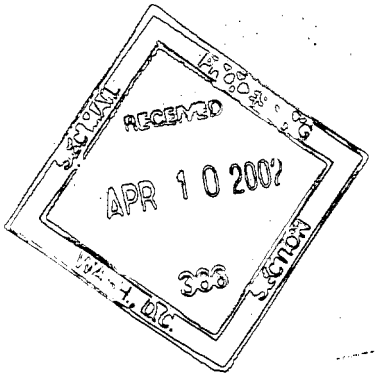
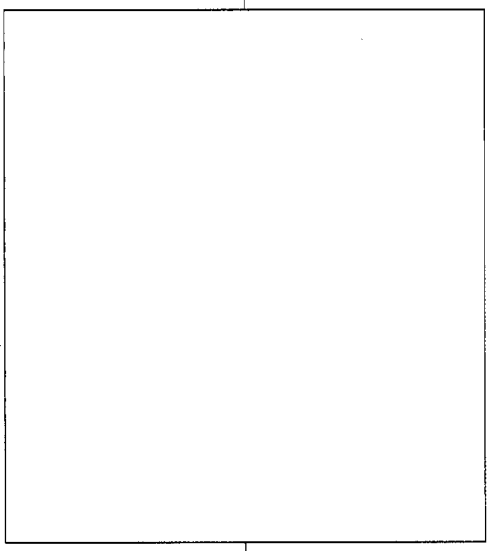
PE
12-31-01



Discovery Laboratories, Inc.

2001 Annual Report



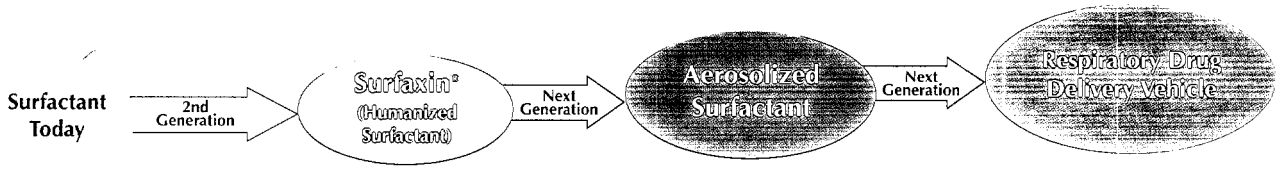
Corporate Profile

Discovery Laboratories, Inc. is a specialty pharmaceutical company leveraging its platform technology in humanized lung surfactants to develop novel respiratory therapies and pulmonary drug delivery products. Surfactants are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen.

Our humanized surfactant technology is being developed initially for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. Surfaxin®, our lead product, is currently in Phase 3 clinical trials for Respiratory Distress Syndrome in premature infants (RDS), a Phase 3 clinical trial for Meconium Aspiration Syndrome in full-term infants (MAS), and a Phase 2 clinical trial for Acute Lung Injury/Acute Respiratory Distress Syndrome in adults (ALI/ARDS).

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

Discovery's Humanized Surfactant Technology Platform



- RDS in Premature Infants
- RDS in premature infants
- MAS in full-term infants
- ALI/ARDS in Adults
- ALI/ARDS Prophylaxis
- Asthma
- Chronic Obstructive Pulmonary Disease
- Otitis Media
- Chronic Bronchitis
- Hepititis
- Diabetes
- Cystic Fibrosis
- Pneumonia
- Tuberculosis

A lack of functional surfactant is associated with several severe respiratory diseases. Research has established that surfactant replacement is highly effective in treating RDS and holds great promise in treating MAS, ALI/ARDS, asthma and other respiratory disorders. However, RDS is the only respiratory disease being treated today with approved surfactants, which are principally animal derived. The current supply of these surfactants is limited and their manufacture is both inexact and expensive, making it difficult to develop these products to treat broader populations for RDS therapy or other respiratory diseases.

Because our products are based on an engineered humanized surfactant, they can be produced economically at scale, as a high quality pharmaceutical, without the risk of potential transmission of animal-borne diseases or adverse immunological reaction. Products from our technology platform have the potential to be superior to currently marketed surfactants, treat critical care respiratory conditions, and treat larger, ambulatory patient populations that could benefit from surfactant therapy or drug delivery.

Building a Specialty Pharmaceutical Company — Initially Serving the Critical Care Markets

Our lead product, Surfaxin®, is in four late-stage clinical trials addressing critical care diseases. To prepare for commercialization, we have entered into the following strategic alliances:

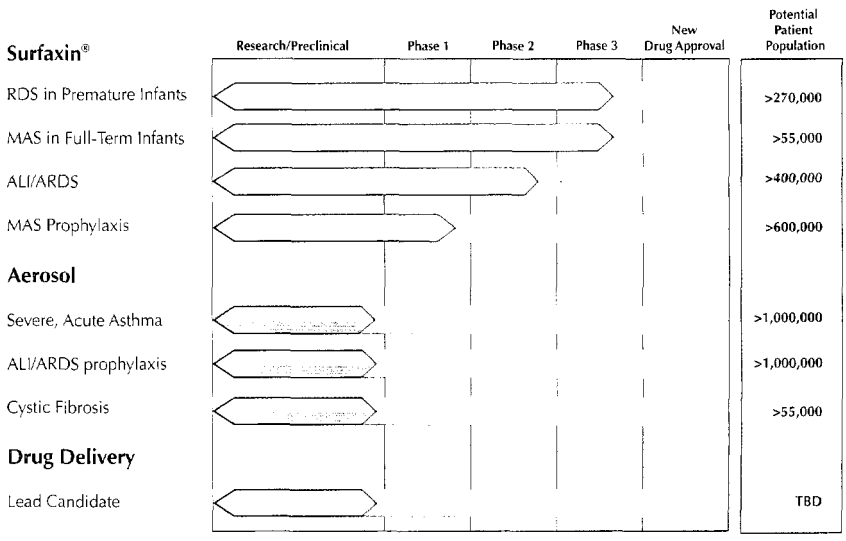
Quintiles Transnational Corp.

In December 2001, we created a strategic alliance with Quintiles to develop a dedicated sales and marketing capability to commercialize Surfaxin for RDS and MAS in the United States. Quintiles made a $3 million equity investment and committed up to $80 million in commercialization support.

Laboratorios del Dr. Esteve, S.A.

In March 2002, we expanded our alliance with Esteve for the development and commercialization of Surfaxin throughout Europe and Latin America for RDS, MAS and ALI/ARDS. Esteve made a $4 million equity investment and a significant co-development and commercialization commitment.

Discovery Laboratories' Product Pipeline



Dear Fellow Shareholders

I am pleased to report to you the important progress of our Company since our last annual report.

WE HAVE CONSTRUCTED THE COMMERCIAL CAPABILITY OF A FULLY INTEGRATED SPECIALTY PHARMACEUTICAL COMPANY TO REACH THE CRITICAL CARE MARKETPLACE WITH A GLOBAL BRAND STRATEGY.

Our lead product, Surfaxin®, has now moved into four late-stage, critical care clinical trials. To prepare for potential product launch, we added commercialization capabilities to build on our existing research, clinical, regulatory and manufacturing strengths. We determined that the best way to launch Surfaxin rapidly while conserving corporate resources is through strategic alliances. Our alliances have been structured to present a uniform and recognizable "Discovery/Surfaxin®" image to critical care markets worldwide, and generate the operating margins of a specialty pharmaceutical company.

To be in position to commercialize Surfaxin in the United States, in December 2001 we entered into a strategic alliance with Quintiles Transnational Corp., a leading provider of development, commercialization and information technology services to pharmaceutical, biotech and medical device companies.

Quintiles will hire, train and deploy a dedicated sales force to sell and market Surfaxin for RDS and MAS in the United States. Quintiles made a significant financial commitment that included a $3 million equity investment, a line of credit of up to $10 million to fund Surfaxin pre-launch activities, and up to $70 million in post-launch funding to cover the first seven years of U.S. sales and marketing costs. In return, Quintiles will receive a commission on net sales of Surfaxin over a ten year period. We may also receive milestone payments that would be used to offset amounts owed under the line of credit.

The agreement with Quintiles allows us to retain product ownership and to have sales and marketing expertise in place for a maximum launch effort following FDA approval. Additionally, the agreement allows for the specialty sales force to become ours at the end of the seven year term, with the option to acquire it sooner.

To develop, market and sell Surfaxin throughout Europe, Central America and South America, we expanded our alliance with Laboratorios del Dr. Esteve S.A. This collaboration supersedes our existing agreements with Esteve, which is one of the largest pharmaceutical companies in Southern Europe.

Esteve will market Surfaxin for RDS, MAS and ALI/ARDS. Esteve paid Discovery $4.5 million, which included a purchase of $4 million of our common stock at a 50% premium, and is committed to milestone payments tied to specific regulatory approvals for Surfaxin. Additionally, Esteve will fund clinical trial costs for ALI/ARDS to obtain regulatory approval for marketing in Europe. We retain manufacturing rights through an exclusive

supply agreement and will receive, as an ongoing revenue stream, a transfer price based on sales of Surfaxin through at least the minimum ten year term of the agreement.

SURFAXIN® IS EVOLUTIONARY AND REPRESENTS THE NEXT GENERATION SURFACTANT THERAPY. IT IS POTENTIALLY THE WORLD'S FIRST APPROVED HUMANIZED PROTEIN B SURFACTANT TO TREAT UNMET CRITICAL CARE RESPIRATORY DISEASES AND EXPAND THE CURRENT ANNUAL SURFACTANT MARKET TO $1.5 BILLION, OR MORE.

We have established a truly multinational clinical trial capability and are positioning our landmark Phase 3 and Phase 2 clinical trials to maintain the highest quality clinical standards in an effort to ensure clinical success. We have also implemented enhanced patient enrollment and clinical standards throughout our sites in the United States, Europe and Latin America, all in the face of a constantly changing regulatory terrain and review process. Here is an update on where we stand.

In the fall of 2001, we initiated two multinational Phase 3 trials for RDS in premature infants — a pivotal, landmark 1,500 patient trial and a 500 patient supporting trial. We expect to complete enrollment in these studies at the end of this year and announce trial results in the first half of 2003.

For ALI/ARDS in adults, we commenced enrollment of a Phase 2 dose-ranging and efficacy study in up to 110 patients in the United States. In this trial, large concentrations of Surfaxin are being administered using our proprietary lavage technique to cleanse and remove injurious inflammatory substances and debris from the lungs. We expect to have data available in the second half of this year.

The completion of patient recruitment for our Phase 3 clinical trial for MAS in full-term infants is now scheduled for late 2003. Given our belief in the importance of the multinational Phase 3 RDS trials to our present development plan, resources have been and may continue to be reallocated from the MAS program to the RDS trial, as needed. Additionally, enrollment is ongoing but has been slower than expected.

BASED ON RESEARCH CONDUCTED AT THE SCRIPPS RESEARCH INSTITUTE, WE HAVE ACCELERATED THE DEVELOPMENT OF AEROSOLIZED HUMANIZED SURFACTANT TO ADDRESS SIGNIFICANT RESPIRATORY INDICATIONS AND ITS USE AS A POTENTIAL DRUG DELIVERY VEHICLE.

We recently established a dedicated research laboratory in the San Francisco Bay Area of California, a region with considerable scientific and product development capability in aerosol technology and pulmonary drug delivery.

We are very pleased to have Dr. Ralph Niven become a member of our executive management as Senior Vice President, Preclinical Development, to develop aerosolized formulations of our proprietary humanized lung surfactants. Dr. Niven is a distinguished scientist and is considered a leader in the field of pulmonary drug delivery.

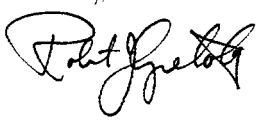
WE HAVE STRENGTHENED OUR FINANCIAL POSITION AND EXECUTIVE MANAGEMENT TEAM.

In order to leverage the potential of our technology platform, since the beginning of 2001, we raised $16 million in a combination of strategic alliances and private placements, in the face of a difficult financial market.

We are pleased to welcome John G. Cooper as Senior Vice President and Chief Financial Officer to lead future financings and strengthen our business operations. John brings more than 20 years of financial management experience in international life science companies.

We believe our platform technology holds enormous medical and economic potential and remain excited about our company's future. I thank our employees, board members, scientific advisors, and shareholders for giving us the support necessary for a specialty pharmaceutical company to bring life-saving respiratory medicine to patients in need.

Sincerely,



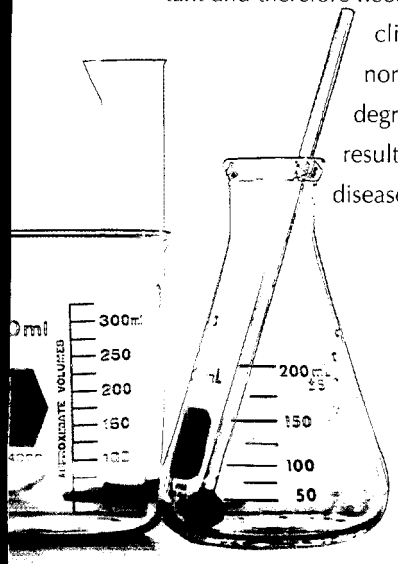
Robert J. Capetola, Ph.D.
President and Chief Executive Officer

The Future of Surfactant Technology

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

Human surfactants include four known surfactant proteins, A, B, C and D, that are associated with various lipids (fats). Surfactant protein B has been found essential for respiratory function in numerous studies. One such study led by Lawrence Nogee, M.D. and his colleagues at Johns Hopkins University School of Medicine demonstrated that absence of the human gene responsible for surfactant protein B is invariably fatal. Babies born without surfactant protein B will die unless they receive a lung transplant. Discovery's humanized surfactant technology is engineered to mimic human surfactant protein B.

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



Surfactant Treatment Today

Saves lives – but is limited

The first replacement surfactant therapies were approved by the FDA in the early 1990's for the treatment and prophylaxis of RDS in premature infants. These products were either synthetic compositions or animal derived. For the first time in the history of developed countries, RDS was no longer a leading cause of neonatal death.

Today there are primarily four marketed surfactants: the three leading products are derived from pig or cow lungs; the fourth product is a synthetic preparation. Though clinically effective, they all have serious drawbacks and cannot be readily scaled and developed to treat broader populations for RDS therapy or other respiratory diseases.

The most commonly used surfactant is prepared using a chemical extraction process from minced cow lung with surfactant protein C as the predominant protein. The most commonly used surfactant in Europe is a pig lung surfactant that also is derived in a chemical extraction process. Because of the animal-sourced materials and the chemical extraction processes used in making these products, there is significant variation in production lots and consequently, product specifications must be broad. Additionally, animal protein levels are inherently less than native human surfactant levels, production costs are high, generation of large quantities is severely limited, and these products cannot readily

be reformulated for aerosol delivery to the lungs. The leading synthetic product is a preparation of various lipids and surface active compounds but does not contain any of the surfactant proteins and is no longer widely used.

As a result, the only approved indication for surfactant therapy today is RDS.

Discovery's Humanized Surfactant Technology

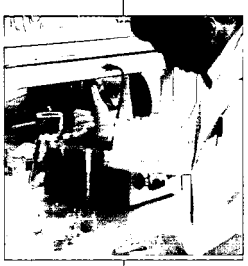
Next generation therapy for respiratory medicine

Discovery's surfactant technology is an engineered version of natural human lung surfactant and is based on our proprietary humanized peptide, sinapultide (KL4), designed to mimic human surfactant protein B. The technology was invented at The Scripps Research Institute in La Jolla, California and Discovery obtained an exclusive worldwide license from Johnson & Johnson in late 1996. Over 30 patents have been issued or are pending worldwide covering the composition of matter, formulation, manufacturing and uses, including pulmonary lavage techniques, of Discovery's proprietary humanized surfactants.

