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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

/X/ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000
OR

/ / TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

COMMISSION FILE NO. 0-23556

INHALE THERAPEUTIC SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	94-3134940
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

150 INDUSTRIAL ROAD, SAN CARLOS, CA 94070
(Address of principal executive offices and zip code)

(650) 631-3100
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: NONE

Securities registered pursuant to Section 12(g) of the Act: COMMON STOCK, $0.0001 PAR VALUE

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 / /

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. / /

The approximate aggregate market value of voting stock held by non-affiliates of the Registrant, based upon the last sale price of the Common Stock on February 1, 2001 as reported by Nasdaq National Market was approximately $1,922,029,208. Determination of affiliate status for this purpose is not a determination of affiliate status for any other purpose.

51,414,532
(Number of shares of common stock outstanding as of February 1, 2001)

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's definitive Proxy Statement to be filed for our 2001 Annual Meeting of Shareholders are incorporated by reference into Part III hereof.

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INHALE THERAPEUTIC SYSTEMS, INC.
2000 ANNUAL REPORT ON FORM 10-K
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PART I

ITEM 1. BUSINESS

OVERVIEW

Inhale Therapeutic Systems, Inc. was incorporated in the state of California in 1990 and reincorporated in the state of Delaware in 1998. Inhale's mission is to be the pre-eminent supplier of drug delivery solutions. We are creating a drug delivery system to deliver a wide range of drugs, including peptides, proteins, nucleic acids and other molecules, by inhalation to the deep lung. We are using this system principally to enable non-invasive delivery of macromolecule drugs currently administered by injection. Our most advanced program, which is sponsored by Pfizer Inc., is inhaleable insulin. Pfizer commenced dosing for its Phase III clinical trials in June 1999. In addition to our insulin program with Pfizer, we have development collaborations with Biogen, Inc., Aventis Behring L.L.C. (formerly Centeon L.L.C., a joint venture of Hoechst AG and Rhone-Poulenc S.A., which have now merged to form Aventis S.A.) and Eli Lilly & Co. We also have early stage feasibility and research collaborations with several other companies and have tested eight drugs in clinical trials.

Currently there are approximately 35 macromolecule drugs marketed in the United States and about 120 other such drugs in clinical trials. Sales of the top 15 genetically engineered protein drugs (a subset of macromolecule drugs) were estimated at $15.6 billion worldwide in 1999. Most of these drugs are currently delivered by injection. Injections are undesirable for numerous reasons including patient discomfort, inconvenience and risk of infection. Poor patient acceptance of, and compliance with, injectable therapies can lead to increased incidence of medical complications and higher disease management costs. Alternatives to injection such as oral, transdermal and nasal delivery have to date been commercially unattractive due to low natural bioavailability--the amount of drug absorbed from the delivery site into the bloodstream relative to injection. As an alternative to the invasiveness of injection, we believe a deep lung or pulmonary delivery system could expand the market for macromolecule drug therapies and may enable new therapeutic uses of certain macromolecule drugs.

We are creating a proprietary platform integrating customized formulation, dry powder processing and packaging with a proprietary inhalation device to enable efficient, reproducible delivery of macromolecule drugs for systemic and local lung indications. For specific drug products, we formulate and process bulk drugs supplied by collaborative partners into dry powders, which are packaged into individual dosing units referred to as "blisters." The blisters are designed to be loaded into our device, which patients then activate to inhale the aerosolized drugs whose particle size permits deep lung delivery. We have developed an inhalation device that is being used several times per day in outpatient trials to deliver insulin to treat diabetes. In addition, we have demonstrated room temperature stability of a year or more for a number of macromolecule drugs, and have scaled-up our powder processing and packaging for late-stage clinical trials and intermediate scale commercial production.

As an alternative to invasive delivery techniques, we believe that a deep lung delivery system could potentially expand the market for macromolecule drug therapies by increasing patient acceptance and improving compliance, which in turn could decrease medical complications and the associated costs of disease management. Additionally, deep lung delivery may enable new therapeutic uses of certain macromolecule drugs. We are focusing development efforts on applying our pulmonary delivery system primarily to drugs that are approved for marketing or have proven efficacy in late stage clinical trials. These drugs may be used to treat local lung diseases or may be systemic drugs that are currently administered through another route, such as injection.

A cornerstone of our business strategy is to work with collaborative partners to develop and commercialize drugs for deep lung delivery. In a typical collaboration, our partner supports the application of our technology to a particular drug by supplying bulk quantities of the active drug, funding the development program, overseeing clinical development, and marketing the resulting commercial product. We typically will formulate the product and supply the delivery system. In return, we will receive research

and development and milestone payments during development, and revenues from dry powder manufacturing, device supply, and royalties from sales of any commercial products. Additionally, after the product has been approved for marketing, we will receive royalties on commercial sales of the product and manufacturing revenues from supplying packaged drug and devices.

In addition to Pfizer's sponsorship of the inhaleable insulin program, we have active pulmonary delivery development programs with Biogen for AVONEX-Registered Trademark-, an interferon beta drug used for the treatment of Multiple Sclerosis, Aventis Behring for an alpha-1 proteinase inhibitor used to treat genetic emphysema, and with Lilly for Forteo-TM-, a form of parathyroid hormone being developed for the treatment of osteoporosis. We are also engaged in early stage feasibility and research programs with respect to other compounds. We anticipate that any product that may be developed would be commercialized with a collaborative partner and believe that our partnering strategy will enable us to reduce the investment required to develop a large and diversified product portfolio.

In January 2001, we acquired all of the capital shares of Bradford Particle Design plc, a United Kingdom company, for approximately 3.75 million in newly issued shares of our common stock and approximately $20 million in cash. Bradford Particle Design plc's supercritical fluid processing technology reduces what is commonly now a multi-stage powder manufacturing process to a single step while improving product purity and consistency. The use of this technology to create powder particles has many potential benefits including: increasing the number of molecules that can be formulated into drug products, improving drug efficacy, shortening drug product development timelines, lengthening product shelf life, reducing the risk of product recalls, and decreasing production costs.

In late 1999, we completed the sale of approximately $108.5 million aggregate principal amount of 6 3/4% convertible subordinated debentures due October 13, 2006. In 2000, we entered into agreements with certain holders of these outstanding debentures to convert their debentures into common stock in exchange for a cash payment. To date, we have made net payments of approximately $15.2 million in the aggregate in connection with agreements that provide for the conversion of approximately $100.7 million aggregate principal amount of outstanding debentures into approximately 6.3 million shares of common stock.

In February 2000, we received approximately $222.4 million in net proceeds from the issuance of $230.0 million aggregate principal amount of convertible subordinated notes to certain qualified institutional buyers under Rule 144A of the Securities Act of 1933, as amended. Interest on the notes will accrue at a rate of 5.0% per year, subject to adjustment in certain circumstances. The notes will mature in February 2007 and are convertible into shares of our common stock at a conversion price of $38.355 per share, subject to adjustment in certain circumstances. In late 2000, we entered into agreements with certain holders of these outstanding notes to convert their notes into common stock in exchange for a cash payment. To date, we have made cash payments of approximately $25.5 million in the aggregate in connection with agreements that provide for the conversion of approximately $168.6 million aggregate principal amount of outstanding notes into approximately 4.4 million shares of common stock.

In October 2000, we received approximately $223.0 million in net proceeds from the issuance of $230.0 million aggregate principal amount of convertible subordinated notes to certain qualified institutional buyers under Rule 144A of the Securities Act of 1933, as amended. Interest on the notes accrue at a rate of 3.5% per year, subject to adjustment in certain circumstances. The notes will mature in October 2007 and are convertible into shares of our common stock at a conversion price of $50.46 per share, subject to adjustment in certain circumstances.

OPPORTUNITIES FOR PULMONARY DRUG DELIVERY

MACROMOLECULES

Innovations in biotechnology and recombinant techniques have led to a large increase in the number of protein therapeutics and other macromolecule drugs over the last several years. These drugs, which are

identical or similar to the body's natural molecules, are enabling new therapies for many previously untreated or poorly treated diseases. Currently, approximately 35 macromolecule drugs are approved for marketing in the United States and approximately 120 additional biotechnology macromolecule drugs are in human clinical trials, many for chronic and subchronic diseases. Sales of genetically engineered protein drugs were estimated at $15.6 billion worldwide in 1999.

Drugs typically enter the body through one of five routes of delivery. The four natural routes are through the digestive tract (oral), the skin (transdermal), the mucosal surfaces (for example, nasal and sublingual), and the lung (inhalation). Drugs are also commonly delivered by injection (subcutaneous, intramuscular, or intravenous), bypassing the natural barrier to entry of foreign substances provided by the skin.

Oral delivery is a common method of delivery for many small molecule drugs. However, proteins and other macromolecules are typically destroyed by the digestive process and are therefore delivered poorly by the oral route. In addition, we believe that this low oral bioavailability may result in poor dosage reproducibility for macromolecules delivered by the oral route. While several companies are working on oral delivery for macromolecule drugs, no commercially viable system is currently being marketed.

The size of most macromolecules makes non-invasive penetration through the skin inefficient or ineffective. Passive transdermal delivery using "patch" technology has not been successful to date for these large molecules since the skin is less naturally permeable than the gastrointestinal tract. No macromolecule drugs have been approved for marketing in the United States using patch technology. High pressure "needleless" injection devices, which inject proteins like insulin through the skin into the body, have been available for many years. However, we believe these devices have not been well accepted due to patient discomfort and relatively high cost.

Nasal delivery of proteins and peptides has been limited by low and variable bioavailability of these molecules through the nasal mucosa. As a result of these limitations, penetration enhancers are often used with nasal delivery systems to achieve higher bioavailability. These enhancers may cause local irritation to the nasal tissue and result in safety concerns with long-term use. Only a limited number of peptides have been approved for marketing in the United States utilizing nasal delivery. We believe these same obstacles will affect sublingual drug delivery, which also relies on the penetration of similar tissue in the mouth.

The principal route of administration of macromolecule drugs, particularly proteins, has been injections. Drug injections administered in hospitals or doctors' offices can be expensive and inconvenient to patients. Many patients find self-injectable therapies unpleasant. As a result, injected drugs for many chronic and subchronic diseases meet with varying degrees of patient acceptance and compliance with the prescribed regimens, which can lead to increased incidence of medical complications and potentially higher disease management costs. In addition, some elderly, infirm or pediatric patients cannot administer their own injections and require assistance, thereby increasing both the inconvenience to these patients and the cost of therapy.

Delivery of protein and other drugs to the lungs via inhalation (pulmonary delivery) has the potential to be a more effective route of administration of macromolecules, with a relatively higher absorption into the bloodstream, or bioavailability, than all alternative routes except injection. As an alternative to invasive injections, we believe a deep lung inhalation delivery system could increase patient acceptance and improve compliance and may enable new therapeutic uses of certain macromolecule drugs. Pulmonary delivery is already in use for a variety of small molecule drugs.

Approximately 35 drugs are currently approved for marketing by the Food and Drug Administration for respiratory delivery using delivery devices such as metered dose inhalers (MDIs), dry powder inhalers (DPIs) and nebulizers, but none of these respiratory delivery devices were designed to optimize drug delivery to the deep lung for absorption into the bloodstream. MDIs, DPIs and nebulizers typically deliver only a fraction of the drug to the deep lung, with most of the drug being lost in the delivery device or in the

mouth and throat. Consequently, we believe that the total efficiency of such systems is generally not high enough to be commercially feasible for systemic delivery of most macromolecule drugs.

Pulmonary drug delivery devices currently do not provide the dosage reproducibility and formulation stability generally needed for commercially viable systemic macromolecule drug delivery. We believe that many MDI and DPI systems do not provide the deep lung dosage reproducibility necessary for many systemic applications because the patient must coordinate the breathing maneuver with the generation of the aerosol. Further, we believe that many macromolecules currently cannot be formulated for use in MDI systems, since macromolecule drugs could be inactivated by the MDI formulating ingredients. In addition, we believe that some macromolecules may also be inactivated by nebulization and that reservoir type dry powder systems do not provide the protection needed for long-term stability of protein and other macromolecule formulations.

We believe that an efficient and reproducible deep lung delivery system for systemic macromolecule drugs used in the treatment of chronic and subchronic diseases represents a significant commercial opportunity. Such a system could improve patient acceptance of systemic macromolecule drug therapy and compliance with prescribed regimens, thereby improving therapeutic outcomes and reducing the costs of administration and treatment of disease. Additionally, pulmonary delivery may enable new therapeutic uses of certain macromolecule drugs.

We also believe that the limitations of current pulmonary devices create opportunities for a deep lung delivery system in the delivery of macromolecules for local lung diseases. Biotechnology and pharmaceutical companies are developing new macromolecule drugs for pulmonary diseases such as asthma, cystic fibrosis, emphysema, lung cancer, pneumonia and bronchitis. Pulmonary delivery is the preferred route for treating most lung diseases since application of the drug directly to the site of action (lung) requires much less drug than systemic administration, thereby potentially reducing systemic side effects.

OTHER MOLECULES

In addition to developing a deep lung delivery system for macromolecules, we are investigating opportunities for pulmonary delivery of small molecules where there is a clear, demonstrable need for an alternative drug delivery system and where our existing technology can be applied without significant modification. Examples include molecules that require rapid systemic absorption for efficacy, such as analgesics and anti-emetics, molecules that undergo massive first pass metabolism when delivered by the oral route or molecules used for local lung delivery for diseases such as asthma that are currently delivered by sub-optimal aerosol systems.

MDIs, existing DPIs and nebulizers have been used primarily to deliver drugs to the upper airways of the lung for local lung applications. Some of the problems associated with traditional small molecule aerosol delivery systems include poor reproducibility, low efficiency, low drug payload per puff, poor moisture barrier and, in the case of wet systems, long dosing time and potential for microbial growth.

We believe that our technology could be used to address these problems by providing efficient dispersion of the drug into the lungs resulting in the reproducible delivery of a consistent amount of drug into the bloodstream. We further believe our technology could potentially be applied economically in market segments where it is essential that significant drug doses reach the lung. Large amounts of drugs taken orally or through inefficient inhalers can result in side effects, which could be avoided or reduced through more efficient and targeted pulmonary delivery.

STRATEGY

Our goal is to become the pre-eminent supplier of drug delivery solutions. We focused initially on inhaleable macromolecules because of the need for non-invasive delivery of these drugs. Our growth strategy is to continue to build on our leadership position in this field, while at the same time leverage our

strengths in inhalation, macromolecule formulations, and powder technologies to enter large opportunity, non-commodity markets in these areas. Our approach is to pick technologies and markets where we can build leadership positions through developing or acquiring platform technologies with broad applications.

We are leveraging our technology base for other applications where our system can provide significant market advantages. Our strategy incorporates the following principal elements:

- DEVELOP A BROADLY APPLICABLE PULMONARY DELIVERY SYSTEM. We are developing our non-invasive deep lung drug delivery system to be applicable to a wide range of peptides, proteins and other molecules currently delivered by injection or poorly delivered by inhalation or other routes. We intend to develop effective non-invasive delivery alternatives that can: (1) expand market penetration for existing therapeutics currently delivered by injection, infusion or other routes; (2) commercialize new indications by using deep lung delivery as a new route of administration; and (3) extend existing patents or seek new patents to gain important competitive advantages for ourselves and our partners.

- BUILD COMPETITIVE ADVANTAGE THROUGH AN INTEGRATED SYSTEMS APPROACH. We are developing a commercially viable deep lung delivery system through an integrated systems solution. We are combining our expertise in pulmonary physiology and biology, aerosol science, powder science, aerosol engineering, chemical engineering, mechanical engineering and product design, protein formulation, fine powder processing and filling to build a proprietary, fully-integrated system for pulmonary delivery of therapeutic drugs. We believe that building expertise in technology across several disciplines provides us with a significant competitive advantage.

- PARTNER WITH PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES. Our strategy is to market our proposed products through collaborative partners. We are seeking to work with partners that have significant clinical development and marketing resources, and currently have collaborations with several large pharmaceutical and biotechnology companies. For patented drug products, we intend to partner with owners or licensees. For drugs that are off-patent or licensed-in, we may perform initial feasibility screening work, formulations development and early stage human clinical trials before entering into a partner relationship for further development. We believe this partnering strategy enables us to reduce our cash requirements while developing a large and diversified potential product portfolio.

- FOCUS ON APPROVED OR LATE STAGE DRUGS. To date, we have focused primarily on drugs that either have proven efficacy and are approved for marketing or are in late stage clinical trials. We believe that working primarily with drugs with demonstrated efficacy reduces the technical risk of our projects. In the future, we anticipate working on drugs at earlier stages of development.

- EXPAND MANUFACTURING CAPABILITY. We intend to formulate, manufacture and package dry powders for most of our drugs and to subcontract manufacturing of our device. We believe that this strategy will provide manufacturing economies of scale across a range of therapeutic products and expand capacity for additional partnerships and commercial scale production.

With the acquisition of Bradford Particle Design plc, a United Kingdom company that has pioneered the use of supercritical fluid technology, Inhale has made a major step toward achieving its long-term goal of being the pre-eminent supplier of drug delivery solutions. Bradford Particle Design plc, has a leading position in the field of supercritical fluid processing technology for pharmaceutical applications. We believe its technology has compelling advantages and over time will become the preferred method for producing powders for a wide range of oral, inhaleable, injectable, and other delivery applications. Bradford Particle Design plc, has entered feasibility and collaboration agreements with 15 major pharmaceutical companies to evaluate Bradford Particle Design plc's supercritical fluid processing technology for use with 24 different compounds. Current partners include GlaxoSmithKline plc, AstraZeneca, and Bristol-Myers Squibb.

OUR DEEP LUNG DRUG DELIVERY SYSTEM

We believe that the following criteria are necessary for a commercially viable non-invasive deep lung drug delivery system:

- SYSTEM EFFICIENCY/COST: The system must attain a certain minimum efficiency in delivering a drug to the bloodstream as compared to injection. Bioavailability (the percentage of drug absorbed into the bloodstream from the lungs relative to that absorbed from injection) is the most important element of system efficiency. Total system efficiency is critical due to the high cost of macromolecule drugs. Total delivery system efficiency is determined by the amount of drug lost during manufacture, in the delivery device, in reaching the site of absorption, and during absorption from that site into the bloodstream. We believe that for most systemic macromolecule drugs, a non-invasive delivery system must show total delivery system efficiency of at least 5% to 25% compared to injection for the system to be commercially viable.

- REPRODUCIBILITY: The system must deliver a consistent and predictable amount of drug to the lung and into the bloodstream.

- FORMULATION STABILITY: Formulations used in the system must remain physically and chemically stable over time and under a range of storage, shipping and usage conditions.

- SAFETY: The system should not introduce local toxicity problems during chronic or subchronic use by a wide population of patients.

- CONVENIENCE: The system must be convenient to the patient in terms of comfort, ease of operation, transportability and required dosage time.

We approach pulmonary drug delivery with the objective of maximizing overall delivery system efficiency while addressing commercial requirements for reproducibility, formulation stability, safety and convenience. To achieve this goal, our delivery system integrates customized drug formulations and packaging with our proprietary inhalation device. We combine an understanding of lung biology, aerosol science, chemical engineering, mechanical engineering and protein formulations in our system development efforts. We believe that this interdisciplinary capability provides an important competitive advantage.

We have chosen to base our deep lung delivery system on dry powders for several reasons. Many proteins are more stable in dry powders than in liquids. In addition, dry powder aerosols can carry approximately five times more drug in a single breath than typical MDIs and, for many drugs, at least 25 times more than currently marketed liquid or nebulizer systems. We believe that a dry powder system for drugs requiring higher doses, such as insulin and alpha-1 proteinase inhibitor, could decrease dosing time as compared with nebulizers.

We take bulk drugs supplied by our partners and then formulate and process them into fine powders that are packaged into individual blister packages. The blisters are designed to be loaded into our device, which patients activate to inhale the aerosolized drugs. Once inhaled, the aerosol particles are deposited in the deep lung, dissolved in the alveolar fluid and absorbed into the bloodstream. Although we are in the advanced stages of developing our system technologies, there can be no assurance that our products will ever be successfully commercialized.

FORMULATIONS

Each macromolecule drug poses different formulation challenges due to differing chemical and physical characteristics and dosing requirements. This requires significant optimization work for each specific drug. We have assembled a team with expertise in protein formulation, powder science and aerosol science, and we are applying this expertise to develop proprietary techniques and methods that we believe will produce stable, fillable, shippable and dispersible dry powder drug formulations. We have developed several protein powders which remain stable at room temperature in excess of one year. Through our work

with numerous macromolecules, we are developing an extensive body of knowledge on aerosol dry powder formulations, including knowledge relating to the physiochemical properties of particles that make up powders and the resulting characteristics such as flowability, dispersability and solubility within the lung, as well as the related properties and influences of various excipients. We have filed and expect to continue to file patent applications on several of our formulations and, through strategic acquisitions, have acquired rights to certain U.S. and foreign patents and patent applications relating to stabilization of macromolecule drugs in dry powder formulations.

POWDER PROCESSING

We are modifying standard powder processing equipment and developing custom techniques to enable us to produce fine dry powders with particle aerosol diameters of between one and five microns without significant drug degradation or significant loss. We have scaled up powder processing to levels sufficient for producing candidate powders for late stage clinical trials. It is expected that production at these levels will be more than sufficient to satisfy the needs of small volume commercial products. We are also in the process of further scaling up our powder processing systems in order to produce quantities sufficient for commercial production of products we believe we will need to supply in high volumes, such as insulin. However, there can be no assurance that we will be successful in further scaling up our powder processing on a timely basis or at a reasonable cost, or that the powder processing system will be applicable for every drug.

POWDER FILLING AND PACKAGING

Powders made up of fine particles intended for inhalation typically require handling that is different than for powders comprised of larger or more massive particles. Common practice in the pharmaceutical industry is to increase the powder's effective particle size by various agglomerative techniques such as pelletization, spheronization, or blending with an excipient of significantly larger particle size, in order to yield materials that handle more favorably in existing processing equipment such as tablet presses and capsule fillers. Thus, currently available commercial filling and packaging systems are generally designed for filling powders of larger particle size and mass, and are most commonly applied to oral dosage forms. Although applications of these capsule filling approaches to aerosol products do exist, they typically can only deliver accurate and precise fills for much higher dose masses than one may desire. Further still, by their method of operation they may overcompress or even damage the morphology of fine, low density powders, and may make them much more difficult to disperse than when in their uncompressed state. We have developed and internally qualified a proprietary automated filling system suitable for use in production of clinical trial supplies and, for certain products, commercial quantities. The system has been tested across a wide variety of powders encountered to date and its performance yields highly accurate and precise fills across a wide range of dose masses, down to the order of a single milligram. Subsequent aerosol performance observed with both active and passive devices is essentially equivalent to the powder's performance when filled by hand, where it is essentially uncompressed. We are further developing a high through-put system for use with products whose market requirements dictate increased capacity. The underlying technology is intended to allow its application to a broad variety of powder types, characteristics, and a wide range of target fill masses, but there can be no guarantee that technology will work for any or all of the intended uses.

INHALATION DEVICE

Our proprietary pulmonary delivery device is designed to provide deep lung delivery of therapeutic powders in a reproducible, safe and efficient manner. The first of a series of patents applied for covering the device was granted in the United States in October 1995. To achieve our objectives, we have designed our pulmonary delivery device to perform the following:

- EFFECTIVELY DISPERSE FINE PARTICLES INTO AN AEROSOL CLOUD. Fine powders have different dispersion requirements or characteristics than large powders. Most current dry powder inhalers use larger

powders and are not efficient in dispersing powders with aerosol diameters of one to five microns. We have developed and are refining the dispersion system for our device specifically for fine powders. Our device has been designed to efficiently remove powders from the packaging, effectively break up the powder particles and create an aerosol cloud while maintaining the integrity of the drug.

- EFFICIENTLY AND REPRODUCIBLY DELIVER THE AEROSOL CLOUD TO THE DEEP LUNG. We are developing a proprietary aerosol cloud handling system in our device that is intended to facilitate deep lung powder deposition and reproducible patient dosing. The handling system design is intended to enable the aerosolized particles to be transported from the device to the deep lung during a patient's breath, reducing losses in the throat and upper airways. In addition, the aerosol cloud handling system, in conjunction with the dispersion mechanism and materials used in the device, is designed to reduce powder loss in the device itself.

- ELIMINATE THE USE OF PROPELLANTS TO AVOID ASSOCIATED ENVIRONMENTAL CONCERNS AND FORMULATION DIFFICULTIES. Unlike MDIs, our device does not use propellants. The oily surfactants required to stabilize propellant formulations can cause aggregation of macromolecules. Current chlorofluorocarbon propellants, which are used in most commercial MDI systems, are being phased out in many countries due to environmental concerns.

Leveraging our experience in aerosol physics, powder science, device technology, and a strong understanding of patient behavior, biological parameters, and product design, we are currently developing a new technology platform called Solo-TM- which we believe will lead to a pocket size inhaler, driven by a patient's breath, that has high delivery efficiency and reproducibility. While preliminary results have been encouraging, there can no assurance that the system will work as intended, or that it will be manufacturable in the large volumes and at the cost levels required. In addition, review of any drug device system by regulatory authorities introduces many uncertainties, and there can be no guarantee of an approval for use.

The success of our deep lung drug delivery system will depend upon our achieving sufficient formulation stability, safety, dosage reproducibility and total system efficiency which is measured by the percentage of bulk drug entering the manufacturing process that eventually is absorbed into the bloodstream relative to injection for systemic indications, or the amount of drug delivered to the lung tissue for local lung indications. The initial screening determinant for the feasibility of pulmonary delivery of any systemic drug is pulmonary bioavailability, which measures the percentage of the drug absorbed into the bloodstream when delivered directly to the lungs. In addition, a certain percentage of each drug dose may be lost at various stages of the manufacturing process, including drug formulation, dry powder processing, or powder filling and packaging, and in moving the drug from a delivery device into the lungs. Excessive drug loss at any one stage or cumulatively in the manufacturing and delivery process could render a drug commercially unfeasible for pulmonary delivery. Formulation stability, the physical and chemical stability of the formulated drug over time and under various storage, shipping and usage conditions, and safety will vary with each macromolecule and the type and amount of excipients that are used in the formulation. Dose reproducibility, the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups, requires the development of an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung, accurate unit dose packaging of dry powder formulations and moisture resistant packaging. There can be no assurance that we will be able to successfully develop such an inhalation device and attendant technologies, or overcome all obstacles to reproducible dosing.

CLINICAL STATUS SUMMARY

The following table sets forth, for both our partner development programs and internal programs available for partnering, the drugs currently in development, the indication(s) for the particular drug, its

present stage of clinical development and, with respect to our partner development programs, the identity of the corporate partner for such drug.

PARTNER DEVELOPMENT PROGRAMS

DRUG	INDICATION(S)	CLINICAL STATUS(1)	PARTNER
Insulin	Type 1 and 2 Diabetes	Phase III	Pfizer
Alpha-1 Proteinase Inhibitor	Genetic Emphysema	Phase I	Aventis Behring
AVONEX-Registered Trademark-	Multiple Sclerosis	Phase I	Biogen
Forteo-TM-	Osteoporosis	Phase I	Lilly

PROGRAMS AVAILABLE OR EXPECTED TO BE AVAILABLE FOR PARTNERING

DRUG	INDICATION(S)	CLINICAL STATUS(1)
Calcitonin	Osteoporosis, Bone Pain, Paget's Disease	Phase I
Interleukin-1 Receptor	Asthma	Phase I/II
Undisclosed Non-Protein, Non-Peptide	Not Released	Phase II
Undisclosed Non-Protein, Non-Peptide	Not Released	Phase I
Undisclosed Non-Protein, Non-Peptide	Not Released	Preclinical
Undisclosed Protein	Not Released	Preclinical

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(1) Clinical Status means:

Phase III--large-scale clinical trials conducted to obtain regulatory approval to market and sell a drug; initiated following encouraging Phase II trial results.

Phase II--clinical trials to establish dosing and efficacy in patients.

Phase I--clinical trials in healthy subjects to test safety, and for drugs with systemic applications, to test bioavailability compared with injection.

Preclinical--formulation development and animal testing in preparation for human trials.

OUR PARTNER DEVELOPMENT PROGRAMS

In general, our partnership arrangements provide funding for development, payments upon the achievement of certain milestones and royalty and manufacturing revenues upon the commencement of commercial sales. The arrangements are cancelable by the partner at any time without significant penalty.

INSULIN PROGRAM

Insulin is a protein hormone naturally secreted by the pancreas to induce the removal of glucose from the blood into cells. Diabetes, the inability of the body to properly regulate blood glucose levels, is caused by insufficient production of insulin by the pancreas or insufficient use of the insulin that is secreted. Over time, high blood glucose levels can lead to failure of the microvascular system, which may lead to blindness, loss of circulation, kidney failure, heart disease or stroke. Insulin is currently marketed only in injectable form. Insulin is supplied by various manufacturers, including Lilly, Novo-Nordisk A/S and Aventis.

According to the United States Centers for Disease Control and Prevention, approximately 16 million people in the United States have diabetes; 10.3 million of which are diagnosed with diabetes and another 5.4 million of which have undiagnosed diabetes, and 798,000 new cases are diagnosed each year. All Type 1 diabetics, estimated at between 5% and 15% of all diabetics, require insulin therapy. Type 1 diabetics require both a baseline treatment of long-acting insulin and multiple treatments of regular, or short acting, insulin throughout the day. Type 2 diabetics, depending on the severity of their disease, may or may not

require insulin therapy. Type 2 diabetics who use insulin are best treated with regular insulin and sometimes require long-acting insulin as well. Because of the inconvenience and unpleasantness of injections, many Type 2 patients who do not require insulin to survive, despite the fact that they would benefit from it, are reluctant to start treatment.

