

> THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS, AND MAY NOT BE SOLD, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED ABSENT SUCH REGISTRATION UNLESS EVIDENCE SATISFACTORY TO COUNSEL FOR THE COMPANY THAT AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE HAS BEEN DELIVERED TO THE COMPANY.

The share certificate may also have such additional legends, if any, as may be required in order to comply with the applicable "blue sky" laws of any jurisdiction. The Purchaser further agrees to the issuance by Seller to its transfer agent of stop transfer instructions with respect to any sale or other transfer of the Shares by Purchaser absent registration under the Securities Act or the establishment by Purchaser of an exemption therefrom in accordance with this Agreement.

Section 4.02. Transfer Restrictions. Purchaser acknowledges that:

(a) the Shares have not been and are not being registered under the provisions of the 1933 Act and are not intended to be registered under the Securities Act and are intended to be exempt from the registration requirements of Section 5 of the Securities Act pursuant to Sections 4(2) of the 1933 Act and Regulation D promulgated thereunder;

(b) the Shares may not be transferred, and Purchaser agrees not to transfer such Shares, unless (A) such sale or transfer is registered under the 1933 Act or (B) Purchaser shall have delivered to Seller an opinion of counsel, reasonably satisfactory in form, scope and substance to Seller, to the effect that the Shares to be sold or transferred may be sold or transferred pursuant to an exemption from such registration;

(c) any sale of the Shares made in reliance on Rule 144 promulgated

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under the 1933 Act may be made only in accordance with the terms of said Rule and further, if said Rule is not applicable, any resale of such Shares under circumstances in which the seller, or the person through whom the sale is made, may be deemed to be an underwriter, as that term is used in the 1933 Act, may require compliance with some other exemption under the 1933 Act or the rules and regulations of the SEC thereunder; and

(d) neither Seller nor any other person is under any obligation to register the Shares under the 1933 Act or, except as provided in Section 4.04, to comply with the terms and conditions of any exemption thereunder.

Section 4.03. Rule 144 Undertaking. For so long as and to the extent necessary to permit Purchaser to sell the Shares pursuant to Rule 144 under the 1933 Act, Seller shall use reasonable efforts to file, on a timely basis, all reports and data required to be filed with the SEC by Seller pursuant to Section 13 of the 1934 Act. Seller has filed all reports required to be so filed by it during the preceding twelve (12) months. Notwithstanding anything contained in this Section 4.03, Seller may deregister under Section 12 of the 1934 Act if it then is permitted to do so pursuant to the 1934 Act and the rules and regulations thereunder.

Section 4.04. Transfer Taxes. Purchaser and Seller shall each be responsible for all transfer and similar taxes assessed or payable in connection with the transfer of the Shares pursuant to this Agreement in their respective jurisdictions; provided that this Section 4.04 shall not apply to (i) taxes which are net income, capital, net worth, franchise, or similar conduct of business taxes which are imposed on either party by any national, provincial, state or local taxing authority; (ii) taxes imposed as a direct and primary result of any party's gross negligence or willful misconduct; and (iii) taxes imposed as a result of either party's failure to file any applicable tax report or return in a timely or proper manner.

Section 4.05. Additional Covenants of Seller. (a) For so long as Purchaser is the holder of any Shares, Seller will use commercially reasonable efforts to pay all taxes (other than those taxes that are being contested in good faith by Seller through appropriate proceedings) and to comply with all applicable laws noncompliance with which would be expected to have a material adverse effect on Seller.

> (b) Seller undertakes to notify Purchaser as soon as reasonably practical of any material change in any representation, warranty or other information relating Seller set forth herein which occurs prior to the Closing.

> (c) Neither the Company nor any of its employees or other persons directly or indirectly affiliated with it will engage in any activity that would jeopardize the status of the Offering as an exempt transaction under the Act or under the laws of any state in which the Offering is made.

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#### ARTICLE V

#### CONDITIONS PRECEDENT TO OBLIGATIONS OF PURCHASER

All obligations of Purchaser to effect the Closing hereunder are, at the option of Purchaser, subject to the conditions precedent that, at the Closing:

Section 5.01. Performance by Seller. All the terms, covenants, agreements and conditions of this Agreement to be complied with and performed by Seller on or before the Closing shall have been complied with and performed in all material respects.

Section 5.02. Representations and Warranties. The representations and warranties made by Seller in this Agreement shall have been true and correct in all material respects at the date hereof and as of the Closing with the same force and effect as though all such representations and warranties had been made as of the Closing.

Section 5.03. No Injunctions. No provision of any applicable law or regulation and no judgment, injunction, order or decree shall prohibit the consummation of the Closing.

Section 5.04. Sublicense Agreement. Seller shall have executed and delivered to Purchaser's affiliate Laboratorios del Dr. Esteve, S.A. the Sublicense Agreement.

Section 5.05. Consents. All consents, approvals, authorizations and orders required to be obtained from, and all registrations, filings and notices required to be made with or given to, any relevant governmental or regulatory authority or any other person or entity shall have been duly obtained, made or given, as the case may be, and shall be in full force and effect, and any waiting period required by any statute, ordinance, law, rule, regulation, code, injunction, judgment, order, decree, ruling or other requirement, standard or procedure enacted, adopted or applied by any Governmental Authority, including judicial decisions applying common law or interpreting any other law or any governmental or regulatory authority in connection with such transactions shall have expired or have been earlier terminated, except such consents as would not, individually or in the aggregate, have a material adverse effect if not received by the Closing Date.

Section 5.06. Approvals. The Seller shall have taken all action necessary to authorize the execution of this Agreement and the consummation of the transactions contemplated hereby, including any actions required to be taken by the Board of Directors of the Seller and/or its shareholders pursuant to State law.

Section 5.07. Seller's Certificate. Purchaser shall have received from Seller, in form and substance reasonably satisfactory to Purchaser and its counsel, a certificate of Seller, dated the Closing Date, of Seller, confirming the satisfaction of the conditions set forth in

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#### Sections 5.01 and 5.02.

Section 5.08. Secretary's Certificate. Purchaser shall have received from Seller, in form and substance reasonably satisfactory to Purchaser and its counsel, a certificate, dated the Closing Date, of the Secretary or an Assistant Secretary of Seller, (i) certifying all documents evidencing the actions of Seller authorizing the transactions contemplated hereby and the execution, delivery and performance by Seller of this Agreement and the documents contemplated hereby, (ii) certifying the Certificate of Incorporation and Bylaws of Seller, (iii) containing a certificate of good standing from the Secretary of State of the State of Delaware, and (iv) containing an incumbency certificate regarding the officers authorized to sign this Agreement and the other documents contemplated hereby.

Section 5.09. Opinion of Counsel. Purchaser shall have received from Seller's counsel an opinion reasonably acceptable to Purchaser.

## ARTICLE VI

#### CONDITIONS PRECEDENT TO OBLIGATIONS OF SELLER

All obligations of Seller to effect the Closing hereunder are, at the option of Seller, subject to the conditions precedent that, at the Closing:

Section 6.01. Performance by Purchaser. All the terms, covenants, agreements and conditions of this Agreement to be complied with and performed by Purchaser on or before the Closing shall have been complied with and performed in all material respects.

Section 6.02. Representations and Warranties. The representations and warranties made by Purchaser in this Agreement shall have been true and correct in all material respects at the date hereof and as of the Closing with the same force and effect as though all such representations and warranties had been made as of the Closing.

Section 6.03. No Injunctions. No provision of any applicable law or regulation and no judgment, injunction, order or decree shall prohibit the consummation of the Closing.

Section 6.04. Sublicense Agreement. Purchaser's affiliate Laboratorios del Dr. Esteve, S.A. shall have executed and delivered to Seller the Sublicense Agreement.

Section 6.05. Consents. All consents, approvals, authorizations and orders required to be obtained from, and all registrations, filings and notices required to be made with or given to, any relevant governmental or regulatory authority or any other person or entity shall have been duly obtained, made or given, as the case may be, and shall be in full force and effect, and any waiting period required by any statute, ordinance, law, rule, regulation, code,

injunction, judgment, order, decree, ruling or other requirement, standard or procedure enacted, adopted or applied by any governmental authority, including judicial decisions applying common law or interpreting any other law or any governmental or regulatory authority in connection with such transactions shall have expired or have been earlier terminated, except such consents as would not, individually or in the aggregate, have a material adverse effect if not received by the Closing Date.

Section 6.06. Approvals. The Purchaser shall have taken all action necessary to authorize the execution of this Agreement and the consummation of the transactions contemplated hereby, including any actions required to be taken by the Board of Directors of the Purchaser and/or its shareholders pursuant to the law of the jurisdiction of its organization.

Section 6.07. Purchaser's Certificate. Seller shall have received from Purchaser, in form and substance reasonably satisfactory to Seller and its counsel, a certificate of Purchaser, dated the Closing Date, of Purchaser, confirming the satisfaction of the conditions set forth in Sections 6.01 and 6.02.

Section 6.08. Secretary's Certificate. Seller shall have received from Purchaser, in form and substance reasonably satisfactory to Seller and its counsel, a certificate, dated the Closing Date, of the Secretary or an Assistant Secretary of Purchaser, (i) certifying all documents evidencing the actions of Purchaser authorizing the transactions contemplated hereby and the execution, delivery and performance by Purchaser of this Agreement and the documents contemplated hereby, (ii) certifying the organizational documents of Purchaser, (iii) containing a certificate of good standing in the jurisdiction of its organization, and (iv) containing an incumbency certificate regarding the officers authorized to sign this Agreement and the other documents contemplated hereby.

Section 6.09. Opinion of Counsel. Seller shall have received from Purchaser's counsel an opinion reasonably acceptable to Seller.

## ARTICLE VII

#### SURVIVAL

The representations, warranties, covenants and agreements contained in this Agreement, and in any agreements, certificates or other instruments delivered pursuant to this Agreement, shall survive the Closing and shall remain in full force and effect, but subject to all limitations and other provisions contained in this Agreement. The representations and warranties contained in this Agreement and such other agreements, certificates and instruments are exclusive and the parties hereto confirm that they have not relied upon any other representation or warranty as an inducement to enter into this Agreement and the transactions contemplated hereby (even though information not represented and warranted to may have been, or may hereafter be, given to or obtained or developed by one or both of the

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parties hereto pertaining to Seller, the transactions contemplated hereby or otherwise). All such representations, warranties, covenants and agreements are made or given by the parties in connection with, and are intended to be relied upon only in entering into, this Agreement and shall not be construed to have been made or given by the parties in connection with, and are not intended to be relied upon only in entering into, the Sublicense Agreement or the Supply Agreement.