By employing a specifically designed humanized surfactant, the products from our technology platform have the potential to be superior to current marketed surfactants, treat critical care respiratory conditions, and treat large patient populations that could benefit from human surfactant therapy or drug delivery:

- Our products can be manufactured in exact and consistent pharmaceutical grade quality, and in volumes to meet significant medical and market needs — at a dramatically lower manufacturing cost than current animal-derived products.
- Our products have the ability to be precisely formulated to address various medical indications. Surfaxin® is presently formulated for intratracheal instillation. Next generation products are being developed as aerosolized liquids or dry powders.
- Our products have greater resistance to proteolytic degradation and oxidation than animal-derived surfactants. This potentially results in longer shelf-life and should result in a reduced number of administrations of surfactant to the lung.
- Our products eliminate the risk of infections associated with prion-related and other animal-derived diseases including the human form of "Mad Cow Disease" (new variant Creutfeldt-Jakob disease) and the risk of adverse immunological responses in young and older adults.

Discovery's new generation, humanized surfactant products bring great promise to patients with respiratory diseases — they may save lives, shorten hospital stays, lower health care costs, and improve the quality of life for critical care and ambulatory patients worldwide.



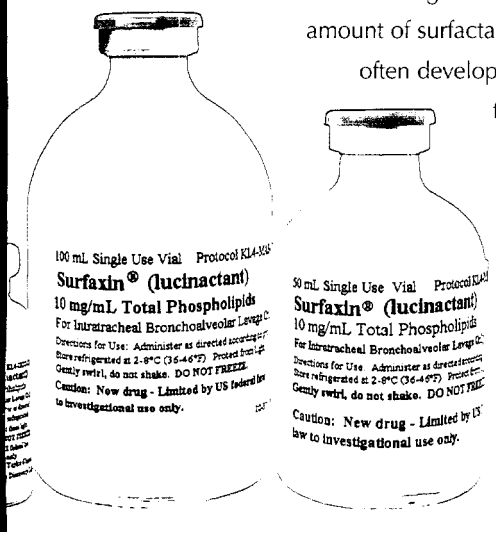
Surfaxin® – First Humanized Surfactant Therapy For Critical Care

Surfaxin®, our lead product, is the first humanized, protein B-based agent that mimics the surface-active properties of human surfactant. Surfaxin has been shown to remove inflammatory and infectious infiltrates from patients' lungs when used by lavage, or "lung wash," and replenish the vital surfactant levels in the lungs. Surfaxin is delivered in bolus form through an endotracheal tube in premature infants, and as a proprietary lavage through a tube, called a bronchoscope, in full-term infants and adults.

Surfaxin, if approved, would be the world's next generation surfactant — significantly improving and expanding the current surfactant therapy for RDS and treating other critical care respiratory conditions for which the only treatment today is mechanical ventilation. The potential attributes of Surfaxin create an opportunity for improving critical care respiratory medicine — a market that could exceed $1.5 billion.

RDS – Phase 3 Trials for Respiratory Distress Syndrome in Premature Infants

The number of premature births is increasing primarily due to the growing number of in-vitro fertilization births — which potentially translates into an increase in respiratory complications and mortality. Infants born prior to 32 weeks of gestation have an insufficient amount of surfactant in their lungs and often develop RDS. The mortality rate for untreated infants ranges from 40 to 70%. Additionally, up to 40% of premature infants will develop further debilitating lung conditions that require extended and costly ventilator support and hospitalization.



Each year approximately two million babies worldwide are born premature with RDS. Approximately 270,000 of these births are in the developed world, yet due to the limitations described earlier, only about 100,000 newborns have access to currently approved surfactant therapy.

In 2001, Discovery initiated two Phase 3 clinical trials — a pivotal, multinational landmark trial in 1,500 patients and a 500 patient supportive, multinational trial. The landmark trial contains endpoints designed to demonstrate the superiority of Surfaxin over certain commercially available treatments. The supportive trial is designed to demonstrate the safety and non-inferiority of Surfaxin over the leading commercial surfactant in Europe. These trials are intended, if successful, to provide the basis for New Drug Applications with the FDA and worldwide regulatory authorities. Enrollment for these trials is expected to be completed by the end of 2002 with data expected to be announced in the first half of 2003.

The FDA has granted Orphan Drug Status for Surfaxin for this indication.

ALI/ARDS – Phase 2 Trial for Acute Lung Injury/Acute Respiratory Distress Syndrome

ALI/ARDS is a life-threatening disorder for which no approved therapies exist anywhere in the world. ALI/ARDS is characterized by an excess of fluid in the

lungs and decreased oxygen levels in the patient. One prominent characteristic is the destruction of surfactants present in lung tissue. The conditions are caused by illnesses including pneumonia and septic shock and events such as smoke inhalation, near drowning, industrial accidents and other traumas. Because there are no approved treatments, the mortality rate can range from 35% to 50%. The current standard of care includes placing patients on mechanical ventilators in intensive care units at a cost of approximately $3,000 to $4,000 per day. There are estimated to be between 150,000 and 250,000 ALI/ARDS patients per year in the United States with similar numbers afflicted in Europe.

Discovery believes its proprietary lavage method, combined with an ability to produce the necessary large quantities of Surfaxin®, will permit Surfaxin to meet this poorly addressed medical condition.

In 2001, Discovery initiated a Phase 2 randomized dose-ranging, open-label, controlled, multi-center clinical trial of Surfaxin in patients with ARDS. Up to 110 adult ARDS patients will receive Surfaxin via a proprietary sequential bronchopulmonary segmental lavage technique. The procedure is intended to cleanse and remove inflammatory substances and debris from the lungs, while leaving Surfaxin to re-establish the lungs' capacity to absorb oxygen. The objective is to restore functional surfactant levels and to get critically ill patients off costly mechanical ventilation. We expect data from this trial to be available in the second half of 2002.

The FDA has granted Fast Track Approval Status and both the FDA and Europe's regulatory equivalent, the EMEA, have granted Orphan Drug Designation for this indication.

MAS – Phase 3 Trial for Meconium Aspiration Syndrome

Each year over 55,000 full-term infants in the developed world suffer from MAS, a condition that results when full-term babies pass their first bowel movement, called meconium, in their mother's womb before birth. The meconium is breathed into the babies' lungs and produces inflammation, which degrades natural lung surfactant. Severe respiratory distress is often the result. There are no drug therapies approved for MAS treatments anywhere in the world. MAS infants receive costly mechanical ventilation and may suffer debilitating lung conditions and other complications.

Surfaxin is being evaluated in a Phase 3 clinical trial in MAS and may be the only product in the world being developed to treat this syndrome. Two hundred newborn infants are being enrolled at medical centers throughout the United States to compare Surfaxin lavage to the standard of care. We expect to complete patient recruitment in 2003.

The FDA has granted Fast Track Approval Status and both the FDA and Europe's EMEA have granted Orphan Drug Designation for this indication.

We are also developing a clinical program for Surfaxin lavage as a prophylactic for MAS at-risk infants who have not yet shown symptoms of compromised respiratory function. There are approximately 600,000 babies born each year that are meconium stained, of which about 10% develop MAS. According to the online healthcare publication All-Net, as many as 66% of all persistent pulmonary hypertension cases are related to MAS. We believe an effective and affordable surfactant prophylactic therapy could significantly lower the risk to infants from chronic respiratory conditions and reduce the need for costly mechanical ventilation.

Aerosolized Surfactants

Leveraging the Technology Platform

Scientific data has demonstrated that the therapeutic use of surfactants in aerosol form have the ability to re-establish airway patency, improve pulmonary mechanics and act as an anti-inflammatory. However, use of currently available, animal-derived surfactants is not considered viable for aerosolization due to the inability to optimize formulations, the inefficiency of current delivery systems, the manufacturing requirements, the cost of goods, and the risk of chronic exposure to animal proteins.

Applying the proprietary attributes of our humanized surfactant technology — an engineered version of human lung surfactant with the ability to be manufactured in large quantities — formulations are being developed in our California laboratory to potentially provide effective aerosol products.

Therapy for millions of people who suffer from acute episodes of a wide range of respiratory diseases

In the case of acute asthma as well as most other respiratory diseases such as chronic obstructive pulmonary disease (COPD) and chronic bronchitis, endogenous lung surfactant is destroyed. If this surfactant is not replaced, the air-sacs in the lung collapse and the patient will require mechanical ventilation to survive. According to data from the Centers for Disease Control in Atlanta, asthma afflicts approximately fourteen million people in the United States and its incidence rate is rising. In the United States alone, there are roughly one million emergency room visits each year due to acute asthma attacks, while the worldwide population of COPD sufferers is estimated at 100 million.

Discovery's proprietary aerosolized surfactant is currently in research and development for the therapeutic indications above and as a prophylactic treatment for ALI/ARDS. We believe our lead aerosol product could be in clinical trials in late 2003.

Respiratory drug delivery vehicle

Existing drug delivery technology has effectively addressed the development of delivery devices, drug storage systems and compatible drug formulations. However, the most significant unmet need in pulmonary drug delivery is to provide better performance once a drug is deposited in the lungs. This includes improving the bioavailability of many biomolecules that are being developed for systemic delivery via the lungs. For example, currently existing technologies for delivering insulin through the respiratory system may require up to seven times the amount of insulin administered by injection.

An aerosol version of our humanized lung surfactant, with its ability to penetrate and spread in an even manner throughout the lungs, has the potential to be an excellent vehicle to more efficiently deliver drugs via or within the respiratory tract. These drugs include antibiotics, pulmonary vasodilators to lower blood pressure in the lung arteries, elastase inhibitors (drugs that inhibit a potentially destructive enzyme that comes from certain types of white blood cells), bronchodilators (drugs that mitigate constriction of small airways), steroids and proteins. Surfactant delivery of drugs through the respiratory tract may efficiently treat tens of millions of people afflicted with hepatitis, diabetes, cystic fibrosis, pneumonia and tuberculosis.

We believe we may have our first drug delivery product in clinical trials in late 2003.

U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-KSB

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

For the fiscal year ended December 31, 2001

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

For the transition period from to

Commission file number 0-26422

DISCOVERY LABORATORIES, INC.

(Name of Small Business Issuer in Its Charter)

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

350 SOUTH MAIN STREET, SUITE 307, DOYLESTOWN, PENNSYLVANIA 18901

(Address of Principal Executive Offices Including Zip Code)

(215) 340-4699

(Issuer's Telephone Number, Including Area Code)

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

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

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

Common Stock, $.001 par value

(Title of Class)

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES X NO

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

State issuer's revenues for its most recent fiscal year. $1,112,000.

The aggregate market value of all of the registrant's outstanding common stock, par value $0.001 per share (26,385,680 shares, including shares of common stock held by each director and executive officer (as such term is defined in Rule 16a-1(f) of the Exchange Act) and each person who beneficially owns 10% or more of the outstanding shares of common stock), was approximately $83 million computed by reference to the closing price of such common equity on the Nasdaq SmallCap Market on March 18, 2002.

As of March 18, 2002, 21,835,063 shares of the registrant's common stock were outstanding. 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 18, 2002, was approximately $69 million. Shares of common stock beneficially owned by each director and executive officer (as such term is defined in Rule 16a-1(f) of the Exchange Act) and each person who beneficially owns 10% or more of the outstanding shares of common stock have been excluded from the calculations set forth in this paragraph in that such persons may be deemed affiliates of the registrant. This determination of affiliate status is not necessarily conclusive.

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

Transitional Small Business Disclosure Format: YES NO X

Unless the context otherwise requires, all references to "we," "us," "our," and the "Company" include Discovery Laboratories, Inc. ("Discovery"), and its wholly-owned, presently inactive subsidiary, Acute Therapeutics, Inc.

FORWARD LOOKING STATEMENTS

The statements set forth under Item 1: "Description of Business" and elsewhere in this prospectus, including in Item 6: "Management's Discussion and Analysis – Risks Related to Our Business" and those incorporated by reference herein which are not historical constitute "Forward Looking Statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including statements regarding the expectations, beliefs, intentions or strategies for the future. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Forward-looking statements are subject to many risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to, the inherent risks and uncertainties in developing products of the type we are developing; possible changes in our financial condition; the progress of our research and development (including the risk that our lead product candidate, Surfaxin®, will not prove to be safe or useful for the treatment of certain indications); the impact of development of competing therapies and/or technologies by other companies; our ability to obtain additional required financing to fund our research programs; our ability to enter into agreements with collaborators and the failure of collaborators to perform under their agreements with us; the results of clinical trials being conducted by us; the progress of the FDA approvals in connection with the conduct of our clinical trials and the marketing of our products; the additional cost and delays which may result from requirements imposed by the FDA in connection with obtaining the required approvals; and the other risks and certainties detailed in Item 6: "Management's Discussion and Analysis - Risks Related to Our Business," and in the documents incorporated by reference in this report.

Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements.

[This page is intentionally left blank]

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

COMPANY SUMMARY

We are a specialty pharmaceutical company applying our platform technology, based on humanized lung surfactants, to develop potential novel respiratory therapies and pulmonary drug delivery products. Surfactants are substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen. Our humanized surfactant technology is being developed initially for critical care patients with life-threatening respiratory disorders where there are few, if any, approved therapies. These severe respiratory disorders generally are associated with a lack of functional surfactant. Surfaxin®, our lead product, is an engineered humanized surfactant and is currently in two Phase 3 clinical trials for Respiratory Distress Syndrome in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome in full-term infants, and a Phase 2 clinical trial for Acute Lung Injury/Acute Respiratory Distress Syndrome in adults.

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

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

PLATFORM TECHNOLOGY

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

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

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

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

Presently, the FDA has only approved replacement surfactants for Respiratory Distress Syndrome in premature infants. The most commonly used of these approved replacement surfactants are derived from pig and cow lungs. Though they are clinically effective, they have drawbacks and cannot readily be scaled and developed to treat broader populations for Respiratory Distress Syndrome in premature infants and other respiratory diseases. These animal-sourced products are prepared using a chemical extraction process from minced cow and pig lung. Because of the animal-sourced materials and the chemical extraction processes, there is significant variation in production lots and, consequently, product quality specifications must be broad. In addition, the protein levels of these animal-derived surfactants are inherently lower than the protein levels of native human surfactant. The production costs of these animal-derived surfactants are high, relative to other pharmaceutical products, generation of large quantities is severely limited, and these products cannot readily be reformulated for aerosol delivery to the lungs.

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

PRODUCTS

Surfaxin®

Surfaxin, our lead product, is the first humanized, protein B-based agent that mimics the surface-active properties of human surfactant. Surfaxin has been shown to remove inflammatory and infectious infiltrates from patients' lungs when used by our proprietary lavage (or "lung wash") and replenish the vital surfactant levels in the lungs. Currently, we are developing Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Surfaxin is delivered in a liquid form and is injected through an endotracheal tube (a tube inserted into the infant's mouth and down the trachea) in premature infants, and as a proprietary lavage through a tube, called a bronchoscope, in full-term infants and adults.

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 condition in which full-term infants are born with meconium in their lungs that depletes the natural surfactant in their lungs. Meconium is a baby's first bowel movement in its mother's womb and Meconium Aspiration Syndrome can occur if the baby breathes it in. Both Respiratory Distress Syndrome and Meconium Aspiration Syndrome can be life-threatening as a result of the failure of the lungs to absorb sufficient oxygen. These conditions can also deplete natural surfactants in the lungs and result in the need for mechanical ventilation.

