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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

/X/ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 1999 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
(State or other jurisdiction of incorporation or organization)

94-3134940 (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 March 1, 2000 as reported by Nasdaq National Market was approximately \$1,860,035,885. Determination of affiliate status for this purpose is not a determination of affiliate status for any other purpose.

20,588,388

(Number of shares of common stock outstanding as of March 1, 2000)

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's definitive Proxy Statement to be filed for its 2000 Annual Meeting of Shareholders are incorporated by reference into Part III hereof.

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ITEM 1. BUSINESS

OVERVIEW

Inhale Therapeutic Systems, Inc. ("Inhale") is creating a drug delivery system to easily and painlessly deliver a wide range of drugs, including peptides, proteins, nucleic acids and other molecules, by inhalation to the deep lung for treatment of systemic and respiratory diseases. Inhale is using this system principally to enable non-invasive delivery of protein drugs currently administered by injection. Inhale's most advanced program, which is sponsored by Pfizer Inc. ("Pfizer"), is inhaleable insulin. Pfizer commenced dosing for its Phase III clinical trials in June 1999. In addition to its insulin program with Pfizer, Inhale has 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. Inhale also has early stage feasibility and research collaborations with several other companies and has tested seven 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 \$14 billion worldwide in 1997. 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, Inhale believes a deep lung inhalation delivery system could expand the market for protein drug therapies by increasing patient acceptance and improving compliance and may enable new therapeutic uses of certain protein drugs.

Inhale is creating a proprietary platform integrating customized formulation, dry powder processing and packaging with a proprietary inhalation device to enable efficient, reproducible delivery of drugs for systemic and local lung indications. For specific drug products, Inhale formulates and processes 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 Inhale's device, which patients then activate to inhale the aerosolized drugs. Inhale has developed an inhalation device that is being used several times per day for several months in outpatient trials for insulin. In addition, Inhale has demonstrated room temperature stability of a year or more for a number of protein drugs, and has scaled-up its powder processing and packaging for late stage clinical trials and small scale production for certain drugs.

As an alternative to invasive delivery techniques, Inhale believes that a deep lung delivery system could potentially expand the market for protein 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 protein drugs. Inhale is focusing development efforts on applying its pulmonary delivery system primarily to drugs for systemic and local lung diseases that either have proven efficacy and are approved for delivery by injection or are in late stage clinical trials.

A cornerstone of Inhale's business strategy is to work with collaborative partners to develop and commercialize drugs for deep lung delivery. In a typical collaboration, Inhale's partner will support the application of Inhale's technology to a particular drug by providing the drug, funding clinical development, and marketing the resulting commercial product. Inhale typically will supply the delivery system and receive research and development and progress payments during development, and receive revenues from powder manufacturing, device supply, and royalties from sales of any commercial products.

In addition to Pfizer's sponsorship of the inhaleable insulin program, Inhale has active development programs with several other corporate partners. Inhale's most recent collaboration is with Biogen for pulmonary delivery of Interferon-Beta-la, sold under the trade name AVONEX-Registered Trademark-, the leading drug worldwide for the treatment of Multiple Sclerosis. Inhale is also engaged in development collaborations with Aventis Behring on alpha-l proteinase inhibitor for genetic emphysema, and with Lilly for an undisclosed protein drug. Inhale is also engaged in early stage feasibility and research programs with respect to other compounds. Inhale anticipates that any product that may be developed would be commercialized with a collaborative partner and believes its partnering strategy will enable it to reduce the investment required to develop a large and diversified potential product portfolio.

In late 1999, Inhale completed the sale of approximately \$108.5 million aggregate principal amount of 6 3/4% Convertible Subordinated Debentures due October 13, 2006. In early 2000, the Company 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, the Company has agreed to make cash payments of approximately \$16.2 million in the aggregate in connection with agreements that provide for the conversion of approximately \$94.2 million aggregate principal amount of outstanding debentures into approximately 2.9 million shares of common stock. Such amounts will be reflected as a charge to interest expense in the first quarter of 2000.

In February 2000, Inhale 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 2007 and are convertible into shares of Inhale's common stock at a conversion price of \$76.71 per share, subject to adjustment in certain circumstances.

Upon completion of the issuance of the February 2007 notes and the exchange of the October 2006 debentures, the Company expects to net approximately \$206.2 million cash.

OPPORTUNITY FOR PULMONARY DRUG DELIVERY

MACROMOLECULES

Innovations in biotechnology and recombinant techniques have led to a large increase in the number of 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 biotechnology drugs are approved for marketing in the United States and approximately 120 additional biotechnology drugs are in clinical trials, many for chronic and subchronic diseases. Sales of genetically engineered protein drugs were estimated at \$14 billion worldwide in 1997.

There are five typical routes of administration of drugs, four natural and one which bypasses natural barriers to entry of molecules into the body. The four natural routes are through the digestive tract (oral), the skin (transdermal), the mucosal surfaces (nasal and sublingual), and the lung (inhalation). Penetration of the skin by injection (subcutaneous, intramuscular, or intravenous) bypasses the major natural barrier to prevent molecules from entering the body.

Oral delivery is a common method of delivery for many small molecule drugs. However, macromolecules are typically extremely vulnerable to digestion and therefore are very poorly delivered by an oral route. In addition, Inhale believes that dosage reproducibility for oral delivery of macromolecules may be very poor because of their low oral bioavailability. 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 penetration of the skin inefficient or ineffective. Passive transdermal delivery using "patch" technology has not been successful to date since the skin is less

naturally permeable to macromolecules than the gastrointestinal tract. No macromolecule drugs have been approved for marketing in the United States utilizing patch technology. Certain peptides and proteins can be transported across the skin barrier into the bloodstream using high pressure "needle-less" injection devices. The devices, which inject proteins like insulin through the skin into the body, have been available for many years. However, Inhale believes these devices have not been well accepted due to patient discomfort and relatively high cost.

The nasal route of drug administration has been limited by low and variable bioavailability for proteins and peptides. As a result of these limitations, penetration enhancers are often used with nasal delivery 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. Inhale believes these same obstacles will affect sublingual drug delivery, which also relies on the penetration of similar tissue in the mouth.

The principal practical and efficient route of administration of macromolecules, particularly recombinant 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, such therapies for many chronic and subchronic diseases meet with varying degrees of patient acceptance and compliance with the prescribed regimens. Poor acceptance and compliance 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 inconvenience to these patients and the cost of therapy.

Delivery of drugs to the lungs via inhalation (pulmonary delivery) has the potential to be a much more effective route of administration of macromolecules, with a relatively higher absorption into the bloodstream (bioavailability) than all alternative routes except injection. As an alternative to the invasiveness of injection, Inhale believes 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.

Existing pulmonary drug delivery systems such as metered-dose inhalers ("MDIs"), dry powder inhalers and nebulizers, are used primarily to deliver drugs to the upper airways of the lung for lung diseases. Approximately 35 drugs are approved for marketing by the FDA for delivery into the respiratory tract, but none of these pulmonary drug delivery devices were designed to optimize drug delivery to the deep lung for absorption into the bloodstream. MDIs, dry powder inhalers 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, Inhale believes that the total efficiency of such systems is generally not high enough to be commercially feasible for systemic delivery of most macromolecule drugs.

In addition, pulmonary drug delivery devices currently do not provide the dosage reproducibility and formulation stability generally needed for commercially viable systemic macromolecule drug delivery. Inhale believes that many MDI and dry powder 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, Inhale believes that many macromolecules currently cannot be formulated for use in MDI systems, since macromolecule drugs could be denatured by the MDI formulating ingredients. In addition, Inhale believes that some macromolecules may be inactivated by nebulization and that many dry powder systems do not provide the protection needed for long-term stability that may be needed for macromolecule formulations.

Inhale believes 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.

Inhale also believes that opportunities for a deep lung delivery system exist in the delivery of macromolecules for local lung diseases due to the limitations of current pulmonary devices. 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, Inhale is investigating opportunities for leveraging its technology for application to small molecules where there is a clear, demonstrable need for an alternative drug delivery system and where Inhale's existing technology can be applied without significant modification. Examples include molecules that require rapid systemic absorption for efficacy (i.e., analgesics and antiemetics), molecules that undergo massive first pass metabolism 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 dry powder inhalers 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.

Inhale believes that its 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. Inhale further believes its 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 better targeted pulmonary delivery.

STRATEGY

Inhale's goal is to become the leading drug delivery company in the field of pulmonary delivery of macromolecules. In addition, Inhale is leveraging its technology base for other applications where its system can provide significant market advantages. Inhale's strategy incorporates the following principal elements:

- DEVELOP A BROADLY APPLICABLE PULMONARY DELIVERY SYSTEM. Inhale is developing its 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. Inhale intends 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 Inhale and its partners.
- BUILD COMPETITIVE ADVANTAGE THROUGH AN INTEGRATED SYSTEMS APPROACH. Inhale is developing a commercially viable deep lung delivery system through an integrated systems solution. Inhale combines its expertise in pulmonary physiology and biology, aerosol science, powder science, 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. Inhale believes that building expertise in technology across several disciplines provides it with a significant competitive advantage.

- PARTNER WITH PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES.Inhale's strategy is to market its proposed products through collaborative partners. Inhale is seeking to work with partners that have significant clinical development and marketing resources, and currently has collaborations with several large pharmaceutical and biotechnology companies. For patented drug products, Inhale intends to partner with owners or licensees from the outset of the project. For drugs that are off-patent or licensed-in, Inhale may perform initial feasibility screening work, formulations development and early stage clinical trials before entering into a partner relationship for further development. Inhale believes this partnering strategy enables it to reduce its cash requirements while developing a large and diversified potential product portfolio.
- FOCUS ON APPROVED OR LATE STAGE DRUGS. To date, Inhale has focused primarily on drugs that either have proven efficacy and are approved for marketing or are in late stage clinical trials. Inhale believes that working primarily with drugs with demonstrated efficacy reduces the technical risk of its projects. In the future, Inhale anticipates working on drugs at earlier stages of development.
- EXPAND MANUFACTURING CAPABILITY. Inhale intends to formulate, manufacture and package dry powders for most of its drugs and to subcontract manufacturing of its device. Inhale believes 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.

INHALE'S DEEP LUNG DRUG DELIVERY SYSTEM

Inhale believes 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 loss during manufacture, in the delivery device, in reaching the site of absorption, and during absorption from that site into the bloodstream. Inhale believes 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.

Inhale approaches 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, Inhale's delivery system integrates customized drug formulations and packaging with its proprietary inhalation device. Inhale combines an understanding of lung biology, aerosol science, chemical engineering, mechanical engineering and protein formulations in its system development efforts. Inhale believes that this interdisciplinary capability provides an important competitive advantage.

Inhale has chosen to base its 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. Inhale believes 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.