#### ARTICLE VIII

#### MISCELLANEOUS

Section 8.01. Brokers. Seller represents and warrants to Purchaser, and Purchaser represents and warrants to Seller, that neither it nor any party acting on its behalf has incurred any liability, either express or implied, to any "broker", "finder", financial adviser or similar person in respect of any of the transactions contemplated hereby. Purchaser agrees to indemnify Seller against, and hold it harmless from, and Seller agrees to indemnify Purchaser against, and hold it harmless from, any liability, cost or expense (including, but not limited to, fees and disbursements of counsel) resulting from any agreement, arrangement or understanding made by such party with any third party for brokerage, finders' or financial advisory fees or other commissions in connection with this Agreement or the transactions contemplated hereby.

Section 8.02. Expenses. Except as otherwise specifically provided in this Agreement, each party will pay its own expenses incident to this Agreement and the transactions contemplated hereby, including legal and accounting fees and disbursements.

Section 8.03. Amendments and Waivers. The parties hereto may, by written agreement signed by the parties, modify any of the covenants or agreements or extend the time for the performance of any of the obligations contained in this Agreement or in any document delivered pursuant to this Agreement. Any party hereto may waive, by written instrument signed by such party, any inaccuracies in the representations and warranties of another party or compliance by another party with any of its obligations contained in this Agreement or in any document delivered pursuant to this Agreement. This Agreement may be amended only by written instrument signed by the parties hereto.

Section 8.04. Transferability. The respective rights and obligations of each party hereto shall not be assignable by either such party without the written consent of the other party hereto (and any purported assignment without such written consent shall be void and of no effect). This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assignees.

Section 8.05. Notices. Any notice, request or other document to be given hereunder to a party hereto shall be effective when received and shall be given in writing and

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If to Purchaser, addressed to it at: Laboratorios P.E.N., S.A. Av. Mare de Deu de Montserrat, 215 08041 Barcelona (Spain) Attn: Managing Director

If to Seller, addressed to it at:

Discovery Laboratories, Inc. 350 South Main Street, Suite 307 Doylestown, Pennsylvania 18901 Attn: Robert J. Capetola, Ph.D. Chief Executive Officer

With a copy to:

Yi Tuan & Brunstein The Empire State Building 350 Fifth Avenue, Suite 5411 New York, New York 10118

Any party hereto may change its address for receiving notices, requests and other documents by giving written notice of such change to the other parties hereto.

Section 8.07. Governing Law; Choice of Forum. This Agreement shall be governed by and construed in accordance with the laws of the State of New York (without regard to conflict of laws doctrines).

Section 8.08. Jurisdiction. The Seller and the Purchaser each hereby irrevocably consents that any legal action or proceeding against it or any of its assets with respect to this Agreement may be brought in any jurisdiction where such party or any of its assets may be found, or in any court of the State of New York or any Federal court of the United States of America located in New York, New York, United States of America, or both, as the other parties may elect, and by execution and delivery of this Agreement, the Seller and Purchaser each hereby irrevocably submits to and accepts with regard to any such action or proceeding, for itself and in respect of its assets, generally and unconditionally, the jurisdiction of the aforesaid courts. Each Seller and Purchaser may serve process in any manner permitted by applicable law or to bring any legal action or proceeding or to obtain execution of judgment in any jurisdiction. Each Seller and Purchaser further agrees that final judgment against such party in any action or proceeding in connection with this Agreement shall be conclusive and may be enforced in any other jurisdiction within or outside the United States of America by suit on the judgment, a certified or exemplified copy of which shall be conclusive evidence of the fact and the amount of such party's indebtedness. Each Seller and Purchaser hereby irrevocably waives, to the fullest extent permitted by applicable law, any objection which such party may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Agreement brought in the State of New York, and hereby further irrevocably waives any claim that any such suit, action or proceeding brought in the State of New York has been brought in an inconvenient forum.

Section 8.09. Partial Invalidity. In the event that any provision of this Agreement shall be held invalid or unenforceable by any court of competent jurisdiction, such holding shall not invalidate or render unenforceable any other provision hereof.

Section 8.10. Section Headings. The section headings and table of contents contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

Section 8.11. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

Section 8.12. Entire Agreement. This Agreement, together with the schedules and exhibits and the agreements, certificates and instruments delivered pursuant hereto, contain the entire agreement among the parties hereto, and supersede all prior agreements and undertakings (written and oral) between the parties hereto, relating to the subject matter hereof.

Section 8.13. Parties in Interest. Nothing in this Agreement, express or implied, is intended to confer on any person other than the parties and their respective successors and permitted assigns any rights or remedies under or by virtue of this Agreement, and no person shall assert any rights as a third party beneficiary hereunder.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

DISCOVERY LABORATORIES, INC.

By: /s/Robert Capetola, Ph.D. Name: Robert J. Capetola, Ph.D. Title: President & CEO

LABORATORIOS P.E.N., S.A.

By: /s/J. Andreu

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Name: J. Andreu Title: Managing Director

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Certain portions have been omitted pursuant to a request for confidentiality and such omitted portions have been separately filed with the Commission.

Exhibit 10.55

#### RESEARCH FUNDING AND OPTION AGREEMENT

This Agreement is entered into this 1st day of March 2000, by and between THE SCRIPPS RESEARCH INSTITUTE, 10550 North Torrey Pines Road, La Jolla, California 92037 ("Scripps"), a California nonprofit public benefit corporation, and Discovery Laboratories, Inc. ("Optionee"), a Delaware corporation located at 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901, with respect to the facts set forth below.

#### RECITALS

A. Scripps is engaged in scientific biomedical and biochemical research, including research relating to synthetic pulmonary surfactants, as more particularly described herein.

B. Optionee is engaged in research and development of synthetic pulmonary surfactants.

C. Optionee desires to provide certain funding as part of the Scripps research activities described above.

D. Scripps has the exclusive right to grant a license in and to any technology developed pursuant to the research program described herein, subject to any non exclusive rights of the U.S. Government, resulting from the receipt by Scripps of U.S. Government funding, to use such technology for its own purposes.

E. Scripps is willing to grant to Optionee an option to acquire an exclusive, worldwide right and license to use, enhance and develop technology arising from the Research Program and develop, market and sell products in the field described below, all as is more particularly described herein.

#### AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants and conditions outlined herein, Scripps and Optionee hereby agree as follows:

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## 1. DEFINITIONS.

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1.1 Confidential Information. The term "Confidential Information" shall mean any and all proprietary information of Scripps or Optionee which may be exchanged between the parties at any time and from time to time during the term hereof. The fact that a party may have marked or identified as confidential or proprietary any specific information shall be indicative that such party believes such information to be confidential or proprietary, but the failure to so mark information shall not conclusively determine that such information was or was not considered confidential information by such party. Information shall not be considered confidential to the extent that it:

a. Is publicly disclosed through no fault of any party hereto, either before or after it becomes known to the receiving party; or

b. Was known to the receiving party prior to the date of this Agreement, which knowledge was acquired independently and not from the other party hereto (including such party's employees); or

c. Is subsequently disclosed to the receiving party in good faith by a third party who has a right to make such disclosure; or

d. Has been published by a third party as a matter of right.

1.2 Core Patent Right. The term "Core Patent Rights" shall mean the following issued U.S. patents and pending U.S. patent applications: (a) Patent No. 5,407,914, issued April 18, 1995; Patent No. 5,260,273, issued November 9, 1993; and Patent No. 5,164,369, issued November 17, 1992; and (b) pending patent applications Serial Nos.  $[^{***}]$ 

1.3 Field. The term "Field" shall mean use in research or as a diagnostic, preventative or therapeutic product in humans or vertebrate animals and shall specifically exclude any agricultural applications or products.

1.4 Jointly Developed Technology. The term "Jointly Developed Technology" shall mean any information, process, technology and materials included within the scope of the Research Program which are developed by both Scripps and Optionee during the term of this Agreement as a result of the Research Program and which, under principles arising under the patent laws of the United States of America, would be found jointly owned by both Scripps and Optionee thereunder.

1.5 Licensed Product. The term "Licensed Product" shall mean any research, diagnostic, preventative or therapeutic product or process which cannot be developed, manufactured, used or sold without utilizing Scripps Patent Rights, any Scripps Technology not otherwise includable within Scripps Patent Rights or Jointly Developed Technology.

1.6 Principal Investigator. The term "Principal Investigator" shall mean the person identified in Section 2.2 below, together with such replacement persons selected in accordance with the provisions thereof.

1.7 Proprietary Property. The term "Proprietary Property" shall mean, with respect to any party hereto, any and all technology, now existing or hereafter arising, in which such party shall have a proprietary interest, including without limitation, any idea, data, compound, molecule, cell line, material, know-how, technique, method, process, use, composition, skill, Confidential Information, trade secret or configuration of any kind, whether or not any such information would be enforceable as a trade secret, the copying of which would be enjoined or restrained by a court as constituting copyright infringement or unfair competition or would be eligible for protection under the patent laws of the United States or elsewhere.

1.8 Research Program. The term "Research Program" shall mean theresearch program to be undertaken by Scripps under the direction and control of the Principal Investigator set forth in Section 2.2 hereof.

1.9 Scripps Patent Rights. The term "Scripps Patent Rights" shall mean the rights arising out of or resulting from (i) any and all U.S. and foreign patent applications and patents covering Scripps Technology, (ii) the patents proceeding from such applications, and (iii) all continuations, divisions, continuations-in-part, reissues, reexaminations, and extensions thereof, so long as said patents have not been held invalid and/or unenforceable by a court of competent jurisdiction from which there is no appeal or, if appealable, from which no appeal has been taken.

1.10 Scripps Technology. The term "Scripps Technology" shall mean any Proprietary Property of Scripps developed, in whole or in part, in the performance of the Research Program during the term of this Agreement, including any intellectual property within the scope of the Research Program developed by any employee of Scripps during the term of this Agreement while such employee is rendering services to Optionee as a consultant or otherwise.

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#### 2. CONDUCT OF RESEARCH PROGRAM.

2.1 Conduct of Research Program. Scripps hereby agrees to conduct the Research Program as expressly set forth on Exhibit A attached hereto, as amended from time to time in accordance with its terms, and subject to the provisions of this Agreement.