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

Respiratory Distress Syndrome in Premature Infants

In 2001, we initiated two Phase 3 clinical trials for the treatment of Respiratory Distress Syndrome in premature infants - a pivotal, multinational landmark trial in 1,500 patients and a 500 patient supportive, multinational trial. The landmark trial is designed to demonstrate the superiority of Surfaxin over certain commercially available treatments. The supportive trial is being conducted in Europe and is designed to demonstrate the safety and non-inferiority of Surfaxin over a certain animal-derived surfactant. These trials are intended, if successful, to provide the basis for New Drug Applications with the FDA and other worldwide regulatory authorities. Enrollment for these trials is expected to be completed by the end of 2002 with data expected to be announced in the first half of 2003.

Respiratory Distress Syndrome in premature infants affects approximately two million babies worldwide with approximately 270,000 cases occurring in the developed world. Due to limitations associated with the products currently approved, only approximately 100,000 infants are estimated to be receiving surfactant therapy worldwide.

The FDA has granted us Orphan Drug Designation for Surfaxin for this indication. Orphan drugs are pharmaceutical products that are intended to treat diseases affecting fewer than 200,000 patients in the United States. The Office of Orphan Product Development of the FDA grants certain advantages to the sponsors of orphan drugs including, but not limited to, seven years of market exclusivity upon approval of the drug, certain tax incentives for clinical research and grants to fund testing of the drug. We also are seeking Orphan Product designation from the European Medicines Evaluation Agency (Europe's regulatory approval agency that is similar to the FDA) for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants.

Meconium Aspiration Syndrome in Full-Term Infants

Surfaxin is being evaluated in a Phase 3 clinical trial for the treatment of Meconium Aspiration Syndrome in full-term infants and may be the only product in the world being developed to treat this syndrome. The trial is designed for the enrollment of up to 200 infants at medical centers throughout the United States to compare Surfaxin lavage to the current standard of care. Enrollment is ongoing but has been slower than expected and completion is now anticipated for late 2003. Given our belief in the importance of the pivotal Phase 3 trial for Respiratory Distress Syndrome in premature infants to our present development plan, resources have been and may continue to be reallocated from the Meconium Aspiration Syndrome program to the Respiratory Distress Syndrome program, as needed.

We are also developing a clinical program for Surfaxin lavage potentially for use as a prophylactic for infants who are at risk for Meconium Aspiration Syndrome but have not shown symptoms of compromised respiratory function. There are approximately 600,000 babies born each year that are at risk for Meconium Aspiration Syndrome, of which about 10% develop the condition. We believe an effective and affordable surfactant prophylactic therapy could significantly lower the risk to meconium-stained infants of chronic respiratory conditions and reduce the need for costly mechanical ventilation.

There are presently no drug therapies approved for the treatment of Meconium Aspiration Syndrome in full-term infants. The FDA has granted us Fast Track Approval Status and Orphan Drug Designation for Surfaxin for the treatment of Meconium Aspiration Syndrome in full-term infants. We have also received Orphan Product designation of Surfaxin for the treatment of Meconium Aspiration Syndrome from the European Medicines Evaluation Agency. In October 1998, the Office of Orphan Products Development awarded us a renewable Orphan Products Development Grant for up to approximately $580,000 over three or more years to finance our Meconium Aspiration Syndrome trial. Continued funding of the grant is subject to our meeting certain performance criteria.

Acute Lung Injury and Acute Respiratory Distress Syndrome in Adults

In 2001, we initiated a Phase 2 randomized dose-ranging, open-label, controlled, multi-center clinical trial of Surfaxin in adults with Acute Respiratory Distress Syndrome. Up to 110 patients will receive high concentrations of Surfaxin via our proprietary lavage technique that administers the drug sequentially to the different segments of the lung through a tube, called a bronchoscope. The procedure is intended to cleanse and remove inflammatory substances and debris from the lungs, while leaving amounts of Surfaxin behind to help re-establish the lungs' capacity to absorb oxygen. The objective is to restore functional surfactant levels and to get critically ill patients off mechanical ventilation. We expect data from this trial to be available in the second half of 2002.

The current standard of care for Acute Lung Injury and Acute Respiratory Distress Syndrome includes placing patients on mechanical ventilators in intensive care units at a cost of approximately $3,000 to $4,000 per day. There are estimated to be between 150,000 and 250,000 adults per year in the United States suffering from Acute Lung Injury and Acute

Respiratory Distress Syndrome with similar numbers afflicted in Europe. Because there are no approved treatments for these diseases, the mortality rate can range from 35% to 50%.

The FDA has granted us Fast Track Approval Status and Orphan Drug Designation for Surfaxin for the treatment of Acute Respiratory Distress Syndrome for adults. The European Medicines Evaluation Agency has granted us Orphan Product designation for Surfaxin for the treatment of Acute Lung Injury in adults (which in this circumstance encompasses Acute Respiratory Distress Syndrome). In October 2000, we were awarded a $1 million Fast-Track Small Business Innovative Research Grant by the National Institutes of Health to develop Surfaxin for the treatment of Acute Respiratory Distress Syndrome and Acute Lung Injury in adults.

Aerosolized Humanized Surfactants for Respiratory Therapy

We have begun preclinical research for the use of our engineered humanized surfactant as an aerosol spray for the treatment of asthma, chronic obstructive pulmonary disease (commonly known as COPD, which is a chronic condition of the lung that prevents enough oxygen from reaching the blood), and a variety of other respiratory diseases. In all of these conditions a patient's endogenous lung surfactant is destroyed. If this surfactant is not replaced, the air-sacs in the lung collapse and the patient will require mechanical ventilation to survive. In addition, upper respiratory conditions such as ear infections and sinusitis are characterized by a loss of functioning surfactants in the upper airways.

According to data from the Centers for Disease Control in Atlanta, asthma afflicts approximately 14 million people in the United States and its incidence rate is rising. In the United States alone, there are roughly one million emergency room visits each year due to acute asthma attacks, while the worldwide population of COPD sufferers is estimated at 100 million. We believe that our engineered humanized surfactant can also be used in an aerosol form as a prophylactic treatment for Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. We believe that we may have our lead aerosol product in a Phase 1 clinical trial in late 2003.

Aerosolized Humanized Surfactants for Pulmonary Drug Delivery

We are also initiating preclinical research to evaluate formulations of our engineered humanized surfactants as novel pulmonary drug delivery vehicles with the potential to deliver other pharmaceutical products to the lungs so that such products can exert their pharmacological effects locally or systemically.

Existing drug delivery technology has effectively addressed the development of delivery devices, drug storage systems and compatible drug formulations. However, a significant unmet need in pulmonary drug delivery is to provide better performance once a drug is deposited in the lungs.

Currently existing technologies for delivering insulin through the respiratory system may require up to seven times the amount of insulin administered by injection. An aerosol version of our humanized lung surfactant, with its ability to penetrate and spread in an even manner throughout the lungs, has the potential to be an excellent vehicle to more efficiently deliver drugs via or within the respiratory tract. These drugs include antibiotics, pulmonary vasodilators that lower

blood pressure in the lung arteries, elastase inhibitors (drugs that are anti-inflammatory by inhibiting a potentially destructive enzyme that comes from certain types of white blood cells), bronchodilators (drugs that mitigate constriction of small airways), steroids and proteins. Surfactant delivery of drugs through the respiratory tract may efficiently treat tens of millions of people afflicted with hepatitis, diabetes, cystic fibrosis, pneumonia and tuberculosis. We believe that we may have our first drug delivery product in a Phase 1 clinical trial in late 2003.

Supervent®

We have decided to discontinue the clinical development of Supervent® for Cystic Fibrosis in its current form. However, we believe that tyloxapol, the active compound of Supervent, is potentially a multi-dimensional therapy and has the possibility to be used in combination with other drugs for the treatment of Cystic Fibrosis or other inflammatory respiratory diseases. We intend to evaluate future development activities for tyloxapol over the next year.

STRATEGIC ALLIANCES

Laboratorios del Dr. Esteve, S.A.

On March 6, 2002, we significantly expanded our existing relationship with Laboratorios del Dr. Esteve by entering into a new collaboration arrangement with Esteve. This new collaboration supersedes the Sublicense and Supply Agreements we entered into with Esteve on October 26, 1999, and expands the territory covered by those original agreements to all of Europe, Central and South America, and Mexico.

In connection with this new Esteve collaboration, Esteve purchased 821,862 shares of our common stock at $4.867 per share for $4.0 million in gross proceeds and paid us a non-refundable licensing fee of $500,000. Esteve agreed to provide certain commercialization services in the expanded territory for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients.

We have agreed to an exclusive supply agreement which provides that Esteve will purchase from us all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve has also agreed to sponsor certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for commercialization of Surfaxin in Europe for the Acute Lung Injury/Acute Respiratory Distress Syndrome indications. Esteve also agreed to make certain milestone payments upon the attainment of European Medicines Evaluation Agency marketing regulatory approval of Surfaxin for sale in Europe for the foregoing indications.

Quintiles Transnational Corp., and PharmaBio Development, Inc.

On December 10, 2001, we entered into a collaboration arrangement with Quintiles Transnational, and its affiliate, PharmaBio Development, to provide certain commercialization services in the United States for Surfaxin for the treatment of Respiratory Distress Syndrome in

premature infants and Meconium Aspiration Syndrome in full-term infants. We issued to PharmaBio 791,905 shares of our common stock and warrants to purchase approximately 677,143 shares of our common stock for aggregate net proceeds of approximately $2.7 million. Quintiles will hire and train a dedicated United States sales force that will be branded in the market as ours. PharmaBio has agreed to fund up to $70 million of the sales force costs and other sales and marketing costs for Surfaxin for seven years of commercialization of Surfaxin in the United States.

PharmaBio also agreed to extend a secured revolving credit facility of up to $8.5 million to $10 million to fund pre-marketing activities associated with the launch of Surfaxin in the United States as we achieve certain milestones. We are obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services to be provided by Quintiles. Principal amounts owed by us under the credit facility may be repaid out of the proceeds of milestone payments to be paid to us by PharmaBio upon our achievement of certain corporate milestones. To the extent that availability under the credit facility is increased to greater than $8.5 million, for each $1 million increase, the amount of shares of common stock issuable pursuant to the warrants will be increased by approximately 38,000 shares.

Under the arrangement, we will receive 100% of the revenues from sales of Surfaxin and have agreed to pay PharmaBio a commission on net sales in the United States of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants and all "off-label" uses for 10 years following first launch of the product in the United States. The arrangement with Quintiles allows us to retain product ownership and to have sales and marketing expertise in place for the commercialization of Surfaxin, if approved. Additionally, the arrangement allows for the specialty sales force to become ours at the end of the seven year term, with an option to acquire it sooner.

LICENSING ARRANGEMENTS; PATENTS AND PROPRIETARY RIGHTS

Johnson & Johnson License Agreement

Our humanized surfactant platform technology, including Surfaxin, is based on the proprietary peptide, sinapultide, (a 21 amino acid protein-like substance that mimics an important human lung protein). This technology was invented at The Scripps Research Institute and was exclusively licensed to and further developed by Johnson & Johnson, and its wholly owned subsidiary, Ortho Pharmaceutical. We have received an exclusive, worldwide sublicense from Johnson & Johnson for, and have rights to, a series of over 30 patents which are important, either individually or collectively, to our strategy of commercializing our humanized surfactant technology for the diagnosis, prevention and treatment of disease. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017.

Patents covering our proprietary humanized surfactant technology that have been issued or are pending worldwide include composition of matter, formulation, manufacturing and uses, including pulmonary lavage, or "lung wash" techniques. Our most significant patent rights principally consist of four issued United States patents and two pending United States patent applications. The four issued patents are: U.S. Patent No. 5,407,914; U.S. Patent No. 5,260,273;

U.S. Patent No. 5,164,369; and U.S. Patent No. 6,013,619. These patents relate to engineered humanized pulmonary surfactants (including Surfaxin), certain related peptides (amino acid protein-like substances) and a method of treating respiratory distress syndrome with these surfactants. The two pending United States applications relate to pulmonary surfactants, including related compositions and methods of treating respiratory distress syndromes with these surfactants and compositions. We also have certain pending United States patent applications that relate to methods of manufacturing certain peptides which may be used in the manufacture of Surfaxin. In October 2000, we were issued European Patent No. 0350506 covering certain surfactant peptides.

The Scripps Research Institute

U.S. Patent No. 6,013,619 was issued to Scripps and licensed to us and covers all known engineered (including Surfaxin), animal- or human-derived surfactants for use in any form of pulmonary lavage for respiratory distress syndromes. Our proprietary pulmonary lavage techniques (using surfactant) include lavage via a bronchoscope in adults as well as direct pulmonary lung lavage via an endotracheal tube in newborn babies with Meconium Aspiration Syndrome. We believe that our proprietary lavage technique may provide a clinical benefit to the treatment of Acute Lung Injury/Acute Respiratory Distress Syndrome in adults and Meconium Aspiration Syndrome in full-term infants by decreasing the amount of infectious and inflammatory debris in the lungs, restoring the air sacs to a more normal state and possibly resulting in patients getting off mechanical ventilation sooner.

We are parties with Scripps to a research funding and option agreement which expired in February 2002. We are currently negotiating an amendment to the agreement to extend the term for an additional three years but we may not be able to agree on terms that are acceptable to us. Pursuant to this agreement, we were required to fund a portion of Scripps' research efforts and Scripps granted us an option to acquire an exclusive worldwide license to the technology developed from the research program during the term of the agreement. Scripps owns all of the technology that it developed pursuant to work performed under the agreement. To the extent we did not exercise our option, we have the right to receive 50% of the net royalty income received by Scripps for inventions that were jointly developed by us and Scripps. It is our belief that Scripps will agree to extend the agreement for an additional three year term according to the same, or substantially similar, terms and conditions.

MANUFACTURING AND DISTRIBUTION – THIRD PARTY SUPPLIERS

Our products must be manufactured in compliance with good manufacturing practice requirements (GMPs) set by the FDA and other relevant worldwide regulatory authorities. We rely on outside manufacturers, for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies of our products and for their commercialization. We are also in the process of qualifying alternate third party suppliers for our manufacturing and raw material needs.

We own certain specialized equipment necessary to manufacture the Surfaxin drug product. This equipment is maintained at and manufacturing occurs at a third-party facility under the direction

and supervision of our manufacturing and quality control personnel. We are presently evaluating investing in additional manufacturing capability in anticipation of optimizing the commercial process for Surfaxin and to scale up the manufacturing process to meet clinical and commercial needs as they expand.

We are currently evaluating third party distribution capability in order to commercialize Surfaxin in the United States. Our collaboration with Esteve provides that Esteve has the responsibility for distribution throughout Europe, Central and South America, and Mexico. See Item 6: "Management's Discussion and Analysis - Risks Related to Our Business-Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales."

COMPETITION

We are engaged in highly competitive fields of pharmaceutical research. Competition from numerous existing companies and others entering the fields in which we operate is intense and expected to increase. We expect 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 we do. 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 we do may enjoy a significant competitive advantage over us. There are also existing therapies that may compete with the products we are developing. See Item 6: "Management's Discussion and Analysis - Risks Related to Our Business."

Presently, there are no approved drugs that are specifically indicated for the treatment of Meconium Aspiration Syndrome in full-term infants or Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Current therapy consists of general supportive care and mechanical ventilation.