Regular insulin is generally administered 30 minutes before mealtimes and generally is given only twice a day. A ten-year study by the National Institutes of Health, however, demonstrated that the side effects of diabetes could be significantly reduced by dosing more frequently. The NIH study recommended dosing regular insulin three to four times per day, a regimen which would more closely mirror the action of naturally produced insulin in non-diabetics. Because of the risk of severe hypoglycemia, this course of treatment is not recommended for children, older adults, people with heart disease or with a history of frequent severe hypoglycemia. In addition, many patients are reluctant to increase their number of daily doses because they find injections unpleasant and inconvenient.

Pursuant to a collaborative agreement originally entered into in January 1995, Pfizer and we are developing an inhaled version of regular insulin that can be administered in one to three blisters per dose using our deep lung delivery system. We believe that our delivery system could provide increased user convenience and result in greater patient compliance by eliminating some injections for Type 1 and Type 2 patients and all injections for some Type 2 patients. In addition, we believe that because inhaleable insulin has a more rapid onset of action than injectible insulin, it offers simpler pre-meal dosing than the slower acting regular insulin.

Phase I and Phase IIa clinical trials indicated that pulmonary insulin was absorbed systemically, reduced blood glucose levels and provided the same control of diabetes as injected insulin. In October 1996, Pfizer initiated a multi-site Phase IIb outpatient trial to include up to 240 diabetes patients, the results of which were announced in June 1998. In 70 Type 1 diabetics treated with either inhaled or conventional injected insulin therapy for three months, blood levels of hemoglobin A1c, or "HbA1c," the best index of blood glucose control, were statistically equivalent. Virtually identical results were obtained in a group of Type 2 diabetics. In September 1998, Pfizer released additional Phase II data from a study of diabetics whose blood glucose was poorly controlled by oral agents alone. In that study, patients who were given inhaleable insulin in addition to their oral medications showed marked improvement in their blood glucose control.

In November 1998, Pfizer and Aventis announced that they entered into a worldwide agreement to manufacture insulin and to co-develop and co-promote inhaleable insulin. Under the terms of the agreement, Pfizer and Aventis agreed to construct a jointly owned, state-of-the-art insulin manufacturing plant in Frankfurt, Germany. Pfizer and Aventis have reported plans to invest over 300 million DM in this new plant which is projected to be the largest of its kind worldwide and would employ about 200 people. The building's foundation was laid at the Frankfort Hoechst Industrial Park in Spring 1999 and is still under construction. Until its completion, Pfizer will provide us with biosynthetic recombinant insulin for powder processing from Aventis's existing plant. We will continue to have responsibility for manufacturing powders and supplying delivery devices and will receive a royalty on inhaleable insulin products marketed jointly by Pfizer and Aventis.

In June 1999, Pfizer began dosing in the Phase III clinical trials and is currently testing inhaleable insulin at more than 120 Phase III sites.

In June 2000, we reported new data on patients using inhaleable insulin therapy from a Phase II continuation, or extension, study being conducted by Pfizer and Aventis. The goal of the extension study was to determine if safety and efficacy results from previously reported short-term Phase II clinical trials could be maintained long term. These data showed that HbA1c, the long-term measurement of blood glucose control, remained stable in patients for up to 30 months of therapy. At the time that this data was compiled, 83 patients had completed 24 months of inhaleable therapy. Further data presented indicated

similar results for patients who completed 30 months of therapy. Additionally, the results of four different lung function tests showed that lung function was sustained during the course of treatment.

In January 1995 and October 1996, Pfizer made two $5.0 million equity investments in our company.

ALPHA-1 PROTEINASE INHIBITOR PROGRAM

In January 1997, we entered into a collaborative agreement with Aventis Behring to develop a pulmonary formulation of alpha-1 proteinase inhibitor to treat patients with alpha-1 antitrypsin deficiency, or genetic emphysema. Alpha-1 proteinase inhibitor is approved in the United States and several European countries for augmentation treatment of alpha-1 antitrypsin deficiency. Current treatment is given by systemic intravenous infusion on a weekly basis. This "replacement therapy" consists of a concentrated form of alpha-1 proteinase inhibitor derived from human plasma. Under the terms of the collaboration, Aventis Behring will receive commercialization rights worldwide excluding Japan and we will receive royalties on product sales, an up-front signing fee and up to an estimated $15.0 million in research and development funding and milestone payments.

The two companies have completed preclinical work that indicates our dry powder formulation of Aventis Behring's alpha-1 proteinase inhibitor has the potential to significantly improve the efficiency of delivery compared with current infusion therapy. We believe our pulmonary delivery system could significantly reduce the amount of drug needed for genetic emphysema therapy since alpha-1 proteinase inhibitor could be delivered directly to the lung where it acts. Aventis Behring is currently negotiating to secure rights under patents that have been granted in Europe directed to aerosol formulations for the treatment of the lung containing serine protease inhibitors, including alpha-1 proteinase inhibitor. Phase I clinical trials have been completed.

AVONEX-REGISTERED TRADEMARK- PROGRAM

In February 1999, we entered into a collaborative agreement with Biogen to develop an inhaleable formulation of Biogen's proprietary Interferon-Beta-1a, marketed as AVONEX-Registered Trademark-, for the treatment of Multiple Sclerosis. Multiple Sclerosis is a neurological disorder characterized by plaques or lesions on the myelin sheath, a protective covering that shields the nerve fibers in the brain and spinal cord. Multiple Sclerosis is reported to be the most common chronic neurological condition of young adults in North America and Europe, with an estimated prevalence in the U.S. of more than 250,000 people. AVONEX-Registered Trademark- is the first product in North America that has been proven in a clinical trial to reduce the rate at which high-risk individuals develop clinically definite Multiple Sclerosis.

Dosing for the Phase IA clinical trial of inhaleable AVONEX-Registered Trademark- began in April 2000 and is now complete. Under the terms of the collaboration agreement, Biogen provides us with bulk AVONEX-Registered Trademark- for formulation into a dry powder for inhalation into the deep lung. We manufacture and package the dry powder and supply inhalation devices. Biogen is responsible for clinical development, commercialization and worldwide marketing of inhaleable AVONEX-Registered Trademark-. In return for developing inhaleable AVONEX-Registered Trademark-, we will receive royalties on product sales, milestone payments and an estimated $25.0 million in research and development funding.

FORTEO-TM- PROGRAM

In January 1997, we entered into a collaborative agreement with Lilly to develop an inhalable formulation of Forteo-TM-, a version of parathyroid hormone, PTH 1-34, used in the treatment of osteoporosis. At that time, osteoporosis was estimated to affect approximately 25 million Americans, mostly women. If not prevented or left untreated, osteoporosis can progress painlessly until a bone breaks. As many as 35,000 people die each year from a cause associated with hip fractures caused by osteoporosis, primarily due to complications that result from surgery or from being confined to bed.

In late 1998, unexpected observations from a long-term test in rats of the injectable version of this osteoporosis drug led Lilly to suspend further clinical development of the injectable and pulmonary versions of Forteo-TM- pending further analysis. In September 2000, we announced the reinitiation of the Forteo-TM- development program with Lilly. Under the terms of the agreement we will receive up to an estimated $20.0 million in research, development and milestone payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products and we will receive royalties on any marketed products. We will manufacture packaged powders for and supply inhalation devices to Lilly.

OUR PROGRAMS AVAILABLE FOR PARTNERING

CALCITONIN PROGRAM

We are funding a proprietary program to develop a pulmonary formulation of calcitonin for the treatment of osteoporosis, bone pain and Paget's disease. Calcitonin is a peptide hormone secreted by the thyroid gland that inhibits bone resorption and lowers serum calcium. Calcitonin is available in two forms, fish and human. Calcitonin is administered daily or every other day by injection in the United States. In the United States, salmon calcitonin is approved for the treatment of postmenopausal osteoporosis, Paget's disease, hypercalcemia of cancer and bone pain. Human calcitonin is approved for Paget's disease and bone pain. Paget's disease is a chronic disorder of the adult skeleton, in which localized areas of bone become hyperactive and are replaced by a softened and enlarged bone structure. About 3% of Caucasians in the United States over age 60 have Paget's disease. Hypercalcemia occurs as a result of excessive serum calcium levels caused by hyperparathyroidism and malignancy. It occurs in approximately 10-20% of cancer patients.

In April 1997, we announced the successful completion of Phase I trials to investigate the tolerability and bioavailability of pulmonary delivery of a dry powder, aerosolized form of salmon calcitonin as a potential treatment for osteoporosis, Paget's disease, hypercalcemia and other bone diseases. The single-dose study conducted in the United Kingdom with a total of 36 fasted healthy subjects indicated that the drug was systemically absorbed when delivered by the pulmonary route with our pulmonary delivery system. We are continuing work on this program while we seek a partner for further clinical development.

INTERLEUKIN-1 RECEPTOR PROGRAM

Interleukin-1 is a cytokine that helps initiate the inflammatory response to foreign pathogens and is believed to be a causative factor for asthma. The interleukin-1 receptor is a molecule which can block the inflammatory action of Interleukin-1. We collaborated with Immunex Corp. to develop a pulmonary formulation of interleukin-1 receptor as a therapeutic product for asthma. Initial formulation development and animal toxicology have been completed, and the two companies successfully completed Phase I/II trials demonstrating pulmonary delivery. This program is awaiting further work and/or licensing by Immunex.

MOLECULE PROGRAMS FORMERLY PARTNERED WITH BAXTER

In March 1996, we entered into a collaborative agreement with Baxter International Inc. to use our dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In connection with the collaboration, Baxter made a $20.0 million equity investment in our company. At that time, Baxter received worldwide commercialization rights for four non-protein/peptide drugs in exchange for up to an estimated $60.0 million in research and development funding and progress payments.

In April 1998, we announced that the first two compounds from our collaboration with Baxter had successfully completed Phase I and Phase II trials respectively. In addition, it was announced that the program would focus on the product that had completed Phase I trials as it was the product with the most commercial potential. The technology from one of the three remaining products was returned to us,

leaving the development of the other two compounds in abeyance. In October 1998, we announced that we had reached an agreement with Baxter to amend their collaborative agreement to facilitate signing a new corporate partner to fund further development and commercialization of the undisclosed compound that had been their focus since April 1998. Baxter's obligations under that amendment expired in September 1999. As a result, rights to the compounds reverted to us and are now available for other partnering opportunities.

PROPRIETARY MOLECULE PROGRAM FORMERLY PARTNERED WITH LILLY

In December 1997, we entered into a collaborative agreement with Lilly to develop an aerosol formulation for an undisclosed protein product based on our deep lung drug delivery system. In September 2000, Lilly announced that it had decided to discontinue development of this therapeutic product which is currently in preclinical development. As a result, we are free to develop the product further independently or in collaboration with another partner.

OTHER PROGRAMS

In addition to the above mentioned programs, we have conducted and continue to conduct feasibility studies of additional drug formulations both on our own account and in cooperation with potential partners. We will continue to pursue these and other feasibility programs to determine the potential for collaborative development programs with respect to these drugs. Included among such studies is initial research on a long-acting inhaleable insulin. Some diabetic patients require a long-acting insulin to maintain baseline insulin levels. A long-acting, inhaleable form of insulin could be used by these patients as a supplement to short-acting, mealtime inhaleable insulin. This program is part of a broader sustained release program announced by us in January 1999.

MANUFACTURING

We generally plan to formulate, manufacture and package the powders for our deep lung delivery products and to subcontract the manufacture of our proprietary pulmonary delivery devices. Under our collaborative agreement with Pfizer to develop inhaleable insulin, we will manufacture insulin powders and Pfizer will be primarily responsible for filling blisters. The terms of the collaborative agreement with Pfizer provide that prior to the commercialization of its first products, we must build and have validated a powder processing facility and must have validated a device manufacturer or manufacturers. We believe our manufacturing strategy will enable it to achieve the following:

- provide economies of scale by utilizing manufacturing capacity for multiple products;

- improve our ability to retain any manufacturing know-how; and

- allow our customers to bring pulmonary delivery products to market faster.

We have built a powder manufacturing and packaging facility in San Carlos, California capable of producing powders in quantities sufficient for clinical trials. This facility has been inspected and licensed by the State of California and is used to manufacture and package powders under current good manufacturing practices. We are expanding our facility to meet our future commercial manufacturing commitments.

We are working to further scale-up our powder processing to a larger production scale system and to further develop the necessary powder packaging technologies. Fine particle powders and small quantity packaging (such as those to be used in our delivery system) require special handling. Current commercial packaging systems are designed for filling larger quantities of larger particle powders and therefore must be modified to dispense finer particles in the small quantities we require. We have developed and internally qualified a proprietary prototype automated filling system which we believe is capable of supporting our requirements through Phase III trials and into commercial production for some products.

We are developing a higher capacity automated filling unit capable of filling blisters on a production scale for moderate and large volume products. There can be no assurance that we will be able to successfully manufacture product on this autofiller system in a timely manner or at commercially reasonable cost. Any failure or delay in further developing such technology would delay product development or inhibit commercialization of our products and would have a materially adverse effect on us.

Our proprietary inhalation device has been developed for commercial use and is being used in the Phase III insulin and other trials. We have identified and have established formal supply agreements with contract manufacturers that we believe have the technical capabilities and production capacity to manufacture our pulmonary delivery devices. It is believed that these contract manufacturers can successfully receive the device technology and know-how transferred from our device development group, scale up the manufacturing process, and meet the requirements of current good manufacturing practices. There can be no assurance that we will be able to maintain satisfactory contract manufacturing on commercially acceptable terms, if at all. Our dependence upon third parties for the manufacture of our inhalation device may adversely affect our cost of goods and our ability to develop and commercialize products on a timely and competitive basis.

GOVERNMENT REGULATION

The research and development, clinical testing, manufacture and marketing of pulmonary drug delivery systems are subject to regulation by the United States Food and Drug Administration and by comparable regulatory agencies in other countries. These national agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing (in vitro and in clinical trials), manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products.

The process required by the FDA before a pulmonary drug delivery system may be marketed in the United States depends on whether the compound has existing approval for use in other dosage forms. If the drug is a new chemical entity that has not been approved, the process includes the following:

- extensive preclinical laboratory and animal testing;

- submission of an Investigational New Drug application, or IND

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for the intended indication: and

- submission to the FDA for approval of a New Drug Application, or NDA, with respect to drugs or a Biological License Application, or BLA, with respect to biological products.

If the drug has been previously approved, the approval process is similar, except that certain preclinical tests relating to systemic toxicity normally required for the IND and NDA/BLA application may not be necessary.

Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulation. Pulmonary drug products must be formulated according to current good manufacturing practices, and pre-clinical safety tests must be conducted by laboratories that comply with FDA good laboratory practices regulations. The results of the pre-clinical tests are submitted to the FDA as part of an IND application and are reviewed by the FDA before clinical trials can begin. Clinical trials may begin 30 days after receipt of the IND by the FDA, unless the FDA raises objections during that period.

Clinical trials involve the administration of the drug to healthy volunteers or to patients under the supervision of a qualified medical investigator according to an approval protocol. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor participant safety and efficacy or other criteria to be evaluated. Each protocol is submitted to the

FDA as part of the IND. Each clinical study is conducted under the auspices of an independent Institutional Review Board, or IRB. The IRB considers, among other things, ethical factors, the potential risks to subjects participating in the trial and the possible liability of the institution. The IRB also approves the consent form signed by the trial participants.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into healthy human subjects, the product generally is tested for tolerability, pharmacokinetics, absorption, metabolism and excretion. Phase II involves studies in a limited patient population to:

- determine the efficacy of the product for specific targeted indications;

- determine dosage tolerance and optimal dosage and regimen of administration; and

- identify possible adverse effects and safety risks.

After Phase II trials demonstrate that administration of the drug by the pulmonary route is effective and has an acceptable safety profile, Phase III trials are undertaken to evaluate further clinical efficacy and safety within an expanded patient population at geographically dispersed clinical study sites. The FDA, the clinical trial sponsor, the investigators or the IRB may suspend clinical trials at any time if any one of them believe that study participants are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as an NDA/BLA for approval of the marketing and commercial shipment of the pulmonary drug product. The FDA may deny an NDA/BLA if applicable regulatory criteria are not satisfied or may require additional clinical testing. Even if such data are submitted, the FDA may ultimately decide that the NDA/ BLA does not satisfy the criteria for approval. Product approvals, once obtained, may be withdrawn if compliance with regulatory standards are not maintained or if safety concerns arise after the product reaches the market. The FDA may require post-marketing testing and surveillance programs to monitor the effect of pulmonary drug products that have been commercialized and has the power to prevent or limit future marketing of the product based on the results of such programs.

Each domestic drug product manufacturing establishment must be registered with, and approved by, the FDA. Drug product manufacturing establishments located in California also must be licensed by the State of California. Establishments handling controlled substances must be licensed by the United States Drug Enforcement Administration. Domestic manufacturing establishments are subject to biennial inspections by the FDA for compliance with current good manufacturing practices. We are also subject to U.S. federal, state and local regulations regarding workplace safety, environmental protection and hazardous and controlled substance controls, among others.

Many of the drugs we are working on are already approved for marketing by the FDA in another form and by another route. We believe that when working with approved drugs, the approval process for delivery by pulmonary drug products may require less time and fewer tests than for new chemical entities. However, we expect that our formulations may use excipients not currently approved for pulmonary use. Use of these excipients will require additional toxicological testing that may increase the costs of or lengthen the time to gain regulatory approval. In addition, regulatory procedures as they relate to our products may change as regulators gain experience in the area of macromolecules, and any such changes may delay or increase the cost of regulatory approval.

For products currently under development, our device is considered to be part of a drug/device combination for deep lung delivery of each specific molecule. Prior to submission of an IND, the FDA Center and division within the FDA Center responsible for the review of the IND and NDA/BLA will be identified. In the case of our products, either the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research, in consultation with the Center for Devices and Radiological Health, could be involved in the review. However, one Center is designated as the Center which has the

lead responsibility for regulating the product. The jurisdiction within the FDA is based on the primary mode of action of the drug and is identified in the FDA's intercenter agreement.

We expect that our partners generally will be responsible for clinical and regulatory approval procedures, but we may participate in this process by submitting to the FDA a drug master file developed and maintained by us which contains data concerning the manufacturing processes for the device or drug product. The clinical and manufacturing development and regulatory review process generally takes a number of years and requires the expenditure of substantial resources. Our ability to manufacture and sell products developed under contract depends upon the partner's completion of satisfactory clinical trials and success in obtaining marketing approvals. We may prepare and submit an IND application and perform initial clinical studies before licensing a product to a corporate partner. Our business strategy contemplates performing more of these studies in the future.

Sales of our products outside the United States are subject to local regulatory requirements governing clinical trials and marketing approval for drugs and pulmonary delivery systems. Such requirements vary widely from country to country.

Prior to marketing a new dosage form of any drug, including one developed for use with our pulmonary drug delivery system, the product must undergo rigorous preclinical and clinical testing and an extensive review process mandated by the FDA and equivalent foreign authorities regardless of whether or not such drug was already approved for marketing in another dosage form. These processes generally take a number of years and require the expenditure of substantial resources. None of our proposed products has yet been submitted to the FDA for marketing approval. We have no experience obtaining such regulatory approval and intend to rely on our partners to fund clinical testing and to obtain product approvals.

In developing the device component of our technology, we have sought to develop our quality systems and design engineering function in adherence to the principles of design control for medical devices as set out in the applicable regulatory guidance. Although hybrid drug-device products are typically reviewed as a drug, we have sought to adhere to the design control approach both as a good business practice, and because it is clear that the drug and biologic Centers of the FDA and other worldwide agencies are moving in this direction. In the EU, this has already taken place and delivery devices are viewed as separate entities and are subject to review as such under the Medical Device Directive. In the US, although not yet formally required, it is our intention to comply with the FDA regulations for devices and develop our device technology in compliance with design control principles. We have not yet successfully applied for and been granted approval for any of our device products or technologies, and there can be no assurance that products designed by us and built by our contract manufacturers will be approved, or meet approval requirements on a timely basis.

PATENTS AND PROPRIETARY RIGHTS

Our policy is to apply for patent protection for the technology, inventions and improvements deemed important to the success of our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and further develop our competitive position. We plan to defend aggressively our proprietary technology and any issued patents.

We expect that our integrated system for pulmonary delivery of both large and small molecule drugs will yield innovations in dry powder formulations, powder processing, powder packaging and device design. It is our strategy to build proprietary positions in each of these technological areas. Our success will depend in part upon our ability to protect our proprietary technology from infringement, misappropriation, duplication and discovery. We have filed patent applications covering certain aspects of our device and powder processing technology and powder formulations and pulmonary route of delivery for certain molecules, and plan to file additional patent applications. There can be no assurance that any of the patents applied for by us will issue, or that any patents that issue will be valid and enforceable. Even if

such patents are enforceable, we anticipate that any attempt to enforce our patents could be time consuming and costly.

We currently have 106 issued U.S. and foreign patents covering certain aspects of our technology and have a number of patent applications pending. Among the significant patents we have received from the United States Patent and Trademark Office, or the "PTO", are the following:

- Patent No. 5,458,135 (October 17, 1995) and Patent No. 6,138,668 (October 31, 2000) for a pulmonary delivery device and its use in a method for delivering aerosolized (including powder) formulations of drugs to the lung.

- Patent No. 5,607,915 (March 4, 1997), Patent No. 5,814,607 (September 29, 1998) and Patent No. 6,080,721 (June 27, 2000) for pulmonary delivery of active fragments of parathyroid hormone (PTH).

- Patent No. 5,654,007 (August 5, 1997), Patent No. 5,922,354 (July 13, 1999) and Patent No. 6,103,270 (August 15, 2000) for systems and methods for processing fine dispersible powders.

- Patent No. 5,740,794 (April 21, 1998) for a method and means to access a packaged drug, to break up a dry powder drug into particles with compressed air (aerosolize), and to transport the aerosolized drug into a holding chamber.

- Patent No. 5,775,320 (July 7, 1998) for a method and means for dispersing a dry-powder or liquid drug, and transferring the drug in its aerosolized "cloud" form to a holding chamber where it is held until a patient is ready to inhale, as well as a method and means to pull in atmospheric "chase" air following the initial inhalation to help push the drug into the deep lung.

- Patent No. 5,780,014 (July 14, 1998) and Patent No. 5,993,783 (November 30, 1999) for methods, means and compositions for pulmonary delivery of dry powder alpha1-antitrypsin, a proteinase inhibitor, for administration to a patient.

- Patent No. 5,785,049 (July 28, 1998) and Patent No. 6,089,228 (July 18, 2000) for methods and means for aerosolizing dry powders through use of a high pressure gas stream to draw dry powder from a receptacle such as a blister pack. We utilize the design described therein to achieve efficient aerosolization of fine dry powders to enable deep lung delivery for systemic absorption.

- Patent No. 5,826,633 (October 27, 1998) relating to our powder handling technologies, including the process of transferring fine powder particles into blister packs in an un-compacted state so that they can be easily dispersed in our pulmonary delivery system.

- Patent No. 5,928,469 (July 27, 1999) for a method for preparing storage stable compositions. In this method, a material to be stored and a glass forming substance are spray-dried to form stable particles.

- Patent No. 5,976,574 (November 2, 1999), Patent No. 5,985,248 (November 16, 1999), Patent No. 6,001,336 (December 14, 1999) and Patent No. 6,077,543 (June 20, 2000) for processes for spray-drying hydrophobic drugs in various solutions and suspensions and compositions formed by the processes.

- Patent No. 5,994,314 (November 30, 1999) for dry powder nucleic acid compositions and methods for their preparation.

- Patent No. 5,997,848 (December 7, 1999) for pulmonary administration of dry powder insulin which is rapidly absorbed through the alveoli into the systemic circulation.

- Patent No. 6,019,968 (February 1, 2000) and Patent No. 6,165,463 (December 26, 2000) for an antibody-based dry powder that is in the form of respirable dry particles of less than 10 microns.

- Patent No. 6,051,256 (April 18, 2000) for our proprietary spray drying method for preparing dry powder macromolecules.

- Patent No. 6,071,428 (June 6, 2000) for storage stable pharmaceuticals or biological cells that are in an amorphous glassy phase and contain a crystalline sugar hydrate.

- Patent No. 6,123,936 (September 26, 2000) for a dispersible dry powder form of interferon in combination with a hydrophobic amino acid.

- Patent No. 6,136,346 (October 24, 2000) for a dispersible spray-dried pharmaceutical composition containing a polypeptide excipient.

In January 2001, we acquired all the outstanding share capital of Bradford Particle Design, providing access to its supercritical fluid processing technology together with its intellectual property portfolio. This technology potentially reduces what is commonly now a multi-stage powder manufacturing process to a single step while, we believe, improving product purity and consistency. The use of this technology to create powder particles has many potential benefits including: increasing the number of molecules that can be formulated into drug products, improving drug efficacy, shortening drug product development timelines, lengthening product shelf life, reducing the risk of product recalls, and decreasing production costs. The intellectual property portfolio of Bradford Particle Design plc includes two issued U.S. patents, two granted European patents and a number of applications that are pending in various countries around the world.

In November 1999, we acquired the Alliance Pharmaceutical Corp. PulmoSphere-TM- technology and other related assets for particle formulation and powder processing, subject to the terms and conditions of an asset purchase agreement. The PulmoSphere-TM- technology utilizes an emulsification process to produce a powder having characteristics that we believe may improve efficiency and reproducibility for drugs delivered to the lung through alternative technologies such as MDIs as well as potentially improve drug delivery through our proprietary deep lung drug delivery system. The assets acquired included Alliance's intellectual property portfolio for the PulmoSphere-TM- technology consisting of, among other things, several patent applications. With respect to applications of the PulmoSphere-TM- technology outside the respiratory field, we have licensed the technology back to Alliance. While Alliance has made several representations in its agreement with us regarding its ownership rights of the PulmoSphere-TM- technology, it is possible that third parties might assert claims challenging Alliance's rights, and thus our rights. Even if we can defend our rights successfully, the uncertainty regarding the status of our rights during the time any such litigation is pending may prevent us from using the underlying technology.

In March 1998, Initiatech, Inc. signed an agreement with us under which we licensed technology, intellectual property, and patents for protecting biologically active compounds in the dry state. We intend to use this technology to expand our current technology base in stabilizing dry powder aerosol formulations for peptides, proteins, and other macromolecules at room temperature. Our license is exclusive for the fields of respiratory delivery of pharmaceutical products and for any delivery form of insulin. The license includes rights to two issued U.S. patents and a Canadian patent covering the protection of biological materials from degradation in the dry state. Initiatech has licensed exclusive rights to this technology from the Boyce Thompson Institute for Plant Research, Inc.

In June 1997, we acquired the intellectual property portfolio of the BioPreservation Division of Pafra. This portfolio includes issued U.S. and foreign Letters Patent and pending applications relating to the stabilization of macromolecule drugs in dry formulations. An application for reissue of the original U.S. patent included in this portfolio is pending in the PTO. There can be no assurance that we will be successful in obtaining a reissued patent. A second U.S. patent from this portfolio issued to us on July 27, 1999. A granted European patent included in this portfolio was the subject of an opposition proceeding before the European Patent Office. The opposition hearing was held on December 16, 1999. We successfully defended the patent and our method claims relating to glass stabilization technology against

four opposing parties. In addition, in late 1999, based on claims of this granted European patent, we filed an infringement action in the courts of the United Kingdom against Quadrant Healthcare plc. There can be no assurance that any of the other Pafra patent applications will be held to be valid and enforceable. The inability to obtain or defend the Pafra patents could have a material adverse effect on us.

We have obtained license rights to certain know-how and patent applications owned by Genentech, Inc. covering formulations, powder processing and pulmonary delivery of certain molecules, which we believe could be important to the development of our business. These license rights are worldwide, nonexclusive, sublicensable and royalty free. In 1997, Genentech successfully defended an opposition proceeding involving a pending European patent licensed to us. Recently, this decision was upheld on appeal. The patent issued in the United States as Patent No. 6,099,517 and covers the pulmonary delivery of cytokines and growth factors.

The patent positions of pharmaceutical, biotechnology and drug delivery companies, including ourselves, are uncertain and involve complex legal and factual issues. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued. As a consequence, we do not know whether any of our patent applications will be granted with broad coverage or whether the claims that eventually issue will be circumvented. Since patent applications in the United States are maintained in secrecy until patents issue, and since publication of discoveries in scientific or patent literature often lag behind actual discoveries, we cannot be certain that we were the first inventor of inventions covered by our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. Moreover, we may have to participate in interference proceedings declared by the PTO to determine priority of invention, which could result in substantial cost to us, even if the eventual outcome is favorable. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute.

We are aware of numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties that relate to aerosol devices and delivery, pharmaceutical formulations, dry powder processing technology and the pulmonary route of delivery for certain powder formulations of macromolecules. We cannot predict with any certainty which, if any, patent references will be considered relevant to our technology by authorities in the various jurisdictions where such rights exist, nor can we predict with certainty which, if any, of these rights will or may be asserted against it by third parties. There can be no assurance that we can obtain any license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. The failure to obtain licenses if needed would have a material adverse effect on us.

We also rely upon trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets.

Third parties from time to time have asserted or may assert that we are infringing their proprietary rights based upon issued patents, trade secrets or know-how that they believe cover our technology. In addition, future patents may issue to third parties which our technology may infringe. We could incur substantial costs in defending ourself and our partners against any such claims. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability to further develop or commercialize some or all of our products in the United States and abroad, and could result in the award of substantial damages. In the event of a claim of infringement, our partners and ourselves may be required to obtain one or more licenses from third parties. There can be no assurance that our partners and us will be able to obtain such licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any such required license could have a material adverse effect on us.