2.2 Supervision of Research Program. Scripps agrees that the Research Program at Scripps shall be conducted by or under the direct supervision of the following Principal Investigator: Charles Cochrane, M.D. In the event that the Principal Investigator leaves Scripps, or terminates his/her involvement in the Research Program, Scripps shall use its best efforts to find a replacement Principal Investigator acceptable to Optionee, which acceptance shall not be unreasonably withheld. In the event that Scripps shall fail to appoint a replacement Principal Investigator reasonably acceptable to Optionee, Optionee shall have a right to terminate this Agreement upon delivery to Scripps of written notice of intent to terminate pursuant to this Section 2.2, which notice must be delivered to Scripps not less than 30 days nor more than 90 days after delivery by Scripps to Optionee of the name of the replacement Principal Investigator.

#### 2.3 Reports.

a. Scripps agrees that within sixty (60) days following the last day of each calendar year during the term of this Agreement, Scripps shall furnish Optionee with a written report summarizing the results of the research included within the scope of the Research Program during the immediately preceding calendar year conducted by Scripps, including but no limited to all data, conclusions, results, observations and a detailed description of all procedures.

b. Optionee agrees that within sixty (60) days following the last day of each calendar year during the term of this Agreement, Optionee shall furnish Scripps with a written report summarizing the results of the research and development included within the scope of the Research Program during the immediately preceding calendar year which Optionee believes constitutes Jointly Developed Technology, including bot not limited to all data, conclusions, results, observations and a detailed description of all procedures.

c. All such information submitted to Optionee by Scripps, and all such information submitted to Scripps by Optionee, as a result of the Research Program under this Agreement is deemed Confidential Information of Scripps, and shall be kept confidential by Optionee, and shall be used by Optionee only for the purpose of evaluating whether or not to exercise an option to obtain a license pursuant to Section 3 hereof, as and when such option is exercisable in accordance with the terms hereof. Optionee shall not, during the term or after the termination hereof, use or disclose any of the Confidential Information, unless and until (i) permitted to do so pursuant to the terms of any license agreement entered into by Optionee

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after exercise of option for such technology or (ii) such information no longer comes within the definition of " Confidential Information" hereunder and otherwise becomes available as public information.

2.4 Contributions of Parties to Research Program. Contributions in the form of financial support, equipment, personnel, technology and other necessary components for the conduct of the Research Program shall be made by the parties in accordance with the terms set forth on Exhibit B attached to this Agreement.

#### 3. OPTION FOR EXCLUSIVE LICENSE.

# 3.1 Grant of Option.

a. It is the intention of the parties hereto that the Proprietary property which is the subject of the option described in this Section 3 is available to Optionee, under the specific terms hereof, on an application-by-application basis, where each application with respect to a specific field. It is the further intention of the parties hereto that Optionee shall elect to exercise its option from time to time and at multiple times during the term thereof, as and when Scripps makes the disclosure of each application of Proprietary Property (whether Scripps Technology, Scripps Patent Rights covering Scripps Technology, or Scripps rights in Jointly Developed Technology). The statement of general intention described in this Subparagraph is qualified in its entirety by the specific provisions of this Section 3.

b. Subject to the terms of this Agreement, Scripps hereby grants to Optionee an exclusive option to acquire an exclusive worldwide license to make, have made, sell or use License Products, with exclusive rights of sublicense, in the Field. Each such license shall be to a specific application of Scripps Technology, Scripps Patent rights covering Scripps Technology, or Scripps' rights in Jointly Developed Technology, as more particularly described in the disclosure (Sections 3.2 or 3.3). Such option shall be for the period (Section 3.4) and exercised as (Section 3.5) more particularly described below.

3.2 Disclosure of Scripps Technology. As soon as reasonably possible, either upon conception or reduction to practice, as the case may be, of each and every application of Scripps Technology, Scripps shall disclose the same in writing to Optionee. Such disclosure shall contain sufficient detail to enable Optionee to evaluate the advisability of exercising the option granted hereunder with respect to such application. All such disclosures shall be maintained in confidence by Optionee.

3.3 Disclosure of Jointly Developed Technology. As soon as reasonably feasible, either upon conception or reduction to practice, as the case may be, of each and every application of Jointly Developed Technology, Optionee shall disclose the same writing to Scripps. Such disclosure shall contain sufficient detail to enable Scripps to evaluate whether such technology is, in fact, within the definition of Jointly Developed. If Scripps, in the

exercise of its good faith discretion, acknowledges that all or some of such technology as so described by Optionee falls within the definition of Jointly Developed Technology, then Scripps shall deliver to Optionee a written notice describing the Jointly Developed Technology and Scripps' intent to license the same to Optionee if Optionee exercises its option.

3.4 Option Period. Optionee shall have a period of one hundred eighty (180) days from receipt of the disclosure from Scripps described in Section 3.2 above or from the notice from Scripps described in Section 3.3 within which to exercise its option to obtain a license in the Field to a particular application of Scripps Technology or to Scripps' rights to a particular application of Jointly Developed Technology pursuant to Section 3.1.

3.5 Exercise of Option. Optionee shall exercise its option to obtain a license hereunder by delivering to Scripps a written notice within the option period which specifies the particular application of Scripps Technology and related Scripps Patent Rights or application of Jointly Developed Technology for which the option is being exercised. Optionee and Scripps shall have a period of ninety (90) days from the date of exercise of option by Optionee within which to agree upon the royalty rate and commercial development obligations, all as is more particularly set forth in the form of License Agreement attached hereto as Exhibit C. The royalty rate shall be determined by the parties in accordance with Exhibit D hereto. The specific application of Scripps Technology and related Scripps Patent Rights, if any, or specific application of Jointly Developed Technology which is the subject of such License Agreement will be as set forth in the notice delivered by Scripps and described in Section 3.2 above or Section 3.3, respectively. The "Field" in such License Agreement shall be no

3.6 Reservation of Rights. Scripps reserves the right to use any Scripps Technology or Jointly Developed Technology that may be subject to an option pursuant to this Agreement or covered by a license granted hereunder solely for Scripps' own educational and research purposes and the educational and research purposes of any other nonprofit organization, provided that such nonprofit organization is not using or disclosing the Scripps Technology or Jointly Developed Technology for research or development purposes for a for-profit entity, without Scripps or such other nonprofit organization being obligated to pay Optionee any royalties or other compensation related thereto.

#### 4. WARRANTIES.

4.1 Warranty of Title: No Other Warranties. Scripps hereby warrants and represents that it has the full right and power to enter into this Agreement and grant the option of Article 3 to Optionee.

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 $4.2~{\rm No}$  Other Warranties. SCRIPPS MAKES NO WARRANTIES CONCERNING THE RESEARCH PROGRAM OR ANY SCRIPPS TECHNOLOGY, SCRIPPS PATENT RIGHTS OR JOINTLY DEVELOPED TECHNOLOGY WHICH MAY

BE SUBJECT TO THIS AGREEMENT. WITHOUT LIMITING THE FOREGOING, SCRIPPS DOES NOT REPRESENT OR WARRANT THAT IT WILL SUCCESSFULLY COMPLETE THE RESEARCH PROGRAM OR THAT, IF COMPLETED, THE RESEARCH PROGRAM WILL RESULT IN SCRIPPS TECHNOLOGY WHICH WILL BE SUBJECT TO AN OPTION HEREUNDER OR WHICH OPTIONEE WILL DESIRE TO LICENSE. SCRIPPS MAKES NO EXPRESS OR IMPLIED WARRANTY, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AS TO ANY LICENSED PRODUCT SCRIPPS MAKES NO WARRANTY OR REPRESENTATION AS TO THE VALIDITY OR SCOPE OF ANY SCRIPPS PATENT RIGHTS OR THAT ANY LICENSED PRODUCT WILL BE FREE FROM ANY INFRINGEMENT OF PATENTS OF THIRD PARTIES, OR THAT NO THIRD PARTIES ARE IN ANY WAY INFRINGING SCRIPPS PATENT RIGHTS.

5. INTERESTS IN INTELLECTUAL PROPERTY.

5.1 Title.

a. Scripps shall retain such ownership and title to Scripps Technology and Scripps Patent Rights as Scripps shall have, subject to the option of Optionee set forth herein. Scripps shall, in the good faith exercise of its discretion, undertake reasonable efforts to reserve and maintain its ownership and title as Scripps deems appropriate. Ownership of and title to Jointly Developed Technology shall be vested jointly in Scripps and Optionee, with each owning an undivided one-half interest therein.

b. In the event Optionee does not exercise its option hereunder to obtain an exclusive license with respect to Scripps' rights in and to any specific application of Jointly Developed Technology, Optionee hereby assigns to Scripps all of Optionee's right, title and interest in and to such Jointly Developed Technology, and Optionee shall have no further rights with respect thereto, other than a right to receive from Scripps fifty percent (50%) of the net royalty income received by Scripps with respect to such application, as and when received. As used herein, "net royalty income" shall mean the gross royalties and other license fees received under any such license agreement, less all Scripps out-of-pocket expenses incurred in connection with the licensing of such Jointly Developed Technology (including without limitation fees of accountants, attorneys and other consultants engaged in connection with such licensing).

5.2 Governmental Interest. Optionee and Scripps acknowledge that Scripps has received and expects to continue to receive funding from the United States Government in support of Scripps' research activities. Optionee acknowledges and agrees that its rights and obligations pursuant to this Agreement with respect to Scripps Technology and Scripps Patent Rights, and to Scripps' rights to Jointly Developed Technology, as applicable, shall be subject to Scripps' obligations and the rights of the United States Government, if any, which arise or result from Scripps' receipt of research support from the United States Government.

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## 6. CONFIDENTIALITY AND PUBLICATION.

6.1 Confidential Information. The parties agree that during the term of and any subsequent extension of this Agreement and of a period of five (5) years after it terminates or for as long as any Confidential Information not otherwise includable within Scripps Patent Rights is being utilized with a Licensed product, whichever is longer, a party receiving Confidential Information of another party will not use or intentionally disclose such Confidential Information to any third party without the prior written consent of the disclosing party.

6.2 Publications. Optionee acknowledges that it is the general policy of Scripps to encourage publication of research results in technical or scientific journals; and subject to Scripps meeting its disclosure obligations under Section 3.2, Optionee agrees that Scripps shall have a right to publish in accordance with its general policy. Prior to such publication, Scripps shall submit to Optionee copies of proposed publications which contain subject matter relating to Scripps Technology or Jointly Developed Technology and afford Optionee a period of thirty (30) days to review the publication. Upon written request by Optionee prior to the expiration of such thirty (30) day period and provided that Optionee shall have exercised its option to one or more applications included within the subject matter of such publication, Scripps shall delay any such publication for up to sixty (60) days from the date of such request to allow for the preparation and filing of a patent application.