For Respiratory Distress Syndrome in premature infants, four products are currently approved for treatment: Curosurf™ is a porcine lung extract that is marketed in Europe by Chiesi Farmaceutici S.p.A., and in the United States by Dey Laboratories, Inc. Exosurf™ is marketed by GlaxoSmithKline, plc, outside the United States and contains only phospholipids (fats that are normally present in the lungs) and synthetic organic detergents and no stabilizing protein or peptides. Survanta™, marketed by the Ross division of Abbott Laboratories, Inc., is derived from a chemical extraction process from minced cow lung that contains the cow version of surfactant protein B. Forrest Laboratories, Inc., markets its calf lung surfactant, Infasurf™, in the United States for the treatment of Respiratory Distress Syndrome in premature infants.

There are a significant number of other potential therapies in development for the treatment of Acute Lung Injury/Acute Respiratory Distress Syndrome in adults that are not surfactant related. Any of these various drugs or devices could significantly impact the commercial opportunity for Surfaxin.

We believe that engineered humanized surfactants such as Surfaxin will be far less expensive to produce than the animal-derived products currently approved for the treatment of Respiratory Distress Syndrome in premature infants and can be produced in exact and consistent pharmaceutical grade quality and in volumes to meet significant medical needs. In addition, we believe that such products might possess other pharmaceutical benefits not currently found with the animal-derived surfactants such as potentially longer shelf-life, reduced number of administrations to the patient's lungs, and would eliminate the risk of animal-borne diseases including the brain-wasting bovine spongiform encephalopathy (commonly called "mad-cow disease") and adverse immunological responses in young and older adults. Our products also have the ability to be precisely formulated, such as aerosolized liquids or dry powders, to address various medical indications.

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 us must undergo an extensive regulatory approval process required by the FDA and by comparable agencies in other countries. This process, which includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and 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 us. The FDA review process can be lengthy and unpredictable, and we may encounter delays or rejections of our 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, we first must conduct preclinical studies in a laboratory and in animal models to obtain preliminary information on a compound's efficacy and to identify any safety problems. The results of these studies are submitted as part of an Investigational New Drug (IND) application that the FDA must review before human clinical trials of an investigational drug can start.

Clinical trials are normally done in three phases and generally take two to five years or longer to complete. Phase 1 consists of testing the drug product in a small number of humans, normally healthy volunteers, 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 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 we may not receive approval 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, we 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 our products under development have been approved for marketing in the United States or elsewhere. We may not 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 us, or our licensees or marketing partners, from marketing our products, or limit the commercial use of our products, and thereby would have a material adverse effect on our business, financial condition and results of operations. See Item 6: "Management's Discussion and Analysis - Risks Related to Our Business."

The FDA has granted us Fast Track Approval Status for the Acute Respiratory Distress Syndrome and Meconium Aspiration Syndrome indications. Fast Track Approval Status facilitates the development and expedites the review of new drugs intended for treatment of life-threatening conditions for which there is presently no medical option by providing for the FDA's review of the New Drug Application for a drug granted such Fast Track Status within six months following filing. We have also received Orphan Drug Designation from the FDA's Office of Orphan Products Development of Surfaxin as a treatment for Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Respiratory Distress Syndrome in adults. We have also received designation of Surfaxin as an Orphan Product for Meconium Aspiration Syndrome and Acute Lung Injury (which, in this circumstance, encompasses Acute Respiratory Distress Syndrome) from the European Medicines Evaluation Agency.

In October 2000, we were awarded a $1 million Fast-Track Small Business Innovative Research Grant by the National Institutes of Health to develop Surfaxin for the treatment of Acute Respiratory Distress Syndrome in adults. In October 1998, the Office of Orphan Products Development awarded us a renewable Orphan Products Development Grant, ranging from $194,390 for the first year to $583,170 over three or more years, to finance our Meconium Aspiration Syndrome trial. Continued funding under both of these grants is subject to our meeting certain performance criteria.

EMPLOYEES

We have approximately 50 full-time employees. Our future success depends in significant part upon the continued service of our key scientific personnel and executive officers and our continuing ability to attract and retain highly qualified scientific and managerial personnel. Competition for such personnel is intense and we may not be able to retain our key employees or attract, assimilate or retain other highly qualified technical and managerial personnel in the future. See Item 6: "Management's Discussion and Analysis - Risks Related to Our Business."

ITEM 2. DESCRIPTION OF PROPERTY.

Our executive offices are located at 350 South Main Street, Suite 307, Doylestown, Pennsylvania 18901. The telephone number of our executive office is (215) 340-4699 and the facsimile number is (215) 340-3940. In January 2002, we established a research facility in Redwood City, California, to develop aerosolized formulations based on our proprietary humanized surfactant technology platform to develop other novel respiratory therapies and pulmonary drug delivery products. In November 2000, we established a satellite office in the United Kingdom to manage and oversee our European clinical research programs. We lease all of these properties.

ITEM 3. LEGAL PROCEEDINGS.

We are not aware of any pending or threatened legal actions other than disputes arising in the ordinary course of our business that would not, if determined adversely to us, have a material adverse effect on our business and operations.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2001.

PART II

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

Our common stock is traded on the Nasdaq SmallCap Market under the symbol "DSCO." As of March 18, 2002, the number of stockholders of record of shares of our common stock was approximately 195, and the number of beneficial owners of shares of our common stock was approximately 4,500. As of March 18, 2002, there were approximately 26,386,000 shares of our common stock issued and outstanding.

The following table sets forth the quarterly price ranges of our common stock for the periods indicated, as reported by Nasdaq.

First Quarter 2000	$2.44	$12.63
Second Quarter 2000	$2.75	$7.69
Third Quarter 2000	$3.88	$7.63
Fourth Quarter 2000	$3.03	$7.44
First Quarter 2001	$2.72	$5.91
Second Quarter 2001	$2.94	$5.49
Third Quarter 2001	$2.00	$4.65
Fourth Quarter 2001	$2.22	$4.38
First Quarter 2002 (through March 18, 2002)	$2.70	$4.19

We have not paid dividends on our common stock. It is anticipated that we will not pay dividends on our common stock in the foreseeable future.

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

Overview

We are a specialty pharmaceutical company applying our platform technology, based on humanized lung surfactants, to develop potential novel respiratory therapies and pulmonary drug delivery products. Surfaxin, our lead product, is currently in two Phase 3 clinical trials for Respiratory Distress Syndrome in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome in full-term infants, and a Phase 2 clinical trial for Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. We are also developing aerosolized formulations of our humanized surfactant to treat respiratory conditions such as asthma and as a novel pulmonary drug delivery vehicle to render drugs more effective when delivered to or via the respiratory tract.

We are presently developing a dedicated sales and marketing capability through a collaboration with Quintiles Transnational Corp. to commercialize Surfaxin in the United States. We have entered into a strategic alliance with Laboratorios del Dr. Esteve, S.A., to commercialize Surfaxin in Europe, Central and South America, and Mexico. In the non-critical care,

ambulatory markets, we plan to establish strategic alliances for the development and commercialization of our products.

Since our inception, we have incurred significant losses and, as of December 31, 2001, had a deficit accumulated during the development stage of approximately $55 million (including historical results of predecessor companies). Most of our expenditures to date have been for research and development activities and general and administrative expenses. Research and development expenses represent costs incurred for clinical trials, regulatory filings and manufacturing efforts (including raw material costs). We expense our research and development costs as they are incurred. General and administrative expenses consist primarily of salaries and related expenses, rents, and general corporate activities.

Plan of Operations

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to new and existing products, manufacturing, initial commercialization, and general and administrative activities.

We anticipate that during the next 12 to 24 months we will:

(i) significantly increase our research, development and regulatory activities. It is anticipated that the primary focus of our research and development activities will be the several clinical trials for Surfaxin indications and related regulatory filings. In the fall of 2001, we initiated two pivotal, landmark multinational Phase 3 trials for Respiratory Distress Syndrome in premature infants: a 1,500 patient trial and a 500 patient supporting trial. The majority of our development resources are focused on the completion of these trials and we anticipate completion of enrollment by the end of 2002 with data announced in the first half of 2003. For Acute Respiratory Distress Syndrome in adults, we currently are conducting a Phase 2 dose-ranging safety and efficacy study of up to 110 patients in the United States. We expect data from the Acute Respiratory Distress Syndrome trial to be available in the second half of 2002. For Meconium Aspiration Syndrome in full-term infants, we currently are conducting a Phase 3 clinical trial of up to 200 patients in the United States. Enrollment is ongoing but has been slower than expected and completion is now anticipated for late 2003. Given our belief in the importance of the pivotal Phase 3 trial for Respiratory Distress Syndrome in premature infants to our present development plan, resources have been and may continue to be reallocated from the Meconium Aspiration Syndrome program to the Respiratory Distress Syndrome program, as needed. The clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the risks discussed in "Risks Related to Our Business-The clinical trial and regulatory approval process for our products will be expensive and time consuming, and the outcome is uncertain."

To develop new products, we are conducting research and development of aerosolized formulations of our humanized surfactant to treat respiratory conditions

such as asthma and as a novel pulmonary drug delivery vehicle to deliver drugs via the respiratory tract.

(ii) invest in additional manufacturing capability in anticipation of optimizing the production process for Surfaxin and to allow scale up of the manufacturing process to meet our clinical and commercial needs as they expand.

(iii) invest in additional general and administrative resources primarily to support our business development initiatives, financial systems and controls and management information technologies.

(iv) invest in marketing and commercialization management infrastructure to manage the strategic relationships with our collaborative partners for the launch of Surfaxin, if approved, and the execution of our "Discovery/Surfaxin" worldwide marketing strategy.

On December 10, 2001, we entered into a collaboration arrangement with Quintiles, and its affiliate, PharmaBio, to provide certain commercialization services in the United States for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants. Quintiles will hire and train a dedicated United States sales force that will be branded in the market as ours. Quintiles made a financial commitment to us that included a $3 million equity investment, a secured, revolving credit facility of up to $8.5 to $10 million to fund Surfaxin pre-launch activities, and up to $70 million in post-launch funding to cover the first seven years of U.S. sales and marketing costs. In return, Quintiles will receive a commission on net sales of Surfaxin over a ten-year period. We may also receive milestone payments from PharmaBio that would be used to offset amounts owed under the credit facility. The Quintiles arrangement allows us to retain product ownership and have sales and marketing expertise in place for the commercialization of Surfaxin in the U.S., if approved. Additionally, the arrangement allows for the specialty sales force to become ours at the end of the seven year term, with an option to acquire it sooner.

In March 2002, we expanded our existing alliance with Esteve to develop, market and sell Surfaxin throughout Europe, Central and South America, and Mexico. In connection with this new Esteve collaboration, Esteve purchased $4 million of common stock and paid us a non-refundable licensing fee of $500,000. Esteve agreed to provide certain commercialization services for Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients. We have agreed to an exclusive supply agreement which provides that Esteve will purchase from us all of its Surfaxin drug product requirements at an established transfer price based on sales of Surfaxin by Esteve and/or its sublicensee(s). Esteve has also agreed to sponsor certain clinical trial costs related to obtaining regulatory approval in Europe for the Acute Lung Injury/Acute Respiratory Distress Syndrome indications. Esteve also agreed to make certain milestone payments to us upon the attainment of European marketing regulatory approval of Surfaxin.

We will need to generate significant revenues from product sales and/or related royalties and transfer prices to achieve and maintain profitability. Through December 31, 2001, we have had no revenues from any product sales, and have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. In addition, our results are dependent upon the performance of our strategic partners and third party suppliers. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

Through December 31, 2001, we had not generated taxable income. At December 31, 2001, net operating losses available to offset future taxable income for Federal tax purposes were approximately $47.5 million. The future utilization of such loss carryforwards may be limited pursuant to regulations promulgated under Section 382 of the Internal Revenue Code. In addition, we have a research and development tax credit carryforward of $846,000. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 and continuing through 2021.

Results of Operations

Our operating expenses increased from $12,639,000 in 2000 to $13,074,000 in 2001. The increase was primarily due to an increase in our research and development activities. Included in the 2000 operating expenses was a non-cash compensation charge of $2,515,000 recorded as a result of the grant of options and the vesting of certain milestone-based stock options. As a result of the increases in expenses from 2000, our net loss increased from $10,861,000 in 2000 to $11,146,000 in 2001. Taking into consideration the increase in the weighted average number of common shares outstanding during 2001 compared to 2000, our net loss per share decreased from $0.58 in 2000 to $0.51 in 2001.

Liquidity and Capital Resources

As of December 31, 2001, we had working capital of approximately $16.5 million. We believe our current working capital is sufficient to meet our planned research and development activities into the second quarter of 2003. We will need additional financing from investors or collaborators to complete research and development and commercialization of our current product candidates under development.

In December 2001, we entered into a secured revolving credit facility of up to $8.5 million to $10 million with PharmaBio to fund pre-marketing activities for a Surfaxin launch in the United States. The credit facility is available for use until December 10, 2004, and monies become available in three tranches upon satisfying certain conditions. In connection with the credit facility, we issued to PharmaBio Class H warrants to purchase 320,000 shares of common stock. The Class H warrants are exercisable at $3.03 per share (subject to adjustment) and are exercisable proportionately only upon use of the credit facility. To the extent the credit facility availability is increased to greater than $8.5 million, for each $1 million increase, the amount of

shares of common stock issuable pursuant to the Class H warrants shall be increased by approximately 38,000 shares.

Interest on amounts advanced under the credit facility will be payable quarterly in arrears. We may repay principal amounts owed by us under the credit facility from proceeds of milestone payments to be paid to us by PharmaBio upon the achievement of certain corporate milestones. As of December 31, 2001, no amounts were outstanding under the credit facility. We are obligated to use a significant portion of the funds borrowed under the credit facility for pre-launch marketing services to be provided by Quintiles and anticipate using a portion of the first tranche during 2002.

Our working capital requirements will depend upon numerous factors, including, without limitation, the progress of our research and development programs, clinical trials, timing and cost of obtaining regulatory approvals, timing and cost of pre-launch marketing activities, levels of resources that we devote to the development of manufacturing and marketing capabilities, levels of resources that our collaboration partners devote to the development of sales and marketing capabilities, technological advances, status of competitors and our ability to establish collaborative arrangements with other organizations, the ability to defend and enforce our intellectual property rights and the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

Historically, the Company's working capital has been provided from the proceeds of private financings:

Pursuant to our collaboration arrangement with Esteve on March 6, 2002, we issued 821,862 shares of common stock to Esteve at a purchase price equal to $4.867 per share and received a licensing fee of $500,000, for approximate net aggregate proceeds of $4.45 million. See Item 1: "Description of Business."

Pursuant to the collaboration arrangement we entered into with Quintiles and PharmaBio on December 10, 2001, we issued to PharmaBio, for approximate net aggregate proceeds of $2.7 million: (i) 791,905 shares of common stock at a price equal to $3.79 per share; and (ii) Class G warrants to purchase 357,143 shares of common stock at an exercise price equal to $3.485 per share. See Item 1: "Description of Business."

On October 1, 2001, we received approximately $7.3 million in net proceeds from a private financing. In the financing, we issued 3,562,759 shares of common stock and 712,553 Class F warrants to purchase shares of common stock at an exercise price of $2.365 per share. The Class F warrants have a five-year term.

On April 27, 2001, we received approximately $1 million in gross proceeds in a private offering of 296,560 shares of common stock at a per share price equal to $3.37.

In March 2000, we received approximately $17,500,000 in net proceeds from the sale of 37.74 units from a private placement offering. Each unit consisted of 76,923 shares of common stock and Class E warrants to purchase an additional 15,385 shares of common stock for $7.38 per

share. The Class E warrants issued in the offering aggregate approximately 581,000 shares and are exercisable through March 2005.

In October 1999, in connection with our strategic alliance with Esteve, we issued to Esteve in a private placement 317,164 shares of common stock at a purchase price of $2.68 per share.