Our ability to develop and commercialize our technology will be affected by ours or our partners' access to the drugs which are to be formulated. Many biopharmaceutical drugs, including some of those which are presently under development by us, are subject to issued and pending United States and foreign patent rights which may be owned by competing entities. There are issued patents and pending patent applications relating to the pulmonary delivery of macromolecule drugs, including several for which we are developing pulmonary delivery formulations. We intend generally to rely on the ability of our partners to provide access to the drugs which are to be formulated for pulmonary delivery. There can be no assurance, however, that our partners will be able to provide access to drug candidates for formulation for pulmonary delivery or that, if such access is provided, we or our partners will not be accused of, or determined to be, infringing a third party's rights and will not be prohibited from working with the drug or be found liable for damages that may not be subject to indemnification. Any such restriction on access or liability for damages would have a material adverse effect on us.

It is our policy to require our employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from us to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. The agreements provide that all inventions conceived by an employee shall be our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

COMPETITION

We believe that products developed using our technology will compete on the basis of system efficiency, dosage reproducibility, safety, patient convenience and cost. There is intense competition to develop a solution to the non-invasive delivery of drugs from several drug delivery and pharmaceutical companies, many of which are much larger and have far greater resources than we do. These include companies working on developing systems for other non-invasive routes of delivery, such as oral, transdermal, bucal, nasal, and needle-less injections, as well as companies working on pulmonary delivery systems. In addition, several companies are working on sustained release injectable systems. While these latter systems involve injections, the lower number of injections could be competitive with our pulmonary delivery technology in certain applications. We believe our technology and integrated pulmonary delivery systems approach provides us with important competitive advantages in the delivery of drugs compared with currently known alternatives. However, new drugs or further developments in alternative drug delivery methods may provide greater therapeutic benefits for a specific drug or indication, or may offer comparable performance at lower cost than our proprietary deep lung drug delivery system.

With respect to pulmonary delivery, several companies are marketing and developing DPI, MDI, liquid and nebulizer devices that could have applications for drug delivery, including Elan Corporation, plc, which completed the acquisition of Dura Pharmaceuticals, Inc. on November 10, 2000, Advanced Inhalation Research, a subsidiary of Alkermes, Inc., AeroGen, Inc., and Aradigm Corporation. Several of these companies may have or may be developing devices that could be used for pulmonary delivery of proteins such as insulin as well as other macromolecules. In addition, Generex Biotechnology Corporation has a collaborative arrangement for the development of buccal delivery systems for insulin. There can be no assurance that competitors will not introduce products or processes competitive with or superior to ours. We intend to monitor competitive device, powder formulations and processing activities and to continue to focus our activities on those products for which we believe we have and can maintain a competitive advantage. If a device or system is developed that is superior to ours for certain applications, we may seek to obtain a license to allow our partners to use such device with our developed powders, although there can be no assurance that we would be able to do so.

Our success depends upon maintaining a competitive advantage in the development of products and technologies for pulmonary delivery of pharmaceutical drugs. If a competing company were to develop or acquire rights to a better system for efficiently and reproducibly delivering macromolecule drugs to the deep lung, a non-invasive drug delivery system which is more attractive for delivery of drugs to the deep lung, a non-invasive delivery system which is more attractive for the delivering of drugs than pulmonary delivery, or an invasive delivery system which overcomes some of the drawbacks of current invasive systems for chronic or subchronic indications (such as sustained release systems), our business would be negatively impacted.

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. We are aware of a number of companies currently seeking to develop new products and non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems, buccal and colonic absorption systems. Several of these companies may have developed or are developing dry powder devices that could be used for pulmonary delivery of macromolecules. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do and represent significant competition for us. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance competitors' financial, marketing and other resources. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than us. Developments by others may render our products or technologies noncompetitive or obsolete.

EMPLOYEES AND CONSULTANTS

As of December 31, 2000, we had 485 employees, of which 419 were engaged in research and development, including manufacturing and quality activities and 66 in general administration and business development. One hundred seventy-eight of the employees hold advanced degrees, of which 77 are Ph.D.s. We employ scientists and engineers with expertise in the areas of pulmonary biology, aerosol science, powder technology, mechanical engineering, protein chemistry and chemical engineering. None of our employees are covered by a collective bargaining agreement and we have experienced no work stoppages. We believe that we maintain good relations with our employees.

To complement our own expertise, we utilize specialists in regulatory affairs, pulmonary toxicology, process engineering, manufacturing, quality assurance, device design, clinical trial design and business development. These individuals include certain of our scientific advisors as well as independent consultants. See Item 10 "Directors and Executive Officers of the Registrant."

RISK FACTORS

THE FOLLOWING RISK FACTORS SHOULD BE READ CAREFULLY IN CONNECTION WITH EVALUATING OUR BUSINESS. ANY OF THE FOLLOWING RISKS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS AND OPERATING RESULTS OR FINANCIAL CONDITION.

WE DO NOT KNOW IF OUR DEEP LUNG DRUG DELIVERY SYSTEM IS COMMERCIALLY FEASIBLE.

We are in an early stage of development. There is a risk that our deep lung drug delivery technology will not be commercially feasible. Even if our deep lung delivery technology is commercially feasible, it may not be commercially accepted across a range of large and small molecule drugs. We have tested eight deep lung delivery formulations in humans, but many of our potential formulations have not been tested in humans.

Many of the underlying drug compounds contained in our deep lung formulations have been tested in humans by other companies using alternative delivery routes. Our potential products require extensive research, development and pre-clinical (animal) and clinical (human) testing. Our potential products also may involve lengthy regulatory review before they can be sold. We do not know if and cannot assure that, any of our potential products will prove to be safe and effective or meet regulatory standards. There is a risk that any of our potential products will not be able to be produced in commercial quantities at acceptable cost or marketed successfully. Failure to achieve commercial feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or, together with partners, successfully market products will negatively impact our revenues and results of operations.

WE DO NOT KNOW IF OUR DEEP LUNG DRUG DELIVERY SYSTEM IS EFFICIENT.

We may not be able to achieve the total system efficiency needed to be competitive with alternative routes of delivery. Total system efficiency is determined by the amount of drug loss during manufacture, in the delivery device, in reaching the site of absorption, and during absorption from that site into the bloodstream. Deep lung bioavailability is the percentage of a drug that is absorbed into the bloodstream when that drug is delivered directly to the lungs as compared to when the drug is delivered by injection. Bioavailability is the initial screen for whether deep lung delivery of any systemic drug is commercially feasible. We would not consider a drug to be a good candidate for development and commercialization if our drug loss is excessive at any one stage or cumulatively in the manufacturing and delivery process or if our deep lung bioavailability is too low.

WE DO NOT KNOW IF OUR DEEP LUNG DRUG FORMULATIONS ARE STABLE.

We may not be able to identify and produce powdered versions of drugs that retain the physical and chemical properties needed to work with our delivery device. Formulation stability is the physical and chemical stability of the drug over time and under various storage, shipping and usage conditions. Formulation stability will vary with each deep lung formulation and the type and amount of ingredients that are used in the formulation. Problems with powdered drug stability would negatively impact our ability to develop and market our potential products or obtain regulatory approval.

WE DO NOT KNOW IF OUR DEEP LUNG DRUG DELIVERY SYSTEM IS SAFE.

We may not be able to prove potential products to be safe. Our products require lengthy laboratory, animal and human testing. Most of our products are in preclinical testing or the early stage of human testing. If we find that any product is not safe, we will not be able to commercialize the product. The safety of our deep lung formulations will vary with each drug and the ingredients used in our formulation.

WE DO NOT KNOW IF OUR DEEP LUNG DRUG DELIVERY SYSTEM PROVIDES CONSISTENT DOSES OF MEDICINE.

We may not be able to provide reproducible dosages of stable formulations sufficient to achieve clinical success. Reproducible dosing is the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups. Reproducible dosing requires the development of:

- an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung;

- accurate unit dose packaging of dry powder formulations; and

- moisture resistant packaging.

We may not be able to develop reproducible dosing of any potential product. The failure to do so means that we would not consider it a good candidate for development and commercialization.

WE DEPEND ON PARTNERS FOR REGULATORY APPROVALS AND COMMERCIALIZATION OF OUR PRODUCTS.

Because we are in the business of developing technology for delivering drugs to the lungs and licensing this technology to companies that make and sell drugs, we do not have the people and other resources to do the following things:

- make bulk drugs to be used as medicines;

- design and carry out large scale clinical studies;

- prepare and file documents necessary to obtain government approval to sell a given drug product; and

- market and sell our products when and if they are approved.

When we sign a collaborative development agreement or license agreement to develop a product with a drug company, the drug company agrees to do some or all of the things described above. If our partner fails to do any of these things, we cannot complete the development of the product.

WE MAY NOT OBTAIN REGULATORY APPROVAL FOR OUR PRODUCTS ON A TIMELY BASIS, OR AT ALL.

There is a risk that we will not obtain regulatory approval for our products on a timely basis, or at all. Our product must undergo rigorous animal and human testing and an extensive review process mandated by the FDA or equivalent foreign authorities. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing such testing and obtaining such approvals is uncertain. We have not submitted any of our products to the FDA for marketing approval. We have no experience obtaining such regulatory approval.

In addition, we may encounter delays or rejections based upon changes in FDA policy, including policy relating to good manufacturing practice compliance, or "cGMP", during the period of product development. We may encounter similar delays in other countries.

Even if regulatory approval of a product is granted, the approval may limit the indicated uses for which we may market our product. In addition, our marketed product, our manufacturing facilities and we, as the manufacturer, will be subject to continual review and periodic inspections. Later discovery from such review and inspection of previously unknown problems may result in restrictions on our product or on us, including withdrawal of our product from the market. The failure to obtain timely regulatory approval of our products, any product marketing limitations or a product withdrawal would negatively impact our revenues and results of operations.

WE DO NOT KNOW IF OUR TECHNOLOGIES CAN BE INTEGRATED SUCCESSFULLY TO BRING PRODUCTS TO MARKET.

We may not be able to integrate all of the relevant technologies to provide a deep lung drug delivery system. Our integrated approach to systems development relies upon several different but related technologies:

- dry powder formulations;

- dry powder processing technology;

- dry powder packaging technology; and

- deep lung delivery devices.

At the same time we must:

- establish collaborations with partners;

- perform laboratory and clinical testing of potential products; and

- scale-up our manufacturing processes.

We must accomplish all of these steps without delaying any aspect of technology development. Any delay in one component of product or business development could delay our ability to develop, obtain approval of or market therapeutic products using our deep lung delivery technology.

WE MAY NOT BE ABLE TO MANUFACTURE OUR PRODUCTS IN COMMERCIAL QUANTITIES.

POWDER PROCESSING. We have no experience manufacturing products for commercial purposes. We have only performed powder processing on the small scale needed for testing formulations and for early stage and larger clinical trials. We may encounter manufacturing and control problems as we attempt to scale-up powder processing facilities. We may not be able to achieve such scale-up in a timely manner or at a commercially reasonable cost, if at all. Our failure to solve any of these problems could delay or prevent late stage clinical testing and commercialization of our products and could negatively impact our revenues and results of operations.

To date, we have relied on one particular method of powder processing. There is a risk that this technology will not work with all drugs or that the cost of drug production will preclude the commercial viability of certain drugs. Additionally, there is a risk that any alternative powder processing methods we may pursue will not be commercially practical for aerosol drugs or that we will not have, or be able to acquire the rights to use, such alternative methods.

POWDER PACKAGING. Our fine particle powders and small quantity packaging require special handling. We have designed and qualified automated filling equipment for small and moderate quantity packaging of fine powders. We face significant technical challenges in scaling-up an automated filling system that can handle the small dose and particle sizes of our powders in commercial quantities. There is a risk that we will not be able to scale-up our automated filling equipment in a timely manner or at commercially reasonable costs. Any failure or delay in such scale-up would delay product development or bar commercialization of our products and would negatively impact our revenues and results of operations.

INHALATION DEVICE. We face many technical challenges in further developing our inhalation device to work with a broad range of drugs, to produce such a device in sufficient quantities and to adapt the device to different powder formulations. In addition, we are attempting to develop a smaller inhalation device, which presents particular technical challenges. There is a risk that we will not successfully achieve any of these challenges. Our failure to overcome any of these challenges would negatively impact our revenues and results of operations.

For late stage clinical trials and initial commercial production, we intend to use one or more contract manufacturers to produce our drug delivery device. There is a risk that we will not be able to maintain arrangements with our potential contract manufacturers or effectively scale-up production of our drug delivery devices through contract manufacturers. Our failure to do so would negatively impact our revenues and results of operations.

WE DEPEND ON SOLE OR EXCLUSIVE SUPPLIERS FOR OUR INHALATION DEVICE AND BULK DRUGS.

We have agreed to subcontract the manufacture of our pulmonary delivery device before commercial production of our first product. We have identified contract manufacturers that we believe have the technical capabilities and production capacity to manufacture our devices and which can meet the requirements of good manufacturing practices. We cannot be assured that we will be able to maintain satisfactory contract manufacturing on commercially acceptable terms, if at all. Our dependence on third parties for the manufacture of our inhalation device may negatively impact our cost of goods and our ability to develop and commercialize products on a timely and competitive basis.

We obtain the bulk drugs we use to formulate and manufacture the dry powders for our deep lung delivery system from sole or exclusive sources of supply. For example, with respect to our source of bulk

insulin, we have entered into a collaborative agreement with Pfizer which has, in turn, entered into an agreement with Aventis to manufacture biosynthetic recombinant insulin. Under the terms of their agreement, Pfizer and Aventis agreed to construct a jointly owned manufacturing plant in Frankfurt, Germany. Until its completion, Pfizer will provide us with insulin from Aventis's existing plant. If our sole or exclusive source suppliers fail to provide bulk drugs in sufficient quantities when required, our revenues and results of operations will be negatively impacted.

WE DO NOT KNOW IF THE MARKET WILL ACCEPT OUR DEEP LUNG DRUG DELIVERY SYSTEM.

The commercial success of our potential products depends upon market acceptance by health care providers, third-party payors like health insurance companies and Medicare, and patients. Our products under development use a new method of drug delivery and there is a risk that our potential products will not be accepted by the market. Market acceptance will depend on many factors, including:

- the safety and efficacy of products demonstrated in our clinical trials;

- favorable regulatory approval and product labeling;

- the frequency of product use;

- the availability of third-party reimbursement;

- the availability of alternative technologies; and

- the price of our products relative to alternative technologies.

There is a risk that health care providers, patients or third-party payors will not accept our deep lung drug delivery system. If the market does not accept our potential products, our revenues and results of operations would be significantly and negatively impacted.

IF OUR PRODUCTS ARE NOT COST EFFECTIVE, GOVERNMENT AND PRIVATE INSURANCE PLANS MAY NOT PAY FOR THEM.

In both domestic and foreign markets, sales of our products under development will depend in part upon the availability of reimbursement from third-party payors, such as government health administration authorities, managed care providers, private health insurers and other organizations. In addition, such third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Legislation and regulations affecting the pricing of pharmaceuticals may change before our proposed products are approved for marketing. Adoption of such legislation and regulations could further limit reimbursement for medical products. A government or third-party payor decision to not provide adequate coverage and reimbursements for our products would limit market acceptance of such products.

WE EXPECT TO CONTINUE TO LOSE MONEY FOR THE NEXT SEVERAL YEARS.

We have never been profitable and, through December 31, 2000, we have an accumulated deficit of approximately $191.9 million. We expect to continue to incur substantial and increasing losses over at least the next several years as we expand our research and development efforts, testing activities and manufacturing operations, and as we further expand our late stage clinical and early commercial production facility. All of our potential products are in research or in the early stages of development except for our insulin collaboration. We have generated no revenues from approved product sales. Our revenues to date have consisted primarily of payments under short-term research and feasibility agreements and development contracts. To achieve and sustain profitable operations, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products using our deep lung drug delivery system. There is a risk that we will not generate sufficient product or contract research revenue to become profitable or to sustain profitability.

WE MAY NEED TO RAISE ADDITIONAL CAPITAL THAT MAY NOT BE AVAILABLE.

We anticipate that our existing capital resources will enable us to maintain currently planned operations through at least the next 32 months. However, this expectation is based on our current operating plan, which is expected to change as a result of many factors, and we may need additional funding sooner than anticipated. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in dilution to our stockholders.

We have no credit facility or other committed sources of capital. To the extent operating and capital resources are insufficient to meet future requirements, we will have to raise additional funds to continue the development and commercialization of our technologies. Such funds may not be available on favorable terms, or at all. In particular, our substantial leverage may limit our ability to obtain additional financing. If adequate funds are not available on reasonable terms, we may be required to curtail operations significantly or to obtain funds by entering into financing, supply or collaboration agreements on unattractive terms. Our inability to raise capital could negatively impact our business.

IF WE FAIL TO MANAGE OUR GROWTH EFFECTIVELY, OUR BUSINESS MAY SUFFER.

Our ability to commercialize our products, achieve our expansion objectives, manage our growth effectively and satisfy our commitments under our collaboration agreements depends on a variety of factors. Key factors include our ability to develop products internally, enter into strategic partnerships with collaborators, attract and retain skilled employees and effectively expand our internal organization to accommodate anticipated growth including integration of any potential businesses that we may acquire. If we are unable to manage growth effectively, there could be a material adverse effect on our business, financial condition and results of operations.

OUR PATENTS MAY NOT PROTECT OUR PRODUCTS AND OUR PRODUCTS MAY INFRINGE ON THIRD-PARTY PATENT RIGHTS.

We have filed patent applications covering certain aspects of our device, powder processing technology, powder formulations and deep lung route of delivery for certain molecules, and we plan to file additional patent applications. We currently have 106 issued U.S. and foreign patents that cover certain aspects of our technology and we have a number of patent applications pending. There is a risk that many of the patents applied for will not issue, or that any patents that issue or have issued will not be valid and enforceable. Enforcing our patent rights would be time consuming and costly.

Our access or our partners' access to the drugs to be formulated will affect our ability to develop and commercialize our technology. Many drugs, including powder formulations of certain drugs that are presently under development by us, are subject to issued and pending U.S. and foreign patents that may be owned by competitors. We know that there are issued patents and pending patent applications relating to the deep lung delivery of large molecule drugs, including several for which we are developing deep lung delivery formulations. This situation is highly complex, and the ability of any one company, including us, to commercialize a particular drug is unpredictable.

We intend generally to rely on the ability of our partners to provide access to the drugs that are to be formulated by us for deep lung delivery. There is a risk that our partners will not be able to provide access to such drug candidates. Even if such access is provided, there is a risk that our partners or we will be accused of, or determined to be, infringing a third-party's patent rights and will be prohibited from working with the drug or be found liable for damages that may not be subject to indemnification. Any such restriction on access to drug candidates or liability for damages would negatively impact our revenues and results of operations.

OUR COMPETITORS MAY DEVELOP AND SELL BETTER DRUG DELIVERY SYSTEMS.

We are aware of other companies engaged in developing and commercializing pulmonary drug delivery systems and enhanced injectable drug delivery systems. Many of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do and represent significant competition for us. Acquisitions of or collaborations with competing drug delivery companies by large pharmaceutical companies could enhance our competitors' financial, marketing and other resources. Accordingly, our competitors may succeed in developing competing technologies, obtaining regulatory approval for products or gaining market acceptance before us. Developments by others could make our products or technologies uncompetitive or obsolete. Our competitors may introduce products or processes competitive with or superior to ours.

INVESTORS SHOULD BE AWARE OF INDUSTRY-WIDE RISKS.

In addition to the risks associated specifically with Inhale described above, investors should also be aware of general risks associated with drug development and the pharmaceutical industry. These include, but are not limited to:

- changes in and compliance with government regulations;

- handling of hazardous materials;

- hiring and retaining qualified people; and

- insuring against product liability claims.

WE EXPECT OUR STOCK PRICE TO REMAIN VOLATILE.

Our stock price is volatile. In the last twelve-month period ending February 1, 2001, based on closing prices on the Nasdaq National Market, our stock price ranged from $23.16 to $63.31. We expect it to remain volatile. A variety of factors may have a significant effect on the market price of our common stock, including:

- fluctuations in our operating results;

- announcements of technological innovations or new therapeutic products;

- announcement or termination of collaborative relationships by Inhale or our competitors;

- governmental regulation;

- clinical trial results or product development delays;

- developments in patent or other proprietary rights;

- public concern as to the safety of drug formulations developed by Inhale or others; and

- general market conditions.

Any litigation brought against us as a result of this volatility could result in substantial costs and a diversion of our management's attention and resources, which could negatively impact our financial condition, revenues and results of operations.

OUR INDEBTEDNESS MAY RESULT IN FUTURE LIQUIDITY PROBLEMS.

As of December 31, 2000, we had approximately $319.3 million in long-term obligations, which represents an increase of $205.9 million from the prior year. In October 2000, in connection with our build-to-suit lease transaction we incurred additional lease liabilities. Also, in October 2000 we issued

approximately $230.0 million of 3.5% convertible subordinated notes due October 2007. This increased indebtedness has and will continue to impact us by:

- increasing our interest expense and related debt service costs;

- making it more difficult to obtain additional financing; and

- constraining our ability to react quickly in an unfavorable economic climate.

Currently, we are not generating sufficient cash flow to satisfy the annual debt service payments that will be required as a result of the consummation of sale of the notes. This may require us to use a portion of the proceeds from the sales of the notes to pay interest or borrow additional funds or sell additional equity to meet our debt service obligations. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result, which would negatively impact our future prospects. As of December 31, 2000 we had cash and short-term investments valued at approximately $484.8 million.

ITEM 2. PROPERTIES

We currently lease facilities in San Carlos, Palo Alto and Belmont, California.

We currently occupy a facility in San Carlos that covers approximately 157,000 square feet and is leased pursuant to a 15-year lease agreement. This facility serves as our corporate headquarters and is used for research and development, manufacturing and administration. The lease provides us with an option to lease approximately 73,000 additional square feet in the same facility. This manufacturing facility operates under cGMP and has been approved and licensed by the State of California to manufacture clinical supplies for use in human clinical trials.

In October 1999, we commenced construction of a second San Carlos facility on a 4.7 acre parcel of land that we had acquired in October 1998, in order to expand our administrative offices and research and development capacity. This facility consists of approximately 80,000 square feet. In October 2000, we leased back the facility pursuant to a build-to-suit lease agreement for a 16-year term, with a 10-year option and a second 8-year option to extend the lease. In November 2000 we began occupancy of this facility. The lease also provides us with approximately 45,500 additional square feet in a second phase to be built in the future along with an option to lease an additional approximately 46,500 square feet.

Our Palo Alto facility is used for research, development and administration. The lease covers approximately 20,000 square feet, has a five-year term, and expires on May 31, 2003.

Our Belmont facility is used for administration, consists of approximately 8,000 square feet of offices and has a lease term expiring November 30, 2002.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

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

No matters were submitted to a vote of our shareholders in the quarter ended December 31, 2000.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

PRICE RANGE OF COMMON STOCK

Our Common Stock trades on the Nasdaq National Market under the symbol INHL. A two-for-one split was declared, which was effected as a 100% common stock dividend on August 22, 2000. All share prices in the following table have been retroactively restated to reflect this split. The table below sets forth the high and low closing sales prices for our Common Stock (as reported on the Nasdaq National Market) during the periods indicated.

	PRICE RANGE OF COMMON STOCK	
	HIGH	LOW
YEAR ENDED DECEMBER 31, 1999:		
1st Quarter	$17.313	$11.938
2nd Quarter	14.844	11.500
3rd Quarter	17.438	11.813
4th Quarter	21.844	13.438
YEAR ENDED DECEMBER 31, 2000:		
1st Quarter	$63.313	$20.844
2nd Quarter	54.344	23.156
3rd Quarter	56.375	40.594
4th Quarter	55.188	38.500
YEAR ENDED DECEMBER 31, 2001:		
1st Quarter (through February 1, 2001)	$48.250	$31.000

As of December 29, 2000, there were approximately 224 holders of record of our Common Stock. We have not paid any cash dividends since our inception and do not intend to pay any cash dividends in the foreseeable future.

SALES OF UNREGISTERED SECURITIES

In January 2001 we issued 3,752,456 shares of our common stock to the holders of all of the existing issued ordinary share capital of Bradford Particle Design, plc, a United Kingdom company. We issued these shares as consideration for the acquisition of the outstanding share capital of Bradford in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended (the "Act") and/or Regulation D or Regulation S promulgated under the Act. For each share of Bradford Particle Design plc common stock we issued 1.8354 new shares of our common stock and paid approximately $9.80 cash, for an aggregate cash payment of approximately $20 million. The acquirers relying upon the exemption from registration afforded by Regulation S signed forms of acceptances indicating respectively their intent to acquire the securities for investment only and not with a view to distribution, and also indicated that if they were an individual, then they were residents of the United Kingdom, or if they were a corporation, limited liability company or other entity, then the offices of the Bradford Particle Design plc shareholder in which its investment decision was made was located in the United Kingdom. The acquirers relying upon the exemption from registration afforded by Regulation D signed forms of acceptances indicating respectively their intent to acquire the securities for investment only and not with a view to distribution, and also represented that they were "accredited investors" as that term is defined under Rule 501 of Regulation D. Appropriate legends are affixed to the shares issued in this transaction. Cazenove & Co. served as financial advisor and broker to the Company in connection with the acquisition of Bradford Particle Design plc and received $650,000 in payment of certain fees. On February 5, 2001, a shelf registration statement for these shares of common stock was declared effective by the SEC.

On November 15, 2000, Inhale issued warrants representing the right to purchase up to an aggregate of 6,000 shares of our common stock to a University, and several individuals who are affiliated with the University, in partial consideration for our acquisition of certain intellectual property rights pursuant to a License Agreement between the University and ourself. These warrants are exercisable at $45.875 per share and terminate on November 15, 2010. These warrants and the shares of our common stock issued upon exercise of these warrants were sold in a private placement exempt from registration under Section 4(2) of the Act. No underwriters were involved in this offering and no commission or remuneration was paid in connection with the sale of these securities. The acquirers respectively indicated their intent to acquire the securities for investment only and not with a view to distribution and appropriate legends are affixed to the warrants issued in the transaction. The entities acquiring the warrants were each sophisticated and deemed to be an "accredited investor" as that term is defined under Rule 501 of Regulation D promulgated under the Act with access to adequate information about us.

In October 2000, we issued $230 million aggregate principal amount of 3.5% convertible subordinated notes, which are convertible at the option of the holder, at any time on or prior to maturity into shares of our common stock. The October 2000 notes were sold only in the United States to certain qualified institutional buyers under an exemption from registration provided by Rule 144A of the Act. The October 2000 notes are convertible at a conversion price of $50.46 per share, which is equal to a conversion rate of approximately 19.8177 shares per $1,000 principal amount of notes, subject to adjustment. Interest on the October 2000 notes will accrue at a rate of 3.5% per year subject to adjustment in certain circumstances. We will pay interest on the October 2000 notes on April 17 and October 17 of each year, beginning April 17, 2001. The October 2000 notes mature on October 17, 2007. We may redeem some or all of the October 2000 notes at any time before October 17, 2003 at a redemption price equal to $1,000 per $1,000 principal amount of notes, if the closing price of our common stock has exceeded 150% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days ending on the trading day before the date of mailing of the provisional redemption notice. Upon any such provisional redemption, we will make additional payment in cash or shares of our common stock, at our option, to compensate investors for interest payments not yet received through the provisional redemption date. This additional payment will be equal to $105.00 per $1,000 principal amount of notes, less the amount of any interest actually paid on the October 2000 notes before the call for redemption. We may redeem some or all of the October 2000 notes at any time after October 17, 2003 at certain redemption prices dependent upon the date of redemption if the closing price of our common stock has exceeded 120% of the conversion price then in effect for at least 20 trading days within a period of 30 connective days. The October 2000 notes are unsecured and subordinated to our existing and future senior indebtedness. The initial purchasers of the 3.5% convertible notes, Merrill Lynch & Co., Deutsche Banc Alex. Brown, Lehman Brothers, and U. S. Bancorp Piper Jaffray, received an aggregate of $6.9 million in the form of discounts to the offering price of these notes.

ITEM 6. SELECTED FINANCIAL DATA

SELECTED FINANCIAL INFORMATION
(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)

	YEARS ENDED DECEMBER 31				
	2000	1999	1998	1997	1996
STATEMENT OF OPERATIONS DATA:					
Contract research revenue	$ 51,629	$ 41,358	$ 21,795	$ 16,249	$ 6,890
Operating costs and expenses:					
Research and development	101,544	64,083	35,398	23,645	14,376
General and administrative	13,932	7,869	8,387	6,328	4,004
Acquired in-process research and development	2,292	9,890	--	--	--
Total operating costs and expenses	117,768	81,842	43,785	29,973	18,380
Loss from operations	(66,139)	(40,484)	(21,990)	(13,724)	(11,490)
Debt conversion premium, net	(40,687)	--	--	--	--
Interest and other income (expense), net	9,423	2,036	3,634	3,741	1,581
Net loss	$(97,403)	$(38,448)	$(18,356)	$ (9,983)	$ (9,909)
Net loss per share	$ (2.32)	$ (1.13)	$ (0.58)	$ (0.36)	$ (0.44)
Shares used in computation of net loss per share(1)	41,998	34,016	31,438	27,584	22,414

	DECEMBER 31,				
	2000	1999	1998	1997	1996
BALANCE SHEET DATA:					
Cash, cash equivalents and short-term investments	$484,841	$138,185	$ 82,862	$100,173	$ 36,309
Working capital	462,840	122,239	71,784	83,811	31,304
Total assets	629,540	226,806	134,496	119,762	41,492
Long-term debt	20,118	4,895	4,940	5,102	187
Convertible subordinated debentures	299,149	108,450	--	--	--
Accumulated deficit	(191,869)	(94,466)	(56,018)	(37,662)	(27,691)
Total stockholders' equity	277,883	86,629	115,881	97,093	35,061

QUARTERLY FINANCIAL DATA

The following table sets forth certain unaudited quarterly financial data for the eight quarters ending December 31, 2000. In our opinion, the unaudited information set forth below has been prepared on the same basis as the audited information and includes all adjustments necessary to present fairly the information set forth herein. The operating results for any quarter are not indicative of results for any future period. All data is in thousands except per common share data.