Inhale takes bulk drugs supplied by partners and formulates and processes them into fine powders that are then packaged into individual blisters. The blisters are designed to be loaded into Inhale's 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 Inhale is in the advanced stages of developing its system technologies, there can be no assurance that Inhale's 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. Inhale has assembled a team with expertise in protein formulation, powder science and aerosol science and is applying this expertise to develop proprietary techniques and methods that it believes will produce stable, fillable and dispersible dry powder drug formulations. Inhale has developed several protein powders which remain stable at room temperature in excess of one year. Through its work with numerous macromolecules, Inhale is developing an extensive body of knowledge on aerosol dry powder formulations, including knowledge relating to powder flow characteristics and solubility within the lung, as well as physical and chemical properties of various excipients. Inhale has filed and expects to continue to file patent applications on several of its formulations and, through strategic acquisitions, has acquired rights to certain U.S. and foreign patents and patent applications relating to stabilization of macromolecule drugs in dry formulations.

POWDER PROCESSING

Inhale is modifying standard powder processing equipment and developing custom techniques to enable it to produce fine dry powders with particle aerosol diameters of between one and five microns without degradation or significant loss of expensive bulk drug. Inhale has scaled up powder processing to levels sufficient for producing test powders for late stage clinical trials and small volume marketed products. Inhale is in the process of further scaling up its powder processing systems in order to produce quantities sufficient for commercial production of products Inhale believes it will need to supply in high volumes, such as insulin. However, there can be no assurance that Inhale will be successful in further scaling up its 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 that do not behave in a granularly flowing way, are generally compressible, and hence require handling that is different than for powders comprised of larger particles. Currently available commercial filling and packaging systems are designed for filling powders of larger particle size and therefore must be re-engineered to dispense finer powders accurately and in the small quantities often required. Initially, during early stages of development, powder filling was performed manually. Inhale has since developed and qualified a proprietary automated filling system suitable for use in production of clinical trial supplies and commercial quantities for certain products. Inhale is further developing a high through-put system for use with products whose market requirements dictate increased capacity.

TNHALATION DEVICE

Inhale's 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 its objectives, Inhale has designed its 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. Inhale has developed and is refining its dispersion system for its device specifically for fine powders. Inhale's 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. Inhale is developing a proprietary aerosol cloud handling system in its 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, the Inhale 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.

The success of Inhale's deep lung drug delivery system for any drug will depend upon Inhale achieving sufficient formulation stability, safety dosage reproducibility and total system efficiency (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 $\ensuremath{\mathsf{I}}$ 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, (e.g., in 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 would 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 Inhale will be able to successfully develop such an inhalation device or overcome such other obstacles to reproducible dosing.

CLINICAL STATUS SUMMARY

The following table sets forth, for both Inhale's partner development programs and Inhale's programs available for partnering, the drug currently in development, the indication(s) for the particular drug, its present stage of clinical development and, with respect to Inhale's partner development programs, the identity of Inhale's 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	Preclinical	Biogen
Undisclosed Protein	Not Released	Preclinical	Lilly
PTH	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	

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(1) Clinical Status means:

Phase III - large-scale out-patient clinical trials conducted to obtain information regarding specific patient groups conducted 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.

 $\label{eq:preclinical-formulation} \mbox{ Preclinical - formulation development and animal testing in preparation for human trials}$

INHALE'S PARTNER DEVELOPMENT PROGRAMS

In general, Inhale's 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. 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 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 are diagnosed with diabetes; another 5.4 million 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 case, 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 ("NIH"), 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, Inhale and Pfizer are developing an inhaled version of regular insulin that can be administered in one to three blisters per dose using Inhale's deep lung delivery system. Inhale believes that its 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, Inhale believes that pulmonary delivery could yield medical advantages by providing a more rapid acting insulin than most currently marketed injectable products.

Through its collaboration with Inhale, Pfizer conducted Phase I and Phase IIa clinical trials which indicated that pulmonary insulin was absorbed systemically, reduced blood glucose levels and provided the same glycemic control 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 Alc, 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 IIb data which indicated that results from 56 to 69 patients in a three-month trial showed that individuals with Type 2 diabetes can markedly improve their glycemic control without insulin injections by combining Inhale's pulmonary insulin with oral diabetes agents.

In November 1998, Pfizer and Aventis announced that they entered into worldwide agreements 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 manufacturing plant in Frankfurt, Germany. Until its completion, Pfizer will provide Inhale with biosynthetic recombinant insulin for powder processing from Aventis's existing plant. Inhale will continue to have responsibility for manufacturing powders and supplying devices and will receive a royalty on inhaleable insulin products marketed jointly by Pfizer and Aventis. In November 1998, Pfizer held a meeting for 117 Phase III sites of the inhaleable insulin trials and in June 1999, Pfizer began dosing for the Phase III clinical trials.

In January 1995 and October 1996, Pfizer made two \$5\$ million equity investments in Inhale at a 25% premium to the market price of Inhale stock at the time of each investment.

In January 1997, Inhale 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 Inhale will receive royalties on product sales, an up-front signing fee and up to an estimated \$15 million in research and development funding and milestone payments.

The two companies have completed preclinical work that indicates Inhale's 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. Inhale believes its 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. 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. In December 1999, patient dosing began for Phase I clinical trials.

AVONEX-REGISTERED TRADEMARK- PROGRAM

In February 1999, Inhale entered into a collaborative agreement with Biogen to develop an inhaleable formulation of Biogen's proprietary Interferon-Beta-la, marketed as AVONEX-Registered Trademark-, for the treatment of Multiple Sclerosis. Multiple Sclerosis is believed to be the most common chronic neurological condition of young adults in North America and Europe. It is estimated that over 250,000 people in the United States are currently affected by Multiple Sclerosis and that approximately 10,000 new cases are diagnosed annually in the United States. Under the terms of the agreement, Inhale will receive royalties on product sales, an up-front signing fee, and up to an estimated \$25 million in research and development funding and potential progress payments. Biogen will provide bulk AVONEX-Registered Trademark- to Inhale for formulation into a dry powder which is stable at room temperature. Inhale will manufacture and package the dry powder and supply inhalation devices. Biogen will be responsible for clinical trials, marketing and commercialization.

PROPRIETARY MOLECULE PROGRAM WITH LILLY

In January 1998, Lilly and Inhale entered into a collaborative agreement to develop an inhaleable formulaton for an undisclosed protein product based on Inhale's deep lung drug delivery system. Under the terms of the agreement, Inhale will receive funding of up to \$20 million in research, development and milestone payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on sales of any marketed products. Inhale will manufacture packaged powders for, and supply inhalation devices to, Lilly.

PTH PROGRAM

In January 1997, Inhale entered into a collaborative agreement with Lilly to develop pulmonary delivery for parathyroid hormone (PTH 1-34) with the target indication of treatment and prevention of osteoporosis. At this 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, 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 PTH 1-34 led Lilly to suspend further clinical development of the injectable and pulmonary versions of this

drug pending further analysis. Inhale is maintaining a minimum development effort in its pulmonary program pending further direction from Lilly. Depending on the continued evaluations by Lilly, this inhalation program could be re-initiated, suspended for an extended period, or possibly terminated. Inhale does not currently believe that this program will be re-initiated by Lilly in the near future, if at all.

INHALE'S PROGRAMS AVAILABLE OR EXPECTED TO BE AVAILABLE FOR PARTNERING

CALCITONIN PROGRAM

Inhale is 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, Inhale 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 Inhale's system. Inhale is continuing work on this program while it seeks 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. Inhale collaborated with Immunex 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, Inhale entered into a collaborative agreement with Baxter International Inc. to use Inhale's dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In connection with the collaboration, Baxter made a \$20 million equity investment in Inhale at a 25% premium to the market price of Inhale stock at the time of the investment. At that time, Baxter received worldwide commercialization rights for four non-protein/peptide drugs in exchange for up to an estimated \$60 million in research and development funding and progress payments.

In April 1998, Inhale announced that the first two compounds from its 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 as it was the product with the most commercial potential. The technology from one of the three remaining products was returned to Inhale, leaving the development of the other two compounds on hold. In October 1998, Inhale announced that it 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 Inhale and are now available for other partnering opportunities.

OTHER PROGRAMS

In addition to the above mentioned programs, Inhale has conducted and continues to conduct feasibility studies with respect to additional drug formulations both for its own account and in cooperation with potential partners. Inhale 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 Inhale in January 1999.

MANUFACTURING

Inhale generally plans to formulate, manufacture and package the powders for its deep lung delivery products and to subcontract the manufacture of its proprietary pulmonary delivery devices. Under its collaborative agreement with Pfizer to develop inhaleable insulin, Inhale 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, Inhale must build and have validated a powder processing facility and must have validated a device manufacturer or manufacturers. Inhale believes its manufacturing strategy will enable it to achieve the following:

- provide economies of scale by utilizing manufacturing capacity for multiple products;
- improve its ability to retain any manufacturing know-how; and
- allow its customers to bring pulmonary delivery products to market faster.

Inhale has built a powder manufacturing and packaging facility in San Carlos, California capable of producing powders in quantities sufficient for clinical trial. 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. Inhale is expanding its facility to meet its future commercial manufacturing commitments.

Inhale is working to further scale-up its 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 Inhale's 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 required by Inhale. Inhale has developed and validated a proprietary prototype automated filling system which Inhale believes is capable of supporting its requirements through Phase III trials and into commercial production for some products. Inhale is developing a higher capacity automated filling unit capable of filling blisters on a production scale for moderate and large volume products. Inhale faces significant technical challenges in developing an automated, commercial-scale filling system that can accurately and economically handle the small dose and particle sizes of its powders. There can be no assurance that Inhale will be able to develop or acquire the technology necessary to develop successfully any such system in a timely manner or at commercially reasonable cost. Any failure or delay in developing such technology would delay product development or bar commercialization of Inhale's products and would have a material adverse effect on Inhale.

Inhale's proprietary inhalation device has been developed for commercial use and is being used in the Phase III insulin and other trials in 2000. Inhale plans to subcontract the manufacture of its pulmonary delivery device before commercial production of its first product. Inhale has identified contract manufacturers that it believes have the technical capabilities and production capacity to manufacture its devices

and which can meet the requirements of current good manufacturing practices. There can be no assurance that Inhale will be able to obtain and maintain satisfactory contract manufacturing on commercially acceptable terms, if at all. Inhale's dependence upon third parties for the manufacture of its inhalation device may adversely affect Inhale's cost of goods and its ability to develop and commercialize products on a timely and competitive basis.

GOVERNMENT REGULATION

The research and development, manufacture and marketing of pulmonary drug delivery systems are subject to regulation by the FDA in the United States 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, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of Inhale's 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 ("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 ("NDA") with respect to drugs or a Biological License Application ("BLA") with respect to biologics.

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 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. 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 ("IRB"). The IRB will consider, among other things, ethical factors, the potential risks to subjects participating in the trial and the possible liability of the institution.

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
- 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 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 ("DEA"). Domestic manufacturing establishments are subject to biennial inspections by the FDA for compliance with current good manufacturing practices compliance. Inhale is 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 with which Inhale is working are already approved for marketing by the FDA. Inhale believes 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, Inhale expects that its formulations often will 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 in, gaining regulatory approval. In addition, regulatory procedures applicable to Inhale's 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 the products currently under development, Inhale's 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 Inhale's 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.