6.3 Publicity. Except as otherwise provided herein or required by law, no party shall originate any publication, news release or other public announcement, written or oral, whether in the public press, or stockholders' reports, or otherwise, relating to this Agreement or to any license granted hereunder, or to the performance thereunder, without the prior written approval of the other parties, which approval shall not be unreasonably withheld.

7. TERM AND TERMINATION.

7.1 Term. Unless terminated sooner, the initial term of this Agreement shall commence on the date set forth above and shall continue for a period of one (1) year, and thereafter, this Agreement shall be renewable for additional periods of one (1) year each upon mutual agreement of the parties.

7.2 Termination by Mutual Agreement. This Agreement may be terminated at any time upon the mutual written agreement of the parties. In the absence of an agreement to the contrary, no such termination shall have the effect of relieving Optionee of its monetary obligations to fund the Research Program which shall have accrued up and to the date of such termination.

7.3 Termination Upon Default. Any one or more of the following events shall constitute an event of default hereunder: (i) the failure of a party to pay any amounts when due hereunder and the expiration of thirty (30) days thereafter; and (ii) the failure of a party to perform any obligation required of it to be performed hereunder, and the failure to cure within sixty (60) days after receipt of notice from the other party specifying in reasonable detail the nature of such default. Upon the occurrence of an event of default, the nondefaulting party may deliver to the defaulting party written notice of intent to terminate, such termination to be effective upon the date set forth in such notice. Such termination rights shall be in addition to and not in substitution for any other remedies that may be available to the non-defaulting party serving such notice against the defaulting party. Termination pursuant to this Section 7.3 shall not relieve the defaulting party of liability and damages to non-defaulting party for breach of this Agreement, Waiver by any party of a single default or a succession of defaults shall not deprive such party of any right to terminate this Agreement arising by reason of any subsequent default.

7.4 Termination Upon Insolvency. This Agreement may be terminated as to any party ("Insolvent Party") by another party giving written notice of termination to the Insolvent Party upon the filing of bankruptcy or bankruptcy of the Insolvent Party or the appointment of a receiver of any of the Insolvent Party's assets, or the making by the Insolvent Party of any assignment for the benefit of creditors, or the institution of any proceedings against the Insolvent Party under any bankruptcy law. Termination shall be effective upon the date specified in this notice.

### 7.5 Effect of Expiration or Termination.

7.5.1 Termination Upon Default of Optionee. Upon the termination of this Agreement by reason of a default by Optionee, neither party shall have any further rights or obligations with respect to this Agreement, other than the obligation of Optionee to make any and all final payments accrued prior to the date of termination and the obligation of the parties to make all reports required hereunder. Upon such termination of this Agreement, the parties shall continue to abide by their non-disclosure obligations as described in Section 6.1 and each party hereto shall fulfill any other obligations incurred prior to such termination. Any such termination of this Agreement shall not constitute the termination of any license or any other agreements between the parties which are then in effect except as expressly provided therein.

7.5.2 Expiration or Termination upon Default of Scripps. Upon theexpiration of this Agreement at its regularly scheduled expiration date, or upon a termination of this Agreement on account of a default by Scripps, then Scripps shall make the disclosures required by Section 3.2 for Scripps Technology conceived or reduced to practice up to the date of said expiration or termination; and Optionee shall have the right to exercise its option with respect to said Scripps Technology in accordance with the schedule and procedures specified in Sections 3.4 and 3.5 above. Additionally, each party shall perform all other obligations up to 935512.1

the date of said expiration or termination; and the parties shall continue to abide by their non-disclosure obligations described in Section 6.1; and any previously existing license agreements or other agreements between the parties shall continue in effect.

8. ASSIGNMENT; SUCCESSORS.

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8.1 Assignment. This Agreement may not be assigned by either party without the prior written consent of the other party except to a successor in interest to all or substantially all of the business assets of assigning party, whether by way of a merger, consolidation, sale of all or substantially all of the assigning party's assets, change of control or similar transaction.

8.2 Binding Upon Successors and Assigns. Subject to the limitations on assignment set forth herein, this Agreement shall be binding upon and inure to the benefit of any successors in interest and assigns of Scripps and Optionee. Any such successor to or assignee of a party's interest shall expressly assume in writing the performance of all the terms and conditions of this Agreement to be performed by such party.

9. GENERAL PROVISIONS.

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9.1 Independent Contractors. The relationship between Scripps and Optionee is that of independent contractors. Scripps and Optionee are not joint venturers, partners, principal and agent, master and servant, employer or employee, and have no other relationship other than independent contracting parties. Scripps and Optionee shall have no power to bind or obligate each other in any manner, other than as is expressly set forth in this Agreement.

9.2 Arbitration. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by binding arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA"), and the procedures set forth below. In the event of any inconsistency between the Rules of AAA and the procedures set forth below, the procedures set forth below shall control. Judgment upon the award rendered by the arbitrators may be enforced in any court having jurisdiction thereof.

 $\ensuremath{9.2.1}$  Location. The location of the arbitration shall be in the City of Philadelphia.

9.2.2 Selection of Arbitrators. The arbitration shall be conducted by a panel of three neutral arbitrators who are independent and disinterested with respect to the parties, this Agreement, and the outcome of the arbitration. Each party shall appoint one neutral arbitrator, and these two arbitrators so selected by the parties shall then select the third arbitrator. If one party has given written notice to the other party as to the identity of the arbitrator appointed by the party, and the party thereafter makes a written demand on the other

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party to appoint its designated arbitrator within the next ten days, and the other party fails to appoint its designated arbitrator within ten days after receiving said written demand, then the arbitrator who has already been designated shall appoint the other two arbitrators.

9.2.3 Discovery. Unless the parties mutually agree in writing to some additional and specific pre-hearing discovery, the only pre-hearing discovery shall be (a) reasonably limited production of relevant and non-privileged documents, and (b) the identification of witnesses to be called at the hearing, which identification shall give the witness's name, general qualifications and position, and a brief statement as to the general scope of the testimony to be given by the witness. The arbitrators shall decide any disputes and shall control the process concerning these pre-hearing discovery matters. Pursuant to the Rules of AAA, the parties may subpoena witnesses and documents for presentation at the hearing.

9.2.4 Case Management. Prompt resolution of any dispute is important to both parties; and the parties agree that the arbitration of any dispute shall be conducted expeditiously. The arbitrators are instructed and directed to assume case management initiative and control over the arbitration process (including scheduling of events, pre-hearing discovery and activities, and the conduct of the hearing), in order to complete the arbitration as expeditiously as is reasonably practical for obtaining a just resolution of the dispute.

9.2.5 Remedies. The arbitrators may grant any legal or equitable remedy or relief that the arbitrators deem just and equitable, to the same extent that remedies or relief could be granted by a state or federal court, provided, however, that no punitive damages may be awarded. No court action may be maintained seeking punitive damages. The decision of any two of the three arbitrators appointed shall be binding upon the parties.

9.2.6 Expenses. The expenses of the arbitration, including the arbitrators' fees, expert witness fees, and attorney's fees, may be awarded to the prevailing party, in the discretion of the arbitrators, or may be apportioned between the parties in any manner deemed appropriate by the arbitrators. Unless and until the arbitrators decide that one party is to pay for all (or a share) of such expenses, both parties shall share equally in the payment of the arbitrators' fees as and when billed by the arbitrators.

9.2.7 Confidentiality. Except as set forth below, the parties shall keep confidential the fact of the arbitration, the dispute being arbitrated, and the decision of the arbitrators. Notwithstanding the foregoing, the parties may disclose information about the arbitration to persons who have a need to know, such as directors, trustees, management, employees, witnesses, experts, investors, attorneys, lenders, insurers, and others who may be directly affected. Additionally, if a party has stock which is publicly traded, the party may make such disclosures as are required by applicable securities laws. Further, if a party is expressly asked by a third party about the dispute or the arbitration, the party may disclose and acknowledge in general and limited terms that there is a dispute with the other party which is

being (or has been) arbitrated. Once the arbitration award has become final, if the arbitration award is not promptly satisfied, then these confidentiality provisions shall no longer be applicable.

9.3 Entire Amendment; Modification. This Agreement sets forth the entire agreement and understanding between the parties as to the subject matter hereof. There shall be no amendments or modifications to this Agreement, except by a written document which is signed by both parties.

 $9.4\ California\ Law.$  This Agreement shall be construed and enforced in accordance with the laws of the State of California.

9.5 Headings. The headings for each article and section in this Agreement have been inserted for the convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section.

9.6 Severability. Should any one or more of the provisions of this Agreement be held invalid or unenforceable by a court of competent jurisdiction, it shall be considered severed from this Agreement and shall not serve to invalidate the remaining provisions thereof. The parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by them when entering this Agreement may be realized.

9.7 No Waiver. Any delay in enforcing a party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed wavier as to a particular matter for a particular period of time.

9.8 Attorneys' Fees. In the event of a dispute among the parties hereto or in the event of any default hereunder, the party prevailing in the resolution of any such dispute or default shall be entitled to recover its reasonable attorneys' fees and other costs incurred in connection with resolving such dispute or default.

9.9 Notices. Any notices required by this Agreement shall be in writing, shall specifically refer to this Agreement and shall be sent by registered or certified airmail, postage prepaid, or by telefax, telex or cable, charges prepaid, or by overnight courier, postage prepaid, and shall be forwarded to the respective addresses set forth below unless subsequently changed by written notice to the other party:

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FOR SCRIPPS:	The Scripps Research Institute 10550 North Torrey Pines Road, TPC-9 La Jolla, California 92037 Attn: Director, Office of Technology Development Fax No.: (868) 784-9910
FOR OPTIONEE:	Discovery Laboratories, Inc. 350 South Main Street Suite 307

Notice shall be deemed delivered upon the earlier of (i) when received, (ii) three (3) days after deposit into the mail, (iii) the date notice is sent via telefax, telex or cable, or (iv) the day immediately following delivery to overnight courier (except Sunday and holidays).

Doylestown, PA 18901 Attn: Mr. Robert Capetola Fax No.: (215) 340-3940

9.10 Compliance with U.S. Laws. Nothing contained in this Agreement shall require or permit Scripps or Optionee to do any act inconsistent with the requirements of any United States law, regulation or executive order as the same may be in effect from time to time.

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized representatives as of the date set forth above.