	FISCAL YEAR 1999				FISCAL YEAR 2000			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Contract research revenue	$ 7,780	$ 9,877	$10,628	$ 13,073	$ 10,633	$ 13,789	$ 14,061	$ 13,146
Net loss	$(5,223)	$(6,006)	$(7,045)	$(20,174)	$(28,832)	$(15,747)	$(13,215)	$(39,609)
Net loss per share(1)	$ (0.16)	$ (0.18)	$ (0.21)	$ (0.59)	$ (0.76)	$ (0.38)	$ (0.31)	$ (0.87)

We have experienced fluctuations in our quarterly results. Our results have included costs associated with the conversion of convertible notes and debentures in 2000, acquisitions of various technologies, increases in research and development expenditures, expansion of late stage clinical and early stage commercial manufacturing facilities. We expect these fluctuations to continue into the future.

(1) Basic and diluted net loss per share is based upon the weighted average number of common shares outstanding. All share amounts have been adjusted to reflect the implementation of FASB Statement No. 128 and Staff Accounting Bulletin No. 98. The shares shown above retroactively reflect a two-for-one split, effective August 22, 2000. See Note 1 of Notes to Financial Statements.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THE FOLLOWING DISCUSSION CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. INHALE'S ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE DISCUSSED HERE. FACTORS THAT COULD CAUSE OR CONTRIBUTE TO SUCH DIFFERENCES INCLUDE, BUT ARE NOT LIMITED TO, THOSE DISCUSSED IN THIS SECTION AS WELL AS IN PART I OF THIS ANNUAL REPORT UNDER THE HEADING "RISK FACTORS."

OVERVIEW

Since our inception in July 1990, we have been engaged in the development of a drug delivery system to deliver a wide range of drugs, including peptides, proteins, nucleic acids and other molecules, by inhalation to the deep lung and as part of our long-term goal to be the pre-eminent provider of the drug delivery solutions. We have been unprofitable since inception and expect to incur significant and increasing additional operating losses over the next several years primarily due to increasing research and development expenditures and expansion of late stage clinical and early stage commercial manufacturing facilities. To date, we have not sold any commercial products and do not anticipate receiving revenue from product sales or royalties in the near future. For the period from inception through December 31, 2000, we incurred a cumulative net loss of approximately $191.9 million. Our sources of working capital have been equity and debt financings, revenues from development contracts and short-term research and feasibility agreements, financings of equipment acquisitions and tenant improvements and interest earned on investments of cash.

We have generally been compensated for research and development expenses during initial feasibility work performed under collaborative arrangements. Partners that enter into collaborative agreements generally pay for some or all research and development expenses and make additional payments to us as we achieve certain key milestones. We expect to receive royalties from our partners based on their revenues received from product sales, and to receive revenue from the manufacturing of powders and the supply of devices. In certain cases, we may enter into collaborative agreements under which our partners would manufacture or package powders or supply inhalation devices, thereby potentially limiting one or more sources of revenue for us. To achieve and sustain profitable operations, we, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products utilizing our pulmonary drug delivery system. There can be no assurance that we can generate sufficient product or contract research revenue to become profitable or to sustain profitability.

In January 2001 we issued 3,752,456 shares of our common stock to the holders of all of the existing issued ordinary share capital of Bradford Particle Design, plc, a United Kingdom company. We issued these shares as partial consideration for the acquisition of the outstanding share capital of Bradford Particle Design plc in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended and/or Regulation D or Regulation S promulgated under the Act. For each share of Bradford Particle Design plc's common stock we issued 1.8354 new shares of our common stock and paid approximately $9.80 cash, for an aggregate cash payment of approximately $20 million.

In October 2000 we issued $230 million aggregate principal amount of 3 1/2% convertible subordinated notes, which are convertible at the option of the holder, at any time on or prior to maturity into shares of

our common stock. The October 2000 notes were sold only in the United States to certain qualified institutional buyers under an exemption from registration provided by Rule 144A of the Act. The October 2000 notes will mature in 2007 and are convertible into shares of our common stock at a conversion price of $50.46 per share, subject to adjustment in certain circumstances.

In February 2000 we issued $230 million aggregate principal amount of 5% convertible subordinated notes, which are convertible at the option of the holder, at any time on or prior to maturity into shares of our common stock. The February 2000 notes were sold only in the United States to certain qualified institutional buyers under an exemption from registration provided by Rule 144A of the Securities Act of 1933, as amended. The February 2000 notes mature in 2007 and are convertible at a conversion price of $38.355 per share, subject to adjustment in certain circumstances. In October and November 2000 we entered into privately negotiated agreements with certain holders of these outstanding February 2000 notes to convert their notes into shares of our common stock in exchange for a cash payment made by us. To date, we have made cash payments of approximately $25.5 million in the aggregate in connection with agreements that provide for the conversion of approximately $168.6 million principal amount of outstanding February 2000 notes into approximately 4.4 million shares of our common stock.

In February 2000, we entered into privately negotiated agreements with certain holders of our outstanding 6 3/4% convertible subordinated debentures sold in October and November 1999, providing for the conversion of approximately $100.7 million aggregate principal amount of the outstanding debentures into approximately 6.3 million shares of common stock for net payments of approximately $15.2 million.

RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

Contract research revenue was $51.6 million for the year ended December 31, 2000 compared to $41.4 million and $21.8 million for the years ended December 31, 1999 and 1998, respectively. Revenue increased 25% in 2000 from 1999 levels and 90% in 1999 from 1998 levels. Costs of contract research revenue approximate such revenue and are included in research and development expense.

The 25% increase in revenue for the year ended December 31, 2000 as compared to December 31, 1999, and the 90% increase in revenue for the year ended December 31, 1999 as compared to December 31, 1998 were both primarily due to expansion of our existing collaborative agreement with Pfizer, and include activities associated with the manufacture of Phase III clinical supplies. Pfizer represented approximately 69% of our revenues for the year ended December 31, 2000. Revenue for 2000 and 1999 included reimbursed research and development expenses as well as the amortization of deferred up-front signing and progress payments received from our collaborative partners. Contract revenues are expected to fluctuate from year to year, and future contract revenues cannot be predicted accurately. The level of contract revenues depends in part upon future success in obtaining new collaborative agreements, timely completion of feasibility studies, the continuation of existing collaborations and achievement of milestones under current and future agreements.

Research and development expenses were $101.5 million for the year ended December 31, 2000, as compared to $64.1 million and $35.4 million for the years ended December 31, 1999 and 1998, respectively. The 58% increase in 2000 as compared to 1999 was due to increased spending related to the scale-up of technologies for current partnered projects, the continuing development of our global manufacturing operations in order to support Phase III inhaleable insulin clinical trials and commercial production, increased investment in internally funded research and development projects for next-generation products and non-cash compensation associated with stock options. The 81% increase in research and development expenses in 1999 from 1998 was primarily due to increased headcount, supplies and services to support our on-going research and development efforts. We expect research and development spending to increase over the next few years as we expand our development efforts under collaborative agreements and start up our commercial operations.

General and administrative expenses were $13.9 million for the year ended December 31, 2000 as compared to $7.9 million and $8.4 million for the years ended December 31, 1999 and 1998, respectively. The 77% increase in general and administrative expenses in 2000 from 1999 was due primarily to a non-cash compensation charge associated with stock options and the costs associated with supporting our increased manufacturing and development efforts, including administrative staffing and business development activities. The 6% decrease in expenses in 1999 from 1998 is attributed to an increased percentage of general and administrative related costs allocated to research and development operations. General and administrative expenses are expected to continue to increase over the next few years as we expand our operations.

Interest income was $20.6 million for the year ended December 31, 2000 as compared to $4.1 million and $3.9 million for the years ended December 31, 1999 and 1998, respectively. The $16.5 million increase in interest income in 2000 from 1999 and the $0.2 million increase in interest income in 1999 from 1998 were primarily due to our maintaining larger cash and investment balances, including the proceeds of our issuance of several offerings of convertible subordinated debentures and higher interest rates. Interest expense was $12.1 million for the year ended December 31, 2000, as compared to $2.1 million and $0.3 million for the years ended December 31, 1999 and 1998, respectively. The $10 million increase in interest expense in 2000 from 1999 primarily relates to interest paid on the various convertible subordinated notes and debentures issued. The $1.8 million increase in interest expense in 1999 from 1998 related to the convertible subordinated debentures issued in October 1999.

At December 31, 2000, we had federal and state net operating loss carryforwards of approximately $187 million. These carryforwards will expire beginning in the year 2000. Utilization of net operating loss carryforwards may be subject to substantial annual limitations due to the ownership change limitations provided for by the Internal Revenue Code of 1986. The annual limitations may result in the expiration of net operating loss carryforwards before utilization.

ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT

On November 4, 1999, we concluded an agreement with Alliance Pharmaceutical Corp. to acquire Alliance's PulmoSphere-TM- particle and particle processing technology for use in respiratory drug delivery. Under the terms of the agreement, we received the rights to PulmoSphere-TM- technology, other related assets (including research materials, laboratory records, and certain equipment that had been used in the development of PulmoSphere-TM- technology and the manufacturing and testing of particles using such PulmoSphere-TM- technology), and Alliance stock valued at $5.0 million in exchange for $15.0 million in cash and $5.0 million of our stock. Additionally, we incurred approximately $0.4 million of acquisition costs, which are included in the total purchase consideration. Alliance also has the right to additional substantial payments upon the achievement of certain milestones and royalties on a defined number of products commercialized using the technology. Of the total purchase consideration, $15.4 million was allocated to the assets acquired based on their fair value on the date of acquisition. Approximately $9.9 million of the purchase price was allocated to IPR&D and was charged as an expense in the year ended December 31, 1999.

In the second quarter of 2000, we recorded a $2.3 million charge for acquired in-process research and development costs ("IPR&D"). The acquisition was recorded as a purchase and a portion of the purchase price was allocated to IPR&D, which under current accounting rules is immediately expensed. At the date of the acquisition, the in-process technology had no alternative future use and did not qualify for capitalization.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations primarily through public and private placements of our debt and equity securities, revenues from development contracts and short-term research and feasibility agreements,

financing of equipment acquisitions and tenant improvements, and interest income earned on it's investments of cash. At December 31, 2000, we had cash, cash equivalents and short-term investments of approximately $484.8 million.

Our operations used cash of $35.7 million, $15.3 million and $19.2 million for the years ended December 31, 2000, 1999 and 1998, respectively. These amounts differed from our net operating losses in these periods principally due to increased debt conversion incentives, non-cash compensation charges associated with stock options and depreciation expense. Additionally, we recorded a $2.3 million and $9.9 million write-off of IPR&D charges for the years ended December 31, 2000 and 1999, respectively.

In October 2000, we entered into a financing arrangement with a special purpose entity to complete construction of existing office facilities and provide financing for future capital improvements of up to $51 million. As a result of our continuing involvement and significant influence in the special purpose entity, and other provisions in the leasing transactions, the facility costs and capital lease obligations of the special purpose entity are recorded in our consolidated financial statements.

We purchased net property and equipment of approximately $53.9 million, $20.5 million and $34.6 million during the years ended December 31, 2000, 1999 and 1998, respectively. The $33.4 million increase in 2000 is primarily due to the purchase of property and equipment, our investment in our commercial manufacturing facilities, including device manufacturing at third-party contract manufacturers, and expansion of our San Carlos powder processing facilities. The Company also invested $15.3 million in the purchase of PulmoSphere-TM-technology in 1999, in addition to our non-cash exchange of common stock for shares of Alliance valued at $5.0 million.

In October 1999, we received approximately $105.2 million in net proceeds from the sale of convertible subordinated debentures. In February 2000 and October 2000, we received approximately $206 million and $197 million, respectively, in net proceeds from the sale of convertible subordinated notes. This includes net payments of approximately $15.2 million and $25.5 million in connection with agreements that provide for the conversion of approximately $100.7 million and $168.6 million of our October 2006 and February 2007 debentures, respectively, that were outstanding at December 31, 2000.

We expect our cash requirements to continue at an accelerated rate due to expected increases in costs associated with further research and development of our technologies, development of drug formulations, process development for the manufacture and filling of powders and devices, marketing and general and administrative costs. These expenses include, but are not limited to, increases in personnel and personnel related costs, purchases of capital equipment, investments in technologies, inhalation device prototype construction and facilities expansion, including the completion of our manufacturing facility and start-up of commercial operations.

Given our current cash requirements, we believe that we will have sufficient cash to meet our operating expense requirements for at least the next 32 months. However, we plan to continue to invest heavily in our growth and the need for cash will be dependent upon the timing of these investments. Our capital needs will depend on many factors, including continued scientific progress in our research and development arrangements, potential acquisitions of technologies, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of developing and the rate of scale-up of our powder processing and packaging technologies, the timing and cost of our late stage clinical and early commercial production facility, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technologies and the status of competitive products. To satisfy our long-term needs, we intend to seek additional funding, as necessary, from corporate partners and from the sale of securities. There can be no assurance that additional funds, if and when required, will be available to us on favorable terms, if at all.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in short term securities and maintain an average maturity of one year or less. A hypothetical 50 basis point increase in interest rates would result in an approximate $0.6 million decrease (less than 0.126%) in the fair value of our available-for-sale securities.

The potential change noted above is based on sensitivity analyses performed on our financial position at December 31, 2000. Actual results may differ materially. The same hypothetical 50 basis point increase in interest rates would have resulted in an approximate $0.3 million decrease (less than 0.217%) in the fair value of our available-for-sale securities at December 31, 1999.

Increases in interest rates could adversely affect the fair market value of our convertible subordinated debentures, which pay a fixed rate of interest.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements for the years ended December 31, 2000, 1999 and 1998 are submitted as a separate section of this report. See Item 14.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not Applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

We incorporate by reference the information concerning our directors set forth under the heading "Election of Directors" in our definitive Proxy Statement to be filed for our 2001 Annual Meeting of Stockholders.

EXECUTIVE OFFICERS AND DIRECTORS.

The following table sets forth the names, ages and positions of the executive officers and directors as of December 31, 2000:

NAME	AGE	POSITION
Robert B. Chess	44	Chairman
Ajit S. Gill	52	Chief Executive Officer, President and Director
Brigid A. Makes	45	Vice President, Finance and Administration, Chief Financial Officer and Assistant Secretary
John S. Patton, Ph.D.	54	Vice President, Research and Director
James B. Glavin	65	Director
Melvin Perelman, Ph.D.	70	Director
Irwin Lerner	70	Director
Roy A. Whitfield	47	Director
Stephen L. Hurst	45	Vice President, General Counsel, Secretary

ROBERT B. CHESS has served as Chairman of the Board of Directors since April 1999. Mr. Chess served as Co-Chief Executive Officer from August 1998 to April 2000. Mr. Chess served as President from December 1991 to August 1998 and as Chief Executive Officer from May 1992 to September 1998.

Mr. Chess was elected a Director in May 1992. From September 1990 until October 1991, he was an Associate Deputy Director in the White House Office of Policy Development. In March 1987, Mr. Chess co-founded Penederm Incorporated, a topical dermatological drug delivery company, and served as its President until February 1989. He left Penederm in October 1989. Prior to co-founding Penederm, Mr. Chess held management positions at Intel Corp., a semiconductor manufacturer, and Metaphor, a computer software company (acquired by International Business Machines). Mr. Chess holds a BS in Engineering from the California Institute of Technology and an MBA from the Harvard Business School. Mr. Chess is a director of Pharsight Corp., a software company.

AJIT S. GILL has served as Chief Executive Officer since April 2000, as President since April 1999, and as a Director since April 1998. Mr. Gill served as Co-Chief Executive Officer from August 1998 to April 2000. Mr. Gill served as Chief Operating Officer from October 1996 to August 1998 and Chief Financial Officer from January 1993 until October 1996. Before joining Inhale, Mr. Gill was Vice President and General Manager of Kodak's Interactive Systems division. Mr. Gill has served as Chief Financial Officer for TRW-Fujitsu, Director of Business Development for Visicorp, and as start-up President for three high technology companies. He completed a BTech at the Indian Institute of Technology, an MS in Electrical Engineering from the University of Nebraska, and holds an MBA from the University of Western Ontario.

BRIGID A. MAKES has served as Vice President of Finance and Administration and Chief Financial Officer since June 1999. Ms. Makes has also served as Assistant Secretary since January 2001. From 1998 until joining Inhale, Ms. Makes served as Vice President, Chief Financial Officer and Treasurer for Oravax, Inc., a life sciences company. From 1992 to 1998, Ms. Makes served in various management positions for Haemonetics Corporation, a developer of automated blood processing systems, including, from 1995 to 1998, Vice President Finance, Chief Financial Officer and Treasurer. Prior to Haemonetics Corporation, Ms. Makes held a number of financial management positions a Lotus Development Corp. (now IBM) and General Electric Co. Ms. Makes holds a Bachelor of Commerce degree from McGill University in Finance and International Business and an MBA from Bentley College.

JOHN S. PATTON, PH.D., a co-founder of Inhale, has been Vice President, Research since December 1991 and a Director of since July 1990. He served as President of Inhale from its incorporation in July 1990 to December 1991. From 1985 to 1990, Dr. Patton was a Project Team Leader with Genentech, Inc., a biotechnology company, where he headed their non-invasive drug delivery activities. Dr. Patton was on the faculty of the Marine Science and Microbiology Departments at the University of Georgia from 1979 through 1985, where he was granted tenure in 1984. Dr. Patton received a BS in Zoology and Biochemistry from Pennsylvania State University, an MS from the University of Rhode Island, a Ph.D. in Biology from the University of California, San Diego and received post doctorate fellowships from Harvard Medical School and the University of Lund, Sweden both in biomedicine.

JAMES B. GLAVIN has been a Director since May 1993. Mr. Glavin is Chairman of the Board of The Immune Response Corporation, a biotechnology company. He was President and Chief Executive Officer of The Immune Response Corporation from 1987 until September 1994. From 1987 to 1990, Mr. Glavin served as Chairman of the Board of Smith Laboratories, Inc. and was President and Chief Executive Officer from 1985 to 1989. From 1985 to 1987, he was a partner in CH Ventures, a venture capital firm. From 1983 to 1985, he served as Chairman of the Board of Genetic Systems Corporation, a biotechnology firm, and as its President and Chief Executive Officer from 1981 to 1983. Mr. Glavin is a director of The Meridian Funds and Avenir Pharmaceuticals, Inc.

MELVIN PERELMAN, PH.D. has been a Director since January 1996. Dr. Perelman spent 36 years at Eli Lilly & Company, most recently as Executive Vice-President and President of Lilly Research Laboratories, a position which he held from 1986 until his retirement in 1993. Dr. Perelman served as President of Lilly International from 1976 until 1986. He was a member of the Board of Directors of Lilly from 1976 until

1993. Dr. Perelman is a member of the Board of Directors of Immusol, Inc. and of The Immune Response Corporation.

IRWIN LERNER has been a Director since April 1999. Mr. Lerner served as Chairman of the Board of Directors and of the Executive Committee of Hoffmann-La Roche Inc., a pharmaceutical and health care company, from January 1993 until his retirement in September 1993, and from 1980 through December 1992, also served as President and Chief Executive Officer. From September 1995 until present, Mr. Lerner has served on the Board of Medarex Inc., a monoclonal antibodies products company and became Chairman of the Board in May 1997. He has served for 12 years on the Board of the Pharmaceutical Manufacturers' Association where he chaired the Association's FDA Issues Committee. Mr. Lerner received a B.S. and an MBA from Rutgers University. He is currently Distinguished Executive-in-Residence at Rutgers University Graduate School of Management. Mr. Lerner is also a director of Public Service Enterprise Group Incorporated, a diversified public utility holding company, Humana Inc., a health care company, Covance, Inc., a contract drug development company, V.I. Technologies, Inc., a blood products company, and Axys Pharmaceuticals, Inc., a biotechnology company.

ROY A. WHITFIELD has been a Director since August 2000. Mr. Whitfield is a member of the Board of Directors of Incyte Genomics, Inc., a genomic information company which he co-founded in 1991, and from June 1993 to present, has served as Chief Executive Officer. He also served as President of Incyte from June 1991 until January 1997 and as Treasurer from April 1991 until October 1995. From 1984 to 1989, Mr. Whitfield held senior operating and business development positions with Technicon Instruments Corporation, a medical instrumentation company, and its predecessor company, Cooper Biomedical, Inc., a biotechnology and medical diagnostics company. Prior to his work at Technicon, Mr. Whitfield spent seven years with the Boston Consulting Group's international consulting practice. Mr. Whitfield received a BS in mathematics from Oxford University and an MBA from Stanford University. Mr. Whitfield also serves as a director of Aurora Biosciences Corp., a biotechnology company, and the Biotechnology Industry Organization (BIO).

STEPHEN L. HURST has been Vice President, General Counsel and Secretary since August 1998. Mr. Hurst served as Vice President, Intellectual Property and Licensing from March 1994 to August 1998. From July 1990 to February 1994, Mr. Hurst was in private law practice and consulted with COR Therapeutics, Inc., a biotechnology company, on intellectual property and business development issues. From November 1987 to June 1990, he was the Campus Patent Coordinator for the University of California, San Francisco. He also worked as an Associate Counsel at Townsend & Townsend, a San Francisco based law firm. He received a BS degree in Environmental Science from the University of California at Berkeley and his JD from Golden Gate University in San Francisco.

SCIENTIFIC ADVISORY GROUP

We have assembled scientific and development advisors that provide us with expertise in critical scientific, development, engineering, manufacturing and business issues facing Inhale. The scientific advisory group assists us on issues related to pulmonary delivery, pulmonary toxicology, aerosol science,

government regulation, product selection and clinical trial design. Our members are called upon individually as needed and include, among others:

NAME	AFFILIATION	AREA OF EXPERTISE
Joseph Brain, Ph.D.....	Professor, Chairman, Department of Environmental Health, Director, Physiology Program, Harvard School of Public Health	Pulmonary safety
Peter Byron, Ph.D.....	Professor of Pharmacy, Virginia Commonwealth University, Medical College of Virginia	Pharmaceutical aerosols
Carl Grunfeld, M.D.....	Professor of Medicine, University of California, San Francisco	Endocrinology
Michael Matthay, M.D.....	Professor of Medicine and Anesthesiology, University of California, San Francisco	Pulmonology
Gerald Smaldone, M.D.....	Professor of Medicine, State University of New York at Stony Brook	Aerosol medicine

REGULATORY AND DEVELOPMENT ADVISORY BOARD

In August 1999, we formed a regulatory affairs board to assist and advise us on matters relating to efficient and effective regulatory processing and to better assist us and our collaborative partners in obtaining regulatory approval for our products. The board currently includes the following:

NAME	AFFILIATION	AREA OF EXPERTISE
Carl C. Peck, M.D.....	Professor of Pharmacology and Medicine, Director, Center for Drug Development, Georgetown University Medical Center	Clinical and regulatory development strategy
David Savello, Ph.D.....	Executive Vice President and Chief Technology Officer, R.P. Scherer, Inc.	Pharmaceutical research and development and regulatory affairs
Phillip B. White.....	Director, Medical Device Consulting, AAC Consulting	Device regulatory affairs

ITEM 11. EXECUTIVE COMPENSATION

We incorporate by reference the information set forth under the heading "Executive Compensation" in our definitive Proxy Statement to be filed for our 2001 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

We incorporate by reference the information set forth under the heading "Security Ownership of Certain Beneficial Owners and Management" in our definitive Proxy Statement to be filed for our 2001 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

We incorporate by reference the information set forth under the heading "Certain Transactions" in our definitive Proxy Statement to be filed for our 2001 Annual Meeting for Stockholders.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a)(1) Consolidated Financial Statements

The Consolidated Financial Statements required by this item, with the report of independent auditors, are submitted in a separate section beginning on page F-1 of this report.

(2) Consolidated Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the Consolidated Financial Statements or notes thereto.

(3) Exhibits

The following exhibits are filed herewith or incorporated by reference:

EXHIBIT NUMBER		EXHIBIT INDEX
2.1	(1)	Agreement and Plan of Merger between Inhale Therapeutic Systems, a California corporation, and Inhale Therapeutic Systems (Delaware), Inc., a Delaware corporation.
2.2	(16)	Recommended Offer, dated December 21, 2000 by Cazenove & Co. on behalf of Inhale Therapeutic Systems, Inc. for Bradford Design plc.
3.1	(1)	Certificate of Incorporation of Inhale.
3.2	(1)	Bylaws of Inhale.
3.3	(14)	Certificate of Amendment of the Amended Certificate of Incorporation.
4.1		Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	(2)	Restated Investor Rights Agreement among Inhale and certain other persons named therein, dated April 29, 1993, as amended October 29, 1993.
4.3	(3)	Stock Purchase Agreement between Inhale and Pfizer Inc., dated January 18, 1995.
4.4	(9)	Form of Purchase Agreement between Inhale and the individual Purchasers, dated January 28, 1997.
4.5	(10)	Stock Purchase Agreement between Inhale and Capital Research and Management Company, dated December 8, 1998.
4.6	(12)	Purchase Agreement among Inhale and Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc. dated October 6, 1999.
4.7	(12)	Registration Rights Agreement among Inhale and Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc., dated October 13, 1999.
4.8	(12)	Indenture between Inhale as Issuer and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated October 13, 1999.
4.9	(12)	Form of Inhale Registration Rights Agreement, between Inhale and Selling Shareholder, dated January 25, 2000.
4.10	(13)	Purchase Agreement among Inhale and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated February 2, 2000.
4.11	(13)	Resale Registration Rights Agreement among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated February 8, 2000.
4.12	(13)	Indenture between Registrant as Issuer and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated February 8, 2000.
4.13	(14)	Specimen common stock certificate.
4.14	(15)	Specimen warrants to purchase shares of common stock.
4.15	(17)	Purchase Agreement among Inhale and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated October 11, 2000.

EXHIBIT NUMBER		EXHIBIT INDEX
4.16	(17)	Resale Registration Rights Agreement among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities, Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated October 17, 2000.
4.17	(17)	Indenture between Registrant, as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated October 17, 2000.
5.1	(18)	Opinion of Cooley Godward LLP.
10.1	(4)	Registrant's 1994 Equity Incentive Plan, as amended.
10.2	(7)	Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended.
10.3	(2)	Registrant's 1994 Employee Stock Purchase Plan, as amended.
10.4	(2)	Standard Industrial Lease between Inhale and W.F. Batton & Co., Inc., dated September 17, 1992, as amended September 18, 1992.
10.5	(2)	Addendum IV dated April 1, 1994 to Lease dated September 17, 1992, between Inhale and W.F. Batton and Marie A. Batton, dated September 17, 1992.
10.6	(6)	Amendment Agreement Number One, dated October 20, 1995, to Lease dated September 17, 1992, between Inhale and W.F. Batton & Co., Inc.
10.7	(6)	Amendment Agreement Number Two, dated November 15, 1995, to Lease, dated September 17, 1992, between Registrant and W.F. Batton and Marie A. Batton, Trustees of the W.F. Batton and Marie A. Batton Trust UTA dated January 12, 1998 ("Batton Trust").
10.8	(11)	Amendment Agreement Number Three, dated February 14, 1996, to Lease, dated September 17, 1992, between Registrant and Batton Trust.
10.9	(11)	Amendment Agreement Number Four, dated September 15, 1996, to Lease, dated September 17, 1992, between Registrant and Batton Trust.
10.10	(2)	Sublicense Agreement between Inhale and John S. Patton, dated September 13, 1991.
10.11	(5)	Stock Purchase Agreement between Inhale and Baxter World Trade Corporation, dated March 1, 1996.
10.12	(8)	Sublease and Lease Agreement, dated October 2, 1996, between Inhale and T.M.T. Associates L.L.C. ("Landlord").
10.13	(11)	First Amendment, dated October 30, 1996, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
10.14	(11)	Letter Agreement, dated April 9, 1997, amending Sublease and Lease Agreement, dated October 2, 1996, between Inhale and Landlord.
10.15	(11)	Third Amendment, dated April 16, 1997, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
10.16	(11)	Fourth Amendment, dated November 5, 1997, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
10.17	(13)	Sublease by and between Webvan Group, Inc., as sublessor and Registrant, as sublessee, dated November 3, 1999.
10.18	(15)	Registrant's 2000 Equity Incentive Plan
10.19	(15)	Registrant's Stock Option Agreement issued in accordance with Inhale's 2000 Equity Incentive Plan.
10.20	(15)	Agreement for the Contribution of 201 Industrial Road Project made and entered into as of September 14, 2000 by and among Inhale, Inhale 201 Industrial Road, L.P., a California limited partnership and Bernardo Property Advisors, Inc., a California corporation.

EXHIBIT NUMBER		EXHIBIT INDEX
10.21	(15)	Agreement of Limited Partnership of Inhale 201 Industrial Road., L.P., a California limited partnership made and entered into September 14, 2000, by and among SCIMED PROP III, Inc., a California corporation, as general partner, 201 Industrial Partnership, a California general partnership, as limited partner, and Inhale, as limited partner.
10.22	(15)	Build-To-Suit Lease made and entered into as of September 14, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
10.23	(15)	Amendment to Lease dated October 3, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
10.24	(15)	Parking Lease Agreement entered into as of September 14, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
10.25	(18)	Registrant's 2000 Non-Officer Equity Incentive Plan
10.26	(18)	Registrant's Stock Option Agreement issued in accordance with Inhale's 2000 Non-Officer Equity Incentive Plan
10.27	(19)	Manufacturing and Supply Agreement among Inhale, Tech Group North America, Bespak Europe, LTD.
23.1	(19)	Consent of Ernst & Young LLP, independent auditors.
24.1	(19)	Power of Attorney. Reference is made to Signature Page.