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

Sales of Inhale's 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 Inhale's 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 Inhale's proposed products has been submitted to the FDA for marketing approval. Inhale has no experience obtaining such regulatory approval, does not have the expertise or other resources to do so and intends to rely on its partners to fund clinical testing and to obtain product approvals.

PATENTS AND PROPRIETARY RIGHTS

Inhale's policy is to apply for patent protection for the technology, inventions and improvements deemed important to the development of its business. Inhale also relies upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and further develop its competitive position. Inhale plans to defend aggressively its proprietary technology and any issued patents.

Inhale expects that its 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 Inhale's strategy to build proprietary positions in each of its technological areas. Inhale's success will depend in part upon its ability to protect its proprietary technology from infringement, misappropriation, duplication and discovery. Inhale has filed patent applications covering certain aspects of its device and powder processing technology and powder formulations and pulmonary route of delivery for certain molecules, and plans to file additional patent applications. There can be no assurance that any of the patents applied for by Inhale will issue, or that any patents that issue will be valid and enforceable. Even if such patents are enforceable, Inhale anticipates that any attempt to enforce its patents could be time consuming and costly.

Inhale currently has 49 issued U.S. and foreign patents covering certain aspects of its technology and has a number of patent applications pending. The United States Patent and Trademark Office (the "PTO") has issued the following patents to Inhale:

- Patent No. 5,458,135 (October 17, 1995) for certain claims covering the use of its device in a method for delivering aerosolized (including powder) formulations of drugs to the lung.
- Patent No. 5,607,915 (March 4, 1997) for pulmonary delivery of active fragments of parathyroid hormone (PTH) 1-34.
- Patent No. 5,654,007 (August 5, 1997) for a system and methods for processing fine dispersible powders for easier processing.
- 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) for methods and means for pulmonary delivery of dry powder alpha1-antitrypsin, a proteinase inhibitor, for administration to a patient.

- Patent No. 5,785,049 (July 28, 1998) for approximately 50 claims directed to 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 and for which Inhale utilizes the design described therein to achieve efficient aerosolization of fine dry powders to enable deep lung delivery for systemic absorption.
- Patent No. 5,814,607 (September 29, 1998) for pulmonary delivery of active fragments of parathyroid hormone of between 34 and 38 amino acids in length.
- Patent No. 5,826,633 (October 27, 1998) relating to Inhale's 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 Inhale's pulmonary delivery system.
- Patent No. 5,922,354 (July 13, 1999) for a method for preparing fine particles by agglomeration.
- 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) for a process for spray-drying hydrophobic drugs in organic solvent suspensions.
- Patent No. 5,985,248 (November 16, 1999) for a process for spray-drying a hydrophobic drug and a hydrophilic excipient in an organic solvent and compositions formed by the process.
- Patent No. 5,993,783 (November 30, 1999) for a respirable alpha-1-antitrypsin dry powder having an areodynamic diameter of less than 5 Microns.
- 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. 6,001,336 (December 14, 1999) for a process for spray drying a hydrophobic drug in an aqueous suspension with a hydrophilic component.

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

In March 1998, Inhale and Initiatech Inc. signed an agreement under which Inhale licensed technology, intellectual property, and patents for protecting biologically active compounds in the dry state. Inhale intends to use this technology to expand its current technology base in stabilizing dry powder aerosol formulations for peptides, proteins, and other macromolecules at room temperature. Inhale's 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, Inhale 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 Inhale will be successful in obtaining a reissued patent. A second U.S. patent from this portfolio issued to Inhale on July 27, 1999 and is noted above. 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. Inhale successfully defended the patent and its method claims relating to glass stabilization technology against four opposing parties. In addition, in late 1999, based on claims of this granted European patent, Inhale 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 Inhale.

Inhale has 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 it believes could be important to the development of its 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 Inhale. Recently, this decision was upheld on appeal. The pending patent covers the pulmonary delivery of cytokines and growth factors.

The patent positions of pharmaceutical, biotechnology and drug delivery companies, including Inhale, 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, Inhale does not know whether any of its 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, Inhale cannot be certain that it was the first inventor of inventions covered by its issued patents or pending patent applications or that it was the first to file patent applications for such inventions. Moreover, Inhale may have to participate in interference proceedings declared by the PTO to determine priority of invention, which could result in substantial cost to Inhale, even if the eventual outcome is favorable. An adverse outcome could subject Inhale to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require Inhale to cease using the technology in dispute.

Inhale is 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. Inhale cannot predict with any certainty which, if any, patent references will be considered relevant to its technology by authorities in the various jurisdictions where such rights exist, nor can Inhale predict with certainty which, if any, of these rights will or may be asserted against it by such third parties. There can be no assurance that Inhale can obtain any license to any technology that it determines it needs, on reasonable terms, if at all, or that Inhale could develop or otherwise obtain alternate technology. The failure to obtain licenses if needed would have a material adverse effect on Inhale.

Inhale also relies upon trade secret protection for its 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 Inhale's trade secrets or disclose such technology, or that Inhale can meaningfully protect its trade secrets.

Third parties from time to time have asserted or may assert that Inhale is infringing their proprietary rights based upon issued patents, trade secrets or know-how that they believe cover Inhale's technology. In addition, future patents may issue to third parties which Inhale's technology may infringe. Inhale could incur substantial costs in defending itself and its partners against any such claims. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief which could effectively block Inhale's ability to further develop or commercialize some or all of its products in the United States and abroad, and could result in the award of substantial damages. In the event of a claim of infringement, Inhale and its partners may be required to obtain one or more licenses from third parties. There can be no assurance that Inhale or its partners 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 Inhale.

Inhale's ability to develop and commercialize its technology will be affected by its or its partners' access to the drugs which are to be formulated. Many biopharmaceutical drugs, including some of those which are presently under development by Inhale, 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 Inhale is developing pulmonary delivery formulations. Inhale intends generally to rely on the ability of its partners to provide access to the drugs which are to be formulated for pulmonary delivery. There can be no assurance, however, that Inhale's partners will be able to provide access to drug candidates for formulation for pulmonary delivery or that, if such access is provided, Inhale or its 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 Inhale.

It is Inhale's policy to require its employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from Inhale to execute confidentiality agreements upon the commencement of employment or consulting relationships with Inhale. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with Inhale 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 the property of Inhale. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for Inhale's trade secrets in the event of unauthorized use or disclosure of such information.

COMPETITION

Inhale believes that products developed using its 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 Inhale. 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 Inhale's pulmonary delivery technology in certain applications. Inhale believes its technology and integrated pulmonary delivery systems approach provides it 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 Inhale's proprietary deep lung drug delivery system.

With respect to pulmonary delivery, several companies are marketing and developing dry powder, MDI, liquid and nebulizer devices that could have applications for drug delivery, including Dura Pharmaceuticals, Inc. and Aradigm Corporation, which also have collaborative arrangements with corporate partners for the development of pulmonary delivery systems for insulin. Several of these companies may have or may be developing dry powder devices that could be used for pulmonary delivery of proteins and other macromolecules. There can be no assurance that competitors will not introduce products or processes competitive with or superior to those of Inhale. Inhale intends to monitor competitive device activities and continue to focus its activities on those products for which Inhale believes it has and can maintain a competitive advantage. If a device is developed that is superior to Inhale's for certain applications, Inhale may seek to obtain a license to allow Inhale's partners to use such device with Inhale-developed powders, although there can be no assurance that Inhale would be able to do so.

Inhale's 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 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 subtonic indications (such as sustained release systems), Inhale's business would be negatively impacted.

Inhale is 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. Inhale is 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, bucal 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 Inhale and represent significant competition for Inhale. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance competitors' financial, marketing and other resources. Accordingly, Inhale's competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than Inhale. Developments by others may render Inhale's products or technologies noncompetitive or obsolete.

EMPLOYEES AND CONSULTANTS

As of December 31, 1999, Inhale had 339 employees, of which 252 were engaged in research and development (including manufacturing) activities and 87 in general administration and business development. One hundred twenty-five of the employees hold advanced degrees, of which 88 are Ph.D.s. Inhale employs scientists and engineers with expertise in the areas of pulmonary biology, aerosol science, powder technology, mechanical engineering, protein chemistry and chemical engineering. None of Inhale's employees are covered by a collective bargaining agreement and Inhale has experienced no work stoppages. Inhale believes that it maintains good relations with its employees.

To complement its own expertise, Inhale utilizes specialists in regulatory affairs, pulmonary toxicology, process engineering, manufacturing, quality assurance, device design, clinical trial design and business development. These individuals include certain of Inhale's scientific advisors as well as independent consultants. See "Management."

THE FOLLOWING RISK FACTORS SHOULD BE READ CAREFULLY IN CONNECTION WITH EVALUATING INHALE'S BUSINESS. ANY OF THE FOLLOWING RISKS COULD MATERIALLY ADVERSELY AFFECT INHALE'S 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 seven 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 you 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. Our 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 its drug loss is excessive at any one stage or cumulatively in the manufacturing and delivery process or if its 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 its 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

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 United States Food and Drug Administration ("FDA") and equivalent foreign authorities. This process generally takes a number of years and requires the expenditure of substantial resources; although 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, 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 Inhale, 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 enter into or maintain arrangements with any 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 plan 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 obtain and 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 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 OUR PRODUCTS.

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, 1999, we have an accumulated deficit of approximately \$94.5 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 24 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.

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, and powder formulations and deep lung route of delivery for certain molecules, and we plan to file additional patent applications. We currently have 49 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 our 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 Inhale, 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 months, based on closing prices on the Nasdaq National Market, our stock price ranged from \$23.00 to \$126.62. 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.

As of December 31, 1999, we had approximately \$113.3 million in long-term debt. Upon the closing of our sale of 5.0% convertible subordinated notes in early 2000, we incurred additional long-term indebtedness of \$230.0 million. In early 2000, we entered into agreements with certain holders of the October 2006 debentures to reduce the principal amount of debentures outstanding by approximately \$94.2 million. Upon closing of the offering of the notes, our long-term debt was approximately \$249.2 million. This increased indebtedness has and will continue to impact us by:

- significantly 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.

ITEM 2. PROPERTIES

Inhale currently leases approximately 156,000 square feet in San Carlos, California, 20,000 square feet in Palo Alto, California and 8,000 square feet in Belmont, California. The Palo Alto facility is used for research, development and administration; the lease has a five-year term, and expires on May 31, 2003. The Belmont facility is used for administration; the lease has a 30-month term and expires on June 30, 2003.

The San Carlos facility is leased pursuant to a 15-year lease agreement. The San Carlos facility serves as the Company's corporate headquarters and is used for research, development, manufacturing and administration. The lease provides Inhale with an option to lease approximately 69,000 additional square feet in the same facility. This manufacturing facility operates under current good manufacturing practices and has been approved and licensed by the State of California to manufacture clinical supplies for use in clinical trials.