In July 1999, we raised approximately $2,231,000 in net proceeds in a private placement offering of an aggregate of 2,024,792 shares of common stock and 2,024,792 Class D warrants to purchase common stock. All of the Class D warrants have been exercised.

During March and April 1999, we 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. The Class C warrants are exercisable through April 2006.

We will require substantial additional funding to conduct our business, including our expanded research and product development activities. Based on our current operating plan, we believe that our currently available resources will be adequate to satisfy our capital needs into the second quarter of 2003. Our future capital requirements will depend on the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. Our operations will not become profitable before we exhaust our current resources; therefore, we will need to raise substantial additional funds through additional debt or equity financings or through collaborative ventures with potential corporate partners. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements and this would increase our cash requirements. We have not entered into any additional arrangements to obtain any additional financing. The sale of additional equity and debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional financing will be available in amounts or on terms acceptable to us, if at all. If we fail to enter into collaborative ventures or to receive additional funding, we may have to reduce significantly the scope of or discontinue our planned research, development and commercialization activities, which could significantly harm our financial condition and operating results. Furthermore, we could cease to qualify for listing of our common stock on the NASDAQ SmallCap Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See "Risks Related to Our Business."

Risks Related to Our Business

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

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

We are a development stage company. Therefore, you must evaluate us in light of the uncertainties and complexities present in a development stage biotechnology company. We are

conducting research and development on our product candidates. As a result, we have not begun to market or generate revenues from the commercialization of any of these products. To date, we have only generated revenues from investments, research grants and collaborative research and development agreements. We will need to engage in significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval for our products under development prior to their commercialization. In addition, pre-clinical or clinical studies may show that our products are not effective or safe for one or more of their intended uses. We may fail in the development and commercialization of our products. As of December 31, 2001, we have incurred a deficit accumulated during the development stage of approximately $55 million, and we expect to continue to incur significant increasing operating losses over the next several years. If we succeed in the development of our products, we still may not generate sufficient or sustainable revenues or we may not be profitable.

If we cannot raise additional capital, we may need to discontinue our research and development activities. In addition, any additional financing could result in equity dilution.

We may need substantial additional funding to conduct our research and product development activities. Based on our current operating plan, we believe that our currently available resources will be adequate to satisfy our capital needs into the second quarter of 2003. Our future capital requirements will depend on the results of our research and development activities, clinical studies and trials, competitive and technological advances and the regulatory process. If our operations do not become profitable before we exhaust our resources, we will likely need to raise substantial additional funds through collaborative ventures with potential corporate partners and through additional debt or equity financings. We may in some cases elect to develop products on our own instead of entering into collaboration arrangements. This would increase our cash requirements for research and development.

However, we have not entered into arrangements to obtain any additional financing, except for the credit facility with PharmaBio. Any additional financing could include unattractive terms or result in significant dilution of stockholders' interests and share prices may decline. If we fail to enter into collaborative ventures or to receive additional funding, we may have to delay, scale back or discontinue our research and development operations, and consider licensing the development and commercialization of products that we consider valuable and which we otherwise would have developed ourselves. Furthermore, we could cease to qualify for listing of our securities on the NASDAQ SmallCap Market if the market price of our common stock declines as a result of the dilutive aspects of such potential financings. See "Risks Related to Our Business-The market price of our stock may be adversely affected by market volatility."

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

In order to sell our products that are under development, we must receive regulatory approvals for each product. The FDA and comparable agencies in foreign countries extensively and rigorously regulate the testing, manufacture, distribution, advertising, pricing and marketing of drug products like our products. This approval process includes preclinical studies and clinical trials of each pharmaceutical compound to establish its safety and effectiveness and confirmation

by the FDA and comparable agencies in foreign countries that the manufacturer maintains good laboratory and manufacturing practices during testing and manufacturing. The process is lengthy, expensive and uncertain. It is also possible that the FDA or comparable foreign regulatory authorities could interrupt, delay or halt our clinical trials. If we, or any regulatory authorities, believe that trial participants face unacceptable health risks, the trials could be suspended or terminated. We also may not reach agreement with the FDA and/or comparable foreign agencies on the design of clinical studies necessary for approval. In addition, conditions imposed by the FDA and comparable agencies in foreign countries on our clinical trials could significantly increase the time required for completion of our clinical trials and the costs of conducting the clinical trials.

To succeed, clinical trials require adequate supplies of drug substance and drug product, which may be difficult or uneconomical to procure or manufacture, and sufficient patient enrollment. Patient enrollment is a function of several factors, including the size of the patient population, the nature of the protocol, the proximity of the patients to the trial sites and the eligibility criteria for the clinical trials. Delays in patient enrollment can result in greater costs and longer trial timeframes. Patients may also suffer adverse medical events or side effects that are common to this class of drug such as a decrease in the oxygen level of the blood upon administration.

Clinical trials generally take two to five years or more to complete, and, accordingly, our first product is not expected to be commercially available in the United States until at least 2004, and our other product candidates will take longer. The FDA has notified us that two of our intended indications for Surfaxin, Meconium Aspiration Syndrome in full-term infants and Acute Respiratory Distress Syndrome in adults, have been granted designation as "fast track" products under provisions of the Food and Drug Administration Modernization Act of 1997, and the FDA has awarded us an Orphan Products Development Grant to support our development of Surfaxin for the treatment of Meconium Aspiration Syndrome. Fast Track Status does not accelerate the clinical trials nor does it mean that the regulatory requirements are less stringent. The Fast Track Status provisions are designed to expedite the FDA's review of new drugs intended to treat serious or life-threatening conditions. The FDA generally will review the New Drug Application for a drug granted Fast Track Status within six months instead of the typical one to three years. Our products may not, however, continue to qualify for expedited review and our other drug candidates may fail to qualify for fast track development or expedited review. Even though some of our drug candidates have qualified for expedited review, the FDA may not approve them at all or any sooner than other drug candidates that do not qualify for expedited review.

The FDA and comparable foreign agencies could withdraw any approvals we obtain. Further, if there is a later discovery of unknown problems or if we fail to comply with other applicable regulatory requirements at any stage in the regulatory process, the FDA may restrict or delay our marketing of a product or force us to make product recalls. In addition, the FDA could impose other sanctions such as fines, injunctions, civil penalties or criminal prosecutions. To market our products outside the United States, we also need to comply with foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products. The FDA and foreign regulators have not yet approved any of our products under development for marketing in the United States or elsewhere. If the FDA and other regulators do not approve our products, we will not be able to market our products.

Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products.

Our strategy for the completion of the required development and clinical testing of our products and for the manufacturing, marketing and commercialization of our products, in many cases, depends upon entering into collaboration arrangements with pharmaceutical companies to market, commercialize and distribute our products. On March 6, 2002, we expanded our relationship with Esteve by entering into a collaboration arrangement with Esteve for Surfaxin covering all of Europe, Central and South America, and Mexico. Esteve will be responsible for the marketing of Surfaxin for the treatment of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adults. Esteve will also be responsible for the sponsorship of certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for commercialization of Surfaxin in Europe for the Acute Lung Injury/Acute Respiratory Distress Syndrome indications. We will be responsible for the remainder of the regulatory activities relating to Surfaxin, including with respect to European Medicines Evaluation Agency filings.

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

If Esteve, Quintiles or we breach or terminate the agreements that make up such collaboration arrangements or Esteve or Quintiles otherwise fail to conduct their Surfaxin-related activities in a timely manner or if there is a dispute about their respective obligations, we may need to seek other partners or we may have to develop our own internal sales and marketing capability for the indications of Surfaxin which Esteve and/or Quintiles have agreed to assist in commercializing. Accordingly, we may need to enter into additional collaboration agreements and our success, particularly outside of the United States, may depend upon obtaining additional collaboration partners. In addition, we may depend on our partners' expertise and dedication of sufficient

resources to develop and commercialize our proposed products. We may, in the future, grant to collaboration partners rights to license and commercialize pharmaceutical products developed under collaboration agreements. Under these arrangements, our collaboration partners may control key decisions relating to the development of the products. The rights of our collaboration partners would limit our flexibility in considering alternatives for the commercialization of our products. If we fail to successfully develop these relationships or if our collaboration partners fail to successfully develop or commercialize any of our products, it may delay or prevent us from developing or commercializing our products in a competitive and timely manner and would have a material adverse effect on the commercialization of Surfaxin. See "Risks Related to Our Business-Our lack of marketing and sales experience could limit our ability to generate revenues from future product sales."

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

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

—defend our patents and otherwise prevent others from infringing on our proprietary rights;
—protect trade secrets; and
—operate without infringing upon the proprietary rights of others, both in the United States and in other countries.

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

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

We, or the parties licensing technologies to us, have filed various United States and foreign patent applications with respect to the products and technologies under our development, and the United States Patent and Trademark Office and foreign patent offices have issued patents with respect to our products and technologies. These patent applications include international applications filed under the Patent Cooperation Treaty. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in the United States Patent and Trademark Office or foreign patent office issuing patents. Also, if patent rights covering our products are not sufficiently broad, they may not provide us with sufficient

proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the United States Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against competitors.

Furthermore, the life of our patents is limited. We have licensed a series of patents from Johnson & Johnson and Ortho Pharmaceutical which are important, either individually or collectively, to our strategy of commercializing our surfactant technology. Such patents, which include relevant European patents, expire on various dates beginning in 2009 and ending in 2017. We have filed, and when possible and appropriate, will file, other patent applications with respect to our products and processes in the United States and in foreign countries. We may not be able to develop additional products or processes that will be patentable or additional patents may not be issued to us. See also "Risks Related to Our Business-If we cannot meet requirements under our license agreements, we could lose the rights to our products."

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

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

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

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

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under

our license agreements in a timely manner, we could lose the rights to our proprietary technology.

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

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

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

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

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

We rely on outside manufacturers for our drug substance and other active ingredients for Surfaxin and to produce material that meets appropriate standards for use in clinical studies for our products. We will also rely on outside manufacturers for production of our products after marketing approval. We may also enter into arrangements with other manufacturers for the manufacture of materials for use in clinical testing and after marketing approval.

Our outside manufacturers may not perform as they have agreed or may not remain in the contract manufacturing business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing relationships, we may fail to find a replacement manufacturer or to develop our own manufacturing capabilities. If we cannot do so, it could delay or impair our ability to obtain regulatory approval for our products and

substantially increase our costs or deplete any profit margins. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and, there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities.

We may in the future elect to manufacture some of our products on our own. Although we own certain specialized manufacturing equipment, are considering an investment in additional manufacturing equipment and employ certain manufacturing managerial personnel, we do not presently maintain a complete manufacturing facility or manufacturing department and we do not anticipate manufacturing on our own any of our products during the next 12 months. If we decide to manufacture products on our own and do not successfully develop manufacturing capabilities, it will adversely affect sales of our products.

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 practices (GMPs) or similar requirements that the FDA or corresponding foreign regulators establish. If our third-party foreign or domestic suppliers or manufacturers of our products or, if we decide to manufacture our products on our own, we, fail to comply with GMP requirements or other FDA and comparable foreign regulatory requirements, it could adversely affect our ability to market and develop our products.

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

We do not have marketing, sales or distribution experience or marketing or sales personnel. As a result, we will depend on our collaboration with Quintiles for the marketing and sales of Surfaxin for indications of Respiratory Distress Syndrome in premature infants and Meconium Aspiration Syndrome in full-term infants in the United States and with Esteve for the marketing and sales of Surfaxin for the treatment of Respiratory Distress Syndrome, Meconium Aspiration Syndrome and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in all of Europe, Central and South America, and Mexico. See "Risks Related to Our Business-Our strategy, in many cases, is to enter into collaboration agreements with third parties with respect to our products and we may require additional collaboration agreements. If we fail to enter into these agreements or if we or the third parties do not perform under such agreements, it could impair our ability to commercialize our products." If we do not develop a marketing and sales force of our own, then we will depend on arrangements with corporate partners or other entities for the marketing and sale of our remaining products.

The sales and marketing of Surfaxin for indications of Respiratory Distress Syndrome in premature infants, Meconium Aspiration Syndrome in full-term infants, and Acute Lung Injury/Acute Respiratory Distress Syndrome in adult patients in the relevant territories depends, in part, on Quintiles' and Esteve's performance of their contractual obligations. The failure of either party to do so would have a material adverse effect on the sales and marketing of Surfaxin. We may not succeed in entering into any satisfactory third party arrangements for the marketing and sale of our remaining products. In addition, we may not succeed in developing marketing and sales capabilities, our commercial launch of certain products may be delayed until we

establish marketing and sales capabilities or we may not have sufficient resources to do so. If we fail to establish marketing and sales capabilities or fail to enter into arrangements with third parties, in a timely manner, it will adversely affect sales of our products.

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

We are highly dependent upon the principal members of our management team, especially our Chief Executive Officer, Dr. Capetola, and our directors, as well as our scientific advisory board members, consultants and collaborating scientists. Many of these people have been involved in our formation or have otherwise been involved with us for many years, have played integral roles in our progress and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business and clinical development and regulatory programs. We have an employment agreement with Dr. Capetola that expires on December 31, 2005. We also have employment agreements with other key personnel with termination dates in 2003 and 2004. Although these employment agreements generally provide for severance payments that are contingent upon the applicable employee's refraining from competition with us, the loss of any of these persons' services would adversely affect our ability to develop and market our products and obtain necessary regulatory approvals, and the applicable noncompete provisions can be difficult and costly to monitor and enforce. Further, we do not maintain key-man life insurance.

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

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

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

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

these competitors, either alone or with their collaborative partners, have significantly greater experience than we do in:

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

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

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

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

this field are made. As a result, we need to continue to devote substantial resources and efforts to research and development activities.

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

The clinical testing of, marketing and use of our products exposes us to product liability claims in the event that the use or misuse of those products causes injury, disease or results in adverse effects. Use of our products in clinical trials, as well as commercial sale, could result in product liability claims. In addition, sales of our products through third party arrangements could also subject us to product liability claims. We presently carry product liability insurance with coverages of up to $10,000,000 per occurrence and $10,000,000 in the aggregate, an amount we consider reasonable and customary relating to our clinical trials of Surfaxin. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional product liability insurance coverage prior to initiating other clinical trials. We expect to obtain product liability insurance coverage before commercialization of our proposed products; however, the insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, could adversely affect our cash available for other purposes, such as research and development. In addition, the existence of a product liability claim could affect the market price of our common stock.

We expect to face uncertainty over reimbursement and healthcare reform.

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

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

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

As of March 18, 2002, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately 24% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of the Company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

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

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

Our common stock is listed for quotation on the NASDAQ SmallCap Market. For the 12-month period ended December 31, 2001, the price of our common stock has ranged from $2.00 to $5.91. We expect the price of our common stock to remain volatile. The average daily trading volume in our common stock varies significantly. For the 12-month period ending December 31, 2001, the average daily trading volume in our common stock was approximately 41,200 shares and the average number of transactions per day was approximately 52. Our relatively low average volume and low average number of transactions per day may affect the ability of our

stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In addition, we may not be able to continue to adhere to the strict listing criteria of the SmallCap Market. If the common stock were no longer listed on the SmallCap Market, investors might only be able to trade in the over-the-counter market in the Pink Sheets® (a quotation medium operated by the National Quotation Bureau, LLC) or on the OTC Bulletin Board® of the National Association of Securities Dealers, Inc. This would impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and reduction in media coverage.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if meritless or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

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

The market price of our common stock could drop due to sales of a large number of shares of our common stock or the perception that these sales could occur. As of March 18, 2002, we had 26,385,680 shares of common stock outstanding. In addition, as of March 18, 2002, up to approximately 8,303,000 shares of our common stock were issuable upon exercise of outstanding options and warrants.