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(1) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.

(2) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-1 (No. 33-75942), as amended.

(3) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-1 (No. 33-89502), as amended.

(4) Incorporated by reference to Inhale's Registration Statement on Form S-8 (No. 333-59735).

(5) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.

(6) Incorporated by reference to the indicated exhibit in Inhale's Annual Report on Form 10-K for the year ended December 31, 1995.

(7) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.

(8) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.

(9) Incorporated by reference to Inhale's Registration Statement on Form S-3 (No. 333-20787).

(10) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-3 (No. 333-68897), as amended.

(11) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.

(12) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-3 (No. 333-94161), as amended.

(13) Incorporated by reference to the indicated exhibit in Inhale's Annual Report on Form 10-K for the year ended December 31, 1999.

(14) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.

(15) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000.

(16) Incorporated by reference to the indicated exhibit in Inhale's Current Report on Form 8-K, filed on January 11, 2001.

(17) Incorporated by reference to Inhale's Registration Statement on Form S-3 (No. 333-53678), filed on January 12, 2001.

(18) Incorporated by reference to Inhale's Registration Statement on Form S-8 (No. 333-54078), filed on January 19, 2001.

(19) Filed herewith.

(b) Reports on Form 8-K.

The following Reports on Form 8-K were filed during the quarter ended December 31, 2000:

(i) A Report on Form 8-K dated December 21, 2000 pertaining to Inhale's offer to acquire all of the outstanding share capital of Bradford Particle Design, plc, a United Kingdom company.

(ii) A Report on Form 8-K dated October 27, 2000 pertaining to the initial purchasers' exercise of their $30 million over-allotment option granted pursuant to a purchase agreement dated October 11, 2000 with respect to Inhale's 3.5% convertible subordinated notes due 2007.

(iii) A Report on Form 8-K dated October 12, 2000 pertaining to Inhale's entering into a purchase agreement providing for the sale to certain initial purchasers of $200 million aggregate principal amount of convertible subordinated notes ($250 million if the over-allotment option exercised in full.)

(iv) A Report on Form 8-K dated October 9, 2000 pertaining to Inhale's intention to issue $150 million aggregate principal amount of convertible subordinated notes ($172.5 million if an over-allotment option is exercised in full).

(v) A Report on Form 8-K dated October 6, 2000 pertaining to Inhale's entering into a build-to-suit lease transaction.

(c) See Exhibits listed under Item 14(a)(3).

(d) Not applicable. See Item 14(a)(2).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Registrant has duly caused this report to be signed on our behalf by the undersigned, thereunto duly authorized, on the 1st day of March 2001.

INHALE THERAPEUTIC SYSTEMS, INC.

By: /s/ AJIT S. GILL

Ajit S. Gill
CHIEF EXECUTIVE OFFICER,
PRESIDENT AND DIRECTOR

/s/ BRIGID A. MAKES

Brigid A. Makes
VICE PRESIDENT, FINANCE AND
ADMINISTRATION,
CHIEF FINANCIAL OFFICER AND ASSISTANT
SECRETARY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, Ajit S. Gill as his attorney-in-fact for him in any and all capacities, to sign any and all amendments to this report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that the said attorney-in-fact, or his substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, 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	TITLE	DATE
/s/ ROBERT B. CHESS Robert B. Chess	Chairman	March 1st, 2001
/s/ AJIT S. GILL Ajit S. Gill	Chief Executive Officer, President and Director (PRINCIPAL EXECUTIVE OFFICER)	March 1st, 2001
/s/ BRIGID A. MAKES Brigid A. Makes	Vice President, Finance and Administration, Chief Financial Officer and Assistant Secretary (PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER	March 1st, 2001
/s/ JOHN S. PATTON John S. Patton	Vice President, Research and Director	March 1st, 2001
/s/ JAMES B. GLAVIN James B. Glavin	Director	March 1st, 2001
/s/ MELVIN PERELMAN Melvin Perelman	Director	March 1st, 2001
/s/ IRWIN LERNER Irwin Lerner	Director	March 1st, 2001
/s/ ROY A. WHITFIELD Roy A. Whitfield	Director	March 1st, 2001

INHALE THERAPEUTIC SYSTEMS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders
Inhale Therapeutic Systems, Inc.

We have audited the accompanying consolidated balance sheets of Inhale Therapeutic Systems, Inc. as of December 31, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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 provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inhale Therapeutic Systems, Inc. at December 31, 2000 and 1999, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2000 in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
January 23, 2001

INHALE THERAPEUTIC SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)

	DECEMBER 31,	
	2000	1999
ASSETS		
Current assets:		
Cash and cash equivalents	$136,012	$ 33,430
Short-term investments	348,829	104,755
Accounts receivable	7,234	1,756
Other current assets	968	7,377
Total current assets	493,043	147,318
Property and equipment, net	110,457	63,852
Marketable equity securities	9,140	6,328
Other assets	16,900	9,308
	$629,540	$226,806
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,501	$ 13,374
Accrued liabilities	12,861	5,244
Interest payable	4,910	1,605
Deferred revenue	4,913	4,811
Capital lease obligation--current portion	977	--
Tenant improvement loan--current portion	41	45
Total current liabilities	30,203	25,079
Capital lease obligation	15,269	--
Tenant improvement loan	4,849	4,895
Convertible subordinated debentures and notes	299,149	108,450
Other long-term liabilities	2,187	1,753
Commitments		
Stockholders' equity:		
Preferred stock, 10,000 shares authorized, no shares issued or outstanding	--	--
Common stock, $0.0001 par value; 300,000 shares authorized; 47,374 shares and 34,452 shares issued and outstanding at December 31, 2000 and 1999, respectively	5	3
Capital in excess of par value	465,593	181,153
Deferred compensation	(1,827)	(1,530)
Accumulated other comprehensive gain	5,981	1,469
Accumulated deficit	(191,869)	(94,466)
Total stockholders' equity	277,883	86,629
	$629,540	$226,806

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
Contract research revenue	$ 51,629	$ 41,358	$ 21,795
Operating costs and expenses:			
Research and development	101,544	64,083	35,398
General and administrative	13,932	7,869	8,387
Acquired in-process research and development	2,292	9,890	--
Total operating costs and expenses	117,768	81,842	43,785
Loss from operations	(66,139)	(40,484)	(21,990)
Other income	995	--	--
Debt conversion premium, net	(40,687)	--	--
Interest income	20,566	4,111	3,904
Interest expense	(12,138)	(2,075)	(270)
Net loss	$(97,403)	$(38,448)	$(18,356)
Basic and diluted net loss per share	$ (2.32)	$ (1.13)	$ (0.58)
Shares used in computing basic and diluted net loss per share	41,998	34,016	31,438

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(IN THOUSANDS)

	COMMON STOCK		CAPITAL IN EXCESS OF	DEFERRED	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	PAR VALUE	PAR VALUE	COMPENSATION	GAIN	DEFICIT	EQUITY
Balance at December 31, 1997	31,084	$3	$135,270	$(538)	$20	$(37,662)	$97,093
Issuance of common stock in private placement, net of issuance costs of $1,997	2,400	--	35,202	--	--	--	35,202
Issuance of common stock and stock options in connection with licensing agreement	12	--	284	--	--	--	284
Common stock issued upon exercise of stock options	352	--	1,514	--	--	--	1,514
Deferred compensation	--	--	576	(576)	--	--	--
Amortization of deferred compensation	--	--	--	183	--	--	183
Unrealized loss on available-for-sale securities	--	--	--	--	(39)	--	(39)
Net loss	--	--	--	--	--	(18,356)	(18,356)
Comprehensive loss	--	--	--	--	--	--	(18,395)
Balance at December 31, 1998	33,848	3	172,846	(931)	(19)	(56,018)	115,881
Issuance of common stock for technology acquisition	360	--	5,000	--	--	--	5,000
Common stock issued upon exercise of stock options, net of costs	244	--	1,545	--	--	--	1,545
Compensation in connection with stock options granted to consultants	--	--	798	--	--	--	798
Deferred compensation	--	--	964	(964)	--	--	--
Amortization of deferred compensation	--	--	--	365	--	--	365
Unrealized gain on available-for-sale securities	--	--	--	--	1,488	--	1,488
Net loss	--	--	--	--	--	(38,448)	(38,448)
Comprehensive loss	--	--	--	--	--	--	(36,960)
Balance at December 31, 1999	34,452	3	181,153	(1,530)	1,469	(94,466)	86,629
Common stock issued upon exercise of stock options, net of costs	2,177	2	17,320	--	--	--	17,322
Compensation in connection with stock granted to employees	57	--	1,900	--	--	--	1,900
Compensation in connection with stock options granted to consultants		--	3,196	--	--	--	3,196
Conversion of convertible subordinated debt into common shares, net of costs	10,688	--	260,862	--	--	--	260,862
Deferred compensation	--	--	1,162	(1,162)			--
Amortization of deferred compensation	--	--	--	865	--	--	865
Unrealized gain on available-for-sale securities	--	--	--	--	4,512	--	4,512
Net loss	--	--	--	--	--	(97,403)	(97,403)
Comprehensive loss	--	--	--	--	--	--	(92,891)
Balance at December 31, 2000	47,374	$5	$465,593	$(1,827)	$5,981	$(191,869)	$277,883

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS
(IN THOUSANDS)

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (97,403)	$ (38,448)	$ (18,356)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	9,259	6,828	3,415
Amortization of deferred compensation	865	365	183
Gain on sale of assets	(159)	61	--
Issuance of common stock for services	5,096	798	--
Issuance of common stock and stock options in connection with licensing agreements	--	--	284
Debt conversion premium, net	40,687	--	--
Acquired in-process research and development	2,292	9,890	--
Changes in assets and liabilities:			
Decrease in accounts receivable, other current assets, and other assets	(964)	(8,004)	(876)
Increase (decrease) in accounts payable and accrued liabilities	4,483	12,724	(1,546)
Increase (decrease) in deferred revenue	102	452	(2,327)
Net cash used in provided by operating activities	(35,742)	(15,334)	(19,223)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Acquisition of technology	(2,292)	(15,288)	--
Purchases of short-term investments	(462,278)	(122,481)	(219,414)
Sales of short-term investments	13,643	28,658	65,189
Maturities of short-term investments	206,261	47,174	182,309
Purchases of property and equipment, net	(53,850)	(20,502)	(34,584)
Other investing activities, net	(1,232)	--	--
Net cash used in investing activities	(299,748)	(82,439)	(6,500)
CASH FLOWS FROM FINANCING ACTIVITIES			
Issuance of convertible subordinated debentures and notes, net	445,241	104,806	--
Payments of loan and capital lease obligations	(50)	(64)	(181)
Proceeds from capital lease financing	16,246	--	--
Payments of debt conversion premium, net	(40,687)	--	--
Issuance of common stock, net of issuance costs	17,322	1,545	36,716
Net cash provided by financing activities	438,072	106,287	36,535
Net increase in cash and cash equivalents	102,582	8,514	10,812
Cash and cash equivalents at beginning of year	33,430	24,916	14,104
Cash and cash equivalents at end of year	$ 136,012	$ 33,430	$ 24,916

See accompanying notes

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION AND BASIS OF PRESENTATION

Inhale Therapeutic Systems, Inc. was incorporated in the State of California in July 1990 and reincorporated in the State of Delaware in July 1998. Inhale's mission is to be the pre-eminent supplier of drug delivery solutions. During 2000, we created two wholly-owned subsidiaries: Inhale Therapeutic Systems Deutschland GmbH, incorporated in the Federal Republic of Germany; and Inhale Therapeutic Systems UK Limited, incorporated in the United Kingdom and consolidated the financial statements of a special purpose entity lessor. Since inception, we have been engaged in the development of systems for the pulmonary delivery of macromolecule drug therapies for systemic and local lung applications.

Our Board of Directors approved a two-for-one split which was effected as a 100% common stock dividend on August 22, 2000 for stockholders of record as of August 1, 2000. The stockholders also increased the number of authorized shares of common stock to 300 million at the 2000 Annual Meeting of the stockholders. All share and per share amounts in these consolidated financial statements have been retroactively restated to reflect the split.

We expect increasing losses over the next several years as research and development and manufacturing scale-up efforts continue, and as we expand our facilities for manufacturing operations. We plan to continue to finance ourselves primarily through issuances of equity or debt securities, research and development contract revenue, and in the longer term, revenue from product sales and royalties.

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 and disclosure of contingent 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.

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements of Inhale Therapeutic Systems, Inc. include the accounts of the Company, its wholly owned subsidiaries and the financial statements of a special purpose entity described in Note 6. All significant intercompany balances and transactions have been eliminated.

CASH, CASH EQUIVALENTS AND INVESTMENTS

We consider all highly liquid investments with a maturity from date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include demand deposits held in banks and interest bearing money market funds. All other liquid investments are classified as short-term investments. Short-term investments consist of federal and municipal government securities, repurchase agreements or corporate commercial paper with A1 or P1 short-term ratings and A+ or better long-term ratings with remaining maturities at date of purchase of greater than 90 days and less than one year. We limit our concentration of risk by diversifying our investments among a variety of industries and issuers. Our professional portfolio managers adhere to this investment policy as approved by our Board of Directors. We have experienced no material losses on our investments.

At December 31, 2000, all short-term investments are designated as available-for-sale and are carried at fair value, with material unrealized gains and losses, if any, reported in stockholders' equity. The amortized cost of securities is adjusted for amortization of material premiums and accretion of discounts to maturity. Such amortization, if any, is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

The following is a summary of operating cash and available-for-sale securities as of December 31, 2000:

	COST	NET UNREALIZED GAINS	ESTIMATED FAIR VALUE
		(IN THOUSANDS)	
Obligations of U.S. government agencies	$299,604	$1,013	$300,617
U.S. corporate commercial paper	147,482	496	147,978
Repurchase agreements, secured by U.S. Government securities	11,261	--	11,261
Cash and other debt securities	24,984	1	24,985
Equity securities	4,669	4,471	9,140
	$488,000	$5,981	$493,981
Amounts included in cash and cash equivalents	$135,873	$ 139	$136,012
Amounts included in short-term investments	347,458	1,371	348,829
Amounts included in marketable equity securities	4,669	4,471	9,140
	$488,000	$5,981	$493,981

The following is a summary of operating cash and available-for-sale securities as of December 31, 1999:

	COST	NET UNREALIZED GAINS	ESTIMATED FAIR VALUE
		(IN THOUSANDS)	
Obligations of U.S. government agencies	$ 81,692	$ 108	$ 81,800
U.S. corporate commercial paper	41,081	33	41,114
Repurchase agreements, secured by U.S. Government securities	3,845	--	3,845
Cash and other debt securities	11,426	--	11,426
Equity securities	5,000	1,325	6,328
	$143,044	$1,466	$144,513
Amounts included in cash and cash equivalents	$ 35,376	$ 54	$ 33,430
Amounts included in short-term investments	104,668	87	104,755
Amounts included in marketable equity securities	5,000	1,325	6,328
	$143,044	$1,466	$144,513

We have determined the estimated fair value amounts by using available market information. The gross realized losses and gains on the sale of available-for-sale debt securities during the years ended

December 31, 2000 and 1999 were not material. At December 31, 2000 and 1999, the average portfolio duration was approximately six months and five months, respectively, and the contractual maturity of any single investment did not exceed eighteen months at December 31, 2000 (eleven months at December 31, 1999).

We own common stock in Alliance Pharmaceutical Corp. and we account for this equity investment as an available-for-sale long-term marketable security. In 1999, due to restrictions on the sale of this stock, we carried that portion of our investment in Alliance that could be sold within one year at market value, with material unrealized gains and losses, if any, reported in stockholders' equity; that portion which could not be sold within one year was carried at cost. As there were no restrictions on the sale of Alliance stock at December 31, 2000, all shares held at that date were reported at market value with unrealized gains and losses reported in stockholders' equity.

PROPERTY AND EQUIPMENT

Property and equipment consist of the following at December 31:

	2000	1999
	(IN THOUSANDS)	
Laboratory and other equipment	$ 34,553	$18,280
Building and leasehold improvements	55,476	35,458
Land	7,422	7,422
Construction in progress	34,732	17,701
Property and equipment at cost	132,183	78,861
Less accumulated amortization and depreciation	(21,726)	(15,009)
Property and equipment, net	$110,457	$63,852

Property and equipment are stated at cost. Major improvements are capitalized, while maintenance and repairs are expensed when incurred. Laboratory and other equipment is depreciated using the straight-line method over estimated useful lives of three to seven years. Leasehold improvements and building subject to build-to-suit lease are amortized using the straight-line method over the shorter of an estimated useful life of fifteen years or the term of the lease.

At December 31, 2000, Building and leasehold improvements included $14.9 million related to a build-to-suit lease with a special purpose entity (See Note 6). Accumulated amortization of the building under lease was approximately $0.1 million in the year ending December 31, 2000.

GOODWILL AND OTHER INTANGIBLE ASSETS

Intangible assets are included in other assets in the balance sheet and consisted of the following at December 31:

	2000	1999	REMAINING LIFE
	(IN THOUSANDS)		(MONTHS)
Goodwill	$2,238	$2,030	70
Intellectual property	3,544	3,171	70
	5,782	5,201	
Less accumulated amortization	(813)	(48)	
	$4,969	$5,153	

Goodwill and other intangible assets arise from an acquisition accounted for under the purchase method (See Note 3) and are amortized on the straight-line basis over an estimated 7-year useful life of the assets. We periodically evaluate whether changes have occurred that would require revision of the remaining estimated useful life of these assets or otherwise render the assets unrecoverable. If such an event occurred, we would determine whether the goodwill or intangibles are impaired. To date, no impairment losses have been recorded.

COMPREHENSIVE GAIN/LOSS

Comprehensive gain/loss includes only unrealized gains and losses on securities held as available-for-sale and is shown in the Statement of Stockholders' Equity. We have no other material components of other comprehensive gain/loss and accordingly the comprehensive loss is the same as net loss for all periods.

REVENUE RECOGNITION

Contract revenue from collaborative research agreements is recorded when earned based on the performance requirements of the contract. Revenue from non-refundable upfront license fees and certain guaranteed payments where we continue involvement through collaborative development are deferred and recognized as revenue over the period of continued involvement. Revenue from grants and feasibility arrangements are recognized as the related costs are incurred. Our research revenue is derived primarily from clients in the pharmaceutical industry. Contract research revenue from three partners represented 69%, 13% and 9% of our revenue in 2000. Three partners accounted for 71%, 10% and 9% of our revenue in 1999 and 51%, 22% and 18% of our revenue in 1998. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

STOCK-BASED COMPENSATION

As permitted by the provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123"), we continue to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations in accounting for our employee stock option plans. Under APB 25, if the exercise price of our employee stock options equals or exceeds the fair market value of the underlying stock on the date of grant as determined by the

closing price of our common stock as quoted on the Nasdaq stock market, no compensation expense is recognized. See Note 7 for pro forma disclosures required by FAS 123.

RESEARCH AND DEVELOPMENT AGREEMENTS

We perform research and development for others pursuant to feasibility agreements and development and license agreements. Under the feasibility agreements, we are generally reimbursed for the cost of work performed. Feasibility agreements are designed to evaluate the applicability of our technologies to a particular molecule and therefore are generally completed in less than one year. Under our development and license agreements, the partner companies generally receive an exclusive license to develop, use and sell a dry powder formulation and a suitable delivery device to be developed by us for one of the partner's macromolecule drugs. Under these development agreements, we will be reimbursed for development costs and may also be entitled to milestone payments when and if certain development milestones are achieved. All of our research and development agreements are generally cancelable by the partner without significant financial penalty to the partner.

ACCOUNTING FOR INCOME TAXES

We account for income taxes under Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("FAS 109"). Under FAS 109, the liability method is used in accounting for income taxes.

NET LOSS PER SHARE

In accordance with Financial Accounting Standard No. 128, basic and diluted net loss per share has been computed using the weighted average number of shares of common stock outstanding during the period, less shares subject to repurchase. Had we been in a net income position, diluted earnings per share would have included the following outstanding options, warrants and convertible debentures:

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
	(IN THOUSANDS)		
Warrants	56	40	40
Options	10,064	9,106	6,326
Convertible debentures and notes	6,644	6,776	--
	16,764	15,922	6,366

RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board issued Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities," which is required to be adopted in years beginning after June 15, 2000. Because our use of derivatives is minimal, management does not anticipate that the adoption of the new Statement will have a significant effect on earnings or the financial position of the Company.

RECLASSIFICATION

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

NOTE 2--COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

We perform research and development for others pursuant to feasibility agreements and development and license agreements. Under the feasibility agreements, we are generally reimbursed for the cost of work performed. Feasibility agreements are designed to evaluate the applicability of our technologies to a particular molecule and therefore are generally completed in less than one year. Under our development and license agreements, the partner companies receive an exclusive license to develop, use and sell a dry powder formulation and a suitable delivery device to be developed by us for one of the partner's macromolecule drugs. Under these development agreements, we will be reimbursed for development costs and may also be entitled to milestone payments when and if certain development milestones are achieved. All of our research and development agreements are generally cancelable by the partner without significant financial penalty to the partner.

In February 1999, we entered into a collaborative agreement with Biogen Inc. ("Biogen") to develop pulmonary delivery for Biogen's AVONEX-Registered Trademark-, a drug used in the treatment of Multiple Sclerosis. Under the terms of the agreement, we will receive royalties on product sales, an up-front signing fee, and up to an estimated $25.0 million in research and development funding and potential progress payments. Biogen will provide bulk AVONEX-Registered Trademark- to us for formulation into a dry powder which is stable at room temperature. We will manufacture and package the dry powder and supply inhalation devices. Biogen will be responsible for clinical trials, marketing and commercialization. We recognized revenue of $4.7 million under this agreement in 2000 ($2.2 million in 1999).

In December 1997, we entered into a collaboration agreement with Eli Lilly and Company to develop pulmonary delivery for an undisclosed protein based on our deep-lung drug delivery system for macromolecules. Under this agreement we recognized revenue of $3.1 million, $1.2 million and $0.9 million in 2000, 1999 and 1998, respectively. In September 2000, Lilly announced that it had decided to discontinue development of this therapeutic product, which is currently in preclinical. As a result we are free to develop the product further independently or in collaboration with another partner.

In January 1997, we entered into a collaborative agreement with Lilly to develop an inhalable formulation of Forteo-TM-, a version of parathyroid hormone, PTH 1-34, used in the treatment of osteoporosis. Under the terms of the agreement, we will receive funding of up to $20.0 million of initial fees, research and development and progress payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products while we receive royalties on any marketed products. We will manufacture packaged powders for and supply devices to Lilly. Under this agreement, we recognized revenue of $3.8 million in 1998. In late 1998, unexpected observations from a long-term test in rats of the injectable version of parathyroid hormone led Lilly to suspend further clinical development of the injectable and pulmonary versions of Forteo-TM- pending further analysis. In September 2000, we announced the reinitiation of the Forteo-TM- development program with Lilly.

In December 1996, we entered into a collaborative agreement with Aventis Behring L.L.C.to develop a pulmonary formulation of alpha-1 proteinase inhibitor to treat patients with alpha-1 antitrypsin deficiency, or genetic emphysema. Under the terms of the collaboration, Aventis Behring will receive commercialization rights worldwide excluding Japan and we will receive royalties on product sales, an up-front signing fee and up to an estimated $15.0 million in research and development funding and milestone payments. Aventis Behring will manufacture the active ingredient for use in our delivery device. We will manufacture and package the dry powder and supply inhalation devices to Aventis Behring for commercialization and marketing. Under this agreement, we recognized revenue of $6.8 million, $3.9 million and $1.6 million in 2000, 1999 and 1998, respectively.

In March 1996, we entered into a collaboration agreement with Baxter Healthcare Corporation to use our dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In connection with the collaboration, Baxter made a $20.0 million equity investment in Inhale at a 25% premium to the market price of Inhale stock at the time of the investment. Baxter received worldwide commercialization rights in exchange for up to an estimated $60 million in research and development funding and milestone payments for four molecules. In October 1998, we announced that we had reached an agreement with Baxter to amend our collaborative agreement to facilitate signing a new corporate partner to fund further development and commercialization of the undisclosed compound that had been the focus since April, 1998. Baxter's obligations under this amendment expired in September, 1999. As a result, rights to the compounds reverted to us and are now available for other partnering opportunities. We recognized revenue associated with this program of $4.3 million and $4.0 million in 1999 and 1998, respectively.

In January 1995, we entered into a collaborative development and license agreement with Pfizer Inc. ("Pfizer") to develop pulmonary delivery for inhaled insulin based on our deep-lung delivery system for macromolecules. Under the terms of the agreement, we will receive funding consisting of initial fees, research and development and progress payments. Upon execution of the agreement Pfizer purchased $5.0 million of Inhale common stock. In addition, in October 1996, Pfizer purchased an additional $5.0 million of Inhale common stock. Pfizer will receive global commercialization rights for the pulmonary delivery of the products while we receive royalties on any marketed products. We will manufacture inhaled insulin for, and supply devices to Pfizer. Under this agreement we recognized revenue of $35.7 million, $29.5 million and $11.1 million in 2000, 1999 and 1998, respectively.

Costs associated with research and development activities attributable to these agreements are expected to approximate the revenues recognized.

NOTE 3--TECHNOLOGY ACQUISITIONS

PULMOSPHERE-TM- TECHNOLOGY

In November 1999, we concluded an agreement with Alliance Pharmaceutical Corp. to acquire Alliance's PulmoSphere-TM- particle and particle processing technology for use in respiratory drug delivery. Under the terms of the agreement, we received the rights to PulmoSphere-TM- technology, other related assets and Alliance stock valued at $5.0 million in exchange for $15.0 million in cash and $5.0 million of Inhale stock. The purchase price, including $0.4 million of acquisition costs, has been allocated to assets acquired and to in-process research and development, which has been charged as an expense on the Statement of Operations for the year ended December 31, 1999. The Company's investment in Alliance

and the assets acquired in connection with the PulmoSphere-TM- acquisition are recorded at their fair market value at acquisition as follows:

Property and equipment, net	$ 200
Acquired in-process research and development charged to operations in 1999	9,890
Intellectual property, net	3,171
Assembled workforce	96
Goodwill	2,030
Total cash purchase consideration	15,387
Common stock of Alliance	5,000
Total purchase consideration	$20,387

Goodwill and other intangible assets are being amortized over seven years.

The purchased research and development was identified and valued through extensive interviews and discussions with appropriate management and scientific personnel and the analysis of data provided by Alliance regarding the PulmoSphere-TM- technology, its stage of development at the time of acquisition, the importance of the technology to our overall development plan, and the projected incremental cash flows from the projects when completed and any associated risks. Associated risks include the uncertainties in overcoming significant technological risks, acquiring FDA approval and establishing commercial viability.

OTHER PURCHASED TECHNOLOGY

In April 2000, the Company recorded a $2.3 million charge for acquired in-process research and development ("IPR&D") costs. The acquisition was recorded as a purchase and a portion of the purchase price was allocated to IPR&D, which was immediately expensed. At the date of the acquisition, the in-process technology had no alternative future use and did not qualify for capitalization.

NOTE 4--OTHER ASSETS

Other Assets consist of the following at December 31:

	2000	1999
	(IN THOUSANDS)	
Debt issuance costs, net	$ 8,579	$ 3,514
Intellectual property, net	3,091	3,172
Goodwill, net	1,878	1,982
Deposits and other assets	3,352	640
Total other assets	$16,900	$ 9,308

Debt issuance costs are associated with our outstanding series of convertible subordinated notes and debentures (See Note 5) and are amortized over the term of the related debt. Intellectual property and goodwill arise from an acquisition accounted for under the purchase method (See Note 3) and are amortized on the straight-line basis over the estimated useful life of the assets. Deposits and other assets at December 31, 2000 included $1.9 million in long-term receivables ($0.5 million in 1999) and $1.5 million in other assets.

NOTE 5--CONVERTIBLE SUBORDINATED DEBENTURES & NOTES

In October 2000, we received approximately $222.7 million in net proceeds from the issuance of $230.0 million aggregate principal amount of convertible subordinated notes to certain qualified institutional buyers pursuant to an exemption under the Securities Act of 1933, as amended. Interest on the notes accrues at a rate of 3.5% per year, subject to adjustment in certain circumstances. The notes will mature in 2007 and are convertible into shares of our common stock at a conversion price of $50.46 per share, subject to adjustment under certain circumstances. The notes are redeemable in part or in total at any time before October 17, 2003 at $1,000 per $1,000 principal amount plus a provisional redemption exchange premium, payable in cash or shares of common stock, of $105.00 per $1,000 principal amount, plus accrued and unpaid interest, if any, to the redemption date, if the closing price of our common stock has exceeded 150% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days. The notes are also redeemable in part or in total at any time after October 17, 2003 at certain redemption prices dependent upon the date of redemption if the closing price of our common stock has exceeded 120% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days. Interest is payable semi-annually on April 17 and October 17. The notes are unsecured obligations, which rank junior in right of payment to all of our existing and future senior debt.

Also, in October 2000, we entered into privately negotiated agreements with certain holders of our outstanding 5.0% convertible subordinated notes due 2007 and sold in February 2000 providing for the conversion of our notes into common stock in exchange for a cash payment. To date, we have secured agreements that provide for the conversion of $168.6 million aggregate principal amount of these outstanding 5.0% convertible subordinated notes into approximately 4.4 million shares of common stock for cash payments of approximately $25.5 million. Approximately $61.4 million of these 5.0% convertible subordinated notes remain outstanding at December 31, 2000.