In October 1998, Inhale acquired 4.7 acres of land adjacent to its San Carlos facility. Inhale intends to use this property to expand future operations. In October 1999, Inhale commenced construction of an 85,000 square foot facility on this site to expand its administrative offices and research and development capacity.

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 Inhale's shareholders in the quarter ended December 31, 1999.

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

PRICE RANGE OF COMMON STOCK

Inhale's Common Stock trades on the Nasdaq National Market under the symbol INHL. The table below sets forth the high and low closing sales prices for Inhale's Common Stock (as reported on the Nasdaq National Market) during the periods indicated.

PRICE RANGE OF COMMON STOCK YEAR ENDED DECEMBER 31, 1998: 1(st) Quarter..... \$ 34.250 \$25.250 2 (nd) Quarter.... 34.000 23.125 3 (rd) Quarter..... 29.875 21.750 4(th) Quarter.... 33.375 21.500 YEAR ENDED DECEMBER 31, 1999: 1(st) Quarter.....\$ 34.625 23.000 34.875 23.625 3 (rd) Quarter..... 4(th) Quarter..... YEAR ENDED DECEMBER 31, 2000:

As of December 31, 1999, there were approximately 225 holders of record of Inhale's Common Stock. Inhale has not paid any cash dividends since its inception and does not intend to pay any cash dividends in the foreseeable future.

RELATED STOCKHOLDER MATTERS

In February 2000 we issued \$230,000,000 aggregate principal amount of 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 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 notes are convertible at a conversion price of \$76.71 per share, which is equal to a conversion rate of approximately 13.037 shares per \$1,000 principal amount of notes, subject to adjustment. Interest on the debentures will accrue at a rate of 5.0% per year subject to adjustment in certain circumstances . We will pay interest on the notes on February 8 and August 8 of each year, beginning August 8, 2000. The notes mature on February 8, 2007. We may redeem some or all of the notes at any time before February 8, 2003 at a redemption price of \$1,000 per \$1,000 principal amount of notes, 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 ending on the trading day before the date of mailing of the provisional redemption notice. We will make additional payment in cash with respect to the notes, call for provisional redemption in an amount equal to \$13.93 per \$1,000 principal amount of notes, less the amount of any interest actually paid on the notes before the call for redemption. We may redeem some or all of the notes at any time after February 8, 2003. The notes are unsecured and subordinated to our existing and future senior indebtedness. Merrill Lynch & Co. served as the sole bookrunner for the offering and received approximately \$7,187,500 in discounts and commissions.

In October and November of 1999 we issued \$108,450,000 aggregate principal amount of convertible subordinated debentures, which are convertible at the option of the holder, at any time on or prior to maturity into shares of our common stock. The debentures 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 debentures are convertible at a conversion price of \$32.0075 per share, which is equal to a conversion rate of approximately 31.2427 shares per \$1,000 principal amount of notes, subject to adjustment. Interest on the debentures will accrue at a rate of 6 3/4% per year subject to adjustment in certain circumstances. We will pay interest on the notes on April 13 and October 13 of each year, beginning April 13, 2000. The debentures mature on October 13, 2006. We may redeem some or all of the debentures after October 13, 2002 at the following prices (expressed in percentage of the principal amount), together with accrued and unpaid interest to, but excluding, the date fixed for redemption:

DURING THE TWELVE MONTHS COMMENCING	REDEMPTION PRICE
October 13, 2002	103.375%
October 13, 2003	102.250%
October 13, 2004	101.125%
October 13, 2005	100.000%

The debentures are unsecured and subordinated to our existing and future senior indebtedness. The initial purchasers of the debentures, Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc., received an aggregate of approximately \$3,253,500 in discounts and commissions relating to this offering. On January 26, 2000 a shelf registration statement for the debentures and the shares of common stock issuable upon conversion of the debentures was declared effective by the SEC. In early, 2000, we entered into agreements with certain holders of these outstanding debentures to convert their debentures into shares of our common stock in exchange for a cash payment made by Inhale. To date, we have agreed to make cash payments of approximately \$16.2 million in the aggregate in connection with agreements that provide for the conversion of approximately \$94.2 million aggregate principal amount of outstanding debentures.

On November 4, 1999 we issued to Alliance Pharmaceutical Corp. 180,099 shares of our common stock having a market value of \$5.0 million in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended. We issued these shares and paid \$15.0 million in cash to Alliance in exchange for acquiring Alliance's PulmoSpheres-Registered Trademark-technology and other related assets

for particle formation and powder processing. Alliance is a sophisticated, qualified investor and defined as an "accredited investor" under Rule 501(a) of the Securities Act, as amended, and acquired these shares in the ordinary course of its business for its own account for investment and not with a view to, or any arrangements or understandings regarding, any subsequent distributions. Alliance signed a Stock Purchase Agreement in which it made certain representations and warranties to us that they met the criteria to be eligible for this exemption from registration. No underwriters were involved in this offering and no commissions or remuneration was paid in connection with the sales of these shares.

On December 9, 1998 we issued 1,200,000 shares of our common stock to two affiliated entities, Smallcap World Fund, Inc. and American Variable Insurance Series Growth Fund, which are managed by Capital Research and Management Company, at a purchase price of \$31 per share, for an aggregate amount of \$37.2 million in cash in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended. These purchasers of shares of our common stock are qualified investors and institutions defined as "accredited investors" under Rule 501(a) of the Securities Act, as amended, and acquired these shares in the ordinary course of their business for their own account for investment and not with a view to, or any arrangements or understandings regarding, any subsequent distributions. These purchasers signed a Stock Purchase Agreement in which they made certain representations and warranties to us that they met the criteria to be eligible for this exemption from registration. Volpe Brown Whelan & Company served as the exclusive placement agent in connection with this offering and received \$1,886,040 in payment of certain fees and commissions. On February 11, 1999, a shelf registration statement for these shares of common stock was declared effective

On April 13, 1998 we issued an aggregate of 5,781 shares of our common stock to several individuals who are affiliated with Boyce Thompson Institute for Plant Research, Inc. and Initiatech, Inc. in partial consideration for Inhale signing an agreement with Initiatech, Inc. under which Inhale licenses technology, intellectual property, and patents for protecting biologically active compounds in the dry state. Initiatech has licensed exclusive rights to this technology from the Boyce Thompson Institute for Plant Research, Inc. These shares were sold in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended. No underwriters were involved in this offering and no commissions or remuneration was paid in connection with the sales of these shares.

On February 7, 1997 we issued 1,800,000 shares of our common stock at a purchase price of \$18 per share, for an aggregate amount of \$32.4 million in cash in private transactions exempt from registration under Rule 506 of Regulation D promulgated under the Securities Act of 1933, as amended to selected institutions qualified as "accredited investors" under Rule 501(a) of Regulation D. These purchasers acquired our shares in the ordinary course of their business for their own account for investment and not with a view to, or any arrangements or understandings regarding, any subsequent distributions. These purchasers each signed a Purchase Agreement in which they made certain representations and warranties to us that they met the criteria to be eligible for this exemption from registration. Vector Securities International, Inc. served as the exclusive placement agent in connection with this offering and received \$1,782,000 in payment of certain fees and commissions. On February 7, 1997 a shelf registration statement for these shares of common stock was declared effective by the SEC.

On June 27, 1997 we sold 28,165 shares of our common stock to Pafra Limited for an aggregate purchase price of \$600,000 in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended. We issued these shares to Pafra in partial consideration for Pafra's assignment to Inhale of certain of its intellectual property rights, the goodwill and know-how. Pafra is a sophisticated, qualified investor and defined as an "accredited investor" under Rule 501(a) of the Securities Act, as amended, and acquired these shares in the ordinary course of it business for its own account for investment and not with a view to, or any arrangements or understandings regarding, any subsequent distributions. Pafra signed an assignment in which it made certain representations and warranties to us that they met the criteria to be eligible for this exemption from registration. No underwriters were involved in this offering and no commissions or remuneration was paid in connection with the sales of these shares.

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

	YEARS ENDED DECEMBER 31				
	1999	1998	1997	1996	1995
STATEMENT OF OPERATIONS DATA:					
Contract research revenue Operating costs and expenses:	\$ 41,358	\$ 21 , 795	\$ 16,249	\$ 6,890	\$ 3,445
Research and development		35,398			9,041
General and administrative Acquired in-process research and	7 , 869	8 , 387	6,328	4,004	3,232
development	9,890				
Total operating costs and expenses		43,785	29,973		12,273
Loss from operations				(11,490)	(8,828)
Interest income (expense), net	2,036	3,634	3,741	1,581	1,166
Net loss	\$(38,448)		\$ (9,983)	\$ (9,909)	\$ (7,662)
Net loss per share					\$ (0.78)
Shares used in computation of net loss per share(1)	17,008 =====	15,719 =====			9 , 837
	DECEMBER 31,				
	1999	1998		1996	1995
BALANCE SHEET DATA: Cash, cash equivalents and short-term					
investments	\$138,185	\$ 82,862	\$100,173	\$ 36,309	\$ 19,927
Working capital Total assets	122,239 226,806	71,784 134,496	83,811 119,762	31,304 41,492	17,701 23,248
Long-term debt	4,895	4,940	5,102	187	353
Convertible subordinated debentures	108,450				
Accumulated deficit	(94,466)	(56,018)	(37,662)	(27,691)	(17,770)
Total stockholders' equity	86,629	115,881	97,093	35,061	20,182

⁽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. 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 its inception in July 1990, Inhale has been engaged in the development of a pulmonary system for the delivery of macromolecules and other drugs for systemic and local lung applications. Inhale has been unprofitable since inception and expects 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, Inhale has not sold any commercial products and does not anticipate receiving revenue from product sales or royalties in the near future. For the period from inception through December 31, 1999, Inhale incurred a cumulative net loss of approximately \$94.5 million. Inhale's sources of working capital have been partner fundings, including milestone payments, from short-term research and feasibility agreements and development contracts, equity financings, financings of equipment acquisitions and tenant improvements, and interest earned on investments of

Inhale has 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 Inhale as Inhale achieves certain key milestones. Inhale expects to receive royalties from its 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, Inhale may enter into collaborative agreements under which Inhale's partners would manufacture or package powders or supply inhalation devices, thereby potentially limiting one or more sources of revenue for Inhale. To achieve and sustain profitable operations, Inhale, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products utilizing its pulmonary drug delivery system. There can be no assurance that Inhale can generate sufficient product or contract research revenue to become profitable or to sustain profitability.

In late 1999, Inhale completed the sale of approximately \$108.5 million aggregate principal amount of 6 3/4% Convertible Subordinated Debentures due October 13, 2006. In early 2000, the Company 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, the Company has agreed to make cash payments of approximately \$16.2 million in the aggregate in connection with agreements that provide for the conversion of approximately \$94.2 million aggregate principal amount of outstanding debentures into approximately 2.9 million shares of common stock. Such amounts will be reflected as a charge to interest expense in the first quarter of 2000.