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

Provisions of our Certificate of Incorporation and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the

holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors, without further stockholder approval, could issue large blocks of preferred stock.

ITEM 7. FINANCIAL STATEMENTS.

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

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not Applicable.

PART III

The information required by Items 9 through 12 of Part III is incorporated by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the end of our 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

We filed two Current Reports on Form 8-K during the three months ended December 31, 2001. A Current Report was filed on October 5, 2001, reporting our completion of a private placement of approximately 3.5 million shares of our common stock and approximately 700,000 warrants to purchase our common stock. On December 19, 2001, a Current Report was filed reporting our collaboration with Quintiles, and the related sale of our common stock to PharmaBio.

SIGNATURES

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

DISCOVERY LABORATORIES, INC.

Date: March 27, 2002 By: /s/ Robert J. Capetola
Robert J. Capetola, Ph.D.
President and 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. President and Chief Executive Officer	March 27, 2002
/s/ John G. Cooper	John G. Cooper Senior Vice President and Chief Financial Officer	March 27, 2002
/s/ Cynthia Davis	Cynthia Davis Vice President, Administrative Operations and Controller (Principal Accounting Officer)	March 27, 2002
/s/ Herbert McDade	Herbert McDade, Jr. Chairman of the Board of Directors	March 27, 2002
/s/ Richard Power	Richard Power Director	March 27, 2002
/s/ Marvin E. Rosenthale	Marvin E. Rosenthale, Ph.D. Director	March 27, 2002
/s/ Mark C. Rogers	Mark C. Rogers, M.D. Director	March 27, 2002
/s/ Max E. Link	Max E. Link, Ph.D. Director	March 27, 2002

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
2.1[1]	Agreement and Plan of Merger dated as of March 5, 1998, among Discovery, ATI Acquisition Corp. and Old ATI.
2.2[3]	Agreement and Plan of Reorganization and Merger, dated as of July 16, 1997, by and between Discovery and Old Discovery.
3.1[1]	Restated Certificate of Incorporation of Discovery.
3.2[12]	Amendment to Restated Certificate of Incorporation of Discovery.
3.3[2]	By-laws of Discovery.
3.4[10]	Certificate of Ownership Merging ATI Acquisition Corp., into Discovery.
4.1[6]	Form of Class C Warrant.
4.2[9]	Class E Warrant issued to PharmaBio.
4.3[10]	Unit Purchase Option issued to Paramount Capital, Inc., in connection with the March 1999 private placement.
4.4[14]	Form of Class F Warrant.
4.5[15]	Form of Class G Warrant issued to PharmaBio Development Inc ("PharmaBio").
4.6[15]	Form of Class H Warrant issued to PharmaBio.
4.7[15]	Form of Promissory Note issued to PharmaBio.
10.1	Reference is made to Exhibits 2.1 and 2.2.
10.2[1]	Investor Rights Agreement, dated as of March 20, 1996, between Old Discovery and RAQ, LLC.
10.3[1]	Registration Rights Agreement, dated as of October 28, 1996, between ATI, Johnson & Johnson Development Corporation ("JJDC"), and The Scripps Research Institute ("Scripps").
10.4[4]+	Sublicense Agreement, dated as of October 28, 1996, between ATI, Johnson & Johnson, Inc., and Ortho Pharmaceutical Corporation.
10.5[4]+	License Agreement, between Discovery and The Charlotte-Mecklenburg Hospital Authority ("CMHA") dated as of March 20, 1996.

10.6[10]+	Amendment of License Agreement between Discovery and CMHA, dated as of March 20, 1996.
10.7[2]	Restated 1993 Stock Option Plan of Discovery.
10.8[2]	1995 Stock Option Plan of Discovery.
10.9[7]	Amended and Restated 1998 Stock Incentive Plan of Discovery.
10.10[6]	Indenture of Lease, dated as of July 1, 1998, between SLT1, LLC and Acute Therapeutics, Inc.
10.11[12]	Amendment, dated as of September 15, 2000, to the Indenture of Lease dated as of July 1, 1998, between SLT1, LLC and Discovery.
10.12[6]	Registration Rights Agreement, dated as of June 16, 1998, among Discovery, JJDC and Scripps.
10.13[6]	Stock Exchange Agreement, dated as of June 16, 1998, between Discovery and JJDC.
10.14[12]	Employment Agreement, dated January 1, 2001, between Discovery and Robert J. Capetola, Ph.D.
10.15	Employment Agreement, dated as of June 16, 2001, between Discovery and Christopher J. Schaber.
10.16	Employment Agreement, dated as of June 16, 2001, between Discovery and Cynthia Davis.
10.17[6]	Form of Intellectual Property and Confidential Information Agreement.
10.18[6]	Form of Stock Purchase Agreement Under the 1998 Stock Incentive Plan of Discovery.
10.19[8]	Notice of Grant of Stock Option.
10.20[10]	Securities Purchase Agreement between Discovery and Laboratorios P.E.N., S.A., dated October 26, 1999.
10.21[10]+	Research Funding and Option Agreement, dated as of March 1, 2000, between Discovery and Scripps.
10.22[13]	Amended and Restated 1998 Stock Incentive Plan of Discovery, amended on June 15, 2001.

10.23	Employment Agreement, dated as of December 1, 2001, between Discovery and Ralph Niven, Ph.D.
10.24	Employment Agreement, dated as of December 11, 2001, between Discovery and John G. Cooper.
10.25	Employment Agreement, dated as of August 15, 2000, between Discovery and Deni M. Zodda, Ph.D.
10.26[16]+	Commercialization Agreement, dated as of December 10, 2001, between Discovery and Quintiles Transnational Corp. ("Quintiles").
10.27[16]+	Investment and Commission Agreement, dated as of December 10, 2001, between Discovery and PharmaBio.
10.28[16]	Common Stock and Warrant Purchase Agreement, dated as of December 10, 2001, between Discovery and PharmaBio.
10.29[16]+	Loan Agreement, dated as of December 10, 2001, between Discovery and PharmaBio.
10.30[17]+	Sublicense and Collaboration Agreement, dated as of March 6, 2002, between Discovery and Laboratorios del Dr. Esteve ("Esteve").
10.31[17]+	Supply Agreement, dated as of March 6, 2002, between Discovery and Esteve.
10.32[17]	Common Stock Purchase Agreement, dated as of March 6, 2002, between Discovery and Esteve.
16.1[5]	Letter dated as of January 28, 1998, from Ernst & Young LLP to the Securities and Exchange Commission.
16.2[11]	Letter dated January 9, 2001, from Richard A. Eisner & Company, LLP, to the Securities and Exchange Commission.
21.1[1]	Subsidiaries of Discovery.
23.1	Consent of Richard A. Eisner & Company, LLP.
23.2	Consent of Ernst & Young LLP.

---

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

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

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

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

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

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

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

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

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

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

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

(12) Incorporated by reference to Discovery's Annual Report on Form 10-KSB for the year ending December 31, 2000.

(13) Incorporated by Reference to Discovery's Quarterly Report on Form 10-QSB for the quarter ending June 30, 2001.

(14) Incorporated by Reference to Discovery's Current Report on Form 8-K filed October 5, 2001.

(15) Incorporated by Reference to Discovery's Current Report on Form 8-K filed December 19, 2001.

(16) Incorporated by Reference to Discovery's Amended Current Report on Form 8-K/A filed January 14, 2002.

(17) Incorporated by Reference to Discovery's Current Report on Form 8-K filed March 8, 2002.

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

[This page is intentionally left blank]

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

Contents

REPORT OF INDEPENDENT AUDITORS

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

We have audited the accompanying consolidated balance sheets of Discovery Laboratories, Inc. (a development stage enterprise) as of December 31, 2001 and 2000, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2001, and for the period May 18, 1993 (inception) through December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The consolidated financial statements for the period May 18, 1993 (inception) through December 31, 1999 include total revenues and net loss of $205,000 and $32,446,000, respectively. Our opinion on the consolidated statements of operations, changes in stockholders' equity, and cash flows for the period May 18, 1993 (inception) through December 31, 2001, insofar as it relates to amounts for prior periods through December 31, 1999, is based solely on the report of other auditors.

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

In our opinion, based on our audits and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Discovery Laboratories, Inc., at December 31, 2001 and 2000, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2001 and the period from May 18, 1993 (inception) through December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 15, 2002

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

REPORT OF INDEPENDENT AUDITORS

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

We have audited the consolidated statements of operations, changes in stockholders' equity and cash flows of Discovery Laboratories, Inc. and subsidiary's (a development stage company) for the period from May 18, 1993 (inception) through December 31, 1999, the consolidated statements of operations and cash flows are not presented separately herein. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

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

In our opinion, the consolidated financial statements enumerated above present fairly, in all material respects, the consolidated results of operations and consolidated cash flows of Discovery Laboratories, Inc. and subsidiary for the period from May 18, 1993 (inception) through December 31, 1999, in conformity with accounting principles generally accepted in the United States of America.

/s/ Richard A. Eisner & Company, LLP

New York, New York
February 25, 2000

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

Consolidated Balance Sheets

	December 31, 2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,758,000	$ 7,281,000
Available-for-sale marketable securities	12,938,000	11,587,000
Note receivable - current	2,000	--
Prepaid expenses and other current assets	1,580,000	149,000
Total current assets	18,278,000	19,017,000
Property and equipment, net of accumulated depreciation	822,000	697,000
Note receivable	197,000	--
Other assets	768,000	3,000
	$ 20,065,000	$ 19,717,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,750,000	$ 2,382,000
Capitalized lease - current	44,000	17,000
Total current liabilities	1,794,000	2,399,000
Deferred revenue	615,000	851,000
Capitalized lease	33,000	31,000
Total liabilities	2,442,000	3,281,000
Stockholders' equity:		
Common Stock, $.001 par value; 35,000,000 authorized; 25,546,293 and 20,871,112 shares issued at December 31, 2001 and 2000, respectively	26,000	21,000
Additional paid-in capital	73,163,000	60,891,000
Unearned portion of compensatory stock options	(264,000)	(347,000)
Deficit accumulated during the development stage	(55,135,000)	(43,989,000)
Treasury stock (at cost; 38,243 and 26,743 shares of Common Stock at December 31, 2001 and 2000, respectively)	(239,000)	(213,000)
Accumulated other comprehensive income	72,000	73,000
	17,623,000	16,436,000
	$ 20,065,000	$ 19,717,000

See notes to consolidated financial statements

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

Consolidated Statements of Operations

	Years Ended December 31,		May 18, 1993 (inception) through December 31,
	2001	2000	2001
Revenues:			
Research and development collaborative contracts	$ 1,112,000	$ 741,000	$ 2,058,000
Expenses:			
Write-off of acquired in-process research and development and supplies	--	--	13,508,000
Research and development	8,007,000	7,494,000	28,370,000
General and administrative	5,067,000	5,145,000	17,967,000
Total expenses	13,074,000	12,639,000	59,845,000
Operating loss	(11,962,000)	(11,898,000)	(57,787,000)
Other income and expense:			
Interest income, dividends, realized gains, and other income	842,000	1,042,000	3,352,000
Minority interest in net loss of subsidiary	--	--	26,000
Interest expense	(26,000)	(5,000)	(44,000)
Net loss	$ (11,146,000)	$ (10,861,000)	$ (54,453,000)
Net loss per common share – basic and diluted	$(0.51)	$(0.58)	
Weighted average number of common shares Outstanding – basic and diluted	22,038,067	18,806,265	

See notes to consolidated financial statements

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

Consolidated Statements of Changes in Stockholders' Equity
May 18, 1993 (Inception) Through December 31, 2001

	Common Stock		Preferred Stock Series B Stock		Preferred Stock Series C Stock		Additional Paid-in	Unearned Portion of Compensatory	Deficit Accumulated During Development	Treasury Stock		Stock Subscriptions	Accumulated Other Comprehensive	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock Options	Stage	Shares	Amount	Receivable	Loss	Total
Issuance of common shares, May 1993	440,720	$1,000					$ 1,000					$ (2,000)		$ -
Expenses paid on behalf of the Company, 1993												1,000		1,000
Payment on stock subscriptions, 1995												2,000		2,000
Issuance of common shares, February 1995	143,016						1,000					(1,000)		-
Expenses paid on behalf of the Company, 1995							18,000							18,000
Issuance of common shares, March 1996	1,070,175	1,000					5,000							6,000
Issuance of private placement units August, October and November 1996	856,138	1,000	2,200,256	$ 2,000			18,933,000							18,936,000
Issuance of common shares for cash and Compensation, September 1996	82,502						42,000							42,000
Exercise of stock options, 1996, 1997, 1998, 1999	288,379						63,000							63,000
Private placement expenses, 1997							(11,000)							(11,000)
Issuance of common shares pursuant to Ansan Merger, November 1997	546,433						2,459,000							2,459,000
Accumulated dividends on preferred stock, 1997									$ (238,000)					(238,000)
Issuance of common shares pursuant to ATI Merger, June 1998	1,033,500	1,000					5,037,000							5,038,000
Fair value of Common Stock issuable on Exercise of ATI options, 1998							2,966,000							2,966,000
Series C preferred stock issued pursuant to ATI Merger, June 1998					2,039	$ 2,039,000								2,039,000
Accrued dividends payable on Series C Preferred stock at time of ATI Merger, 1998						238,000								238,000
Common Stock issued in settlement of Series C preferred stock dividends, 1998	49,846					(204,000)	204,000							-
Common Stock and warrants in a private placement offering in March and April 1999	826,447	1,000					999,000							1,000,000
Issuance of private placement units in July and August 1999 (net of offering costs)	2,024,792	2,000					2,231,000							2,233,000
Common Stock issued in connection with sublicense agreement, 1999	317,164	1,000					563,000							564,000
Series B preferred stock converted, 1998, 1999	1,980,588	2,000	(669,500)				(2,000)							-
Noncash exercise of private placement warrants, 1998	8,372													-
Common Stock issued in payment for services, 1998, 1999	21,168						47,000							47,000
Compensatory stock options granted							37,000	$ (37,000)						-
Dividends payable on Series C preferred stock, 1998, 1999						408,000			(408,000)					-
Treasury stock acquired, 1998, 1999										(33,750)	$ (95,000)			(95,000)
Treasury stock issued in payment for services, 1998, 1999							14,000			31,750	90,000			104,000
Unrealized gain (loss) on Available-for-sale marketable securities, 1998, 1999													$ -	-
Fair value of options granted, 1998							142,000	(142,000)						-
Amortization of unearned portion of Compensatory stock options, 1998, 1999								142,000						142,000
Net loss, Inception through 12/31/99									(32,446,000)					(32,446,000)
Balance – December 31, 1999 (carried forward)	9,689,240	$ 10,000	1,530,756	$ 2,000	2,039	$ 2,481,000	$ 33,749,000	$ (37,000)	$ (33,092,000)	(2,000)	$ (5,000)	$ -	$ -	$ 3,108,000

See notes to consolidated financial statements

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

Consolidated Statements of Changes in Stockholders' Equity
May 18, 1993 (Inception) Through December 31, 2001
(continued)