SCRIPPS:	OPTIONEE:	
THE SCRIPPS RESEARCH INSTITUTE	DISCOVERY LABORATORIES, INC.	
By:	By:	
Arnold LaGuardia	Robert Capetola	
Title: Executive Vice President	Title: President & CEO	

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# EXHIBIT A

# DISCLOSURE OF TECHNOLOGY

EXHIBIT B

[\*\*\*]

[\*\*\*] Confidential treatment requested

# EXHIBIT C

# LICENSE AGREEMENT

# By and between

## THE SCRIPPS RESEARCH INSTITUTE, a California nonprofit public benefit corporation and

DISCOVERY LABORATORIES, INC., a Delaware corporation

## LICENSE AGREEMENT

This License Agreement is entered into and made effective as of this day of , 19 by and between THE SCRIPPS RESEARCH INSTITUTE, a California nonprofit public benefit corporation ("Scripps") located at 10550 North Torrey Pines Road, La Jolla, California 92037, and Discovery Laboratories, Inc. a Delaware corporation ("Licensee") located at 350 South Main Street, Suite 307, Doylestown, PA 18901 with respect to the facts set forth below.

#### RECITALS

A. Scripps is engaged in fundamental scientific biomedical and biochemical research including research relating to synthetic pulmonary surfactants.

B. Licensee is engaged in research and development of synthetic pulmonary surfactants for use in humans and vertebrate animals.

C. Scripps has disclosed to Licensee certain technology described in \_\_\_\_\_\_, a copy of which is attached hereto as Exhibit A and incorporated herein by reference (the "\_\_\_\_\_").

D. Scripps has the exclusive right to grant a license to file technology described in \_\_\_\_\_\_\_, subject to certain rights of the U.S. Government to use such technology for its own purposes, resulting from the receipt by Scripps of certain funding from the U.S. Government.

E. Scripps desires to grant to Licensee, and Licensee wishes to acquire, an exclusive worldwide right and license to the technology described in the \_\_\_\_\_\_\_ and to certain patent rights and know-how of Scripps with respect thereto, subject to the terms and conditions set forth herein, with a view to developing and marketing [diagnostic and/or therapeutic] products within the Field (as defined below).

#### AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants and conditions set @h herein, Scripps and Licensee hereby agree as follows:

1. Definitions. Capitalized terms shall have the meaning set forth below.

1.1 Affiliate. The term "Affiliate" shall mean any entity which directly or indirectly controls, is controlled by or is under common control with Licensee. The term "control" as used herein means the possession of the power to direct or cause the direction of the management and the policies of an entity, whether through the ownership of a majority of the outstanding voting securities or by contract or otherwise.

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1.2 Confidential Information. The term "Confidential Information" shall mean any and all proprietary or confidential information of Scripps or Licensee which may be exchanged between the parties at any time and from time to time during the term of this Agreement Information shall not be considered confidential to the extent that it:

a. Is publicly disclosed through no fault of any party hereto, either before or after it becomes known to the receiving party; or

b. Was known to the receiving party prior to the date of this Agreement, which knowledge was acquired independently and not from the other party hereto (or such party's employees); or

c. Is subsequently disclosed to the receiving party in good faith by a third party who has a right to make such disclosure; or

d. Has been published by a third party as a matter of right.

1.3 Core Patent Rights. The term "Core Patent Rights' shall mean thefollowing issued U.S. patents and pending U.S. patent applications: (a) Patent No. 5,407,914, issued April 18, 1995; Patent No. 5,260,273, issued November 9, 1993; and Patent No. 5,164,369, issued November 17, 1992; and (b) pending patent applications Serials Nos. [\*\*\*]

1.4 Field. The term "Field" shall mean use in research or as a diagnostic or therapeutic product in humans or vertebrate animals and shall specifically exclude any agricultural applications or products.

1.5 Licensed Product. The term "Licensed Product" shall mean any product or process which cannot be developed, manufactured, used or sold without (i) infringing one or more claims under Scripps Patent Rights or (ii) utilizing any part of Scripps Technology not otherwise includable within Scripps Patent Rights.

1.6 Net Sales. The term "Net Sales" shall mean the gross amount actually received by Licensee, or its Affiliates and sublicensees, or any of them, on all sales of Licensed Products, less (i) prepaid freight and (ii) sales taxes or other governmental charges actually paid in connection with sales of Licensed Products (but excluding what is commonly known as income taxes). Sales of Licensed Products by Licensee, or an Affiliate or sublicensee of Licensee to any Affiliate or sublicensee which is a reseller thereof shall be excluded, and only the subsequent sale of such Licensed Products by Affiliates or sublicensees of Licensee to unrelated parties shall be deemed Net Sales hereunder.

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1.7 Scripts Patent Rights. The term "Scripps Patent Rights" shall mean rights arising out of or resulting from (i) any and all U.S. and foreign patent applications and patents covering Scripps Technology, (ii) the patents proceeding from such applications, (iii) all claims of continuations-in-part directed solely to subject matter specifically described in Scripps Technology, and (iv) divisionals, continuations, reissues, reexaminations, and extensions of any patent or application set forth in (i)-(iii) above, so long as said patents have not been held invalid and/or unenforceable by a court of competent jurisdiction from which there is no appeal or, if appealable, from which no appeal has been taken.

1.8 Scripps Technology. The term "Scripps Technology" shall mean so much of the technology as is proprietary to Scripps disclosed in

\_\_\_\_\_\_, \_\_\_\_\_\_\_, \_\_\_\_\_\_), a copy of which is attached as Exhibit A hereto and incorporated herein by reference, together with materials, information and know-how related thereto [as described on \_\_\_\_\_] whether or not the same is eligible for protection under the

\_\_\_\_\_] whether or not the same is eligible for protection under th patent laws of the United States or elsewhere, and whether or not any such processes and technology, or information related thereto, would be enforceable as a trade secret or the copying of which would be enjoined or restrained by a court as constituting unfair competition.

2. License Terms and Conditions.

2.1 Grant of License. Scripps hereby grants to Licensee an exclusive, worldwide license, including the right to sublicense, to Scripps Technology and under Scripps Patent Rights, to develop, to make, to have made, to use, to modify, to market, to sell and to otherwise dispose of Licensed Products in the Field, subject to the terms of this Agreement.

2.2 Royalties.

2.2.1 Percentage Royalty, As consideration for the exclusive license granted pursuant to Section 2. 1 hereof, Licensee shall pay to Scripps a continuing royalty on a country-by-country basis in the amount of (i) \_ percent (%) of Net Sales of Licensed Products which cannot be made, used or sold in such country without utilizing one or more valid claims under Scripps Patent Rights and (ii) \_ percent (\_%) of Net Sales of all other Licensed Products.

2.3 Combination Products.

2.3.1 Definition of Combination Product. As used herein, the term "Combination Product" shall mean a Licensed Product which cannot be manufactured, used or sold without infringing Scripps Patent Rights or utilizing Scripps Technology licensed hereunder, and infringing or utilizing one or more patents or proprietary technology or knowhow of (i) Licensee, (ii) a third party which has licensed the same to Licensee pursuant to

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an agreement between Licensee and such third party, or (iii) Scripps under a license agreement other than this Agreement (referred to herein as "other licensed rights").

2.3.2 Royalty Payable on Combination Products. The royalty payable on Combination Products shall be the royalty rate set forth in Section 2.2. 1 above based on a pro rata portion of Net Sales of Combination Products in accordance with the following formula:

> A X=-

B, where

X = the pro rata portion of Net Sales attributable to Scripps Patent Rights or other Scripps Technology licensed herein (expressed as a percentage), and

A = the fair market value of the component in the Combination Product utilizing Scripps Technology licensed hereunder, and

B = A plus the fair market value of all other components in the Combination Product using other licensed rights.

The fair market values described above shall be determined by the parties hereto in good faith. In the absence of agreement as to the fair market value of all of the components contained in a Combination Product, the fair market value of each component shall be determined by arbitration in accordance with the provisions of Section 10.2 hereof.

2.4 Quarterly Payments.

2.4.1 Sales by Licensee. With regard to Net Sales made by Licensee or its Affiliates, royalties shall be payable by Licensee quarterly, within sixty (60) days after the end of each-calendar quarter, based upon the Net Sales of Licensed Products during such preceding calendar quarter, commencing with the calendar quarter in which the first commercial sale of any Licensed Product is made.

2.4.2 Sales by Sublicensees. With regard ton@et Sales made by sublicensees of Licensee or its Affiliates, royalties shall be payable by Licensee quarterly, within ninety (90) days after the end of each calendar quarter, based upon the Net Sales of Licensed Products by such sublicensee during such preceding calendar quarter, commencing with the calendar quarter in which the first commercial sale of any Licensed Product. is made by such sublicensee.

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2.5 Term of License. Unless terminated sooner in accordance with the provisions of this Agreement, the term of this license shall expire when the last of the royalty obligations set forth has expired. Notwithstanding the foregoing, if applicable government regulations require a shorter term and/or a shorter term of exclusivity than provided for herein, then the term of this License Agreement shall be so shortened or this License Agreement shall be amended to provide for a non-exclusive license, and, in such event, the parties shall negotiate in good faith to reduce appropriately the royalties payable as set forth under the section heading "Royalties" hereof.

2.6 Sublicense. Licensee shall have the sole and exclusive right to grant sublicenses to any party with respect to the rights conferred upon Licensee under this Agreement, provided, however, that any such sublicense shall be subject in all respects to the restrictions, exceptions, royalty obligations, reports, termination provisions, and other provisions contained in this Agreement and shall not exceed the scope of the license granted to Licensee hereunder. Promptly after execution of any sublicense agreement, Licensee shall give written notice to Scripps of the grant of such sublicense and details of the following material terms: (i) the name of the sublicensee, (ii) the duration of the sublicense, (iii) the Scripps Patent Rights and Scripps Technology that are the subject of the sublicensee, and (iv) the commercialization obligations imposed upon the sublicensee. Licensee shall pay Scripps, or cause its Affiliate or sublicensee to pay Scripps, the same royalties on all Net Sales of such Affiliate or sublicense the same as if said Net Sales had been made by Licensee. Each Affiliate and sublicensee shall report its Net Sales to Scripps through Licensee, which Net Sales shall be aggregated with any Net Sales of Licensee for purposes of determining the Net Sales upon which royalties are to be paid to Scripps.