In February 2000, we received approximately $222.4 million in net proceeds from the issuance of $230.0 million aggregate principal amount of convertible subordinated notes to certain qualified institutional buyers pursuant to an exemption under Rule 144A of the Securities Act of 1933, as amended. Interest on the notes accrues at a rate of 5.0% per year, subject to adjustment in certain circumstances. The notes will mature in 2007 and are convertible into shares of our common stock at a conversion price of $38.355 per share, subject to adjustment in certain circumstances. The notes are redeemable in part or in total at any time before February 8, 2003 at an exchange premium of $137.93 per $1000 principal amount, less any interest actually paid on the notes before the call for redemption, if the closing price of our common stock has exceeded 150% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days. We can redeem some or all of the notes at any time after February 8, 2003. Interest is payable semi-annually on August 8 and February 8. The notes are unsecured subordinated obligations which rank junior in right of payment to all of our existing and future Senior Debt.

Also in February 2000, we entered into privately negotiated agreements with certain holders of our outstanding 6 3/4% convertible subordinated debentures sold in October and November 1999, providing for the conversion of approximately $100.7 million aggregate principal amount of the outstanding debentures into approximately 6.3 million shares of common stock for net payments of approximately $15.2 million. Approximately $7.8 million of these 6 3/4% convertible subordinated debentures remain on the books at December 31, 2000. These debentures will mature in 2007 and are convertible into shares of our common stock at a conversion price of $16.01 per share, subject to adjustment in certain circumstances. The debentures are redeemable in part or in total at our option on or after October 13, 2002. Interest is payable semi-annually on April 13 and October 13. The debentures are unsecured subordinated obligations which rank junior in right of payment to all of our existing and future Senior Debt.

Costs relating to the issuances of these notes and debentures are recorded as long-term assets and are amortized over the term of the debt. As of December 31, 2000, we had approximately $299 million in outstanding convertible subordinated debentures with a fair market value of approximately $338 million. The fair market was valued through quoted market prices.

NOTE 6--COMMITMENTS, LONG-TERM DEBT AND TENANT IMPROVEMENT LOAN

FACILITIES LEASE & FINANCING

We lease our office and laboratory facilities under several arrangements expiring through the year 2012. Rent expense was approximately $3.1 million, $2.5 million and $1.8 million for the years ended December 31, 2000, 1999 and 1998, respectively.

In November 1997, we received from the landlord of our facility in San Carlos, California a loan of $5.0 million to fund a portion of the cost of improvements made to the facility. The loan bears interest at 9.46% per annum, and principal and interest payments are payable monthly over the ten-year loan term with a balloon payment of $4.5 million due November 2007. The loan is classified on the balance sheet as a tenant improvement loan.

Future noncancelable commitments under operating leases and the tenant improvement loan at December 31, 2000 are as follows:

	OPERATING LEASES	TENANT IMPROVEMENT LOAN
	(IN THOUSANDS)	
Years ending December 31,		
2001	$ 2,000	$ 503
2002	2,492	503
2003	2,336	503
2004	2,273	503
2005	2,342	503
2006 and thereafter	16,879	5,467
Total minimum payments required	$28,322	$ 7,981
Less amount representing interest		(3,091)
Present value of future payments		4,890
Less current portion		(41)
Non-current portion		$ 4,849

BUILD-TO-SUIT LEASE

In October 2000, we entered into a build-to-suit lease transaction with a special purpose entity to finance and manage construction of a San Carlos research and office facility. We contributed land and existing construction in progress to the special purpose entity and leased to property back for a period of 16 years. In addition, all costs related to the construction paid by us prior to the October transaction were reimbursed to us, and are recorded as a component of our capital lease financing obligations. Due to our continuing involvement in the special purpose entity and other provisions of the agreement, the special purpose entity is consolidated in our financial statements, as a capital lease obligation.

The future minimum lease payments under the terms of this lease agreement are as follows:

	(IN THOUSANDS)
Years ending December 31,	
2001	$ 3,792
2002	5,508
2003	5,619
2004	5,731
2005	5,846
2006 and thereafter	73,976
Total minimum payments required	$100,472

NOTE 7--STOCKHOLDERS' EQUITY

COMMON STOCK

EMPLOYEE STOCK PURCHASE PLAN

In February 1994, our Board of Directors adopted the Employee Stock Purchase Plan (the "Purchase Plan"). Under the Purchase Plan, 300,000 shares of common stock have been reserved for purchase by our employees pursuant to section 423(b) of the Internal Revenue Code of 1986. As of December 31, 2000, no shares of common stock have been issued under the Purchase Plan.

STOCK OPTION PLANS

2000 EQUITY INCENTIVE PLAN

Our 1994 Equity Incentive Plan was adopted by the Board of Directors on February 10, 1994 and was amended and restated in its entirety and renamed the "2000 Equity Incentive Plan" on April 19, 2000. The purpose of the 2000 Equity Incentive Plan is to attract and retain qualified personnel, to provide additional incentives to our employees, officers, consultants and employee directors and to promote the success of our business. Pursuant to the 2000 Equity Incentive Plan, we may grant or issue incentive stock options to employees and officers and non-qualified stock options, rights to acquire restricted stock and stock bonuses to consultants, employees, officers and employee directors. Options granted to non-employees are recorded at fair value based on the fair value measurement criteria of FAS 123.

The maximum term of a stock option under the 2000 Equity Incentive Plan is ten years, but if the optionee at the time of grant has voting power of more than 10% of our outstanding capital stock, the maximum term of an incentive stock option is five years. The exercise price of incentive stock options granted under the 2000 Equity Incentive Plan must be at least equal to 100% (or 110% with respect to holders of more than 10% of the voting power of our outstanding capital stock) of the fair market value of the stock subject to the option on the date of the grant. The exercise price of non-qualified stock options, and the purchase price of rights to acquire restricted stock, granted under the 2000 Equity Incentive Plan are determined by the Board of Directors.

The 2000 Equity Incentive Plan may be amended at any time by the Board, although certain amendments would require shareholder approval. The 2000 Equity Incentive Plan will terminate on February 9, 2010 unless earlier terminated by the Board.

NON-EMPLOYEE DIRECTORS' STOCK OPTION PLAN

On February 10, 1994, our Board of Directors adopted the Non-employee Directors' Stock Option Plan under which options to purchase up to 400,000 shares of our common stock at the then fair market value may be granted to our non-employee directors.

2000 NON-OFFICER EQUITY INCENTIVE PLAN

Our 1998 Non-officer Equity Incentive Plan was adopted by the Board of Directors in on August 18, 1998 and was amended and restated in its entirety and renamed the "2000 Non-officer Equity Incentive Plan" on June 6, 2000 (the "2000 Plan"). The purpose of the 2000 Plan is to attract and retain qualified personnel, to provide additional incentives to employees and consultants and to promote the success of our business. Pursuant to the 2000 plan, we may grant or issue non-qualified stock options, rights to acquire

restricted stock and, stock bonuses to employees and consultants who are neither Officers nor Directors of Inhale.

The maximum term of a stock option under the 2000 Plan is ten years. The exercise price of stock options, and the purchase price of restricted stock granted under the 2000 Plan are determined by the Board of Directors. The 2000 Non-officer Equity Incentive Plan may be amended by the Board of Directors at any time.

A summary of activity under the 2000 Equity Incentive Plan, the Non-employee Directors' Stock Option Plan and the 2000 Non-officer Equity Incentive Plan is as follows:

		OPTIONS OUTSTANDING		
	OPTIONS AVAILABLE FOR GRANT	NUMBER OF SHARES	EXERCISE PRICE PER SHARE	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE
	(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)			
Balance at December 31, 1997	1,914	4,702	$ 0.01-17.63	$ 6.74
Shares authorized	3,100	--	--	--
Options granted	(2,138)	2,138	0.01-17.07	14.08
Options exercised	--	(348)	0.03-11.38	4.35
Options canceled	166	(166)	2.78-17.63	10.95
Balance at December 31, 1998	3,042	6,326	0.01-17.63	9.24
Shares authorized	2,500	--	--	--
Options granted	(3,150)	3,150	0.01-20.94	13.58
Options exercised	--	(248)	0.01-17.06	6.3
Options canceled	122	(122)	5.01-17.06	13.23
Balance at December 31, 1999	2,514	9,106	0.01-20.94	10.76
Shares authorized	5,500	--	--	--
Options granted	(4,283)	4,283	0.01-61.63	33.62
Shares awarded	(57)	--	--	--
Options exercised	--	(2,173)	0.01-42.50	8.40
Options canceled	280	(280)	7.25-60.88	28.07
Balance at December 31, 2000	3,954	10,936	$ 0.01-61.63	$19.79

At December 31, 2000, 1999 and 1998, options were exercisable to purchase 2.9 million, 3.0 million and 2.1 million shares at weighted-average exercise prices of $7.66, $7.46 and $5.68 per share, respectively.

Weighted average fair value of options granted during the year ended December 31, 2000, 1999 and 1998, was $34.20, $14.17 and $14.21, respectively. The following table provides information regarding Inhale's stock option plans as of December 31, 2000.

	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
RANGE OF EXERCISE PRICES	NUMBER	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	NUMBER	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE
	(IN THOUSANDS)			(IN THOUSANDS)	
$0.01-0.03	227	$ 0.01	8.0	47	$ 0.02
0.11-1.39	103	0.63	2.9	103	0.63
2.78-9.81	1,827	6.50	5.1	1,225	5.64
10.94-38.53	7,453	19.18	8.5	1,524	16.35
40.19-61.63	1,326	46.37	9.6	25	42.78
$0.01-61.63	10,936	$19.79	7.9	2,924	$11.27

In 2000, the Company granted approximately 0.1 million options to employees and consultants with exercise prices below the market price of the stock on the grant date. The weighted-average exercise price and weighted-average fair value of these options as of December 31, 2000 were $20.07 and $26.61, respectively.

Pro forma information regarding net income and earnings per share is required by FAS 123, which also requires that the information be determined as if we had accounted for our employee stock options under the fair value method of that Statement. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	2000	1999	1998
Risk-free interest rate	6.4%	5.6%	4.8%
Dividend yield	0.0%	0.0%	0.0%
Volatility factor	0.688	0.600	0.700
Weighted average expected life	5 years	5 years	5 years

The Black-Scholes options valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in our opinion, the existing models do not necessarily provide a reliable single measure of the fair value of our employee stock options. However, we have presented the pro forma net loss and pro forma basic and diluted net loss per common share using the assumptions noted above.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period, generally five years. Our pro forma information follows (in thousands except for earnings per share):

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
Pro forma net loss	$(122,989)	$(48,077)	$(24,325)
Pro forma basic and diluted net loss per common share	$ (2.93)	$ (1.42)	$ (0.78)

WARRANTS

During the year ended 2000, we issued six warrants to purchase a total of 16,000 shares of common stock. Some of the warrants bear an exercise price of $45.88 per share, expire in 10 years and are fully vested. Other warrants are exercisable under certain circumstances at a price to be determined and expire six years from the date on which any vested shares become exercisable. Total charges recorded during 2000 as a result of these issuances was approximately $0.1 million.

STOCK COMPENSATION

We recorded deferred compensation of approximately $1.2 million during the year ended December 31, 2000. Deferred compensation of $0.1 million had been recorded in the year ended December 31, 1999. These amounts represent the difference between the exercise price and the deemed fair market value of certain of our stock options granted in these periods and are being amortized to expense over the three-year vesting period of the options.

RESERVED SHARES

A total of 14.9 million shares of common stock have been reserved for issuance at December 31, 2000 for equity incentive plans and warrant exercises.

NOTE 8--INCOME TAXES

As of December 31, 2000, we had federal and state net operating loss carryforwards of approximately $156.2 million and $30.8 million, respectively. We also had federal and state research and other tax credit carryforwards of approximately $3.1 million and $2.6 million, respectively. The federal and state net operating loss and credit carryforwards will expire at various dates beginning through 2020 if not utilized.

Utilization of the federal and state net operating loss and credit carryforwards may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

Significant components of our deferred tax assets for federal and state income taxes as of December 31 are as follows:

	2000	1999
	(IN THOUSANDS)	
Deferred tax assets:		
Net operating loss carryforwards	$55,000	$28,500
Research and other credits	4,900	3,700
Capitalized research expenses	3,400	1,600
Deferred revenue	1,900	1,900
Depreciation	1,000	1,300
Other	1,900	2,100
Total deferred tax assets	68,100	39,100
Valuation allowance for deferred tax assets	(68,100)	(39,100)
Net deferred tax assets	$ --	$ --

Because of our lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $29.0 million and $14.5 million during the years ended December 31, 2000 and 1999, respectively.

NOTE 9--STATEMENT OF CASH FLOWS DATA

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
	(IN THOUSANDS)		
Supplemental disclosure of cash flows information:			
Interest paid	$7,031	$ 470	$270
Supplemental schedule of non-cash investing and financing activities:			
Deferred compensation related to the issuance of stock options	$1,162	$ 964	$576
Issuance of common stock in connection with technology	$ --	$5,000	$ --
Issuance of common stock and options in connection with licensing agreement	$ --	$ --	$284

NOTE 10--SUBSEQUENT EVENTS (UNAUDITED)

In January 2001, we acquired all of the capital shares of Bradford Particle Design plc, a United Kingdom company, for approximately 3.75 million in newly issued shares of our common stock and approximately $20 million in cash. Bradford Particle Design plc's supercritical fluid processing technology reduces what is commonly now a multi-stage powder manufacturing process to a single step while improving product purity and consistency. A formal valuation by an independent third party is currently in process which will result in a charge reflecting purchased in-process research and development in connection with the acquisition.

Exhibit 10.27

MANUFACTURING AND SUPPLY AGREEMENT

AMONG

INHALE THERAPEUTIC SYSTEMS, INC.,

TECH GROUP NORTH AMERICA, INC.

AND

BESPAK EUROPE LTD.

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[**] CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

EXHIBITS

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MANUFACTURING AND SUPPLY AGREEMENT

THIS MANUFACTURING AND SUPPLY AGREEMENT is made and entered into as of August 16, 2000 (the "Effective Date"), by and among INHALE Therapeutic Systems, Inc., a Delaware corporation ("INHALE"), Tech Group North America, Inc., an Arizona corporation ("Tech Group") and Bespak Europe Ltd., a corporation existing under the laws of England and Wales ("Bespak"). INHALE, Tech Group and Bespak are sometimes referred to herein individually as a "Party" and collectively as the "Parties." Bespak and Tech Group are also referred to individually as a "Contract Manufacturer" or a "CM" and collectively as the "CMs." References to "INHALE," "Bespak" and "Tech Group" shall include their respective Affiliates.

WHEREAS, INHALE has developed proprietary devices, dry powder formulations and dry powder processing and filling technology for pulmonary drug delivery;

WHEREAS, INHALE has established collaborative arrangements with pharmaceutical companies for the development and commercialization of products comprising dry powder formulations of certain pharmaceutical products and devices for the pulmonary delivery of such formulations;

WHEREAS, INHALE desires to obtain a commercial supply of such pulmonary devices or components thereof in order to resell such devices or components to such pharmaceutical companies, and the CMs desire to manufacture and supply such devices;

WHEREAS, in order to facilitate the coordinated manufacture of the Devices, Base Units, Transjectors and Chambers, the Parties desire to establish manufacturing processes and procedures, based upon applicable laws and regulations, good engineering and workmanship practices and industry standards, to (a) assure consistent, and high quality manufacture of devices at competitive prices; (b) implement approved changes in specifications in a consistent, controlled and coordinated manner, and (c) anticipate risks and develop effective, coordinated strategies and solutions, all on the terms and for the consideration set forth herein;

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Agreement, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

As used herein, the following terms shall have the following meanings:

1.1 "AFFILIATE" means a corporation, partnership, trust or other entity that directly, or indirectly through one or more intermediates, controls, is controlled by or is under common control with a Party to this Agreement. For such purposes, "control," "controlled by" and "under common control with" shall mean the possession of the

power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting stock or partnership interest, by contract or otherwise. In the case of a corporation, the direct or indirect ownership of more than fifty percent (50%) of its outstanding voting shares shall in any event be deemed to confer control, it being understood that the direct or indirect ownership of a lesser percentage of such shares shall not necessarily preclude the existence of control.

1.2 "AGREED CAPACITY LEVELS" shall have the meaning set forth in Section 2.1(c)(iv).

1.3 "[**]" shall have the meaning set forth in Section 2.1(c)(viii).

1.4 "APPLICABLE REGULATIONS" means all statutes, laws and regulations applicable to the manufacture and testing of pharmaceutical materials and/or medical devices in effect at a particular time and promulgated by the United States Food and Drug Administration ("FDA") and any foreign agency or authority equivalent to the FDA, including without limitation current good manufacturing practices ("cGMP") and quality system regulations ("QSR"), ISO 9002 and EN46002, and any successor or replacement statutes, laws and regulations.

1.5 "BASE UNIT" means the base unit portion of the Device.

1.6 "BUSINESS DAY" means Monday through Friday, and excluding holidays for the applicable Party, provided that each Party shall provide the other Parties with a written schedule of its holidays in order for those dates to be excluded from the definition of Business Day.

1.7 "CHAMBER" means that component of a Device that captures the drug cloud.

1.8 "COMMERCIAL LAUNCH" means the date on which Devices, Base Units, Transjectors or Chambers are first shipped by a Pharmaceutical Collaborator in commercial quantities for commercial sale to unaffiliated third parties.

1.9 "DEVICE" means any pulmonary device [**] and consisting of a Base Unit, Transjector and Chamber.

1.10 "DEVICE MASTER RECORD" or "DMR" means the compilation of the records containing the procedures and specifications for a Device, Base Unit, Transjector and Chamber. The DMR includes, but is not limited to drawings, CAD files, batch records, manufacturing procedures, test protocols and procedures and inspection protocols and procedures. The DMR may be amended from time to time as provided in Section 3.6.

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1.12 "ENVIRONMENTAL LAW" means any statute, ordinance, rule, regulation, code, order, judgment, decree or injunction relating to the protection of the environment, occupational safety and health, or human exposure to, or the use, storage, recycling, treatment, generation, labeling, protection, release or disposal of, Hazardous Materials, and that applies to activities contemplated by this Agreement in the place where such activities are carried out.

1.13 "FILLED DRUG" means Processed Drug that has been filled into blister packs and sealed.

1.14 [**]

1.15 "HAZARDOUS MATERIALS" means all materials regulated by law as capable of causing harm or injury to human health or the environment, including, without limitation, (a) hazardous substances as defined at 42 U.S.C. Section 9601(14), (b) friable asbestos-containing material or polychlorinated biphenyls, (c) medical waste within the meaning of 40 CFR Part 259, (d) materials designated as carcinogens or reproductive toxicants by the International Agreement for Research on Cancer, National Toxicology Program, Environmental Protection Agency, Occupational Safety and Health Administration ("OSHA") or National Institute for Occupational Safety and Health, (e) highly toxic materials as defined by OSHA at 29 CFR 1910.1200, and (f) radioactive materials.

1.16 "IMPROVEMENTS" means any improvements, enhancements or modifications to the Devices, Base Units, Transjectors or Chambers that may be developed, conceived or made by INHALE and/or either CM during the term of this Agreement.

1.17 "INFORMATION" means techniques and data relating to the manufacture of the Devices, Base Units, Transjectors or Chambers including, but not limited to, ideas (including patentable inventions), inventions, practices, methods, knowledge, know-how, trade secrets, skill, experience, documents, apparatus, equipment and associated designs, clinical and regulatory strategies, test data, including pharmacological, toxicological and clinical test data, analytical and quality control data, manufacturing and manufacturing processes, patent and legal data, occupational health and safety data and materials (including, but not limited to, material safety data sheets, occupational exposure limits, and complaints of adverse reaction associated with exposure to bulk, Processed, or Filled Drug), environmental fate or effect data, analyses, or assessments, and descriptions and chemical formulations, compositions of matter, product samples and assays.

1.18 "INHALE KNOW-HOW" means all Information that is (a) owned or Controlled by INHALE at any time during the Term (including, without limitation, any

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Improvements) and (b) useful or necessary to manufacture the Devices, Base Units, Transjectors or Chambers. INHALE Know-how does not include INHALE Patent Rights. As used in this Agreement, "Controlled" means the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any third party.

1.19 "INHALE PATENT RIGHTS" means the rights granted by any governmental authority under (a) the Patents listed on Exhibit B, (b) any Patents that issue from the Patent Applications listed on Exhibit B, and (c) any other Patent that covers a method, apparatus, material or manufacture necessary or useful to manufacture the Devices, Base Units, Transjectors or Chambers, which Patent is owned or Controlled by INHALE and covers an invention made before or during the Term (including, without limitation, any Improvements).

1.20 "MANUFACTURING PROCESS" means a production, assembly, test or inspection process by which the physical shape, performance, property or functioning of a Device, Base Unit, Transjector or Chamber is modified, improved or enhanced.

1.21 "MANUFACTURING REQUIREMENTS" means the manufacturing requirements for the Devices, Base Units, Transjectors or Chambers, attached hereto as Exhibit C and as amended from time to time as provided in Section 3.3.

1.22 "MANUFACTURING SYSTEMS" means the integrated processes of information systems, personnel, organizational structure and information flow, used by a CM in the manufacture of a Device, Base Unit, Transjector or Chamber.

1.23 "NDA OR EQUIVALENT" means (a) the single application or set of applications for approval to make and sell commercially a Device, Base Unit, Transjector or Chamber, filed by INHALE or any of its Pharmaceutical Collaborators with the FDA or any successor agency having the administrative authority to regulate the approval for marketing of new human pharmaceutical or biological therapeutic products, delivery systems and devices in the United States, and (b) any application or notification comparable to those set forth in (a) filed by INHALE or any of its Pharmaceutical Collaborators in a country other than the United States with regulatory authorities having jurisdiction comparable to that of the FDA.

1.24 "PATENT" means (a) valid and enforceable Letters Patent and utility models including any extension, registration, confirmation, reissue, re-examination or renewal thereof and (b) to the extent valid and enforceable rights are granted by a governmental authority thereunder, a Patent Application.

1.25 "PATENT APPLICATION" means an application or provisional patent application for Letters Patent.

1.26 "PHARMACEUTICAL COLLABORATORS" means any third party and its affiliated companies that have entered into a collaborative agreement with INHALE for the

manufacture and sale of the Devices, Base Units, Transjectors and Chambers for use with particular Processed Drugs.

1.27 "PROCESSED DRUG" means the dry powder formulation of the applicable pharmaceutical product to be delivered by the Devices.

1.28 "PRODUCTS" means, singly and collectively, Processed Drug, Filled Drug, and any and all Devices, Base Units, Transjectors or Chambers.

1.29 "REGULATORY APPROVAL" means, as applicable, (a) approval by the FDA of an NDA or equivalent and satisfaction of related applicable FDA registration and notification requirements (if any) and, in any country other than the United States, approval by regulatory authorities having jurisdiction over such country of an NDA or equivalent, filed by INHALE or one or more Pharmaceutical Collaborator(s) together with any other approval, certification and/or registration necessary to make and sell in the United States or in such country both Filled Drug and a compatible Device, including, where applicable, satisfactory labeling and pricing approval, and, if necessary for commercialization of Products, governmental or third party reimbursement approval and/or inclusion of such Filled Drug and Device on any governmental formularies effective in the United States or in such country, and/or (b) the approval of any amendment to any approval described in item (a), or any notification to or registration with the FDA or such other regulatory authorities, relating to the qualification of a manufacturing facility for the purpose of the manufacture at such facility of Processed Drug, Filled Drug and/or Devices as contemplated by this Agreement.

1.30 "TERM" means the term of this Agreement as set forth in Section 14.1.

1.31 "TOOLING" means any molds or dies for fabrication of plastic parts for Devices, Base Units, Transjectors and Chambers.

1.32 "TRADEMARKS" means those trademarks, trade names and logos of INHALE or its Pharmaceutical Collaborators from time to time specified in writing to the CMs.

1.33 "TRANSJECTOR" means that component of the Device that disperses Processed Drug.

ARTICLE 2
MANAGEMENT OF COLLABORATION

2.1 STEERING COMMITTEE.

(a) ESTABLISHMENT OF STEERING COMMITTEE. Following the Effective Date, the CMs and INHALE shall promptly organize a steering committee (the "Steering Committee"), with three (3) members from each Party. One member from INHALE will be selected by INHALE to be chairperson of the Steering Committee. A quorum of the

Steering Committee shall be two (2) members of each Party. All decisions of the Steering Committee must be made on a unanimous basis.

(b) STEERING COMMITTEE MEETINGS. The Steering Committee shall hold regular quarterly meetings. Consultants and non-Steering Committee member employees of the Parties may attend meetings of the Steering Committee as non-voting observers as required to further the manufacture of the Devices (who may be excused as necessary). INHALE shall be entitled to invite representatives of the Pharmaceutical Collaborators to sit in on Steering Committee meetings as non-voting observers. The Steering Committee meetings will alternate between INHALE's designated facility and the CMs' facilities (or such other location as the Steering Committee may decide). Minutes of all such meetings will be prepared. Responsibility for the minutes will alternate between the Parties attending, INHALE being responsible for the minutes of the first meeting, but minutes will not become official until agreed upon by all of the members.[**]

(c) RESPONSIBILITIES. The Steering Committee shall perform the following functions:

(i) manage the final process development and monitor the technology transfer process set forth in Section 3.5 and the initial implementation of manufacturing processes and assembly operations pursuant to the Manufacturing Requirements;

(ii) review and monitor the on-going manufacture and overall quality of the Devices, Base Units, Transjectors and Chambers including without limitation the tracking and reporting of trends and metrics relating to the manufacture of the Devices, Base Units, Transjectors and Chambers and discuss and address operational issues arising under this Agreement;

(iii) monitor marketing data for the Devices, Base Units, Transjectors and Chambers including without limitation, reviewing on a quarterly basis any long-term marketing data then available to INHALE or the CMs (the Parties acknowledge that [**] month marketing data will be made available whenever possible);

(iv) determine manufacturing capacity levels (the "Agreed Capacity Levels") in accordance with Manufacturing Requirements and consistent with any long-term marketing data then available to INHALE and the CMs, and review and revise the Capital Plan (as defined in Section 3.1) consistent with such Agreed Capacity Levels, as provided in Section 3.1 and determine the allocation of INHALE's requirements between the CMs, as provided in Section 4.2;

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(v) ensure that any changes to the Agreed Capacity Levels [**] are subject to unanimous approval of the Steering Committee, and that [**](the Parties acknowledge that additional capital investments are subject to each Party's internal capital approval process);

(vi) discuss changes in the DMR and Manufacturing Requirements, and discuss and approve any changes to the manufacturing process (including without limitation any deviations from such manufacturing process as provided in Section 3.4);

(vii) [**]

(viii) [**]; and

(ix) review and resolve disputes regarding the manufacture hereunder (excluding disputes relating to the interpretation of this Agreement), and if the Steering Committee is unable to resolve the dispute within [**] after receipt of a request from any Party to resolve a dispute, it shall be determined in accordance with Section 2.2.

(d) WORKING GROUPS. The Steering Committee may designate working groups to address specific issues arising under the Agreement regarding the process of manufacturing hereunder. Initial working groups will be the quality and regulatory working group, tooling working group and assembly processes working group. The working groups will meet as agreed by the Parties, will report to their respective plant managers or heads of manufacturing, as the case may be, and will be responsible to the Steering Committee.

2.2 STEERING COMMITTEE DISPUTES. If the Steering Committee is unable to resolve a dispute described in Section 2.1(c)(ix) within [**] of being requested by a Party to resolve such a dispute, it will be decided as follows: [**] The Parties shall use good faith efforts to resolve mutually and amicably all other such

disputes, and if the Parties are unable to do so, any Party may refer such dispute to an independent third party, with experience or expertise in the field of drug delivery device manufacturing, and reasonably acceptable to the other Parties, for determination consistent with standards then prevailing in the drug delivery device manufacturing field for products that are regulated in a similar manner to the Products. The Parties shall bear equally the costs and expenses of such third party. Such determination shall be binding upon the Parties.

2.3 COOPERATION WITH PHARMACEUTICAL COLLABORATORS. The CMs acknowledge that INHALE intends to resell all or a substantial portion of the Devices, Base Units, Transjectors and Chambers to its Pharmaceutical Collaborators, and, as such, that such Pharmaceutical Collaborators may desire from time to time to obtain information regarding, or to observe, the manufacture hereunder. Upon reasonable request from INHALE, the CMs will provide to INHALE's Pharmaceutical Collaborators reasonable cooperation and access during regular business hours to their facilities and records, with respect to the manufacture and supply hereunder; provided that an authorized representative of INHALE is present for any such site visits. In addition, INHALE will use reasonable efforts to have a representative of each CM invited to participate in regularly scheduled meetings of its steering committees with its Pharmaceutical Collaborators to discuss the market for the Devices, Base Units, Transjectors and Chambers.

ARTICLE 3
CAPITAL PLAN, PROCESS DEVELOPMENT AND TECHNOLOGY TRANSFER

3.1 CAPITAL PLAN. Capital expenditures will be incurred in accordance with the capital plan (the "CAPITAL PLAN") attached hereto as Exhibit D. [**]

3.2 [**]. The Parties acknowledge that the CMs will incur capital expenses in accordance with the Capital Plan in order to meet the Agreed Capacity Levels, as determined by the Steering Committee pursuant to Section 2.1(c)(iv). The Parties further acknowledge that the CMs may incur such capital expenses at different rates and in different amounts, depending upon the availability to each CM of existing facilities and equipment and other factors. In order to provide the CMs with some assurance with respect to such capital investments, the Parties agree to implement the following mechanism:

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3.3 MANUFACTURING REQUIREMENTS.