In February, 2000, Inhale received approximately \$222.4 million in net proceeds from the issuance of \$230.0 million aggregate principal amount of convertible subordinated debentures to certain qualified institutional buyers under Rule 144A of the Securities Act of 1933, as amended. Interest on the debentures will accrue at a rate of 5.0% per year, subject to adjustment in certain circumstances. The debentures will mature in 2007 and are convertible into shares of Inhale's common stock at a conversion price of \$76.71 per share, subject to adjustment in certain circumstances.

YEARS ENDED DECEMBER 31, 1999, 1998 AND 1997

Contract research revenue was \$41.4 million for the year ended December 31, 1999 compared to \$21.8 million and \$16.2 million for the years ended December 31, 1998 and 1997, respectively. Revenue increased 90% in 1999 from 1998 levels and 34% in 1998 from 1997 levels. Costs of contract research revenue approximate such revenue and are included in research and development expense.

The 90% increase in revenue for the year ended December 31, 1999 as compared to December 31, 1998 was primarily due to expansion of Inhale's existing collaborative agreement with Pfizer, and includes activities associated with the manufacture of Phase III clinical supplies. Pfizer represented approximately 71% of Inhale's revenues for the year ended December 31, 1999. Revenue for 1999 and 1998 included reimbursed research and development expenses as well as the amortization of up-front signing and progress payments received from Inhale's collaborative partners. Recognition of up-front signing and progress payments is based on actual efforts expended. 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 \$64.1 million for the year ended December 31, 1999, as compared to \$35.4 million and \$23.6 million for the years ended December 31, 1998 and 1997, respectively. These expenses represent proprietary research expenses as well as the costs related to contract research revenue and include the salaries and benefits of scientific and development personnel, clinical manufacturing costs, laboratory supplies, consulting services, facilities, costs of obtaining intellectual property protection for Inhale's technologies and expenses associated with the development of manufacturing processes. The 81% increase in such expenses in 1999 from 1998 was due to increased spending related to the scale-up of technologies and the continuing development of global manufacturing capabilities in order to support Phase III inhaleable insulin clinical trials and commercial production. In addition, the Company hired additional scientific and development personnel to handle an increase in the number of development projects and incurred increased expenses associated with device development and clinical manufacturing. The largest components of the 1999 increase in research and development were the increases of \$11.8 million in salaries and employee benefits expense, a \$9.3 million increase in research and development supplies and services, and a \$3.8 million increase in facilities and administrative expense allocations associated with supporting the research and development efforts. The \$11.8 million increase in research and development expenses in 1998 from 1997 was primarily attributable to the development of infrastructure necessary to manufacture the Company's products on a late stage clinical scale. Inhale expects research and development spending to increase over the next few years as Inhale expands its development efforts under collaborative agreements and scales up its commercial manufacturing facility.

General and administrative expenses were \$7.9 million for the year ended December 31, 1999 as compared to \$8.4 million and \$6.3 million for the years ended December 31, 1998 and 1997, respectively. The \$0.5 million decrease in general and administrative expenses in 1999 from 1998 is attributed to an increased percentage of general and administrative related costs allocated to research and development operations. The \$2.1 million increase in such expenses in 1998 was due primarily to costs associated with supporting Inhale's increased research efforts including administrative staffing, business development activities and marketing activities. General and administrative expenses are expected to continue to increase over the next few years as Inhale expands its operations.

Interest income was \$4.1 million for the year ended December 31, 1999 as compared to \$3.9 million and \$3.8 million for the years ended December 31, 1998 and 1997, respectively. The 5% increase in interest income in 1999 from 1998 and the 3% increase in interest income in 1998 from 1997 were primarily due to Inhale maintaining larger cash and investment balances, including the proceeds of its October, 1999

issuance of convertible subordinated debentures which resulted in net proceeds of \$105.2 million. Interest expense was \$2.1 million for the year ended December 31, 1999, as compared to \$0.3 million and \$0.1 million for the years ended December 31, 1998 and 1997, respectively. The \$1.8 million increase in interest expense in 1999 from 1998 primarily relates to interest on the above-mentioned convertible subordinated debentures. The \$0.2 million increase in interest expense in 1998 from 1997 related to increased debt balances, including the proceeds of the Company's November, 1997 tenant improvement loan.

At December 31, 1999, Inhale had federal and state net operating loss carryforwards of approximately \$92.6 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, Inhale concluded an agreement with Alliance Pharmaceutical Corp. to acquire Alliance's PulmoSpheres-Registered Trademarkparticle and particle processing technology for use in respiratory drug delivery. Under the terms of the agreement, Inhale received the rights to PulmoSpheres-Registered Trademark- technology, other related assets (including research materials, laboratory records, and certain equipment that had been used in the development of PulmoSpheres technology and the manufacturing and testing of particles using such PulmoSpheres technology), and Alliance stock valued at \$5 million in exchange for \$15 million in cash and \$5 million of Inhale stock. 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. \$15.0 million of the purchase consideration 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 in-process research and development and has been charged as an expense in the year ended December 31, 1999.

The PulmoSpheres-Registered Trademark- technology utilizes an emulsification process to produce a powder having characteristics that Inhale believes may improve efficiency and reproducibility for drugs delivered to the lung through alternative technologies such as metered-dose inhalers ("MDI's"), as well as potentially improve drug delivery through Inhale's proprietary deep lung drug delivery system. Inhale evaluates this technology to be in the pre-clinical stage of development.

The purchased research and development had no alternative future use at the date of acquisition. It 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 PulmoSpheres-Registered Trademark- technology, its stage of development at the time of acquisition, the importance of the technology to Inhale's 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.

Inhale does not expect the products which utilize the PulmoSpheres-Registered Trademark- technology to obtain FDA approval before 2005. Inhale is in process of evaluating which projects will benefit the most from the PulmoSpheres-Registered Trademark- technology and is estimating the associated future development costs, which are expected to be substantial through 2006.

LIOUIDITY AND CAPITAL RESOURCES

Inhale has financed its operations primarily through public and private placements of its equity securities, convertible debentures, contract research revenues, interest income earned on its investments of cash and financing of equipment acquisitions. In its initial public offering completed May 1994, Inhale raised net proceeds of approximately \$14.4 million and raised additional net proceeds of \$7.2 million in its

public offering completed in March 1995. In February 1997, Inhale completed a private placement of its Common Stock, selling 1.8 million newly issued shares for net proceeds of \$30.5 million. In November 1997, Inhale completed a public offering of its Common Stock, selling 1.725 million newly issued shares for net proceeds of \$40.0 million. Inhale secured a \$5 million loan in November 1997 to finance the purchases of equipment and facility improvements. In December 1998, Inhale completed a private placement of its Common Stock, selling 1.2 million newly issued shares for net proceeds of \$35.3 million. In October 1999, the Company received approximately \$105.2 million in net proceeds from the sale of convertible subordinated debentures. At December 31, 1999, Inhale had cash, cash equivalents and short-term investments of approximately \$138.2 million. In February 2000, Inhale completed the sale of convertible subordinated notes netting proceeds of approximately \$206.0 million. This includes cash payments of approximately \$16.2 million in connection with agreements that provide for the conversion of approximately \$94.2 million of its October 2006 debentures that were outstanding at December 31, 1999.

Inhale's operations used cash of \$15.3 million and \$19.2 million, and provided cash of \$5.0 million in the years ended December 31, 1999, 1998 and 1997, respectively. These amounts differed from Inhale's net operating losses in these periods principally due to increased depreciation expense and fluctuations in the Company's accounts receivable, other assets, accrued liabilities and deferred revenue balances. Fluctuations in these balances reflect Inhale's increased research, development and manufacturing activities, as well as timing differences in the receipt of cash from Inhale's development partners. Additionally, in 1999, Inhale, recorded a \$9.9 million write-off of acquired research and development in connection with the acquisition of PulmoSpheres-Registered Trademark- technology.

Inhale purchased property and equipment of approximately \$20.5 million, \$34.6 million and \$17.3 million during the years ended December 31, 1999, 1998 and 1997, respectively. The decrease in 1999 is primarily due to the increased expenditures in 1998 for the purchase of land and the build out of Inhale's manufacturing facility and corporate headquarters located in San Carlos, California. The Company also invested \$15.3 million in the purchase of PulmoSpheres-Registered Trademark- technology in 1999, in addition to its non-cash exchange of common stock for shares of Alliance valued at \$5.0 million.

Inhale expects its cash requirements to continue at an accelerated rate due to expected increases in costs associated with further research and development of its 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 Inhale's commercial manufacturing facility and scale-up of device manufacturing with its outside contract manufacturers.

Given its current cash requirements, the Company believes that it will have sufficient cash to meet its operating expense requirements for at least the next 24 months. However, the Company plans to continue to invest heavily in its growth and the need for cash will be dependent upon the timing of these investments. Inhale's capital needs will depend on many factors, including continued scientific progress in its research and development arrangements, progress with pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of developing and the rate of scale-up of Inhale's powder processing and packaging technologies, the timing and cost of its 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 its long-term needs, Inhale intends 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 Inhale on favorable terms, if at all.

Inhale is currently considering expansion opportunities which would likely involve the sale and leaseback of land adjacent to its current facilities and the development of new facilities on such land.

Inhale anticipates that its lease obligations relating to this proposal would be approximately \$60.0 million over the term of the lease, which Inhale expects to extend approximately 15 years.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of Inhale's investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, Inhale invests in highly liquid and high quality debt securities. Inhale's investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, Inhale invests in short term securities and maintains an average maturity of one year or less. A hypothetical 50 basis point increase in interest rates would result in an approximate \$291,000 decrease (less than 0.217%) in the fair value of Inhale's available-for-sale securities.

The potential change noted above is based on sensitivity analyses performed on Inhale's financial position at December 31, 1999. Actual results may differ materially. The same hypothetical 50 basis point increase in interest rates would have resulted in an approximate \$150,000 decrease (less than 0.185%) in the fair value of Inhale's available-for-sale securities at December 31, 1998.

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements for the years ended December 31, 1999, 1998 and 1997 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.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Inhale incorporates by reference the information concerning its directors set forth under the heading "Election of Directors" in Inhale's definitive Proxy Statement to be filed for its 2000 Annual Meeting of Shareholders.

EXECUTIVE OFFICERS AND DIRECTORS

The following table sets forth the names, ages and positions of the executive officers and directors as of December 31, 1999:

NAME	AGE	POSITION
Robert B. Chess	43	Chairman and Co-Chief Executive Officer
Ajit S. Gill	51	Co-Chief Executive Officer, President and
Brigid A. Makes	4.4	Director Vice President of Finance and
Dilgia II. Hakes		Administration, Chief Financial Officer
Stephen L. Hurst	44	General Counsel and Secretary
John S. Patton, Ph.D	53	Vice President, Research and Director
Robert M. Platz	48	Vice President, Technology
Mark J. Gabrielson	43	Director
James B. Glavin	64	Director
Irwin Lerner	69	Director
Melvin Perelman, Ph.D	69	Director

ROBERT B. CHESS has served as Chairman of the Board of Directors since April 1999 and Co-Chief Executive Officer since August 1998. 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 ("Penederm"), 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.