2.7 Aggregate Royalties. In the event that a percentage of sublicense income or royalties are paid by the Licensee, an Affiliate or a sublicensee to an unaffiliated third party or to Scripps under a separate agreement in respect of a Licensed Product ("Additional Royalties") for which royalties are also due to Scripps pursuant to this Agreement, then the following provisions shall apply (either separately or jointly, as applicable):

(a) if the Licensed Product is or was claimed in whole or in part, in one or more of the Core Patent Rights and the Additional Royalties are due pursuant to a license agreement between Scripps and Licensee that is executed pursuant to that certain Research Funding and Option Agreement of even date herewith between Scripps and Licensee (such licenses are collectively referred to herein as "Other Research Licenses"):

(i) until the expiration of the last to expire of the Core Patent rights, the royalties under this Agreement shall be reduced such that the aggregate royalties due under this Agreement and the Other Research Licenses do not exceed [\*\*\*] of Net Sales of the Licensed Product;

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[\*\*\*] Confidential treatment requested

(ii) after the expiration of the last to expire of the Core Patent Rights, the royalties under this Agreement shall be increased such that the aggregate royalties due under this Agreement and the Other Research Licenses do not exceed [\*\*\*] of Net Sales of the Licensed Product.

(b) if the Licensed Product is or was claimed in whole or in part in one or more of the Core Patent Rights and the Additional Royalties are due under any license with a third party or any other license agreement between Licensee and Scripps, or if the Licensed Product is or was not claimed in any of the Core Patent Rights, then the royalties under this Agreement shall be reduced by the amount of the payments due to the third party or Scripps under such license agreements, subject to a maximum reduction of fifty percent (50%) of the royalties due hereunder.

2.8 Duration of Royalty Obligations. The royalty obligations of Licensee as to each Licensed Product shall terminate on a country-by-country basis concurrently with the expiration of the last to expire of Scripps Patent Rights utilized by or in such Licensed Product in each such country or, with respect to Licensed Products not utilizing, any Scripps Patent Rights, ten (10) years after the date of first commercial sale of such Licensed Product in such country.

2.9 Reports. Licensee shall furnish to Scripps at the same time as each royalty payment is made by Licensee, a detailed written report of Net Sales of the Licensed Products and the royalty due and payable thereon, including a description of any offsets or credits deducted therefrom, on a product-by-product and country-by-country basis, for the calendar quarter upon which the royalty payment is based.

2.10 Records. Licensee shall keep, and cause its Affiliates and sublicensees to keep, full, complete and proper records and accounts of all Sales of Licensed Products in sufficient detail to enable the royalties payable on Net Sales of each Licensed Product to be determined. Scripps shall have the right to appoint an independent certified public accounting firm approved by Licensee, which approval shall not be unreasonably withheld, to audit the records of Licensee, its Affiliates and sublicensees as necessary to verify the royalties payable pursuant to this Agreement. Licensee, its Affiliates and sublicensees shall pay to Scripps an amount equal to any additional royalties to which Scripps is entitled as disclosed by the audit, plus interest thereon at the rate of one and one-half percent (1.5%) per month. Such audit shall be at Scripps' expense; provided, however, that if the audit discloses that Scripps was underpaid royalties with respect to any Licensee, its Affiliates or sublicensees, as the case may be shall[ reimburse Scripps for any such audit costs. Scripps may exercise its right of audit as to each of Licensee, its Affiliates or sublicensees no more frequently than once in any calendar year.

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The accounting firm shall disclose to Scripps only information relating to the accuracy of the royalty payments. Licensee, its Affiliates and sublicensees shall preserve and maintain all such records required for audit for a period of three (3) years after the calendar quarter to which the record applies.

2.11 Foreign Sales. The remittance of royalties palpable on sales outside the United States shall be payable to Scripps in United States Dollar equivalents at the official rate of exchange of the currency of the country from which the royalties are payable, as quoted in the Wall Street Journal for the last business day of the calendar quarter in which the royalties are payable. If the transfer of or the conversion into the United States Dollar equivalents of any such remittance in any such instance is not lawful or possible, the payment of such part of the royalties as is necessary shall be made by the deposit thereof, in the currency of the county where the sale was made on which the royalty was based to the credit and account of Scripps or its nominee in any commercial bank or trust company of Scripps' choice located in that country, prompt written notice of which shall be given by Licensee to Scripps.

2.12 Foreign Taxes. Any tax required to be withheld by Licensee under the laws of any foreign country for the accounts of Scripps shall be promptly paid by Licensee for and on behalf of Scripps to the appropriate governmental authority, and Licensee shall use its best efforts to furnish Scripps with proof of payment of such tax together with official or other appropriate evidence issued by the applicable government authority. Any such tax actually paid on Scripps' behalf shall be deducted from royalty payments due Scripps.

#### 3. Patent Matters.

3.1 Patent Prosecution and Maintenance. From and after the date of this Agreement, the provisions of this Section 3 shall control the prosecution and maintenance of any patent included within Scripps Patent Rights. Subject to the requirements, limitations and conditions set forth in this Agreement, Scripps shall direct and control (i) the preparation, filing and prosecution of the United States and foreign patent applications within Scripps Patent Rights (including any interferences and foreign oppositions) and (ii) maintain the patents issuing therefrom. Scripps shall select the patent attorney, subject to Licensee's written approval, which approval shall not be unreasonably withheld. Both parties hereto agree that Scripps may, at its sole discretion, utilize Scripps' Office of Patent Counsel in lieu of outside counsel for patent prosecution and maintenance described herein, and the fees and expenses incurred by Scripps with respect to work done by such Office of Patent Counsel shall be paid as set forth below. Licensee shall have full rights of consultation with the patent attorney so selected on all matters relating to Scripps Patent Rights. Scripps shall use its best efforts to implement all reasonable requests made by Licensee with regard to the preparation, filing, prosecution and/or maintenance of the patent applications and/or patents within Scripps Patent Rights.

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3.2 Information to Licensee. Scripps shall keep Licensee informed with regard to the patent application and maintenance processes. Scripps shall deliver to Licensee copies of all patent applications, amendments, related correspondence, and other related matters.

3.3 Patent Costs. Licensee acknowledges and agrees that Scripps does not have independent funding to cover patent costs, and that the license granted hereunder is in part in consideration for Licensee's assumption of patent costs and expenses as described herein, Licensee shall pay for all expenses incurred by Scripps pursuant to Section 3.1 hereof. In addition, Licensee agrees to reimburse Scripps for all patent costs and expenses paid or incurred by Scripps to date in connection with Scripps Patent Rights licensed hereunder. Licensee agrees to pay all such past and future patent expenses directly or to reimburse Scripps for the payment of such expenses within sixty (60) days after Licensee receives an itemized invoice therefor. In the event Licensee elects to discontinue payment for the filing prosecution and/or maintenance of any patent application and/or patent within Scripps Patent Rights, any such patent application or patent shall be excluded from the definition of Scripps Patent Rights and from the scope of the license granted under this Agreement, and all rights relating thereto shall revert to Scripps and may be freely licensed by Scripps. Licensee shall give Scripps at least sixty (60) days' prior written notice of such election. No such notice shall have any effect on Licensee's obligations to pay expenses incurred up to the effective date of such election.

3.4 Ownership. The patent applications filed and the patents obtained by Scripps pursuant to Section 3.1 hereof shall be owned solely by Scripps, assigned to Scripps and deemed a part of Scripps Patent Rights.

3.5 Scripps Right to Pursue Patent. If at any time during the term of this Agreement, Licensee's rights with respect to Scripps Patent Rights are terminated, Scripps shall have the right to take whatever action Scripps deems appropriate to obtain or maintain the corresponding patent protection at its own expense. If Scripps pursues patents under this Section 3.5, Licensee agrees to cooperate fully, including by providing, at no charge to Scripps, all appropriate technical data and executing all necessary legal documents.

3.6 Licensee's Right to Pursue Patent . If subsequent to filing a patent application on an invention within the Scripps Patent Rights, Scripps elects not to direct and control the prosecution or maintenance of such patent application or ensuing patent Scripps shall give Licensee notice thereof within a reasonable period prior to allowing such patent application or patent to lapse or become abandoned or unenforceable and Licensee may direct and control prosecution or maintenance of such patent application or patent at its expense and its exclusive benefit. If subsequent to filing of a United States patent application, Scripps chooses not to file in foreign countries, Scripps shall inform Licensee within six (6) months of the United States filing date and shall permit Licensee to effect such foreign filings not made by Scripps at Licensee's sole expense.

#### 3.7 Infringement Actions.

3.7.1 Prosecution of Infringements. Scripps and Licensee shall promptly notify the other in writing if any infringement of the Scripps Patent Rights by a third party is discovered or comes to its attention. Provided Licensee shall have supplied Scripps with reasonable evidence of infringement of Scripps Patent Rights by a third party, Licensee shall have the right, at Licensee's sole expense to bring suit against the infringer for infringement of the Scripps Patent Rights. In the event that Licensee has not caused such infringement to terminate (for whatever cause) or initiated legal proceedings against the infringer within three (3) months following receipt or giving of notice pursuant to this Section 3.7, Scripps shall have the right (but not the obligation), at Scripps's sole expense, to bring suit against the infringer for infringement of the Scripps Patent Rights.

3.7.2 Reasonable Assistance. In the event either party hereto shall initiate or carry on legal proceedings to enforce the Scripps Patent Rights against an alleged infringer, as provided herein, the other party hereto shall render reasonable assistance to and cooperate with the party initiating or carrying on such proceedings.

3.7.3 Control. In the event that either party shall institute suit or other legal proceedings to enforce the Scripps Patent Rights, it shall have sole control of such suit and the other party shall be entitled to be represented in any such suit by counsel of its choosing, at its sole expense. Licensee shall not discontinue or settle any such proceedings brought by it without obtaining the concurrence of Scripps (which concurrence shall not be unreasonably withheld) and giving Scripps a timely opportunity to continue such proceedings in its own name, under its sole control, and at this sole expense. In the event Scripps does not incur in such settlement, it must continue such proceeding in its own name, under its sole control and expense within three (3) months of being given notice by Licensee of its desire to settle or Licensee shall be entitled to settle without Scripps's concurrence.

3.7.4 Allocation of Recovery. All damages, settlements and rewards made or obtained in connection with any suit or other legal proceeding under this section 3.7 shall be shared among the parties as follows:

(a) The party initiating the suit shall first be reimbursed for all costs and expenses of such suit or legal proceeding; in the event that the suit or other legal proceeding is initiated by Licensee but is later assumed, under Section 3.7.3, by Scripps, Licensee shall first be reimbursed its costs and expenses and then Scripps shall be reimbursed its costs and expenses of such proceeding.

(b) If the Licensee initiated the suit and prosecuted it to its conclusion, Licensee shall be entitled to retain the balance of any damages, settlements and awards, less the royalty on such amounts due Scripps in accordance with Article 2.