(a) INHALE shall establish, and may amend from time to time in writing, the Manufacturing Requirements for the Devices, Base Units, Transjectors and Chambers. Each CM shall implement the then current Manufacturing Requirements in accordance with their terms, and each CM shall periodically report to INHALE on its performance under such Manufacturing Requirements. Each CM shall agree to any changes in the Manufacturing Requirements so long as they (a) are required by the Regulatory Approvals or the Applicable Regulations or (b) are compatible with the scope

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of such CM's overall business, and if not, the Parties shall discuss such changes to the Manufacturing Requirements in good faith. INHALE shall allow the CMs a commercially reasonable period of time to implement changes to the Manufacturing Requirements. The CMs agree to implement such changes in an expeditious and commercially prudent manner. [**] Any changes in the Manufacturing Requirements hereunder shall also be subject to the change control procedures set forth in Section 3.9.

(b) INHALE acknowledges that the Manufacturing Requirements are determined by INHALE and transferred to each CM, [**] a Device, Base Unit, Transjector or Chamber that is not manufactured in accordance with the Manufacturing Requirements, it shall promptly notify INHALE thereof and the CMs shall cooperate with INHALE in trying to resolve such issue.

3.4 PROCESS DEVELOPMENT. To minimize variations in quality and performance of Devices, Base Units, Transjectors and Chambers, the CMs will manufacture the foregoing under a consistent and coordinated manufacturing process. The materials, Tooling, testing and production processes and equipment will be identical at the facilities of each CM; provided that, subject to the terms of this Agreement and the Manufacturing Requirements, and subject to the Applicable Regulations, (a) where it is impractical or infeasible to maintain the foregoing as identical, any deviation shall be subject to the applicable CM providing written justification to the Steering Committee and the Steering Committee providing written approval of such deviation, and (b) each CM may (i) implement its own Manufacturing Systems and (ii) maintain such production schedules as appropriate to meet its obligations hereunder. To capitalize on each CM's unique competencies and expertise, the CMs will divide process development responsibility, with Bespak [**] and Tech Group [**]. Each CM's responsibilities for process development are

described in detail in the Manufacturing Requirements. The CMs shall also collaborate with each other to complete development and implementation of the manufacturing process for the Devices, Base Units, Transjectors and Chambers. Both CMs will mold and assemble the Devices, Base Units, Transjectors and Chambers.

3.5 TRANSFER.

(a) The initial technology transfer from INHALE to the CMs will occur prior to the Effective Date. From time to time thereafter and consistent with the licenses granted hereunder, INHALE shall provide to the CMs (a) all documentation, information and other materials embodying the INHALE Patent Rights and INHALE Know-How, as may be reasonably necessary for the CMs to manufacture the Devices, Base Units, Transjectors and Chambers as contemplated herein, and (b) reasonable assistance in transferring such technology and materials to the CMs, including providing reasonable access to INHALE engineers.

(b) From time to time during the Term of this Agreement, and consistent with the licenses granted hereunder and Applicable Regulations, the CMs shall provide to each other and to INHALE (a) all documentation, information and other materials embodying any Improvements or Device Manufacturing Inventions (as defined in Section 7.4(d)), as may be reasonably necessary for the CMs or INHALE to manufacture the Devices or exercise their respective rights as contemplated herein, and (b) reasonable assistance in transferring such technology and materials to the other CM and to INHALE, including providing reasonable access to the transferring CM's engineers. Notwithstanding the foregoing, the Parties acknowledge and agree that the CMs shall not be required to disclose to each other their respective Manufacturing Systems.

3.6 DEVICE MASTER RECORD.

(a) INHALE shall establish, and may amend from time to time in writing, the DMR for the Devices, Base Units, Transjectors and Chambers. Each CM shall manufacture the Devices, Base Units, Transjectors and Chambers according to the then current DMR, and each CM shall periodically report to INHALE on its performance. The Parties acknowledge that there may be [**], and that [**] Each CM shall agree to any changes in the DMR so long as they (a) are required by the Regulatory Approvals or the Applicable Regulations or (b) are compatible with the scope of such CM's overall business, and if not, the Parties shall discuss such changes to the DMR in good faith. INHALE shall allow the CMs a commercially reasonable period of time to implement changes to the DMR. The CMs agree to implement such changes in an expeditious and commercially prudent manner. [**]

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[**] Any changes to the DMR shall also be subject to the change control procedure set forth in Section 3.9.

(b) INHALE acknowledges that the DMR is generated by INHALE and transferred to each CM, [**] a Device, Base Unit, Transjector or Chamber that does not conform to the DMR, it shall promptly notify INHALE thereof and shall cooperate with INHALE in trying to resolve such issue.

3.7 PACKAGING SPECIFICATIONS. The packaging specifications shall be included in the DMR. Each CM shall package the Devices, Base Units, Transjectors or Chambers in accordance with the then current DMR, and each CM shall periodically report to INHALE on its performance under the DMR. If INHALE orders packaging for the Devices, Base Units, Transjectors or Chambers, such items shall be packaged in accordance with the then current packaging specifications. INHALE will determine the wording and trade dress for the packaging and labeling content for such items including, without limitation, the use of any trademark of INHALE or any of its Pharmaceutical Collaborators.

3.8 LAUNCH DELAY.

(a) The Parties shall allocate costs associated with launch delays as provided herein. A "Launch Delay" shall be deemed to have occurred if INHALE does not place an order for Devices, Transjectors and Chambers consistent with Section 4.4(b) by [**] A Launch Delay shall be deemed to commence at the time specified in the previous sentence and to continue until [**] The Parties acknowledge that there could be multiple Launch Delays during the Term of this Agreement.

(b) The CMs shall use commercially reasonable efforts to minimize costs associated with delay (including, for example, rescheduling delivery or installation of equipment without fee or with minimum fee, deleting additional hires or the purchase of additional material, or using their personnel on other projects where possible). In

addition, at INHALE's request, the CMs shall continue to manufacture Devices, Base Units, Transjectors and Chambers at levels requested by INHALE (subject to the Agreed Capacity Levels) for inventory to be held by INHALE and/or its Pharmaceutical Collaborators or for other purposes.

(c) Costs of a Launch Delay shall be borne as follows:

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3.9 CONTINUOUS IMPROVEMENT, CHANGE CONTROL PROCEDURES. The Parties acknowledge that testing and inspection methods and manufacturing processes may need to be refined and modified as INHALE, its Pharmaceutical Collaborators and the CMs gain experience with the manufacture, testing and use of the Devices and Products. Accordingly, the Parties shall mutually agree on a change control procedure within [**] of the Effective Date. In addition, the Parties agree to undertake a proactive

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program of developing and implementing improvements to the manufacturing processes for the Devices, Base Units, Transjectors and Chambers, and the Parties shall jointly define such a continuous improvement program, [**], to provide a mechanism for the Steering Committee to evaluate, approve and implement mutually agreed improvements in the manufacturing processes for the Devices, Base Units, Transjectors and Chambers.

3.10 ADDITIONAL PRODUCTS AND ADDITIONAL DEVELOPMENT.

(a) The Parties intend that if INHALE desires to have the CMs manufacture additional pulmonary delivery device products for it, this Agreement will serve as a master manufacturing and supply agreement, which may be used to cover the terms for manufacture and supply of additional pulmonary delivery device products, including, for example, future generations of the Devices. If INHALE so desires, it may also enter into one or more development agreements with Bespak and/or Tech Group to develop such additional products. The Parties acknowledge that any agreements for the development or manufacture of additional pulmonary devices will require the consent of each Party that elects to become a party to any such agreement.

(b) The Parties acknowledge and agree that if INHALE desires to have one or both of the CMs develop any evolutionary or revolutionary changes to the Devices, Base Units, Transjectors or Chambers, such development program or programs will be subject to a separate written development agreement, [**], to be mutually agreed by INHALE and the applicable CM(s).

ARTICLE 4
PURCHASE AND SUPPLY OF DEVICES

4.1 EXCLUSIVE SUPPLY.

(a) During the Term of this Agreement, except as expressly provided herein, INHALE shall not enter into any agreement with any third party for the manufacture of Devices, Base Units, Transjectors or Chambers, nor shall it directly manufacture the foregoing itself.

(b) At any time during the Term of this Agreement, INHALE shall be entitled to manufacture Devices, Base Units, Transjectors and Chambers for clinical trials and other development purposes. Nothing herein shall be deemed to restrict INHALE's rights to develop the Devices, Base Units, Transjectors or Chambers or similar devices.

4.2 PURCHASE AND SUPPLY.

(a) Subject to the terms and conditions of this Agreement, INHALE agrees to purchase, and each CM agrees to supply to INHALE, [**] of

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INHALE's requirements for packaged Devices, Base Units, Transjectors and Chambers (by volume) based on the then current forecasts and orders submitted pursuant to Section 4.4(a) and (b), up to the levels set forth in the forecast [**] attached hereto as Exhibit E for the Term of this Agreement. The parties further acknowledge and agree that [**] The applicable percentage of INHALE's requirements that each CM is, from time to time, obligated and entitled to manufacture hereunder shall be referred to as such CM's "Allocation."

(b) The CMs will cooperate to minimize shortages or delays by providing components of Devices, Base Units, Transjectors and Chambers to each other at agreed-upon prices, in the event of any shortfall, to the extent reasonably feasible without jeopardizing the providing CM's ability to meet its own supply commitments to INHALE. In addition, if a CM fails to supply its Allocation of INHALE's requirements by [**], subject to agreement by the other CM, INHALE shall have the right to reduce such CM's right and obligation to supply by [**] by providing written notice of such reduction to the applicable CM no later than [**] in which the shortfall occurred, and such reduction shall be effective on the first day of the month following the date of the CM's receipt of such notice. The other CM's right and obligation to supply shall thereafter be increased by [**]; provided, however that if, within [**] of such shortfall, the non-performing CM demonstrates and documents its ability to supply its full Allocation of INHALE's requirements, such non-performing CM shall be entitled and obligated to supply such Allocation of INHALE's requirements effective on [**] (or at INHALE's discretion, such earlier date as INHALE may deem appropriate). If the other CM is unwilling or unable to supply such shortfall, INHALE shall be entitled to enter into an agreement with a third party or manufacture itself such additional quantities of Devices, Base Units, Transjectors and Chambers.

(c) Furthermore, if INHALE desires to have manufactured an improvement or option for, or variation of, the Devices, Transjectors or Chambers, of which its annual purchases are not anticipated to exceed [**] of Devices, [**] of Transjectors, or [**] of Chambers, INHALE may designate one of the CMs as the sole supplier of such improvement, option or variation. If one CM supplies all of INHALE's requirements of such Devices, Transjectors or Chambers, the Parties shall reallocate the overall volume of Devices, Transjectors and Chambers (including the volumes of Devices, Transjectors and Chambers set forth in this Section 4.2(c)) between the CMs such that each CM shall continue to have the right and obligation to manufacture and supply its then current Allocation of such overall volume.

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4.3 SCALE-UP. The CMs shall initially scale-up the Facilities (as defined in Section 6.2) and equipment based on an initial scale-up level determined by the Steering Committee. Unless delayed as a result of an action (or inaction) by INHALE, [**]; provided any changes to the DMR or Manufacturing Requirements made after the Effective Date may affect the scale-up date, and the Parties agree to monitor such potential delays through the change control procedure set forth in Section 3.9. [**] Thereafter, the CMs shall scale-up additional capacity to meet the Agreed Capacity Levels.

4.4 FORECASTS AND ORDERS.

(a) PRODUCTION FORECASTS. INHALE shall provide the CMs with rolling [**] production forecasts of its anticipated purchases of Devices, Base Units, Transjectors and Chambers. Such production forecasts shall not require Devices, Base Units, Transjectors or Chambers to be manufactured in amounts in excess of the Agreed Capacity Levels. The first of these production forecasts will be provided no less than [**] and will state the quantities of Devices, Base Units, Transjectors and Chambers that INHALE expects to be delivered during the calendar quarter in which the anticipated first delivery of Devices, Base Units, Transjectors and Chambers will occur. Each production forecast will be dated and production forecasts will thereafter be updated on a quarterly basis not later than [**]. Each subsequent production forecast will state the quantities of Devices, Base Units, Transjectors and Chambers that INHALE expects to be delivered in each of the [**] calendar [**] beginning, [**] The production forecast for deliveries occurring in the calendar quarter beginning [**] shall be binding and shall provide for quantities [**] of the quantities contained in the production forecast for such quarter given one quarter earlier. The production forecast for deliveries occurring in the [**] calendar [**] shall be non-binding. The Parties recognize that such production forecasts may change over time based on commercial and regulatory developments and other factors. In this connection, the CMs agree to work with INHALE and its Pharmaceutical Collaborators to reduce, as reasonably practicable, their financial exposure relative to changes in such production forecasts. Such cooperation will be consistent with the CMs' obligations under Section 4.9 hereof. In the event it is not reasonably practicable for the CMs to reduce their financial exposure with respect to changes in any binding production forecast, nothing in this Section 4.9 shall relieve INHALE of its obligations with respect to any binding purchase order.

(b) ORDERS FOR DEVICES. No later than [**] before each calendar quarter, INHALE shall provide each CM with a firm purchase order or orders specifying the quantities of Devices, Base Units, Transjectors and Chambers in each case

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desired for delivery during each month of such calendar quarter. Each such firm purchase order shall provide for quantities for delivery in such quarter that are no less than the quantities contained in the binding production forecast. Such orders shall not require Devices, Base Units, Transjectors or Chambers to be manufactured in amounts in excess of the Agreed Capacity Levels. Orders shall call for shipment no less than [**] from the date thereof. The CMs will accept any purchase order for Devices, Base Units, Transjectors and Chambers that does not exceed the applicable maximum provided for in the most recent forecast for that quarter and will use commercially reasonable efforts to accept any purchase orders for amounts in excess of such maximum. If a CM agrees to supply amounts in excess of such maximum, such amounts shall not count against either CM's right to supply its Allocation of INHALE's requirements for the Devices, Base Units, Transjectors and Chambers. The parties anticipate that the initial order will be placed in accordance with Section 3.8(a).

(c) REGULATORY APPROVAL. Notwithstanding anything to the contrary herein, INHALE shall not be obligated to place any orders for Devices, Base Units, Transjectors and Chambers prior to receipt of Regulatory Approval thereof and INHALE shall have the right to amend reasonably its forecasts and purchase orders in the event of unexpected delays in such Regulatory Approval. [**]

(d) PURCHASE ORDER FORMS. INHALE shall be entitled to use its own form of purchase order or to pass through to the CMs the purchase order forms submitted by its Pharmaceutical Collaborators to INHALE; provided, however, that any terms of such purchase orders that conflict with or are in addition to the terms of this Agreement shall not apply unless the Parties otherwise agree in writing.

4.5 PRODUCT TESTING. The CMs will test each shipment of Devices, Base Units, Transjectors and Chambers supplied to INHALE or its designee under this Agreement for conformance to the Manufacturing Requirements in accordance with the procedures set forth therein. The CMs shall include with each shipment of Devices, Base Units, Transjectors and Chambers written confirmation of such conformance. Such testing shall in no way limit INHALE's rights to inspect the Devices, Base Units, Transjectors and Chambers pursuant to Section 4.7 or its rights under the product warranty or of indemnification hereunder.

4.6 SHIPMENT. [**], the CMs shall ship Devices, Base Units, Transjectors and Chambers ordered by INHALE on the requested shipment date. The CMs shall arrange for shipping as instructed by INHALE, which instructions may include separate and direct shipments to one or more Pharmaceutical Collaborators or third parties. Deliveries by Bespak shall be made F.O.B (U.C.C.) Bespak's facility in Milton Keynes, England and Tech Group's facility in Tempe, Arizona, as applicable, and shall be shipped to one or more addresses as directed by INHALE in writing. If requested by INHALE or its Pharmaceutical

Collaborators, the CMs will insure any shipment against damage or loss at the expense of INHALE. Title and risk of loss to the Devices, Base Units, Transjectors and Chambers shall pass to INHALE (or its designee) upon delivery to the carrier. The CMs will invoice INHALE for freight and insurance upon shipment.

4.7 ACCEPTANCE AND REJECTION.

(a) ACCEPTANCE TESTING. Any Devices, Base Units, Transjectors and Chambers manufactured hereunder shall be received by INHALE subject to inspection and performance testing of Devices, Base Units, Transjectors and Chambers by INHALE or its Pharmaceutical Collaborators in accordance with the testing protocol set forth in the DMR. INHALE may reject any Devices, Base Units, Transjectors or Chambers (or lot thereof) that do not meet the Manufacturing Requirements or otherwise comply with the warranties provided in Section 9. INHALE or its Pharmaceutical Collaborators shall retain a quantity of Devices, Base Units, Transjectors or Chambers when provided by the CMs hereunder sufficient to conduct such testing. INHALE shall be allowed a maximum of [**] from the date of receipt of any shipment for inspection and testing and provision of written notice to the applicable CM of rejection of a portion or all of that shipment. If INHALE does not deliver such written notice to the applicable CM within such [**] period, INHALE shall be deemed to have accepted the shipment. The acceptance (or non-rejection) of any Devices, Base Units, Transjectors or Chambers shall in no way limit INHALE's rights under the CMs' product warranty or for indemnification hereunder.

(b) REMEDY FOR REJECTED DEVICES. The applicable CM shall, at INHALE's election, replace rejected Devices, Base Units, Transjectors and Chambers free of any additional charge or reimburse or credit INHALE the purchase price, including freight and insurance (if the purchase price has actually been paid by INHALE) for Devices, Base Units, Transjectors and Chambers rejected by INHALE hereunder in accordance with Section 4.7(a). Rejected Devices, Base Units, Transjectors and Chambers shall be returned to the CM or disposed of at the CM's option. In the event of any destruction of nonconforming goods, INHALE shall, if requested by the CM, deliver to the CM an appropriate written confirmation of destruction. The costs of return or disposal shall be borne by the CM. Items rejected in accordance with Section 4.7(a) shall not be counted toward the applicable CM's obligation to supply its Allocation of INHALE's requirements [**] unless such CM provides conforming replacement Devices, Base Units, Transjectors and Chambers within [**] of receipt of INHALE's notice of rejection of such items pursuant to Section 4.7(a).

4.8 FAILURE TO SUPPLY.

(a) Notwithstanding Section 15.4 and subject to the Agreed Capacity Levels, if a CM (i) is unable to supply its full Allocation of INHALE's requirements [**], unless such failure results from an action or inaction by INHALE, (ii) has

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declined or failed to implement any changes to the Manufacturing Requirements or DMR, or (iii) has declined or failed to add additional manufacturing capacity for the Devices, Base Units, Transjectors and Chambers, reasonably requested by INHALE and consistent with the long term marketing data reviewed by the Steering Committee pursuant to Section 2.1(c)(iii), [**]

(b) Notwithstanding Section 15.4 and subject to the Agreed Capacity Levels, if a CM (i) is not able to manufacture and supply its full Allocation of INHALE's requirements for Devices, Base Units, Transjectors and Chambers [**] unless such failure results from an action or inaction by INHALE, (ii) has declined or failed to implement any changes to the Manufacturing Requirements or DMR, or (iii) has declined or failed to add additional manufacturing capacity for the Devices, Base Units, Transjectors and Chambers, reasonably requested by INHALE and consistent with the long term marketing data reviewed by the Steering Committee pursuant to Section 2.1(c)(iii), [**]

(c) [**]

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[**] Such supply shall otherwise be subject to the terms and conditions of this Agreement.

(d) [**]), the defaulting CM shall meet the obligations in Sections 3.5(b) and 14.4(b) (to the extent it has not already done so) during the period set forth in Section 4.8(c), [**]

4.9 [**]

ARTICLE 5
PRICING AND PAYMENT

5.1 PRICING. The prices for the Devices, Base Units, Transjectors and Chambers supplied to INHALE pursuant to this Agreement shall be determined in accordance with Exhibit A.

5.2 INVOICING AND PAYMENT.

(a) TECH GROUP. All payments due hereunder to Tech Group shall be paid by INHALE in United States Dollars, and shall be paid in accordance with the terms set forth in Section 5.2(c).

(b) BESPAK. All payments due hereunder to Bespak shall be paid in United States Dollars, and shall be paid in accordance with the terms of Section 5.2(c). INHALE. The U.S. Dollar payment will be arrived at by converting the then current payment in British Pounds Sterling into U.S. Dollars [**] as set forth in Exhibit F.

(c) PAYMENT TERMS. Terms for all payments due hereunder shall be net [**]. Past due invoices will bear interest at the rate of [**]

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[**].

5.3 REIMBURSEMENT. [**]

ARTICLE 6
MANUFACTURE AND MANUFACTURING FACILITIES

6.1 MANUFACTURE. The CMs will manufacture and supply Devices, Base Units, Transjectors and Chambers in sufficient quantities to meet INHALE's orders submitted pursuant to Section 4.4(b).

6.2 MANUFACTURING FACILITIES, CAPACITY. Bespak and Tech Group shall manufacture the Devices in such facilities specified in the Manufacturing Requirements and sufficient to meet the Agreed Capacity Levels, at their respective manufacturing facilities in Milton Keynes, England and Tempe, Arizona (the "Facilities"), during the term of the Agreement as contemplated herein. [**] The Parties shall mutually agree on the scope and timing of any transfer of manufacturing hereunder to such other facilities.

6.3 RECONCILIATION AND TRACEABILITY SYSTEM, RECORDKEEPING. The CMs shall implement a manufacturing system capable of reconciliation (inputs and outputs) and traceability, reasonably acceptable to INHALE and, upon request, shall provide INHALE with access to such system for the purposes of conducting audits and implementing recalls, and for other purposes consistent with this Agreement. In addition, the CMs shall maintain adequate records of the manufacture of Devices, Base Units, Transjectors and Chambers to establish compliance with regulatory requirements with respect to such manufacture. The CMs shall permit INHALE and its Pharmaceutical Collaborators on reasonable notice to review and obtain copies of such records in order to confirm such compliance.

6.4 MANUFACTURING AUDITS AND INSPECTIONS.

(a) AUDIT RIGHT. INHALE or its designee (which designee shall be reasonably acceptable to the CMs) shall have the right, upon [**] notice to the CMs and during regular business hours, to inspect and audit the facilities

being used by the CMs (or its third party suppliers) for production and storage of Devices, Base Units, Transjectors and Chambers to assure compliance by the CMs (or its third party suppliers) with (i) all Applicable Regulations, (ii) any quality assurance requirements set forth in the DMR, and (iii) the terms and provisions of this Agreement. Such audits shall be restricted to areas of each CM's facilities in which the Devices, Base Units, Transjectors and Chambers are manufactured, packaged or stored, and may occur on a monthly basis. INHALE shall provide the applicable CM with a written report of any material deficiencies found in the course of such audit. The applicable CM shall, within [**] of receipt of such report, remedy or cause the remedy of any material deficiencies described on such report and agreed in writing by such CM or, if any such deficiencies can not reasonably be remedied within such [**] period, present to INHALE a written plan to remedy such deficiencies as soon as possible; and the failure by such CM to remedy or cause the remedy of any such material deficiencies within such [**] period or to present such a plan within such [**] period and then use commercially reasonable efforts to remedy or cause the remedy of such deficiencies in accordance with such written plan, as the case may be, shall be deemed a material breach of this Agreement.

(b) CONTINUING OBLIGATIONS. The CMs acknowledge that the provisions of this Section 6.4 granting INHALE certain audit rights shall in no way relieve the CMs of any of its obligations under this Agreement, nor shall such provisions require INHALE to conduct any such audits.

6.5 NO SUBCONTRACTING. Except to the extent provided in the Manufacturing Requirements or as otherwise agreed by the Steering Committee, the CMs shall not be entitled to subcontract any of the manufacture, testing or inspection of the Devices, Base Units, Transjectors or Chambers or any component thereof.

6.6 ACCESS TO MANUFACTURING FACILITIES. INHALE shall be entitled to have access to the Facilities where the Devices, Base Units, Transjectors and Chambers are manufactured, packaged or stored during normal business hours and upon reasonable notice to the CMs, for the purposes of observing the manufacture of the foregoing. In addition, INHALE shall have the right, but not the obligation, to provide one or more manufacturing or quality engineers to observe the manufacture of the foregoing at the Facilities; and each CM agrees to provide reasonable office space, telephone and other customary office services to such personnel. [**]

ARTICLE 7
MANUFACTURING LICENSES AND INTELLECTUAL PROPERTY

7.1 MANUFACTURING LICENSE TO CMS. Subject to the terms and conditions of this Agreement, INHALE hereby grants each CM an exclusive (except as to the other CM), nontransferable and royalty-free license, without right of sublicense, under the INHALE Patent Rights and the INHALE Know-How, to make Devices, Base Units,

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Transjectors and Chambers for the sole purpose of reselling the foregoing to INHALE or its designee as contemplated herein.

7.2 TRADEMARK LICENSE. INHALE hereby grants to each CM a non-exclusive, nontransferable and royalty-free license, without right of sublicense, to use the Trademarks, for the sole purpose of affixing such Trademarks to the Devices, Base Units, Transjectors and Chambers in accordance with the DMR. Such use of the Trademarks shall be subject to review and approval by INHALE or its Pharmaceutical Collaborators. Neither CM shall adopt, use or register any words, phrases or symbols or logos that are identical to or confusingly similar to the Trademarks.

7.3 OWNERSHIP OF PREEXISTING TECHNOLOGY. Subject only to those rights and licenses granted expressly hereunder, each Party shall retain all right, title and interest in and to any Patents or Know-How owned or controlled by such Party prior to the Effective Date.

7.4 OWNERSHIP OF DEVELOPED TECHNOLOGY.

(a) The Parties intend that the Devices, Base Units, Transjectors and Chambers be manufactured on a coordinated and consistent basis, and that the manufacturing processes therefor may be refined and changed during the term of this Agreement. The Parties anticipate that during the course of process development and/or manufacturing Devices, Base Units, Transjectors and Chambers hereunder, the Parties will collaborate with each other and may develop, solely or jointly with another Party, inventions and discoveries in both the Devices, Base Units, Transjectors and Chambers themselves and the manufacturing processes therefor. The Parties therefore agree to allocate the intellectual property rights arising hereunder as provided in this Section 7.4.

(b) [**]

(c) [**].

(d) [**].

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[**]

7.5 DISCLOSURE OF DEVELOPED TECHNOLOGY. The Parties shall adopt, within [**] of the Effective Date, a mutually agreeable procedure for logging and disclosing to INHALE all Improvements and Device Manufacturing Inventions developed by them. Each Party shall also give the other Parties or their designees all such assistance as is reasonably required to transfer, document, otherwise obtain, maintain, enforce and perfect the rights set forth in this Article 7, including, without limitation, the execution of written assignments and other documentation.

ARTICLE 8
REGULATORY MATTERS

8.1 RECALLS; ADVERSE EVENT REPORTING; COMPLAINTS.

(a) RECALLS.

(i) In the event INHALE or any of its Pharmaceutical Collaborators is required (or voluntarily decides) to initiate a recall, product withdrawal or field correction of any Devices, Base Units, Transjectors or Chambers supplied by the CMs pursuant to this Agreement, whether or not such recall has been requested or ordered by any federal, state or foreign agency, INHALE shall give notice to the CMs and the CMs shall fully cooperate with INHALE or its Pharmaceutical Collaborators. Neither CM shall have the right to recall the Devices, Base Units, Transjectors or Chambers at any time unless required to do so by law or order of court.

(ii) If any recall, product withdrawal, or field correction is initiated because of a defect in any Devices, Base Units, Transjectors or Chambers arising from any breach by a CM of any warranty, representation or other material obligation contained in this Agreement or the negligence of a CM, then such CM will [**]

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(iii) If any recall, product withdrawal or field correction is initiated, but Section 8.1(a)(ii) does not apply, the costs of such recall, product withdrawal or field correction, including the costs of any of the CMs' work in process affected by the recall, shall be borne by INHALE. If there are multiple causes of a recall, product withdrawal or field correction, including those set forth in Section 8.1(a)(ii), the Parties shall agree in good faith on an appropriate allocation of the costs of the foregoing in a manner consistent this Section 8.1(a).

(b) ADVERSE EVENT REPORTING. INHALE or its designee shall be responsible for all reporting to regulatory authorities of adverse drug and device experiences ("ADEs") associated with the use of Devices, Base Units, Transjectors or Chambers. The CMs agree to report to INHALE any information received by them with respect to ADEs relating to the Devices on timely basis, to the extent necessary to enable INHALE to meet its legal and regulatory obligations with respect to such ADEs. If a CM shall be subject to legal or regulatory reporting requirements concerning ADEs relating to the Devices, Base Units, Transjectors or Chambers, INHALE agrees that it shall report to such CM information received by INHALE with respect to such ADEs on a timely basis to the extent necessary to enable the CM to meet its legal and regulatory obligations with respect to such ADEs. INHALE shall also work with the CMs to establish a reasonable procedure to take account of the CMs' need to be advised of ADEs involving the Devices, Base Units, Transjectors and Chambers that could reasonably be foreseen to damage or adversely affect the CMs' reputation as developers of high quality drug delivery devices. Prior to Commercial Launch, the Parties shall establish a reasonable mutual protocol to set forth the specific measures that shall be taken to implement the foregoing. The reporting obligations under such protocol shall be subject to the confidentiality obligations each Party may have to third parties. From time to time during the Term of this Agreement, the Parties shall amend such protocol as necessary or appropriate to enable each Party to continue to meet its legal and regulatory responsibilities with respect to such ADEs. INHALE will furnish to the CMs, according to agreed procedures, quarterly summary reports on ADEs concerning the Devices, Base Units, Transjectors and Chambers.