AJIT S. GILL has served as President since April 1999, as Co-Chief Executive Officer since August 1998 and as a Director since April 1998. 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. 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, developer of automated blood processing systems, including, from 1995 to 1998, Vice President Finance, Chief Financial Officer and Treasurer. Ms. Makes holds a Bachelor of Commerce degree from McGill University in Finance and International Business and an MBA from Bentley College.

STEPHEN L. HURST has been General Counsel and Secretary since August 1998. Mr. Hurst served as Vice President, Intellectual Property and Licensing of Inhale 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, the San Francisco area's largest intellectual property 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.

JOHN S. PATTON, PH.D., a co-founder of Inhale, has been Vice President, Research since December 1991 and a Director 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.

ROBERT M. PLATZ, a co-founder of Inhale, has served as Vice President, Technology since August 1990. He also served as a Director of Inhale from July 1990 to August 1991. From January 1983 to August 1991, Mr. Platz was employed by SRI International, a contract research company, most recently as Senior Chemical Engineer, where he headed the pharmaceutical aerosol group. Mr. Platz received a BS in biology and an MS in Chemical Engineering from the University of California, Los Angeles.

MARK J. GABRIELSON has been a Director since May 1992. Since January 1991 he has been a general partner of Prince Ventures, L.P., a venture capital management firm that serves as the general partner of Prince Venture Partners III, L.P. Mr. Gabrielson is a Director of several private companies. From 1978 until joining Prince, Mr. Gabrielson served in a variety of marketing and business development positions with SmithKline Beecham plc.

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 Fund and Gish Biomedical, Inc.

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 Hoffman-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. Mr. Lerner served as the Chairman of the Board of Sequana Therapeutics, Inc., a biotechnology company, from May 1995 until Sequana merged with Arris Pharmaceuticals Inc., a pharmaceutical company, to form Axys Pharmaceuticals, Inc. in January 1998 and has served on the Board of Axys since then. Mr. Lerner served for 12 years on the Board of Pharmaceutical Manufacturers' Association where he chaired the Association's FDA Issues Committee. Mr. Lerner received a B.S. and an M.B.A. 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, and V.I. Technologies, Inc., a blood products company.

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

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. Its 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

Inhale incorporates by reference the information set forth under the heading "Executive Compensation" in Inhale's definitive Proxy Statement to be filed for its 2000 Annual Meeting of Shareholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Inhale incorporates by reference the information set forth under the heading "Security Ownership of Certain Beneficial Owners and Management" in Inhale's definitive Proxy Statement to be filed for its 2000 Annual Meeting of Shareholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Inhale incorporates by reference the information set forth under the heading "Certain Transactions" in Inhale's definitive Proxy Statement to be filed for its 2000 Annual Meeting for Shareholders.

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

(a)(1) Financial Statements

The 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) Financial Statement Schedules

EXHIBIT EXHIBIT TITLE

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

(3) Exhibits

The following exhibits are filed herewith or incorporated by reference:

21111221	B1311
2.1(1)	Agreement and Plan of Merger between Inhale Therapeutic
2.1(1)	Systems, a California corporation, and Inhale Therapeutic Systems (Delaware), Inc., a Delaware corporation.
3.1(1)	Certificate of Incorporation of Registrant.
3.2(1)	Bylaws of the Registrant.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2(2)	Restated Investor Rights Agreement among the Registrant and certain other persons named therein, dated April 29, 1993, as amended October 29, 1993.
4.3(2)	Specimen stock certificate.
4.4(3)	Stock Purchase Agreement between the Registrant and Pfizer Inc., dated January 18, 1995.
4.5(9)	Form of Purchase Agreement between the Registrant and the individual Purchasers, dated January 28, 1997.
4.6(10)	Stock Purchase Agreement between the Registrant and Capital Research and Management Company, dated December 8, 1998.
4.7(12)	Purchase Agreement among the Registrant and Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc., dated October 6, 1999.
4.8 (12)	Registration Rights Agreement among the Registrant and Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc., dated October 13, 1999.
4.9(12)	Indenture between the Registrant as Issuer and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated October 13, 1999.
4.10(12)	Form of Registration Rights Agreement between the Registrant and Alliance Pharmaceutical Corp.
4.11(13)	Purchase Agreement among the Registrant and Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated February 2, 2000.
4.12(13)	Resale Registration Rights Agreement among Registrant and Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated February 8, 2000.

EXHIBIT	EXHIBIT TITLE
4.13(13)	Indenture between Registrant as Issuer and Chase Manhattan Bank and Trust Company, National Association as Trustee, dated February 8, 2000.
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 the Registrant 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 the Registrant 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 the Registrant 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)	Senior Loan and Security Agreement between the Registrant and Phoenix Leasing Incorporated, dated September 15, 1993.
10.11(2)	Sublicense Agreement between the Registrant and John S. Patton, dated September 13, 1991.
10.12(5)	Stock Purchase Agreement between the Registrant and Baxter World Trade Corporation, dated March 1, 1996.
10.13(8)	Sublease and Lease Agreement, dated October 2, 1996, between the Registrant and T.M.T. Associates L.L.C. ("Landlord").
10.14(11)	First Amendment, dated October 30, 1996, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
10.15(11)	Letter Agreement, dated April 9, 1997, amending Sublease and Lease Agreement, dated October 2, 1996, between the Registrant and Landlord.
10.16(11)	Third Amendment, dated April 16, 1997, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
10.17(11)	Fourth Amendment, dated November 5, 1997, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
10.18(13)	Sublease by and between Webvan Group, Inc., as sublessor and Registrant, as sublessee, dated November 3, 1999.
23.1(13)	Consent of Ernst & Young LLP, independent auditors.
24.1(13)	Power of Attorney. Reference is made to Signature Page.
25.1(13)	Form T-1 Statement of Eligibility and Qualification of Trustee.
27.1	Financial Data Schedule.

⁽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) Filed herewith
 - (b) Reports on Form 8-K.

The following Report on Form 8-K was filed during the quarter ended December 31, 1999: A Report on Form 8-K dated October 4, 1999 pertaining to the Registrant's acquisition of Alliance's PulmoSpheres-Registered Trademark- particle and particle processing technology and other related assets.

- (c) See Exhibits listed under Item 14(a)(3).
- (d) Not applicable. See Item $14\left(a\right)\left(2\right)$.

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 its behalf by the undersigned, thereunto duly authorized, on the 14th day of March 2000.

INHALE THERAPEUTIC SYSTEMS, INC.

By: /s/ AJIT S. GILL

Ajit S. Gill CO-CHIEF EXECUTIVE OFFICER, PRESIDENT AND DIRECTOR

INHALE THERAPEUTIC SYSTEMS, INC. INDEX TO FINANCIAL STATEMENTS

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

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

We have audited the accompanying balance sheets of Inhale Therapeutic Systems, Inc. as of December 31, 1999 and 1998, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1999. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our 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 financial position of Inhale Therapeutic Systems at December 31, 1999 and 1998, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1999 in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California January 24, 2000

BALANCE SHEETS

(IN THOUSANDS, EXCEPT PAR VALUE)

	DECEMBE	ER 31,
	1999	1998
ASSETS		
Current assets: Cash and cash equivalents	\$ 33,430 104,755 1,756 7,377	\$ 24,916 57,946 1,013 665
Total current assets Property and equipment, net Investment in Alliance Pharmaceutical Corp Other assets	147,318 63,852 6,328 9,308	84,540 49,863 93
	\$226,806	\$134 , 496
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities: Accounts payable	\$ 13,374 6,849 4,811 45 	\$ 3,678 4,655 4,359 64
Tenant improvement loan	4,895 108,450 1,753	4,940 919
Commitments (See Note 4)		
Stockholders' equity: Preferred stock, 10,000 shares authorized, no shares issued or outstanding		
17,226 shares and 16,924 shares issued and outstanding at December 31, 1999 and 1998, respectively	2 181,154 (1,530) (94,466) 1,469	2 172,847 (931) (56,018) (19)
Total stockholders' equity	86,629	115,881
	\$226,806 ======	\$134,496 ======

STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)

		NDED DECEME	
	1999	1998	1997
Contract research revenue		\$ 21,795	
Operating costs and expenses: Research and development	7,869	35,398 8,387	6,328
Acquired in-process research and development Total operating costs and expenses		 13 785	
Loss from operations	(40,484)	(21,990)	(13,724)
Interest income	(2,075)	3,904 (270)	(66)
Net loss	\$(38,448) ======	\$(18,356) ======	
Basic and diluted net loss per share	\$ (2.26) ======	\$ (1.17) ======	
Shares used in computing basic and diluted net loss per share	17,008 =====	15,719 =====	-, -

STATEMENT OF STOCKHOLDERS' EQUITY

(IN THOUSANDS)

		N STOCK	CAPITAL IN EXCESS OF	DEFERRED	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL STOCKHOLDERS'
	SHARES	PAR VALUE	PAR VALUE	COMPENSATION	DEFICIT	GAIN/(LOSS)	EQUITY
Balance at December 31, 1996	11,835	\$ 1	\$ 62,839	\$ (88)	\$(27,679)	\$ (12)	\$ 35,061
private placement, net of issuance costs of \$1,940 Issuance of common stock in connection with licensing	1,800	1	30,459				30,460
agreement Issuance of common stock in public offering, net of	28		600				600
issuance costs of \$2,885 Common stock issued upon exercise of stock	1,725		40,024				40,024
options Issuance of common stock in connection with exercise of	125		798				798
warrant	29		 1	 (FF1)			
Deferred compensation Amortization of deferred			551	(551)			101
compensation Unrealized gain on available-for-sale				101			101
securities						32	32
Net loss					(9,983)		(9,983)
Comprehensive loss							(9,951)
Balance at December 31,							
1997 Issuance of common stock in private placement, net of	15 , 542	2	135,271	(538)	(37,662)	20	97,093
issuance costs of \$1,997 Issuance of common stock and stock options in connection	1,200		35,202				35 , 202
with licensing agreement Common stock issued upon	6		284				284
exercise of stock options	176		1,514				1,514
Deferred compensation			576	(576)			1,314
Amortization of deferred compensation				183			183
securities						(39)	(39)
Net loss					(18,356)		(18,356)
Comprehensive loss							(18,395)
Balance at December 31,	16,924	2	172,847	(931)	(56,018)	(19)	115,881
Issuance of common stock to Alliance	180		5,000				5,000
Common stock issued upon exercise of stock options,			,				,,,,,,
net of costs Compensation in connection with stock options granted	122		1,545				1,545
to consultants			798				798
Deferred compensation Amortization of deferred			964	(964)			
compensation Unrealized gain on available-for-sale				365			365
securities					 (38,448)	1,488	1,488 (38,448)
					, ,		
Comprehensive loss							(36 , 960)
Balance at December 31, 1999	17,226 =====	\$ 2 =======	\$181,154 ======	\$(1,530) =====	\$(94,466) ======	\$1,469 =====	\$ 86,629

STATEMENTS OF CASH FLOWS

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS

(IN THOUSANDS)