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(c) In all other circumstances other than that described in Section 3.7.4(b) above, Scripps and Licensee shall divide the balance of any damages, settlements and awards 60% to Scripps and 40% to Licensee.

## 4. Obligations Related to Commercialization.

4.1 Commercial Development Obligation. In order to maintain the license granted hereunder in force, Licensee shall use reasonable efforts and due diligence to develop Scripps Technology and Scripps Patent Rights which are licensed hereunder into commercially viable Licensed Products, and thereafter to produce and sell reasonable quantities of Licensed Products. Licensee shall keep Scripps generally informed as to Licensee's progress in such development, production and sale, including its efforts, if any and only to the extent it may do so without breaching the terms of any confidentiality agreement, to sublicense Scripps Technology and Scripps Patent Rights. Licensee shall deliver to Scripps a semiannual written report and such other reports as Scripps may reasonably request. The parties hereto acknowledge and agree that achievement of the milestones described in Exhibit C attached hereto on or before the dates set forth therein shall be evidence of compliance by Licensee with its commercial development obligations hereunder for the time periods specified in Exhibit \_ In the event Scripps has a reasonable basis to believe that Licensee is not using reasonable efforts and due diligence as required hereunder, upon notice by Scripps to Licensee which specifies the basis for such belief, Scripps and Licensee shall negotiate in good faith to attempt to mutually resolve the issue. In the event Scripps and Licensee cannot agree upon any matter related to Licensee's commercial development obligations, the parties agree to utilize arbitration pursuant to Section 10.2 hereof in order to resolve the matter. If the arbitrator determines that Licensee has not complied with its obligations hereunder, and such default is not fully cured within sixty (60) days after the arbitrator's decision, Scripps may terminate Licensee's rights under this Agreement.

4.2 Governmental Approvals and Marketing of Licensed Products. Licensee shall be responsible for obtaining all necessary governmental approvals for the development, production, distribution, sale and use of any Licensed Product, at Licensee's expense, including, without limitation safety studies. Licensee shall have sole responsibility for any warning labels, packaging and instructions as to the use of Licensed Products and for the quality control for any Licensed Product.

4.3 Indemnity. Licensee hereby agrees to indemnify defend and hold harmless Scripps and any parent, subsidiary or other affiliated entity of Scripps and their trustees, officers, employees, scientists and agents from and against any liability or expense arising from any product liability claim asserted by any party as to any Licensed Product or any claims arising from the use of any Scripps Patent Rights or Scripps Technology pursuant to this Agreement. Such indemnity and defense obligation shall apply to any product liability or other claims, including without limitation, personal injury, death or property damage, made by employees, subcontractors, sublicensees, or agents of Licensee, as well as any member of the

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general public. Licensee shall use its best efforts to have Scripps and, if requested in writing by Scripps, any parent, subsidiary or other affiliated entity of Scripps and their trustees, officers, employees, scientists and agents named as additional insured parties on any product liability insurance policies maintained by Licensee its Affiliates and sublicensees applicable to Licensed Products.

4.4 Patent Marking. To the extent required by applicable law, Licensee shall mark all Licensed Products or their containers in accordance with the applicable patent marking laws.

 $4.5~\rm No$  Use of Name. The use of the name "The Scripps Research Institute", "Scripps", or any variation thereof in connection with the advertising or sale of Licensed Products is expressly prohibited.

4.6 U.S. Manufacture. To the extent required by applicable United States laws, if at all, Licensee agrees that Licensed Products will be manufactured in the United States, or its territories, subject to such waivers as may be required, or obtained, if at all, from the United States Department of Health and Human Services, or its designee.

4.7 Foreign Registration. Licensee agrees to register this Agreement with any foreign governmental agency which requires such registration, and Licensee shall pay all costs and legal fees in connection therewith. In addition, Licensee shall assure that all foreign laws affecting this Agreement or the sale of Licensed Products are fully satisfied.

5. Limited Warranty. Scripps hereby represents and warrants that it has full right and power to enter into this Agreement and grant the licenses to Licensee granted herein. SCRIPPS MAKES NO OTHER WARRANTIES CONCERNING SCRIPPS PATENT RIGHTS OR SCRIPPS TECHNOLOGY COVERED BY THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS TO SCRIPPS PATENT RIGHTS, SCRIPPS TECHNOLOGY OR ANY LICENSED PRODUCT. SCRIPPS MAKES NO WARRANTY OR REPRESENTATION AS TO THE VALIDITY OR SCOPE OF SCRIPPS PATENT RIGHTS, OR THAT ANY LICENSED PRODUCT WILL BE FREE FROM AN INFRINGEMENT ON PATENTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR THAT NO THIRD PARTIES ARE IN ANY WAY INFRINGEMENT SCRIPPS PATENT RIGHTS OR SCRIPPS TECHNOLOGY COVERED BY THIS AGREEMENT.

6. Interests in Intellectual Property Rights.

6.1 Preservation of Title. Scripps shall retain full ownership and title to Scripps Technology, and Scripps Patent Rights licensed hereunder and shall preserve and

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maintain such full ownership and title, subject to Licensee fully performing all of its obligations under this Agreement.

6.2 Royalty-Free License to Improvements. Licensee hereby grants to Scripps a non-exclusive, royalty-free license to any improvement to Scripps Technology developed by Licensee, to use for its own non-commercial research purposes or grant to other nonprofit institutions for their non-commercial research purposes.

6.3 Governmental Interest. Licensee and Scripps acknowledge that Scripps has received, and expects to continue to receive, funding from the United States Government in support of Scripps' research activities. Licensee and Scripps. acknowledge and agree that their respective rights and obligations pursuant to this Agreement shall be subject to Scripps' obligations and the rights of the United States Government, if any, which arise or result from Scripps' receipt of research support from the United States Government including without limitation, the grant by Scripps to the United States a non-exclusive, irrevocable, royalty-free license to Scripps Technology and Scripps Patent Rights licensed hereunder for governmental purposes.

6.4 Reservation of Rights. Scripps reserves the right to use for any 9 non commercial research purposes and the right to allow other nonprofit institutions to use for any non-commercial research purposes (provided that such nonprofit institutions are not using or disclosing the Scripps Technology and Scripps Patent Rights for research or development purposes on behalf of a for-profit entity) any Scripps Technology and Scripps Patent Rights licensed hereunder, without Scripps or such other institutions being obligated to pay Licensee any royalties or other compensation.

7. Confidentiality and Publication.

7.1 Treatment of Confidential Information. The parties agree that during the term of this Agreement, and for a period of three (3) years after this Agreement terminates, a party receiving Confidential Information of the other party will (i) maintain in confidence such Confidential Information to the same extent such party maintains its own proprietary industrial information, (ii) not disclose such Confidential Information to any third party without prior written consent of the other party and (iii) not use such Confidential Information for any purpose except those permitted by this Agreement.

7.2 Publications. Licensee agrees that Scripps shall have a right to publish in accordance with its general policies.

7.3 Publicity. otherwise provided herein or required by law, no party shall originate any publication, news release or other public announcement, written or oral, whether in the public press, stockholders' reports, or otherwise, relating to this Agreement or to any sublicense hereunder, or to the performance hereunder or any such agreements, without the

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prior written approval of the other party, which approval shall not be unreasonably withheld. Scientific publications published in accordance with Section 7.2 of this Agreement shall not be construed as publicity governed by this Section 7.3.

8. Term and Termination.

8.1 Term. Unless terminated sooner in accordance with the terms set forth herein, this Agreement, and the license granted hereunder, shall terminate as provided in Section 2.6 hereof.

8.2 Termination Upon Default. Any one or more of the following events shall constitute an event of default hereunder: (i) the failure of a party to pay any amounts when due hereunder and the expiration of thirty (30) days after receipt of a written notice requesting the payment of such amount; (ii) the failure of a party to perform any material obligation required of it to be performed hereunder, and the failure to cure within sixty (60) days after receipt of notice from the other party specifying in reasonable detail the nature of such default; and, (if applicable) (iii) any material default by Licensee under the Research Funding and Option Agreement dated March 1, 2000 between Scripps and Licensee and the failure to cure within thirty (30) days after receipt of notice from the other party specifying in reasonable detail the nature of such default. Upon the occurrence of any event of default, the non-defaulting party may deliver to the defaulting party written notice of intent to terminate such termination to be effective upon the date set forth in such notice.

Such termination rights shall be in addition to and not in substitution for any other remedies that may be available to the non-defaulting party. Termination pursuant to this Section 8.2 shall not relieve the defaulting party from liability and damages to the other party for breach of this Agreement. Waiver by either party of a single default or a succession of defaults shall not deprive such party of any right to terminate this Agreement arising by reason of any subsequent default.

8.3 Termination Upon Bankruptcy or Insolvency. This Agreement may be terminated by Scripps giving written notice of termination to Licensee upon occurrence of any of the following events:

(a) Licensee is dissolved or any assignment is made of the Licensee's business for the benefit of creditors;

(b) A receiver, or similar officer, is appointed to take charge of a substantial part of the Licensee's assets; or

(c) Any petition in bankruptcy is filed by the Licensee or any petition in bankruptcy is filed against the Licensee and which is not dismissed within ninety (90) days.

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8.4 Rights Upon Expiration, Neither party shall have any further rights or obligations upon the expiration of this Agreement upon its regularly scheduled expiration date with respect to this Agreement, other than the obligation of Licensee to make any and all reports and payments for the final quarter period. Provided, however, that upon such expiration, each party shall be required to continue to abide by its non-disclosure obligations, as described in Section 7.1, and Licensee shall continue to abide by its obligation to indemnify Scripps as described in Section 4.3 and by its obligations under Section 6.2 hereof.

8.5 Rights Upon Termination. Notwithstanding any other provision of this Agreement, upon any termination of this Agreement prior to the regularly scheduled expiration date of this Agreement, the license granted hereunder shall terminate. Except as otherwise provided in Section 8.6 of this Agreement with respect to work- in-progress, upon such termination, Licensee shall have no further right to develop, manufacture or market any Licensed Product, or to otherwise use any Scripps Patent Rights or any Scripps Technology not otherwise includable therein. Upon any such termination, Licensee shall promptly return all materials, samples, documents, information, and other materials which were provided to Licensee by Scripps. Any such termination shall not relieve either party from any obligations accrued to the date of such termination. Upon such termination, each party shall be required to abide by its non-disclosure obligations as described in Section 7.1, and Licensee shall continue to abide by its obligations to indemnify Scripps as described in Section 4.3.