(c) PRODUCT COMPLAINTS. INHALE shall have sole responsibility and authority to respond to any customer or other complaints with respect to the Products. Each CM shall promptly advise INHALE with full details if it receives any such complaints. The CMs shall provide reasonable cooperation and assistance to INHALE in responding to complaints with respect to the Products, including, if necessary, by carrying out appropriate investigations if any complaint relates to operations performed by a CM. [**]

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8.2 COMPLIANCE WITH LAWS AND REGULATIONS.

(a) APPLICABLE REGULATIONS. The CMs shall manufacture the Devices, Base Units, Transjectors and Chambers in accordance with the Applicable Regulations subject to the proviso set forth in Section 9.1. Each Party shall promptly notify the other of any new laws, regulations, rules or requirements of which it becomes aware that pertain to Devices, Base Units, Transjectors and Chambers, and shall confer with the other with respect to the best means to comply with such requirements.

(b) COMPLIANCE WITH LAWS AND REGULATIONS. With respect to its performance hereunder, the CMs shall obtain and comply in all material respects with all applicable permits, and comply in all material respects with all applicable present and future orders, regulations, requirements and laws of any governmental authority in addition to those specified in Section 8.2(a), including without limitation any of the same that apply to any Environmental Law.

(c) REGULATORY AUDITS. Each CM agrees to promptly notify INHALE of any FDA audit, or any audit by any other regulatory body, of its facilities used for the manufacture, storage or packaging of Devices, Base Units, Transjectors or Chambers, or any request for information from the FDA, or other regulatory body, related to the manufacture of Devices, as soon as practicable after it received notice of such audit or request. Each CM shall also promptly provide INHALE with a written report on the results of such audit or request for information, including without limitation, a copy of any report, request or demand issued by the FDA or other regulatory body. Failure to remedy any such deficiencies as required by the applicable regulatory body or a repeated pattern of such deficiencies shall constitute a material breach of this Agreement.

ARTICLE 9
DEVICE WARRANTY

9.1 PRODUCT WARRANTY. Each CM hereby represents, warrants and covenants to INHALE that the Devices, Base Units, Transjectors and Chambers manufactured by it hereunder (a) shall meet and be manufactured in accordance with the applicable DMR and the Manufacturing Requirements therefor; (b) shall be manufactured and packaged in accordance with the Applicable Regulations; (c) shall not be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act of 1938, as amended, or constitute an article that may not be introduced into interstate commerce under the provisions of said Act; (d) shall be tested as provided in Section 4.5; (e) shall be packaged and shipped in compliance herewith, including the DMR, and (f) shall be free and clear of any lien or encumbrance; provided however, that a CM will not be deemed to have breached the warranties set forth in (b) and (c) above if the CM's compliance with the DMR or Manufacturing Requirements results in a violation of Applicable Regulations or the Federal Food Drug and Cosmetic Act of 1938. The warranty hereunder shall not extend to Devices, Base Units, Transjectors or Chambers that are defective as a result of mishandling during shipment or storage by INHALE or a third party or that are defective notwithstanding such CM's compliance with the DMR, Manufacturing Requirements, Regulatory Approvals and Applicable Regulations.

9.2 REMEDIES. INHALE shall notify the applicable CMs in writing of any warranty claim hereunder. The defective Devices, Base Units, Transjectors and Chambers shall be returned to the applicable CM or destroyed, at the CM's option, and the CM shall, at INHALE's election, promptly replace the same free of any additional charge or reimburse or credit INHALE the purchase price, including freight and insurance (if the purchase price has actually been paid by INHALE) for the rejected goods. The costs of return or disposal shall be borne by the CM. Breach of any warranty hereunder by a CM shall be deemed a material breach of this Agreement, and shall be subject to the provisions of Section 14.3(a), in addition to any other remedies available to INHALE at law or in equity.

9.3 WARRANTY DISCLAIMERS AND LIMITATIONS. EXCEPT AS EXPRESSLY PROVIDED IN SECTIONS 9.1 AND 10.1 OF THIS AGREEMENT, THE CMS MAKE NO OTHER WARRANTIES WITH RESPECT TO THE DEVICES, BASE UNITS, TRANSJECTORS OR CHAMBERS, WHETHER EXPRESS OR IMPLIED INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF NON-INFRINGEMENT, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND ANY OTHER IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, WARRANTIES THROUGH COURSE OF DEALING OR USAGE OF TRADE.

ARTICLE 10
REPRESENTATIONS AND WARRANTIES, LIMITATION ON LIABILITY

10.1 BY CMS. Each CM hereby represents, warrants and covenants to INHALE as follows:

(a) INTELLECTUAL PROPERTY. To the best of its knowledge, it has sufficient legal and/or beneficial title under its intellectual property rights necessary to manufacture and supply the Devices, Base Units, Transjectors and Chambers as contemplated herein. It is not aware of any communications alleging that it has violated or, by conducting its business as currently proposed under this Agreement, would violate any of the intellectual property rights of any other person or entity relating to the Devices, Base Units, Transjectors or Chambers. To the best of such CM's knowledge there is no material unauthorized use, infringement or misappropriation of any of these intellectual property rights. As used in this Section 10.1(a), the CM's intellectual property rights shall mean all Patents, copyrights, trademarks, trade secret rights and know-how rights owned or controlled by the CM necessary or useful to manufacture and supply the Devices, Base Units, Transjectors and Chambers as contemplated herein, including without limitation any of such CM's Sole and Joint Inventions.

(b) ASSIGNMENT AGREEMENTS. All of its employees, officers and consultants who have performed, or will be performing, any of its obligations under this Agreement have executed agreements (i) requiring, in the case of employees and officers, assignment to such CM of all inventions made during the course of and as a result of their

association with the CM and (ii) obligating the individual to maintain as confidential the CM's Confidential Information (as defined in Section 12.1), as well as the Confidential Information of INHALE, the other CM or any third party which the CM may receive.

(c) YEAR 2000 COMPLIANCE. The systems and equipment used by such CM in manufacturing and supplying the Devices, Base Units, Transjectors and Chambers as contemplated herein (collectively "System") are Year 2000 Compliant. As used herein, the term "Year 2000 Compliant" means that the System will, in all material respects: (i) Continue to operate as contemplated herein on or after January 1, 2000; (ii) Function in such a manner as to allow the error-free recognition, processing and computation of dates before, during and after January 1, 2000 (which shall include the recognition of the calendar year 2000, and subsequent leap years, as leap years); (iii) Properly record, store, process, manage, specify and print any and all dates, including four digit dates (and data involving or based on four digit dates), falling on or after January 1, 2000, in the same manner, and with the same functionality, accuracy, data integrity and performance as it records, stores, processes, manages, specifies and prints calendar dates and date data (and data utilizing or based on that data) falling on or before December 31, 1999; and (iv) Function in such a manner as to allow the error-fee recognition, processing and computation of data consisting of, based on, or derived in any way from year dates within a single century or within multiple centuries without abnormally ending or generating incorrect values or results. The applicable CM will use commercially reasonable efforts to correct, without delay and at its own expense, any failure of the System to meet the warranty stated herein. If such CM fails to resolve such a warranty defect within fifteen (15) days after a request to correct a defect is made by INHALE, INHALE will have the right to terminate this Agreement with respect to such CM.

(d) THIRD PARTY YEAR 2000 COMPLIANCE. It has made reasonable inquiry into the Year 2000 Compliance of all third party products, equipment, systems, software, interfaces or other technology used by such CM in manufacturing and supplying the Devices, Base Units, Transjectors and Chambers hereunder and is reasonably satisfied that INHALE will not experience any loss as a result of the failure of such third party goods to be Year 2000 Compliant.

10.2 BY INHALE. INHALE hereby represents and warrants to each CM as follows:

(a) INTELLECTUAL PROPERTY. To the best of its knowledge, it has sufficient legal and/or beneficial title under the INHALE Patent Rights and INHALE Know-How necessary to grant the licenses contained herein. It is not aware of any communications alleging that it has violated or, by conducting its business as currently proposed under this Agreement, would violate any of the intellectual property rights of any other person or entity relating to the Devices, Base Units, Transjectors and Chambers. To the best of INHALE's knowledge, there is no material unauthorized use, infringement or misappropriation of any of these intellectual property rights.

(b) ASSIGNMENT AGREEMENTS. All of its employees, officers and consultants have executed agreements (i) requiring, in the case of employees and officers, assignment to INHALE of all inventions made during the course of and as a result of their association with INHALE and (ii) obligating the individual to maintain as confidential the Confidential Information of INHALE, as well as the Confidential Information of the CMs or any third party which INHALE may receive.

10.3 LIMITATION OF LIABILITY. EXCEPT WITH RESPECT TO ARTICLE 11, AND, EXCEPT WITH RESPECT TO ANY INTENTIONAL OR WILLFUL BREACH OF ARTICLE 12, IN NO EVENT SHALL ANY PARTY HEREUNDER BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS OR BUSINESS OPPORTUNITY, INCURRED BY ANOTHER PARTY, WHETHER IN CONTRACT OR TORT OR BASED ON A WARRANTY, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 11
INDEMNIFICATION

11.1 RESPONSIBILITY AND CONTROL. The CMs and INHALE shall each be solely responsible for the safety of their respective employees, agents, licensees or sublicensees with respect to manufacture of the Devices, Base Units, Transjectors and Chambers, and each shall hold the others harmless with regard to any damages or personal injuries sustained by such Party's employees, agents, licensees, or sublicensees with respect to the manufacture thereof, unless such damages or personal injuries result from breach by another Party of any warranty, representation, or other material obligation contained in this Agreement.

11.2 INDEMNIFICATION BY CMS. Each CM shall indemnify, defend (except as provided below) and hold harmless each of INHALE, the other CM, their respective Affiliates and their successors and assigns, and the directors, officers, employees, agents and counsel thereof (the "INHALE Indemnitees"), from and against any and all liabilities, damages, losses, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys' fees) (any of the foregoing, "Damages") incurred by or asserted against any INHALE Indemnitee of whatever kind or nature, including, without limitation, any claim or liability based upon negligence, warranty, strict liability, violation of government regulation or infringement of patent or other proprietary rights, but only to the extent arising from or occurring as a result of a claim or demand made by a Third Party (a "Third Party Claim") against any INHALE Indemnitee because of [**]

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[**]. The indemnified party shall promptly notify such CM of any Third Party Claim, upon becoming aware thereof, shall permit such CM at its cost to defend against such Third Party Claim and to control the defense and disposition (including, without limitation, all decisions to litigate, settle or appeal) of such claim and shall cooperate in the defense thereof. INHALE may, at its option and expense, have its own counsel participate in any proceeding that is under the direction of such CM and shall cooperate with such CM and its insurer in the disposition of any such matter. [**]

11.3 INDEMNIFICATION BY INHALE. INHALE shall indemnify, defend and hold harmless each CM, its successors and assigns, and the directors, officers, employees, agents and counsel thereof (the "CM Indemnitees"), from and against any and all Damages incurred by or asserted against any CM Indemnitee of whatever kind or nature, including, without limitation, any claim or liability based upon negligence, warranty, strict liability, violation of government regulation or infringement of patent or other proprietary rights, but only to the extent arising from or occurring as a result of a Third Party Claim against any CM Indemnitee because of [**]

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[**] The CMs shall promptly notify INHALE of any Third Party Claim, upon becoming aware thereof, and permit INHALE at INHALE's cost to defend against such Third Party Claim and to control the defense and disposition (including, without limitation, all decisions to litigate, settle or appeal) of such Third Party Claim and shall cooperate in the defense thereof. Each CM may, at its option and expense, have its own counsel participate in any proceeding that is under the direction of INHALE and will cooperate with INHALE or its insurer in the disposition of any such matter.

11.4 INTELLECTUAL PROPERTY INDEMNIFICATION. INHALE shall indemnify, defend and hold harmless each CM Indemnitee from and against any and all Damages incurred by or asserted against any CM Indemnitee of whatever kind or nature, because of a Third Party Claim that the manufacture, use or sale of the Devices, Base Units, Transjectors or Chambers, to the extent arising from any of the INHALE Patent Rights or INHALE Know-how, infringes any patent or other intellectual property rights of any third parties. The CMs shall promptly notify INHALE of any such Third Party Claim, upon becoming aware thereof, and permit INHALE at INHALE's cost to defend against such Third Party Claim and to control the defense and disposition (including, without limitation, all decisions to litigate, settle or appeal) of such Third Party Claim and shall cooperate in the defense thereof. Each CM may, at its option and expense, have its own counsel participate in any proceeding that is under the direction of INHALE and will cooperate with INHALE or its insurer in the disposition of any such matter. In the event that Devices are held to infringe any right of any party covered by the foregoing indemnity, INHALE shall be entitled to (i) obtain for the CMs a license to such right or (ii) modify the DMR for the infringing Devices, Base Units, Transjectors or Chambers so that they no longer infringe, or (iii) in the event INHALE is unable to obtain a license or to cause the infringing item to no longer so infringe, INHALE or each CM may, at its option, terminate this Agreement on [**] written notice to the other Parties.

ARTICLE 12
CONFIDENTIALITY

12.1 CONFIDENTIALITY OBLIGATION. Except to the extent otherwise agreed in writing, the Parties agree that, for the Term of this Agreement and thereafter, each Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Information or other information furnished to it by the other Parties pursuant to this Agreement, including, without limitation, the terms of this Agreement and any information furnished by or relating to any Pharmaceutical Collaborator (collectively, "Confidential Information"). If a Party discloses to another Party Confidential Information by means of oral communication, such disclosing Party shall reduce to writing the Confidential Information so disclosed within thirty (30) days after the date of such oral communication in order for such communication to be deemed Confidential Information hereunder. The obligation of confidentiality set forth in this Section 12.1 shall not apply if the receiving Party can establish that the Confidential Information:

(a) was already known by the receiving Party, other than under an obligation of confidentiality, at the time of disclosure to the receiving Party;

(b) was generally available to the public or otherwise part of the public domain at the time of disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after the time of disclosure to the receiving Party other than through any act or omission of the receiving Party in breach of this Agreement; or

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a third party not obligated to the disclosing Party not to disclose such Information to others.

12.2 AUTHORIZED DISCLOSURES. Each Party may disclose another Party's Confidential Information hereunder to the extent reasonably necessary in connection with the exercise of its rights and discharge of its obligations under this Agreement, provided all such disclosures are subject to written confidentiality obligations containing provisions no less protective than those contained herein. Such permitted disclosures include those made in connection with filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations, or conducting non-clinical or clinical trials. If a Party is required by law or regulation to make any such disclosure of another Party's Confidential Information it will, except where impractical for necessary disclosures (for example in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and will use reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed. In addition, each Party may disclose the terms of this Agreement to lenders, investment bankers and other financial institutions of its choice solely for the purposes of financing the business operations of such party either (a) upon the written consent of the other Parties or (b) if the disclosing Party obtains a signed confidentiality agreement with such financial institution with respect to such information on terms no less protective than those contained herein.

12.3 DISCLOSURE OF CM CONFIDENTIAL INFORMATION. Notwithstanding the Parties' intent to implement a coordinated manufacturing process hereunder, INHALE acknowledges that the CMs may not desire to disclose to each other certain of their Confidential Information (e.g., pre-existing proprietary manufacturing processes or business practices). The CMs shall mark all such Confidential Information with a restrictive legend (e.g: "CONFIDENTIAL - DO NOT DISCLOSE THIS INFORMATION TO [the other CM]") and INHALE shall not disclose such Confidential Information to the other CM unless the disclosing CM otherwise agrees in writing. In any event, the CMs shall be entitled to use the Confidential Information of the other CM solely for the purposes of this Agreement.

12.4 DELIVERY OF CONFIDENTIAL INFORMATION. Upon the termination or expiration of this Agreement for any reason, except to the extent necessary to exercise its rights under Section 7.4(d), if any, each Party shall deliver to the disclosing Party its

Confidential Information or, if the disclosing Party so requests, destroy such Confidential Information and certify such destruction in writing to the disclosing Party.

12.5 PUBLICITY. Subject to this Article 12, all publicity, press releases and other announcements relating to this Agreement or the transactions contemplated hereby shall be reviewed in advance by all Parties and shall be subject to the approval of all Parties, not to be unreasonably withheld.

12.6 INJUNCTIVE RELIEF. The Parties acknowledge and agree that any breach or threatened breach of this Article 12 will result in irreparable harm to the Party whose Confidential Information is subject to such breach or threatened breach, for which remedies at law will not be adequate. Each Party, as a disclosing Party, shall therefore be entitled to obtain injunctive relief in any court of competent jurisdiction in addition to any other remedy at law or in equity in the event of a material breach of this Article 12.

ARTICLE 13
RECORDKEEPING, AUDITS AND INSURANCE

13.1 RECORDS RETENTION. Each CM shall keep complete and accurate records pertaining to the development, manufacture, use and sale of Devices, Base Units, Transjectors and Chambers, including without limitation, records relating to the determination of [**] in sufficient detail to permit INHALE to confirm the accuracy of calculations of all payments hereunder. Such records shall be maintained for the longer of (a) four (4) years following the year in which any such efforts or payments were made hereunder and (b) such longer period as may be required by law.

13.2 AUDIT REQUEST. INHALE shall have the right to audit such records, at its own expense, to determine, with respect to any calendar year, the correctness of any report or invoice made under this Agreement, but only once with respect to any calendar year; provided that INHALE may perform additional audits in a calendar year if an audit demonstrates that any report or invoice submitted by a CM hereunder is materially incorrect. If INHALE desires to audit such records, INHALE shall designate the auditors to examine such records, which auditors shall be reasonably acceptable to the CM. Such auditors shall be instructed to provide to INHALE a report on the findings of the agreed upon procedures verifying any report made or invoice submitted by the audited CM during such period. The expense of such audit shall be borne by INHALE; provided, however, that if an undisputed error in favor of INHALE of more than [**], is discovered, then such expenses shall be paid by the CM. Any Information received by INHALE pursuant to this Section 13.2 shall be deemed to be Confidential Information (as defined in Section 12.1) hereunder. This Section 13.2 shall survive any termination of this Agreement for a period of four (4) years.

13.3 INSURANCE.

(a) Each CM, at its sole cost, agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies

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in connection with its activities as contemplated hereby which policies shall provide coverage in an amount not less than [**]. Such policy shall name or include INHALE as an insured or an additional insured. Upon INHALE 's request, each CM shall provide to INHALE a certificate of coverage or other written evidence reasonably satisfactory to INHALE of such insurance coverage. Such insurance policy shall provide that in the event such insurance coverage should be materially adversely changed or terminated for any reason, the insurer thereunder will give the applicable CM and INHALE ten (10) days' prior notice.

(B) INHALE agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated hereby, which policies shall provide coverage in an amount not less than [**]. Such policy shall name or include the CMs as an insured or an additional insured. Upon the CMs' request, INHALE shall provide to CMs a certificate of coverage or other written evidence reasonably satisfactory to CMs of such insurance coverage. Such insurance policy shall provide that in the event such insurance coverage should be materially adversely changed or terminated for any reason, the insurer thereunder will give the applicable CM and INHALE ten (10) days' prior notice.

ARTICLE 14
TERM AND TERMINATION

14.1 TERM. The Term of this Agreement shall commence upon the Effective Date and, unless terminated earlier pursuant to Section 14.2 or 14.3, shall continue in effect until the tenth anniversary of the Effective Date. Thereafter, unless terminated earlier pursuant to Section 14.2 or 14.3, the Term shall be renewed for additional three (3) year periods with respect to each CM, provided that such CM is in full compliance with the terms of this Agreement.

14.2 TERMINATION WITHOUT CAUSE. [**], (a) either CM may terminate this Agreement with respect to such CM by giving at least [**] written notice to INHALE and to the other CM, and (b) INHALE may terminate this Agreement with respect to one or both CMs by giving at least [**] written notice to the applicable CM or CMs.

14.3 TERMINATION FOR DEFAULT.

(a) If a CM is in default of any of its material obligations under this Agreement and fails to remedy that default within [**] after receipt of written notice of such default, INHALE may terminate this Agreement with respect to such CM immediately by giving written notice of such termination. In the event of a dispute regarding any amounts payable to a CM hereunder, all undisputed amounts shall be paid when due and the balance, if any, shall be paid promptly after settlement of such dispute.

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(b) If INHALE is in default of any of its material obligations under this Agreement and fails to remedy that default within [**] after receipt of written notice of such default, either CM or both CMs may terminate this Agreement with respect to such CM or CMs immediately by giving written notice of such termination.

[**]

[**]

[**]

(d) [**]

14.4 PROTECTIVE PROVISIONS.

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(a) Upon a CM's failure to cure any material breach of its obligations under this Agreement within the time provided in Section 14.3 or upon termination of this Agreement pursuant to Section 14.3(c), INHALE shall automatically have the right to engage in or make arrangements for substitute performance. To this end, the defaulting CM agrees to reasonably cooperate with INHALE and its Pharmaceutical Collaborators in negotiating agreements with such CM's vendors that supply to such CM critical goods and services relating to the Devices, Base Units, Transjectors and Chambers to ensure that such vendors will sell goods and/or provide services directly to INHALE or its Pharmaceutical Collaborators immediately after any termination of this Agreement by INHALE pursuant to Section 14.3. Upon any such termination, the defaulting CM shall reasonably cooperate in transferring to INHALE, and/or its Pharmaceutical Collaborators or any contractor of the foregoing that manufactures Devices, Base Units, Transjectors or Chambers under this Section 14.4 ("Subsequent Suppliers") all Improvements to the foregoing and all Device Manufacturing Inventions, at INHALE's cost.

(b) At INHALE's request, from time to time during the Term of this Agreement, the applicable CM shall furnish to INHALE, for possible use under circumstances described in Section 14.4(a), such of such CM's know-how necessary or useful for the manufacture of Devices, Base Units, Transjectors and Chambers, including, without limitation, blueprints and other technical information necessary to produce Tooling and otherwise manufacture such items. Such information shall be placed in escrow pursuant to an escrow agreement to be negotiated by the Parties and a mutually agreed upon escrow agent which agreement shall contain terms typical of standard technology escrow agreements. Such terms shall provide among other things that information held in escrow shall be delivered by the escrow agent to INHALE or its designee upon the delivery of a statement from an executive officer of INHALE or its designee certifying that a material breach by such CM has occurred, and remained uncured, under the terms of Section 14.3 and that INHALE is entitled as a result to the remedies provided under Section 14.4(a).

(c) [**]

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[**]

14.5 EFFECT OF TERMINATION.

(a) Termination, relinquishment or expiration of the Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve any Party from obligations that are expressly indicated to survive termination or expiration of the Agreement and shall not terminate any obligation to pay all amounts which shall have accrued and are payable hereunder. Without limitation of the foregoing, the obligations of the Parties under Sections 5.2 (Invoicing and Payment), 7.3 (Ownership of Pre-existing Technology), 7.4 (Ownership of Developed Technology), 8.1 (Recalls; Adverse Event Reporting; Complaints), 9 (Device Warranty), 10 (Representations and Warranties, Limitation on Liability), 11 (Indemnification), 12 (Confidentiality), 13 (Record Keeping and Audits), 14.4 (Protective Provisions), 14.5 (Effect of Termination) and 15 (Miscellaneous) of this Agreement will survive the termination or expiration of this Agreement.

(b) Promptly upon termination or expiration of this Agreement for any reason, the CMs shall transfer to INHALE or its designee all Tooling and other equipment, inventory or materials funded or purchased by INHALE, and, consistent with the licenses set forth in Section 7.4(d) and to the extent not already provided to INHALE pursuant to Section 3.5(b), shall provide INHALE or its designee with all Improvements and Device Manufacturing Inventions in its possession (including, without limitation, any blueprints, drawings, documents, Pro-E and other computer files and databases and other technical information) and necessary to produce the Tooling and otherwise manufacture the Devices, Base Units, Transjectors and Chambers. In addition, the CMs shall provide to INHALE or its designee, [**], reasonable assistance to enable INHALE or such designee to commence manufacture of the foregoing.

ARTICLE 15
MISCELLANEOUS

15.1 AGENCY. No Party is, or shall be deemed to be, an employee, agent, co-venturer or legal representative of another Party for any purpose. No Party shall be entitled to enter into any contracts in the name of or on behalf of another Party, nor shall a Party be entitled to pledge the credit of another Party in any way or hold itself out as having the authority to do so.

15.2 ASSIGNMENT.

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(a) Neither this Agreement nor any interest hereunder shall be assignable by any Party without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed; provided, however, that a Party may assign this Agreement to any wholly-owned subsidiary or to any successor by merger or sale of substantially all of its business unit to which this Agreement relates in a manner such that the assignor (if it continues as a separate entity) shall remain liable and responsible for the performance and observance of all its duties and obligations hereunder.

(b) [**]

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[**].

(c) This Agreement shall be binding upon the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section shall be void.

15.3 FURTHER ACTIONS. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of the Agreement.

15.4 FORCE MAJEURE. No Party shall be liable to the other for loss or damages or shall have any right to terminate this Agreement for any default or delay attributable to any event beyond its reasonable control, including, but not limited, to acts of God, acts of government (excluding the failure to obtain a Regulatory Approval), fire, flood, earthquake, and the like, if the Party affected shall give prompt notice of any such cause to the other Parties. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled and for [**] thereafter; provided, however, that such affected Party commences and continues to take reasonable and diligent actions to cure such cause. Notwithstanding the foregoing, nothing in this Section 15.4 shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.

15.5 NOTICES. All notices and other communications required or permitted hereunder shall be in writing and shall be deemed effectively given and received (a) upon personal delivery, (b) on the fifth day following mailing by registered or certified mail, return receipt requested, postage prepaid, addressed to the INHALE or the CMs at their respective addresses as listed below (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof), (c) upon transmission of telegram or facsimile (with telephonic notice), or (d) upon confirmed delivery by overnight commercial courier service:

If to Bespak, addressed to:	Bespak Europe Ltd. Bergen Way Kings Lynn, Norfolk PE 30 2JJ England Attention: Commercial Director
With copy to:	Bespak Plc Number 4, Stanhope Gate London England W1Y 5LA Attention: Company Secretary

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If to Tech Group, addressed to:	Tech Group North America, Inc. Suite D-100 7979 North Hayden Road Scottsdale, Arizona 85258-3241 Attention: Chief Executive Officer
With copy to:	Snell & Wilmer L.L.P. One Arizona Center Phoenix, AZ 85004 Attention: Matthew P. Feeney, Esq.
If to INHALE, addressed to:	INHALE Therapeutic Systems, Inc. 150 Industrial Road San Carlos, CA 94070 Attention: Chief Executive Officer
With copy to:	Dorsey & Whitney LLP 220 South Sixth Street Minneapolis, MN 55402 Attention: Karin Keitel, Esq.

15.6 AMENDMENT; APPROVAL. No amendment, modification or supplement of any provision of this Agreement (excluding Exhibits C (Manufacturing Requirements) and D (DMR)) shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party. No approval provided for in this Agreement shall be valid or effective unless confirmed in writing.

15.7 WAIVER. No provision of the Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

15.8 COUNTERPARTS. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

15.9 DESCRIPTIVE HEADINGS. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

15.10 GOVERNING LAW, JURISDICTION AND VENUE. This Agreement shall be governed by and interpreted in accordance with the substantive laws of the state of California and the United States of America, without regard to choice of law rules. The Parties hereby agree that the exclusive jurisdiction and venue of any disputes arising out of or relating to this Agreement shall be the state and federal courts located in [**]

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15.11 SEVERABILITY. Whenever possible, each provision of the Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of the Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

15.12 ENTIRE AGREEMENT OF THE PARTIES. This Agreement, including the specified provisions of other written agreements expressly incorporated by reference herein and the Exhibits attached hereto constitute and contain the complete, final and exclusive understanding and agreement of the Parties hereto, and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties with respect to the subject matter hereof.

15.13 SECTIONS. Unless specified otherwise, references to Sections are to Sections of this Agreement.

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IN WITNESS WHEREOF, the Parties hereto have as of the Effective Date duly executed this Agreement, including the attached Exhibits that are incorporated herein and made a part hereof.

INHALE THERAPEUTIC SYSTEMS, INC.	BESPAK EUROPE LTD.
By_____	By_____
Name_____	Name_____
Title_____	Title_____

TECH GROUP NORTH AMERICA, INC.

By_____

Name_____

Title_____

EXHIBITS

Exhibit A:	Pricing
Exhibit B:	INHALE Patents
Exhibit C:	Manufacturing Requirements
Exhibit D:	Capital Plan
Exhibit E:	[**] Forecast
Exhibit F:	Bespak Currency Provisions

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EXHIBIT 10.27A

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EXHIBIT 10.27C

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EXHIBIT 10.27D

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EXHIBIT 10.27E

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EXHIBIT 10.27F

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EXHIBIT 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the inclusion in this Annual Report (Form 10-K) of Inhale Therapeutic Systems, Inc., of our report dated January 23, 2001.

We also consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-79630, 333-07969, 333-59735, 333-65919, 333-74699, 333-32788, 333-54078, and 333-55032) pertaining to the 1994 Equity Incentive Plan, the 1998 Non-Officer Equity Incentive Plan, and the 2000 Non-Officer Equity Incentive Plan of Inhale Therapeutic Systems, Inc., and pertaining to the Bradford Particle Design PLC Share Option Schemes, respectively and in the Registration Statements (Form S-3 Nos. 333-94161, 333-32576, 333-36152, 333-53678, 333-54080) and related Prospectuses for the registration of its common stock, respectively, of our report dated January 23, 2001, with respect to the consolidated financial statements of Inhale Therapeutic Systems, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2000.

Ernst & Young LLP

Palo Alto, California
February 23, 2001