	YEARS ENDED DECEMBER 31,		
		1998	1997
CASH FLOWS FROM (USED IN) OPERATING ACTIVITIES Net loss	\$ (38,448)	\$ (18,356)	\$ (9,983)
operating activities: Depreciation and amortization. Amortization of deferred compensation Issuance of common stock for services Issuance of common stock and stock options in connection	6,889 365 798	183	2,337 101
with licensing agreements	9,890		600
Decrease (increase) in accounts receivable, other current assets, and other assets		(876)	
liabilities Increase (decrease) in deferred revenue	452		3,963
Net cash (used in) provided by operating activities	(15,334)		4,979
CASH FLOWS USED IN INVESTING ACTIVITIES Acquisition of PulmoSpheres-Registered Trademark-			
technology. Purchases of short-term investments. Sales of short-term investments. Maturities of short-term investments. Purchases of property and equipment, net.	28,658	(219,414) 65,189 182,309 (34,584)	(483,247) 80,662 334,289 (17,261)
Net cash used in investing activities		(6,500)	(85,557)
CASH FLOWS FROM FINANCING ACTIVITIES Issuance of convertible subordinated debentures, net Payments of loan and capital lease and obligations Proceeds from tenant improvement loan Issuance of common stock, net of issuance costs	1,545	(181) 36,716	71,282
Net cash provided by financing activities	106,287	36,535	76,114
Net increase (decrease) in cash and cash equivalents Cash and cash equivalents at beginning of year	8,514 24,916	10,812 14,104	(4,464) 18,568
Cash and cash equivalents at end of year		\$ 24,916	

NOTES TO FINANCIAL STATEMENTS

DECEMBER 31, 1999

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION AND BASIS OF PRESENTATION

Inhale Therapeutic Systems, Inc. ("Inhale", the "Company") was incorporated in the State of California in July 1990 and reincorporated in the State of Delaware in July 1998. Since inception, Inhale has been engaged in the development of a system to deliver drugs to the bloodstream through the lungs by inhaling a powdered version of the drug. The system is applicable to a wide range of peptides, proteins and other molecules.

Inhale expects increasing losses over the next several years as research and development and manufacturing scale-up efforts continue, and as Inhale expands its facilities for commercial manufacturing. Management plans to continue to finance Inhale 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 generally accepted accounting principles 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.

CASH, CASH EQUIVALENTS AND INVESTMENTS

Inhale considers 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 Al or Pl 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. Inhale limits its concentration of risk by diversifying its investments among a variety of industries and issuers. Inhale has experienced no material losses on its investments.

At December 31, 1999, 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.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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

AVAILABLE-FOR-SALE DEBT SECURITIES

	COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
		(IN TH	OUSANDS)	
Obligations of U.S. government agencies	\$ 81,692	\$108	\$	\$ 81,800
U.S. corporate commercial paper	41,081	33		41,114
securities	3,845			3,845
Other	7,872			7,872
	\$134,490	\$141 ====	\$ ========	\$134,631 ======
Amounts included in cash and cash equivalents	\$ 29,822	\$ 54	\$	\$ 29,876
Amounts included in short-term investments	104,668	87		104,755
	\$134,490	\$141	\$	\$134,631
	=======	====		=======

The following is a summary of available-for-sale debt securities as of December 31, 1998:

AVAILABLE-FOR-SALE DEBT SECURITIES

	COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
		(IN THO	OUSANDS)	
Obligations of U.S. government agencies U.S. corporate commercial paper	\$20,758 42,773	\$ 	\$ (19)	\$ 20,758 42,754
securities	17,704 105			17,704 105
	\$81,340	\$ ========	\$(19) ====	\$ 81,321
Amounts included in cash and cash equivalents Amounts included in short-term investments	\$23,375 57,965	\$ 	\$ (19)	\$ 23,375 57,946
	\$81,340	\$ ========	\$(19) ====	\$ 81,321 ======

The gross realized losses and gains on the sale of debt securities available-for-sale during the years ended December 31, 1999 and 1998 were not material. At December 31, 1999 and 1998, the average portfolio duration was approximately five months and three months, respectively, and the contractual maturity of any single investment did not exceed eleven months at December 31, 1999 and 1998.

The estimated fair value amounts have been determined by Inhale using available market information and appropriate valuation methodologies. However, market data must be interpreted to develop the estimates of fair value. Accordingly, the estimates presented herein are not necessarily indicative of the amounts that Inhale could realize in a current market exchange.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Inhale owns common stock in one technology company. These shares of Alliance Pharmaceutical Corp. ("Alliance") are accounted for as long-term available-for-sale securities. Due to restrictions on the sale of this stock, the Company carries that portion of its investment in Alliance that can be sold within one year at market value, with material unrealized gains and losses, if any, reported in stockholders' equity. That portion which cannot be sold within one year is carried at cost.

PROPERTY AND EQUIPMENT

Property and equipment consist of the following at December 31:

	1999	1998
	(IN THOU	JSANDS)
Laboratory and other equipment Leasehold improvements Land	\$ 24,317 47,101 7,443	\$15,012 36,003 7,443
Less accumulated depreciation	78,861 (15,009)	,
	\$ 63,852 ======	\$49,863 ======

Property and equipment are stated at cost. Major renewals and improvements are capitalized, while maintenance and repairs are expensed when incurred. Other equipment is depreciated using the straight-line method over estimated useful lives of four to seven years. Manufacturing equipment is depreciated using the straight-line method over its useful life estimated to be ten years. Leasehold improvements and assets acquired under capital leases are amortized using the straight-line method over the shorter of an estimated useful life of fifteen years or the term of the lease.

Interest is capitalized in connection with the construction of leasehold improvements to the Company's manufacturing facility in San Carlos, California. The capitalized interest is recorded as part of the asset to which it relates and is amortized over the asset's estimated useful life. In 1999 and 1998, Inhale capitalized \$0 and \$203,000 of interest cost, respectively.

COMPREHENSIVE GAIN/LOSS

Effective January 1, 1998, Inhale adopted the Financial Accounting Standards Board's ("FASB") Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130"). The Company's other component of 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. Inhale has no other material components of other comprehensive 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 and as the related costs are incurred. Payments received which are related to future performance are deferred and recognized as revenue when earned over future performance periods. In accordance with contract terms, upfront and

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED) milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements, and accordingly, are generally recognized based on actual efforts expended over the remaining terms of the agreements. Inhale's research revenue is derived primarily from clients in the pharmaceutical industry. Contract research revenue from three partners represented 71%, 10% and 9% of Inhale's revenue in 1999. Three partners accounted for 51%, 22% and 18% of Inhale's revenue in 1998 and 47%, 25% and 21% of Inhale's revenue in 1997. 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"), Inhale continues to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations in accounting for its employee stock option plans. Under APB 25, if the exercise price of Inhale's 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 Inhale's common stock as quoted on the Nasdaq stock market, no compensation expense is recognized. See Note 5 for pro forma disclosures required by FAS 123

RESEARCH AND DEVELOPMENT AGREEMENTS

Inhale performs research and development for others pursuant to feasibility agreements and development and license agreements. Under the feasibility agreements, Inhale generally is reimbursed for the cost of work performed. Feasibility agreements are designed to evaluate the applicability of Inhale's technologies to a particular molecule and therefore are generally completed in less than one year. Under Inhale's 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 Inhale for one of the partner's macromolecule drugs. Under these development agreements, Inhale will be reimbursed for development costs and may also be entitled to milestone payments when and if certain development milestones are achieved. All of Inhale's research and development agreements are generally cancelable by the partner without significant financial penalty to the partner.

ACCOUNTING FOR INCOME TAXES

Inhale accounts 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.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 1--ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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. Had Inhale 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,

	1999	1998	1997
		(IN THOUSANDS)
Warrants	20	20	20
Options	4,553	3,163	2,351
Convertible debentures	3,388		
Total	7,961	3,183	2,371
	=====	=====	=====

SEGMENT INFORMATION

Effective January 1, 1998, Inhale adopted the FASB's Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS 131"). SFAS 131 superseded FASB Statement No. 14, "Financial Reporting for Segments of a Business Enterprise." SFAS 131 establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. SFAS 131 also establishes standards for related disclosures about products and services, geographic areas, and major customers.

Management has organized Inhale's business in one operating segment which includes activities related to the development of systems for the pulmonary delivery of macromolecule drugs. Inhale's operations and all of its assets are presently located in the United States and the Company derives all of its revenues within the United States.

RECLASSIFICATION

Certain prior year amounts have been reclassified to conform to the 1999 presentation.

NOTE 2--COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Inhale performs research and development for others pursuant to feasibility agreements and development and license agreements. Under the feasibility agreements, Inhale generally is reimbursed for the cost of work performed. Feasibility agreements are designed to evaluate the applicability of Inhale's technologies to a particular molecule and therefore are generally completed in less than one year. Under Inhale's 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 Inhale for one of the partner's macromolecule drugs. Under these development agreements, Inhale will be reimbursed for development costs and may also be entitled to milestone payments when and if certain development milestones are achieved. All of Inhale's research and development agreements are generally cancelable by the partner without significant financial penalty to the partner.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 2--COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CONTINUED)

In February 1999, Inhale entered into a collaborative agreement with 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, Inhale will receive royalties on product sales, an up-front signing fee, and up to an estimated \$25 million in research and development funding and potential progress payments. Biogen will provide bulk AVONEX-Registered Trademark- to Inhale for formulation into a dry powder which is stable at room temperature. Inhale will manufacture and package the dry powder and supply inhalation devices. Biogen will be responsible for clinical trials, marketing and commercialization. The Company recognized revenue of \$2.2 million under this agreement in 1999.

In December 1997, the Company entered into a collaboration agreement with Eli Lilly and Company ("Lilly") to develop pulmonary delivery for an undisclosed protein based on Inhale's deep-lung drug delivery system for macromolecules. Under the terms of the agreement, Inhale will receive funding of up to \$20 million in research, development and progress payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. Inhale will manufacture packaged powders for and supply devices to Lilly. Under this agreement the Company recognized revenue of \$1.2 million in 1999 and \$0.9 million in 1998. No revenue was recognized under this agreement in 1997.

In January 1997, the Company executed a collaboration agreement with Lilly to develop pulmonary delivery for parathyroid hormone ("PTH"). Under the terms of the agreement, Inhale will receive funding of up to \$20 million of initial fees, research and development and progress payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. Inhale will manufacture packaged powders for and supply devices to Lilly. Under this agreement, the Company recognized revenue of \$3.8 million and \$3.4 million in 1998 and 1997, respectively. 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 PTH pending further analysis. Inhale is maintaining a minimum development effort in its pulmonary program pending further direction from Lilly. Inhale does not currently believe that the program will be reinitiated in the near future, if at all.

In December 1996, Inhale 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. Under the terms of the collaboration, Aventis Behring will receive commercialization rights worldwide excluding Japan and Inhale will receive royalties on product sales, an up-front signing fee and up to an estimated \$15 million in research and development funding and milestone payments. Aventis Behring will manufacture the active ingredient for use in Inhale's delivery device. Inhale will manufacture and package the dry powder and supply inhalation devices to Aventis Behring for commercialization and marketing. Under this agreement, the Company recognized revenue of \$3.9 million, \$1.6 million and \$0.9 million in 1999, 1998 and 1997, respectively.