	Common Stock		Preferred Stock Series B Stock		Preferred Stock Series C Stock		Additional Paid-in Capital	Unearned Portion of Compensatory Stock Options	Deficit Accumulated During Development Stage	Treasury Stock		Stock Subscriptions Receivable	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount	Shares	Amount				Shares	Amount			
(brought forward)														
Balance - December 31, 1999	9,689,240	$ 10,000	1,530,756	$ 2,000	2,039	$ 2,481,000	$ 33,749,000	$ (37,000)	$ (33,092,000)	(2,000)	$ (5,000)	$ -	$ -	$ 3,108,000
Comprehensive loss:														
Net loss									(10,861,000)					(10,861,000)
Other comprehensive income – unrealized gain on marketable securities available-for-sale													73,000	73,000
Total comprehensive loss														(10,788,000)
Exercise of stock options	532,059						524,000			(31,743)	(245,000)			279,000
Common placement warrant conversions	18,232													-
Preferred placement warrant conversions	18,511													-
Exercise of Class C & D warrant conversions	2,536,911	3,000					3,792,000							3,795,000
Series B preferred stock converted	4,765,631	5,000	(1,530,756)	(2,000)			(3,000)							-
Treasury stock issued in payment for services										7,000	37,000			37,000
Common Stock issued in payment for services	9,496						47,000							47,000
Compensation charge on vesting of options and warrants							2,330,000							2,330,000
Compensatory stock options and warrants granted							495,000	(310,000)						185,000
Dividend payable on Series C stock						36,000			(36,000)					-
Series C preferred stock conversions	398,186				(2,039)	(2,517,000)	2,517,000							-
Issuance of private placement units	2,902,846	3,000					17,440,000							17,443,000
Balance – December 31, 2000	20,871,112	21,000	-	-	-	-	60,891,000	(347,000)	(43,989,000)	(26,743)	(213,000)	-	73,000	16,436,000
Comprehensive loss:														
Net loss									(11,146,000)					(11,146,000)
Other comprehensive loss – unrealized loss on marketable securities available-for-sale													(1,000)	(1,000)
Total comprehensive loss														(11,147,000)
Exercise of stock options	6,224						2,000							2,000
Common Stock issued in payment for services	10,902						42,000							42,000
Compensation charge on modification of options							109,000							109,000
Compensatory stock options and warrants granted/earned							325,000	83,000						408,000
Common Stock issued in April 2001 private financing	296,560						998,000							998,000
Common Stock and warrants issued in October 2001 private financing	3,562,759	4,000					7,256,000							7,260,000
Common Stock and warrants issued in December 2001	791,905	1,000					3,540,000							3,541,000
Placement agent warrant exercise	6,831													-
Purchase of Treasury Stock										(11,500)	(26,000)			(26,000)
Balance – December 31, 2001	25,546,293	$ 26,000	-	$ -	-	$ -	$ 73,163,000	$ (264,000)	$ (55,135,000)	(38,243)	$ (239,000)	$ -	$ 72,000	17,623,000

See notes to consolidated financial statements

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

Consolidated Statements of Cash Flows

	Year Ended December 31,		May 18, 1993 (inception) through December 31,
	2001	2000	2001
Cash flows from operating activities:			
Net loss	$ (11,146,000)	$ (10,861,000)	$ (54,453,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Write-off of acquired in-process research and development and supplies	--	--	13,508,000
Write-off of licenses	--	--	683,000
Depreciation and amortization	205,000	123,000	544,000
Compensatory stock options	517,000	2,515,000	3,174,000
Expenses paid using treasury stock and Common Stock	42,000	84,000	204,000
Loss on sale of property	--	4,000	4,000
Changes in:			
Prepaid expenses, inventory and other current assets	(876,000)	492,000	(419,000)
Accounts payable and accrued expenses	(632,000)	1,957,000	1,617,000
Other assets	(18,000)	15,000	(21,000)
Proceeds from R&D collaborative contracts	--	605,000	1,641,000
Amortization of deferred revenue	(791,000)	(790,000)	(1,581,000)
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	(12,699,000)	(5,856,000)	(35,200,000)
Cash flows from investing activities:			
Purchase of property and equipment	(257,000)	(948,000)	(1,751,000)
Proceeds from sale of property and equipment	--	550,000	575,000
Purchase of marketable securities	(10,676,000)	(11,514,000)	(43,935,000)
Proceeds from sale or maturity of marketable securities	9,324,000	--	31,474,000
Loan from related party	(200,000)	--	(200,000)
Related party loan payments received	1,000	--	1,000
Net cash payments on merger	--	--	(1,670,000)
Acquisition of licenses	--	--	(711,000)
Net cash used in investing activities	(1,808,000)	(11,912,000)	(16,217,000)
Cash flows from financing activities:			
Proceeds from issuance of securities, net of expenses	11,033,000	21,517,000	55,344,000
Purchase of treasury stock	(26,000)	--	(121,000)
Principal payments under capital lease obligation	(23,000)	(15,000)	(48,000)
Net cash provided by financing activities	10,984,000	21,502,000	55,175,000
Net (decrease) increase in cash and cash equivalents	(3,523,000)	3,734,000	3,758,000
Cash and cash equivalents - beginning of period	7,281,000	3,547,000	--
Cash and cash equivalents - end of period	$ 3,758,000	$ 7,281,000	$ 3,758,000
Supplementary disclosure of cash flows information:			
Interest paid	$ 26,000	$ 5,000	$ 44,000
Noncash transactions:			
Class H warrants issued	$ 768,000	$ --	$ 768,000
Accrued dividends on Series C preferred stock	$ --	$ 36,000	$ 682,000
Series C preferred stock dividends paid using Common Stock	$ --	$ --	$ 204,000
Preferred stock issued for inventory	$ --	$ --	$ 575,000
Equipment acquired through capitalized lease	$ 52,000	$ --	$ 125,000
Unrealized (loss) gain on marketable securities	$ (1,000)	$ 73,000	$ 72,000
Common stock and treasury stock issued in payment for payables	$ --	$ --	$ 73,000

See notes to consolidated financial statements

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION

Discovery Laboratories, Inc. (the "Company") is a specialty pharmaceutical company leveraging its platform technology in humanized lung surfactants to develop novel respiratory therapies and pulmonary drug delivery products. Surfactants are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen.

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

The Company is also performing research and development of aerosolized formulations of its humanized surfactant technology to treat respiratory conditions such as asthma and as a novel pulmonary drug delivery vehicle to render drugs more effective when delivered to or via the respiratory tract.

Historical Founding Transactions

The Company, formerly known as Ansan Pharmaceuticals, Inc. ("Ansan"), was incorporated in Delaware on November 6, 1992. In November 1997, Ansan merged (the "Ansan Merger") with Discovery Laboratories, Inc., a former Delaware corporation ("Old Discovery"), and was the surviving corporate entity. Immediately following 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. The consolidated financial statements include the accounts of Ansan from November 25, 1997 (the date of acquisition).

In October 1996, the company invested $7,500,000 in exchange for 600,000 shares of Series A preferred stock, of Acute Therapeutics, Inc., a Delaware Corporation ("Old ATI"). The stock represented 75% of the voting securities of Old ATI. In June 1998, ATI Acquisition Corp., a Delware Corporation and 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 (the "Old ATI Exchange Ratio") of the common stock ("Common Stock"), par value $0.001 per share, of the Company; each share of Old ATI's Series B preferred stock was converted into one share of the Company's Series C preferred stock and all outstanding options to purchase Old ATI Common Stock were assumed by the Company and became exercisable for shares of the Common Stock on the basis of the Old ATI Exchange Ratio.

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

The value of the Common Stock 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 was recorded as an expense in connection with the Old ATI Merger.

NOTE 1 - THE COMPANY AND BASIS OF PRESENTATION (CONTINUED)

The cost of the Old ATI Merger is as follows:

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

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

Management's Plans and Financings

The Company is a development stage company and has incurred substantial losses since inception. To date, the Company has funded its operations primarily through the issuance of equity. The Company expects to continue to expend substantial amounts for continued product research, development, and initial commercialization activities for the foreseeable future. Management's plans with respect to funding this development are to secure additional equity, if possible, and to secure collaborative arrangements that will provide available cash funding for operations. 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 ultimately will be successful.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and cash equivalents

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

Available-for-sale marketable securities

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

Property and equipment

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Use of estimates

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

Long-lived assets

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

Research and development

Research and development costs are charged to operations as incurred.

Revenue recognition – research and development collaborative agreements

The Company received nonrefundable fees from companies under license, sublicense, collaboration and research funding agreements. The Company initially records such funds as deferred revenue and recognizes research and development collaborative contract revenue when the amounts are earned, which occurs over a number of years as the Company performs research and development activities. See Note 6 – License, Research Funding, and Commercialization Agreements for a detailed description of the Company's revenue recognition methodology under these agreements.

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

Stock-based compensation

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Net loss per common share

Net loss per common share is computed pursuant to the provisions of Statement of Financial Accounting Standards No. 128, "Earnings per Share", and is based on the weighted average number of common shares outstanding for the periods. For the years ended December 31, 2001 and 2000, 5,211,000 and 2,891,000 common shares, respectively, are potentially issuable upon the exercise of certain of the Company's stock options and warrants and are not included in the calculation of net loss per share as the effect would be anti-dilutive.

NOTE 3 – INVESTMENTS

The available-for-sale marketable securities are as follows:

	December 31, 2001	December 31, 2000
Cost	$ 12,866,000	$ 11,514,000
Gross unrealized gain	131,000	240,000
Gross unrealized loss	(59,000)	(167,000)
Estimated fair value	$ 12,938,000	$ 11,587,000

NOTE 4 – NOTE RECEIVABLE

Note receivable pertains to a $200,000, 7% per annum mortgagor's note due from a vice president of the Company. This note is secured by a mortgage agreement dated July 24, 2001. The note calls for monthly payments of principal and interest over a 360-month period. The principal balance outstanding at December 31, 2001 was approximately $199,000.

NOTE 5 - PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2001 and 2000 was comprised of the following:

	December 31, 2001	December 31, 2000
Leasehold improvements	$ 144,000	$ 140,000
Furniture	189,000	141,000
Equipment	989,000	732,000
	1,322,000	1,013,000
Less accumulated depreciation	500,000	316,000
	$ 822,000	$ 697,000

NOTE 5 - PROPERTY AND EQUIPMENT (CONTINUED)

The equipment balance at December 31, 2001 and 2000 includes $125,000 and $73,000, respectively, of property under a capital lease. The related accumulated depreciation was $26,000 at December 31, 2001 and $13,000 at December 31, 2000.

NOTE 6 - INCOME TAXES

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

The reconciliation of the income tax benefit computed at the Federal statutory rates to the Company's recorded tax benefit for the years ended December 31, 2001 and 2000 is as follows:

	December 31, 2001	2000
Income tax benefit, statutory rates	$ 3,783,000	$ 3,652,000
State taxes on income, net of Federal benefit	698,000	836,000
Research and development tax credit	90,000	85,000
Other	3,000	(95,000)
Income tax benefit	4,574,000	4,478,000
Valuation allowance	(4,574,000)	(4,478,000)
Income tax benefit	$ --	$ --

The increase in valuation allowance was $96,000 and $2,489,000 in 2001 and 2000, respectively.

The tax effects of temporary differences that give rise to deferred tax assets and deferred tax liabilities, at December 31, 2001 and 2000, are as follows:

	December 31, 2001	2000
Long-term deferred tax assets:		
Net operating loss carryforwards (Federal and state)	$ 19,275,000	$ 14,771,000
Research and development tax credits	846,000	660,000
Capitalized research and development	268,000	363,000
Total long-term deferred tax assets	20,389,000	15,794,000
Long-term deferred tax liabilities:		
Property and equipment	(69,000)	(49,000)
Net deferred tax assets	20,320,000	15,745,000
Less: valuation allowance	(20,320,000)	(15,745,000)
	$ --	$ --

NOTE 6 - INCOME TAXES (CONTINUED)

The Company was in a net deferred tax asset position at December 31, 2001 and 2000 before the consideration of a valuation allowance. Due to the fact that the Company is in the development stage and has never realized a profit, management believes it is prudent at this time to fully reserve the net deferred tax asset.

At December 31, 2001, the Company had available carryforward net operating losses for Federal tax purposes of approximately $47,496,000 and a research and development tax credit carryforward of $846,000. The Federal net operating loss and research and development tax credit carryforwards expire beginning in 2008 and continuing through 2021. Additionally, at December 31, 2001, the Company had available carryforward losses of approximately $43,244,000 for state tax purposes. The utilization of $9,700,000 of the Federal net operating loss carryforwards is subject to annual limitations in accordance with Section 382 of the Internal Revenue Code. Certain state carryforward net operating losses are also subject to annual limitations.

The difference between the deficit accumulated during the development stage for financial reporting purposes and the net operating loss carryforwards for tax purposes is primarily due to the write-off of the acquired in-process research and development and supplies, which were not deducted for tax purposes.

NOTE 7 - LICENSE, RESEARCH FUNDING, AND COMMERCIALIZATION AGREEMENTS

On December 10, 2001, the Company entered into a collaboration arrangement with Quintiles Transnational Corp. ("Quintiles"), and its affiliate, PharmaBio Development, Inc. ("PharmaBio") whereby Quintiles will provide pre- and post-launch marketing services for the commercialization of Surfaxin® for MAS and/or IRDS in the United States. In connection therewith, the Company issued to PharmaBio for aggregate consideration of $3 million: (i) 791,905 shares of Common Stock; (ii) Class G warrants to purchase 357,143 shares of Common Stock at an exercise price equal to $3.485 per share (subject to adjustment); and (iii) Class H warrants to purchase 320,000 shares of Common Stock at an exercise price equal to $3.03 per share (subject to adjustment).

PharmaBio also committed to provide the Company with a secured revolving credit facility (the "Credit Facility"), primarily for use to pay pre-launch marketing services to be provided by Quintiles, subject to the Company satisfying certain conditions, for up to $8.5 million, which may be increased to $10 million in specified circumstances. To the extent the Credit Facility availability is increased to greater than $8.5 million, for each $1 million dollar increase, the amount of shares of Common Stock issuable pursuant to the Class H warrants will be increased by approximately 38,000 shares. Principal amounts owed under the Credit Facility may be paid out of the proceeds of milestone payments to be paid by PharmaBio to the Company at certain intervals upon the achievement of certain corporate milestones by the Company. At December 31, 2001, no amounts were outstanding under the Credit Facility.

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

- the Company was paid a nonrefundable license fee of $375,000;
- the Company will be the exclusive supplier (except in certain events) of Surfaxin®;

NOTE 7 - LICENSE, RESEARCH FUNDING, AND COMMERCIALIZATION AGREEMENTS (CONTINUED)

- Esteve agreed to reimburse certain research and development expenditures borne by the Company in conducting certain clinical trials in the above countries; however, costs as defined in the license agreement, incurred in connection with such clinical trials in excess of an agreed upon amount, will not be reimbursed;
- Esteve paid $375,000 in advance for Surfaxin® supplied for clinical trials described above;
- an affiliate of Esteve 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 the investment; the Company has accounted for the premium as additional license fees amounting to $286,000; and
- an option to an exclusive license for Italy for additional specified payments.

The Company has accounted for the license fees (including the premium paid for Common Stock), the reimbursement of research and development expenditures and advance payment for Surfaxin® to be used in clinical trials as deferred revenue. The balance in deferred revenue at December 31, 2001 relates entirely to the license agreement with Esteve for which the Company will recognize revenue using a straight line method through the anticipated date of FDA approval for the first Surfaxin® neonatal indication. See Note 11 – Subsequent Event for details concerning a new arrangement with Esteve which supercedes the agreement entered into in October 1999.

Concurrent with the Company's original investment in Old ATI, Ortho Pharmaceuticals, Inc., a wholly owned subsidiary of Johnson & Johnson, Inc., and Old ATI entered into an agreement (the "J&J License Agreement") granting an exclusive license of the Surfaxin® 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. 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.