8.6 Work-in-Progress. Upon any such early termination of the license granted hereunder in accordance with this Agreement, Licensee shall be entitled to finish any work-in-progress and to sell any completed inventory of a Licensed Products covered by such license which remain on hand as of the date of the termination, so long as Licensee pays to Scripps the royalties applicable to said subsequent sales in accordance with the terms and conditions as set forth in this Agreement, provided that no such sales shall tie permitted after the expiration of six (6) months after the date of termination.

#### 9. Assignment; Successors.

9.1 Assignment. Neither this Agreement nor any rights granted hereunder may be assigned or transferred by Licensee except (i) to an Affiliate of Licensee, (ii) to any entity with which it may merge or consolidate, or to which it may transfer all or substantially all of its assets or business to which this Agreement relates or (iii) as expressly permitted hereunder, without the prior written consent of Scripps.

9.2 Binding Upon Successors and Assigns. Subject to the limitations on assignment herein, this Agreement shall be binding upon and inure to the benefit of any successors in interest and assigns of Scripps and Licensee. Any such successor or assignee of Licensee's interest shall expressly assume in writing the performance of all the terms and conditions of this Agreement to be performed by Licensee.

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10. General Provisions.

10.1 Independent Contractors. The relationship between Scripps and Licensee is that of independent contractors. Scripps and Licensee are not joint venturers, partners, principal and agent, master and servant, employer or employee, and have no other relationship other than independent contracting parties. Scripps and Licensee shall have no power to bind or obligate each other in any manner, other than as is expressly set forth in this Agreement.

10.2 Arbitration. Any controversy or claim arising out of or relating to this Agreement, or the breach thereof, shall be settled by binding arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA"), and the procedures set forth below. In the event of any inconsistency between the Rules of AAA and the procedures set forth below, the procedures set forth below shall control. Judgment upon the award rendered by the arbitrators may be enforced in any court having jurisdiction thereof.

10.2.1 Location. The location of the arbitration shall be in the City of Philadelphia.

10.2.2 Selection of Arbitrators. The arbitration shall be conducted by a panel of three neutral arbitrators who are independent and disinterested with respect to the parties, this Agreement, and the outcome of the arbitration. Each party shall appoint one neutral arbitrator, and these two arbitrators so selected by the parties shall then select the third arbitrator. If one party has given written notice to the other party as to the identity of the arbitrator appointed by the party, and the party thereafter makes a written demand on the other party to appoint its designated arbitrator within the next ten days, and the other party fails to appoint its designated arbitrator within already been designated shall appoint the other two arbitrators.

10.2.3 Discovery. Unless the parties mutually agree in writing to some additional and specific pre-hearing discovery, the only pre-hearing discovery shall be (a) reasonably limited production of relevant and non-privileged documents, and (b) the identification of witnesses to be called at the hearing, which identification shall give the witness's name, general qualifications and position, and a brief statement as to the general scope of the testimony to be given by the witness. The arbitrators shall decide any disputes and shall control the process concerning these pre-hearing discovery matters. Pursuant to the Rules of AAA, the parties may subpoena witnesses and documents for presentation at the hearing.

10.2.4 Case Management. Prompt resolution of any dispute is important to both parties; and the parties agree that the arbitration of any dispute shall be conducted expeditiously. The arbitrators are instructed and directed to assume case management initiative and control over the arbitration process including scheduling of events, pre-hearing discovery and activities, and the conduct of the hearing), in order to complete the arbitration as expeditiously as is reasonably practical for obtaining a just resolution of the dispute.

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10.2.5 Remedies. The arbitrators may grant any legal or equitable remedy or relief that the arbitrators deem just and equitable, to the same extent that remedies or relief could be granted by a state or federal court, provided however, that no punitive damages may be awarded. No court action may be maintained seeking punitive damages. The decision of any two of the three arbitrators appointed shall be binding upon the parties.

10.2.6 Expenses. The expenses of the arbitration, including the arbitrators' fees, expert witness fees, and attorney's fees, may be awarded to the prevailing party, in the discretion of the arbitrators, or may be apportioned between the parties in any manner deemed appropriate by the arbitrators. Unless and until the arbitrators decide that one party is to pay for all (or a share) of such expenses, both parties shall share equally in the payment of the arbitrators' fees as and when billed by the arbitrators.

10.2.7 Confidentiality. Except as set forth below, the parties shall keep confidential the fact of the arbitration, the dispute being arbitrated, and the decision of the arbitrators. Notwithstanding the foregoing, the parties may disclose information about the arbitration to persons. who have a need to know, such as directors, trustees, management employees, witnesses, experts, investors, attorneys, lenders, insurers, and others who may be directly affected. Additionally, if a party has stock which is publicly traded, the party may make such disclosures as are required by applicable securities laws. Further, if a party is expressly asked by a third party about the dispute or the arbitration, the party may disclose and. acknowledge in general and limited terms that there is a dispute with the other party which is being (or has been) arbitrated. Once the arbitration award has become final, if the arbitration award is not promptly satisfied, then these confidentiality provisions shall no longer be applicable.

10.3 Entire Agreement; Modification. This Agreement sets forth the entire agreement and understanding between the parties as to the subject matter hereof. There shall be no amendments or modifications to this Agreement, except by a written document which is signed by both parties.

10.4 California Law. This Agreement shall be construed and enforced in accordance with the laws of the State of California.

10.5 Headings. The headings for each article and section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section.

10.6 Severability. Should any one or more of the provisions of this Agreement be held invalid or unenforceable by a court of competent jurisdiction, it shall be considered severed from this Agreement and shall not serve to invalidate the remaining provisions thereof The parties shall make a good faith effort to replace any invalid or

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unenforceable provision with a valid and enforceable one such that the objectives contemplated by them when entering this Agreement may be realized.

10.7 No Waiver. Any delay in enforcing a party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

10.8 Name. Whenever there has been an assignment or sublicense by Licensee as permitted by this Agreement, the term "Licensee" as used in this Agreement shall also include and refer to, if appropriate, such assignee or sublicensees.

10.9 Attorneys' Fees. In the event of a dispute between the parties hereto or in the event of any default hereunder, the party prevailing in the resolution of any such dispute or default shall be entitled to recover its reasonable attorneys' fees and other costs incurred in connection with resolving such dispute or default.

10.10 Notices. Any notices required by this Agreement shall be in writing, shall specifically refer to this Agreement and shall be sent by registered or certified airmail, postage prepaid, or by telefax, telex or cable, charges prepaid, or by overnight courier, postage paid and shall be forwarded to the respective addresses set forth below unless subsequently changed by written notice to the other party:

For Scripps	The Scripps Research Institute 10550 North Torrey Pines Road, TPC-9 La Jolla, California 92037
	Attention: Director, Technology Development
	Fax No.: (858) 784-9910
For Licensee:	Discovery Laboratories
	350 South Main Street
	Suite 307
	Doylsetown PA 18901
	Attention: Mr. Robert Capetola
	Fax No.:(215) 340-3940
oo shall ha doomad daliy	(ared upon the earlier of (i) when received (ii)

Notice shall be deemed delivered upon the earlier of (i) when received, (ii) three (3) days after deposit into the mail, or (iii) the date notice is sent via telefax, telex or cable, (iv) the day immediately following delivery to overnight courier (except Sunday and holidays).

10.11 Compliance with U.S. Laws. Nothing contained in this Agreement shall require or permit Scripps or Licensee to do any act inconsistent with the requirements of any

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United States law, regulation or executive order as the same may be in effect from time to time.

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized representatives as of the date set forth above.

SCRIPPS:

LICENSEE:

THE	SCRIPPS	RESEARCH	INSTITUTE

 By:	 

By:\_\_\_\_\_ Arnold LaGuardia

Title: Senior Vice President Title:\_\_\_\_

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EXHIBIT A DISCLOSURE OF TECHNOLOGY

### Royalty Rates

1. Different royalty arrangements will apply depending on whether the Licensed Product is or was claimed in whole or in part by one or more of the Core Patent Rights.

2. In respect of Licenses Products that are or were claimed in whole or in part by one or more of the Core Patent Rights:

a. Until the last to expire of the issued patents and patents that may issue from the pending applications within the Core Patent Rights, Optionee will pay Scripps a royalty of between [\*\*\*] and [\*\*\*] of "Net Sales", which term shall have the meaning ascribed to it in the form of License Agreement attached to this Agreement as Exhibit C. There will be no royalty payable on patented inventions which merely represent "speed bumps" (i.e., patents that represent merely a potential block to competitors, but do not cover any new significant improvements to the inventions claimed in the Core Patient Rights). The aggregate of any royalties paid to Scripps for such Licensed Products during such period shall not exceed [\*\*\*] of Net Sales.

b. After the expiration of last to expire of the issued patents or patents issued from the pending applications within the Core Patent Rights, the royalty for such Licensed Products due to Scripps shall increase to [\*\*\*], subject to the additional royalty provision in Section 2.7 of the form of License Agreement attached to this Research Agreement as Exhibit C.

3. In respect of Licensed Products that are not and were not claimed in whole or in part by one or more of the Core Patent Rights, the parties will negotiate on a case by case basis the applicable royalty rates.

[\*\*\*] Confidential treatment requested

We consent to the incorporation by reference in Discovery Laboratories, Inc.'s registration statements on Form S-3 (File No. 333-86105) and Form S-8 (File No. 333-59945) of our report dated February 25, 2000 (with respect to the last paragraph of Note A, March 23, 2000, Note F[3], March 1, 2000, the second paragraph of Note G, March 14, 2000 and the last paragraph of Note G, March 3, 2000), on our audit of the consolidated financial statements as of December 31, 1999 and for each of the two years in the period ended December 31, 1999 and the period from May 18, 1993 (inception) through December 31, 1999, which report is included in this Annual Report on Form 10-KSB.

Richard A. Eisner & Company, LLP

New York, New York March 29, 2000 THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION FROM DISCOVERY LABORATORIES, INC. FORM 10-KSB FOR THE PERIOD ENDED DECEMBER 31, 1999 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

> 000946486 DISCOVERY LABORATORIES, INC. 1 YEAR DEC-31-1999 JAN-01-1999 DEC-31-1999 3,547,000 0 0 0 575,000 4,188,000 619,000 193,000 4,632,000 1,476,000 0 2,481,000 2,000 10,000 615,000 4,632,000 178,000 0 0 0 5,292,000 0 0 (4,958,000) 0 0 0 0 0 (4,958,000) (0.66) (0.66)