The Company and Scripps were parties to a research funding and option agreement which expired in February 2002. The Company is currently negotiating to amend the agreement to extend the term, if at all, for an additional three years. Pursuant to this agreement, the Company was required to fund a portion of Scripps' research efforts and Scripps was obligated to grant an option to the Company to acquire an exclusive license for the application of technology developed from the research program. Payments to Scripps were $545,000 and $468,000 in 2001 and 2000, respectively.

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

NOTE 8 - STOCKHOLDERS' EQUITY

2001 private placements

In October 2001, the Company received approximately $7.3 million in net proceeds from the sale of 3,562,759 shares of Common Stock and 712,553 Class F warrants to purchase Common Stock at an exercise price of $2.365 per share. The Class F warrants are exercisable through September 30, 2006. In connection with this private placement, the placement agent received fees of approximately $360,000 and warrants to purchase 164,911 shares of Common Stock at $2.394 per share. All of the warrants remain unexercised as of December 31, 2001.

In April 2001, the Company received approximately $1 million in proceeds in a private placement sale of 296,560 shares of Common Stock to a limited partnership. This partnership may be deemed to be a related party, in that one of the partners is a member of the Company's board of directors. The investor is entitled to certain registration rights with respect to the resale of the shares of Common Stock issued in the offering.

2000 private placement

In March 2000, the Company received approximately $17,500,000 in net proceeds from the sale of 37.74 units in a private placement offering. Each unit consisted of 76,923 shares of Common Stock and Class E warrants to purchase additional 15,385 shares of Common Stock at $7.38 per share. The Class E warrants of the Company, aggregating approximately 581,000, are exercisable through March 2005. In connection with this private placement, the placement agent received fees of approximately $1,321,000 and warrants to purchase 348,341 shares of Common Stock at $8.113 per share. All of the warrants remain unexercised as of December 31, 2001.

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. The Class C warrants are exercisable through April 2006. As of December 31, 2001, approximately 57,000 Class C warrants remain unexercised.

In July 1999, the Company raised approximately $2,231,000 in net proceeds (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. All Class D warrants have been exercised. The placement agent received fees of 7% of the gross proceeds, reimbursement of certain expenses and an option to purchase 0.49 units at a per unit exercise price of $550,000. As of December 31, 2001, approximately 395,000 options issued to placement agent remain unexercised.

1996 private placement

In 1996, in a private placement offering, Old Discovery sold approximately 44 units (each unit consisting of securities converted in the Ansan Merger into 50,000 shares of Series B convertible preferred stock of the Company and 19,458 shares of Common Stock). Net proceeds from the private placement approximated $19,000,000. On December 1, 1998, the conversion rate was adjusted whereby each share of preferred stock was convertible at the option of the holders into 3.11 shares of Common Stock. Conversions took place at various dates and on March 14, 2000, all of the remaining Series B shares were converted into 4,766,000 shares of Common Stock of the Company.

NOTE 8 - STOCKHOLDERS' EQUITY (CONTINUED)

The placement agent for the offering received approximately $2,860,000 in cash plus warrants which, pursuant to the Ansan Merger gave the holders thereof the right to acquire 220,026 shares of Series B preferred stock (which as a result of the conversion of the Series B preferred stock were convertible into 685,000 shares of Common Stock) at a price of $11 per share, through November 8, 2006, and to acquire 85,625 shares of Common Stock at a price of $0.64 per share through November 8, 2006. The warrants contain certain anti-dilution provisions and may be exercised on a "net exercise" basis pursuant to a provision that does not require the payment of any cash to the Company. As of December 31, 2001, approximately 56,000 warrants were outstanding.

1995 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. Each unit consisted of one share of Common Stock, one redeemable Class A warrant, and one Class B warrant. All Class A and Class B Warrants remaining unexercised at August 2000 expired by their terms.

Common shares reserved for issuance

As of December 31, 2001 and 2000, the Company has reserved shares of Common Stock for issuance upon exercise of options and warrants as follows:

	December 31, 2001	2000
Stock option plans	4,296,000	3,162,000
Placement agent and underwriter warrants	1,619,000	1,464,000
Class C warrants (1999 private placement)	57,000	57,000
Class E warrants (2000 private placement)	581,000	581,000
Class F warrants (2001 private placement)	713,000	--
Class G warrants (2001 Quintiles Alliance)	357,000	--
Class H warrants (2001 Quintiles Credit Facility)	565,000	--
Other warrants	115,000	65,000
	8,303,000	5,329,000

Treasury stock/Common Stock issued for services

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

During 2001, the Company acquired 11,500 shares of Common Stock for approximately $26,000. Such shares are accounted for as treasury stock. In addition, during 2001, the Company issued 10,902 shares of Common Stock in lieu of cash payments for services and rent.

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

NOTE 8 - STOCKHOLDERS' EQUITY (CONTINUED)

During 1999, the Company acquired 2,000 shares of Common Stock for approximately $5,000 and issued 15,600 shares of treasury stock, having a value of approximately $53,000, in settlement of $39,000 of indebtedness. The difference between fair market value and amount of indebtedness was charged to expense and credited to paid-in-capital.

Series C preferred stock

The Company's Series C redeemable convertible preferred stock was convertible at the option of the holder into Common Stock at a conversion price equal to the market price of the Common Stock, as defined. On March 3, 2000, the sole Series C shareholder, Johnson & Johnson, Inc., elected to convert its Series C preferred stock shares into 398,186 shares of Common Stock.

NOTE 9 - STOCK OPTIONS

In March 1998, the Company adopted its 1998 Stock Incentive Plan which includes three equity programs (the "1998 Plan"). Under the Discretionary Option Grant Program, options to acquire shares of the Common Stock may be granted to eligible persons who are employees, nonemployee directors, consultants and other independent advisors. Pursuant to the Stock Issuance Program, such eligible persons may be issued shares of the Common Stock 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. Options granted under the 1998 Plan expire no later than ten years from the date of the grant. On June 16, 2000, the 1998 Stock Incentive Plan was amended to increase the maximum number of shares of Common Stock reserved for issuance over the term of the plan from 2,200,959 to 3,000,000. Further, on June 15, 2001, the 1998 Stock Incentive Plan was amended to increase the maximum number of shares of Common Stock reserved for issuance over the term of the plan from 3,000,000 to 4,150,000.

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, 2001 and 2000 would have been approximately $13,455,000 or $0.061 per share and $14,092,000 or $0.75 per share per share, respectively. The weighted average fair value of the options granted are estimated at $1.93 and $3.40 per share, respectively, for the years ended December 31, 2001 and 2000, on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions: dividend yield 0%, volatility of 118% and 130%, respectively, risk-free interest rate of 4% and 6%, respectively and expected life of three and a half years.

NOTE 9 - STOCK OPTIONS (CONTINUED)

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

	Year Ended December 31,							
	2001				2000			
	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 - $7.00	3,095,594	$3.39	8.33 years	$0.0026 - $4.87	2,479,653	$2.27	7.93 years
Options granted	2.10 - 5.25	1,279,000	2.58		1.66 – 7.00	1,187,000	4.36	
Options exercised	0.3205 – 0.87	(6,224)	0.47		0.08 – 4.44	(532,059)	0.98	
Options forfeited	2.10 – 5.19	(92,983)	4.01		0.32	(39,000)	0.32	
Options expired	--	--	--		--	--	--	
Options outstanding at end of year	$0.0026 – $7.00	4,275,387	$3.16	8.018 years	$0.0026 – $7.00	3,095,594	$3.39	8.33 years
Options exercisable at end of year	$0.0026 – $7.00	4,275,387	$3.16	8.018 years	$0.0026 – $7.00	3,095,594	$3.39	8.33 years

The following table provides further detail with regard to the options outstanding and exercisable at December 31, 2001:

Price per share	Shares	Weighted Average Price per Share	Weighted Average Remaining Contractual Life
$0.0026 - $2.50	1,605,214	$1.62	8.36 years
$2.51 - $7.00	2,670,173	$4.08	7.82 years

The following table pertains to options granted and exercisable at less than fair value:

	Year Ended December 31, 2001	Year Ended December 31, 2000
Weighted average exercise price	$2.11	$1.94
Weighted average fair value	$3.53	$3.24

Currently, all options granted under the 1998 Plan are exercisable immediately upon grant, however, the shares issuable upon exercise of the options are subject to repurchase by the Company at the exercise price paid per share. Such repurchase rights lapse as the options vest according to their stated terms.

In September 1999, management was granted, in the aggregate, options to purchase 500,000 shares of the Common Stock subject to the achievement of certain corporate milestones. In January 2000, certain milestones related to the options had been achieved and 50% of the 250,000 related options vested. In September 2000, the Board of Directors accelerated the remaining 50% of the 250,000 milestone options and the Company incurred non-cash compensation charges amounting to $2,515,000, representing the excess of the fair value over the exercise price of the options granted.

Included in the options outstanding at December 31, 2001, are options to purchase 123,200 shares of the Common Stock (at an exercise price of $4.44) granted during 1998, which vest upon the Company achieving specified milestones and expire in June 2008. On vesting, the Company will incur a charge amounting to the excess, if any, of the fair value over the exercise price.

NOTE 10 – COMMITMENTS

At December 31, 2001, the Company had employment agreements with six officers providing for an aggregate annual salary of $1,157,000. The agreements expire on various dates through December 2005. The Company also had employment agreements with five other executives that provide for an aggregate annual salary of $709,000. The agreements expire on various dates through July 2003. All of the foregoing agreements provide for the issuance of annual bonuses and the granting of options subject to approval by the Board of Directors.

The Company leases office and laboratory space in Doylestown, Pennsylvania under leases which expire in September 2004 and September 2005. Additionally, the Company leases office space in Windsor, United Kingdom. Aggregate future minimum annual rents for these leases are as follows:

2002	$ 365,000
2003	375,000
2004	304,000
2005	111,000
	$1,155,000

The Company entered into agreements to lease laboratory equipment, which are being accounted for as capital leases. Future minimum lease payments for these leases are as follows:

2002	$ 50,000
2003	36,000
	86,000
Less interest included	9,000
	$ 77,000

NOTE 11 - RELATED PARTY TRANSACTIONS

In November, 2001, the Company entered into an agreement with Clinical Data Management, Inc. (CDM), replacing an earlier agreement, to perform duties associated with processing data for the Company's ongoing clinical trials. CDM is wholly-owned by the spouse of the Company's President and Chief Executive Officer. Payments made to CDM and its owner, including payments made prior to the agreement, for the years ended December 31, 2001 and 2000 were approximately $221,400 and $110,700, respectively.

The Company, from time to time, engages the spouse of an officer to render certain facility-based services. Payments made to this party for the years ended December 31, 2001 and 2000 were approximately $38,700 and $77,900, respectively.

In April 2001, the Company sold 296,560 shares of Common Stock to a limited partnership. This partnership may be deemed to be a related party, in that one of the partners is a member of the Board of Directors.

NOTE 12 – SUBSEQUENT EVENT

On March 6, 2002, the Company entered into an expanded collaboration arrangement with Esteve. This new Esteve collaboration supersedes the Sublicense and Supply Agreements entered into with Esteve on October 26, 1999 and expands the territory covered by those original agreements to all of Europe, Central and South America, and Mexico. Pursuant to the new Esteve collaboration, the Company issued 821,862 shares of Common Stock to Esteve at a price equal to $4.867 per share (based on a 50% premium over the average closing price for the 30 days prior to the closing date).

The Company also received a non-refundable licensing fee of $500,000 and Esteve is committed to make certain milestone payments to the Company upon the attainment of certain regulatory objectives. Esteve has agreed to pay for certain clinical trial costs related to obtaining European Medicines Evaluation Agency approval for Surfaxin® for the Acute Lung Injury/Acute Respiratory Distress Syndrome indication. In addition, the Company entered into an exclusive supply agreement for the expanded territory which provides that Esteve will purchase all of its Surfaxin® drug product requirements from the Company at an established transfer price based on sales of Surfaxin® by Esteve and or its sublicensee(s).

[This page is intentionally left blank]

Corporate Information

Discovery Executive Management

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

John G. Cooper
Senior Vice President, Chief Financial Officer

Cynthia Davis
Vice President, Administration and Controller

David L. Lopez, C.P.A., Esq.
Vice President, General Counsel

Ralph Niven, Ph.D., M.R.Pharm.S.
Senior Vice President, Preclinical Development

Christopher J. Schaber
Executive Vice President & Chief Operating Officer

Robert Segal, M.D.
Vice President, Clinical Research & New Drug Evaluation

Huei Tsai, Ph.D.
Vice President, Biometrics

Deni M. Zodda, Ph.D.
Senior Vice President, Business Development

Board of Directors

Herbert H. McDade, Jr. (Chairman)
Chairman, Access Pharmaceuticals, Inc.
Former President of Revlon Health Care and
Armour Pharmaceutical Company

Robert J. Capetola, Ph.D.
President & Chief Executive Officer, Discovery Laboratories, Inc.

Max Link, Ph.D.
Retired, Former Chief Executive Officer of Sandoz Pharma, Ltd.

Richard G. Power
Partner, The Sage Group

Mark C. Rogers, M.D.
President, Paramount Capital, Inc.

Marvin E. Rosenthale, Ph.D.
Retired, Former President & Chief Executive Officer of Allergan
Ligand Retinoid Therapeutics, Inc.

Mark S. Siegel
President, Remy Investors & Consultants, Inc.,
Chairman, Patterson-UTI Energy, Inc.

Scientific Advisory Board

Charles G. Cochrane, M.D.
Professor of Immunology
The Scripps Research Institute

Thomas R. Martin, M.D.
Professor of Medicine, Division of
Pulmonary and Critical Care Medicine
University of Washington
School of Medicine, VA Medical Center

Michael A. Matthay, M.D.
Professor of Medicine and Anesthesia
University of California – San Francisco

T. Allen Merritt, M.D.
Professor of Pediatrics
St. Charles Medical Center

Fernando R. Moya, M.D.
Division of Neonatology
University of Texas at Houston Medical Center

Milton Packer, M.D.
Professor of Medicine
Chief of the Division of Circulatory Physiology
Columbia University College of Physicians and Surgeons

Thomas E. Wiswell, M.D.
Professor of Pediatrics
Division of Neonatology
SUNY at Stony Brook

Corporate Counsel

Roberts, Sheridan & Kotel
The New York Practice of Dickstein
Shapiro's Corporate & Finance Group
1177 Avenue of the Americas
New York, NY 10036-2714

Independent Auditors

Ernst & Young LLP
Two Commerce Square, Suite 4000
2001 Market Street
Philadelphia, PA 19103

Investor Relations

Focus Partners LLC
805 Third Avenue, 14th Floor
New York, NY 10022
Phone: 212.752.9445
Fax: 212.752.9446

The Redstone Group
200 Barr Harbor Drive, Suite 400
West Conshohocken, PA 19428
Phone: 610.941.2741
Fax: 610.941.2990

When used in this report, the words "believes," "anticipates," "expects," "intends," "may" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause the Company's actual results to differ materially from those indicated by the forward-looking statements, which speak only as of the date made. The Company undertakes no obligation to republish revised forward-looking statements to reflect subsequent events or circumstances or to reflect the occurrence of unanticipated events. Readers are also urged to review carefully and consider the various disclosures made by the Company that attempt to advise interested parties of the factors that affect the Company's business, including this report, as well as the Company's periodic filings with the SEC including the most recent reports on Form 10-KSB, 8-K and 10-QSB, and amendments thereto.

Discovery Laboratories, Inc.
350 South Main Street, Suite 307
Doylestown, PA 18901
T 215.340.4699
F 215.340.3940
www.discoverylabs.com