In March 1996, Inhale entered into a collaboration agreement with Baxter Healthcare Corporation ("Baxter") to use Inhale's dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In connection with the collaboration, Baxter made a \$20 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

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 2--COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CONTINUED) \$60 million in research and development funding and milestone payments for four molecules. In October 1998, Inhale announced that it 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 this amendment expired in September, 1999. As a result, rights to the compounds reverted to Inhale and are now available for other partnering opportunities. The Company recognized revenues associated with this program of \$4.3 million, \$4.0 million and \$4.1 million in 1999, 1998, and 1997, respectively.

In January 1995, the Company entered into a collaborative development and license agreement with Pfizer Inc. ("Pfizer") to develop pulmonary delivery for inhaled insulin based on Inhale's deep-lung delivery system for macromolecules. Under the terms of the agreement, Inhale 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 with Inhale receiving royalties on any marketed products. Inhale will manufacture inhaled insulin for, and supply devices to Pfizer. Under this agreement the Company recognized revenue of \$29.5 million, \$11.1 million and \$7.6 million in 1999, 1998 and 1997, respectively.

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

NOTE 3--ACQUISITION OF PULMOSPHERES-REGISTERED TRADEMARK- TECHNOLOGY

In November 1999, Inhale concluded an agreement with Alliance Pharmaceutical Corp. to acquire Alliance's PulmoSpheres-Registered Trademark- particle and particle processing technology for use in respiratory drug delivery. Under the terms of the agreement, Inhale received the rights to PulmoSpheres-Registered Trademark- technology, other related assets and Alliance stock valued at \$5 million in exchange for \$15 million in cash and \$5 million of Inhale stock. The purchase price, including \$387,000 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 PulmoSpheres-Registered Trademark- acquisition are recorded at their fair market value at acquisition as follows:

Property and equipment, net	\$	200
operations at December 31, 1999		9,890 3,171 96 2,030
Total cash purchase consideration		15,387 5,000
Total purchase consideration	\$2	20 , 387

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 3--ACQUISITION OF PULMOSPHERES-REGISTERED TRADEMARK- TECHNOLOGY (CONTINUED) 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 PulmoSpheres-Registered Trademark- technology, its stage of development at the time of acquisition, the importance of the technology to Inhale's 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.

NOTE 4--COMMITMENTS, LONG-TERM DEBT AND TENANT IMPROVEMENT LOAN

As of December 31, 1999, Inhale had \$108,450,000 aggregate principal amount of 6 3/4% Convertible Subordinated Debentures ("the Debentures") which will mature on October 13, 2006 and are convertible into shares of Inhale's common stock at a conversion price of \$32.0075 per share, subject to adjustment in certain circumstances. The Debentures are redeemable in part or in all at the option of the Company 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 the Company's existing and future Senior Debt. The Company had approximately \$4.9 million of Senior Debt outstanding at December 31, 1999. Costs relating to the issuance of the Debentures are recorded as long-term assets and are being amortized over the term of the debt (see Note 8).

Inhale leases its office and laboratory facilities under several arrangements expiring through the year 2012. Rent expense was approximately \$2,484,000, \$1,777,000 and \$1,106,000 for the years ended December 31, 1999, 1998 and 1997, respectively. In November 1997, Inhale received from the landlord of its 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 at the end of the tenth year. The loan is recorded on the balance sheet as a tenant improvement loan.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 4--COMMITMENTS, LONG-TERM DEBT AND TENANT IMPROVEMENT LOAN (CONTINUED) Future noncancelable commitments under operating leases and the tenant improvement loan at December 31, 1999 are as follows:

	OPERATING LEASES	TENANT IMPROVEMENT LOAN
		DUSANDS)
Years ending December 31, 2000. 2001. 2002. 2003. 2004. 2005 and thereafter.	\$ 1,841 2,028 2,136 1,792 1,713 14,484	\$ 510 503 503 503 503 503
Total minimum payments required	\$23,994 =====	
Present value of future payments Less current portion		(3,556) 4,940 (45)
Non-current portion		\$ 4,895 ======

NOTE 5--STOCKHOLDERS' EQUITY

COMMON STOCK

EMPLOYEE STOCK PURCHASE PLAN

In February 1994, Inhale's Board of Directors adopted the Employee Stock Purchase Plan (the "Purchase Plan"). Under the Purchase Plan, 150,000 shares of common stock have been reserved for purchase by Inhale's employees pursuant to section 423(b) of the Internal Revenue Code of 1986. As of December 31, 1999, no shares of common stock have been issued under the Purchase Plan.

STOCK OPTION PLANS

EQUITY INCENTIVE PLAN

Inhale's 1994 Equity Incentive Plan (the "Equity Incentive Plan") was adopted by the Board of Directors in February 1994. The Equity Incentive Plan is an amendment and restatement of Inhale's 1992 Stock Option Plan. The purpose of the Equity Incentive Plan is to attract and retain qualified personnel, to provide additional incentives to employees, officers, consultants and employee directors of Inhale and to promote the success of Inhale's business. Pursuant to the Equity Incentive Plan, Inhale may grant or issue incentive stock options to employees and officers and non-qualified stock options, restricted stock purchase awards, stock bonuses and stock appreciation rights 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.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 5--STOCKHOLDERS' EQUITY (CONTINUED)

The maximum term of a stock option under the Equity Incentive Plan is ten years, but if the optionee at the time of grant has voting power of more than 10% of Inhale's outstanding capital stock, the maximum term of an incentive stock option is five years. The exercise price of incentive stock options granted under the 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 Inhale's 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 restricted stock purchase awards, granted under the Equity Incentive Plan are determined by the Board of Directors. Stock appreciation rights authorized for issuance under the Equity Incentive Plan may be tandem stock appreciation rights, concurrent stock appreciation rights or independent stock appreciation rights.

The Equity Incentive Plan may be amended at any time by the Board, although certain amendments would require shareholder approval. The Equity Incentive Plan will terminate in February 2004 unless earlier terminated by the Board.

NON-EMPLOYEE DIRECTORS' STOCK OPTION PLAN

In February 1994, Inhale's Board of Directors adopted the Non-employee Directors' Stock Option Plan under which options to purchase up to 200,000 shares of Inhale's common stock at the then fair market value may be granted to Inhale's non-employee directors. As of December 31, 1999, options on 34,800 shares had been exercised and options to purchase 102,066 shares were exercisable.

1998 NON-OFFICER EQUITY INCENTIVE PLAN

Inhale's 1998 Non-officer Equity Incentive Plan ("1998 Plan") was adopted by the Board of Directors in June 1998. The purpose of the 1998 Plan is to attract and retain qualified personnel, to provide additional incentives to employees and consultants and to promote the success of Inhale's business. Pursuant to the 1998 plan, Inhale may grant or issue non-qualified stock options, restricted stock purchase awards, stock bonuses and stock appreciation rights to employees and consultants who are neither Officers or Directors of Inhale.

The maximum term of a stock option under the 1998 Plan is ten years. The exercise price of stock options, and the purchase price of restricted stock purchase awards granted under the 1998 Plan are determined by the Board of Directors. Stock appreciation rights authorized for issuance under the 1998 Plan may be tandem stock appreciation rights, concurrent stock appreciation rights or independent stock appreciation rights. The 1998 Non-officer Equity Incentive Plan may be amended by the Board of Directors at any time.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 5--STOCKHOLDERS' EQUITY (CONTINUED)

A summary of activity under the Equity Incentive Plan, the Non-Employee Directors' Stock Option Plan and the 1998 Non-officer Equity Incentive Plan is as follows:

	OPTIONS OUTSTANDING				
	OPTIONS AVAILABLE FOR GRANT	NUMBER OF SHARES	EXERCISE PRICE	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE	
	(IN	THOUSANDS, EXCEPT PI			
Balance at December 31, 1996 Options granted Options exercised Options canceled	(851)	1,659 851 (125) (34)	\$ 0.06-19.25 0.01-35.25 0.06-16.13 0.56-22.75	21.01	
Balance at December 31, 1997 Shares authorized Options granted Options exercised Options canceled	,	2,351 1,069 (174) (83)	0.01-35.25 0.01-34.13 0.06-22.75 5.56-35.25	13.48 28.16 8.69	
Balance at December 31, 1998 Shares authorized Options granted Options exercised Options canceled	(1,575)	3,163 1,575 (124) (61)	0.01-35.25 0.01-41.88 0.01-34.12 10.01-34.12	12.60 26.46	
Balance at December 31, 1999	1,257	4,553	0.01-41.88	\$21.52	

At December 31, 1999, 1998 and 1997, options were exercisable to purchase approximately 1,511,484, 1,077,000 and 784,000 at weighted-average exercise prices of \$14.91, \$11.36 and \$8.17 per share, respectively.

Weighted average fair value of options granted during the year ended December 31, 1999, 1998 and 1997, was \$28.34, \$28.42 and \$21.89, respectively. The following table provides information regarding Inhale's stock option plans as of December 31, 1999.

		OPTIONS OUTSTANDING		OPTIONS	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)			
\$ 0.01-7.75	595	\$ 3.82	5.03	496	\$ 4.42		
8.88-12.00	454	10.09	5.60	272	10.12		
14.25-19.63	743	17.55	6.90	299	16.92		
21.88-32.38	2,655	28.01	9.0	409	27.66		
34.13-41.88	106	35.19	8.10	35	34.83		
\$ 0.01-41.88	4,553	\$21.52	7.80	1,511	\$14.91		
	=====	=====	====	=====	=====		

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 5--STOCKHOLDERS' EQUITY (CONTINUED)

In 1999, the Company granted 67,100 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, 1999 were \$0.01 and \$27.87, 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 Inhale has accounted for its employee stock options granted subsequent to December 31, 1994 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:

	1999	1998	1997
Risk-free interest rate	5.6%	4.8%	5.7%
Dividend yield	0.0%	0.0%	0.0%
Volatility factor	0.600	0.700	0.578
Weighted average expected life	5 years	5 years	6 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 Inhale's 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 management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. However, Inhale has 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. Inhale's pro forma information follows (in thousands except for earnings per share):

	YEARS I	ENDED DECEMB	BER 31,
	1999	1998	1997
Pro forma net loss	\$(48,077) ======	\$(24,325) ======	\$(13,168) ======
Pro forma basic and diluted net loss per common share	\$ (2.83) ======	\$ (1.55) ======	\$ (0.95)

Because FAS 123 is applicable only to options granted subsequent to December 31, 1994, the pro forma effect of the statement will not be fully reflected until approximately the year 2000.

WARRANTS

In October 1996 Inhale issued two warrants ("the warrants") to purchase a total of 20,000 shares of Common Stock (10,000 shares each) at a price of \$13.125 per share in connection with a facility lease. The warrants expire in October 2006 and were both outstanding and exercisable at December 31, 1999.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 5--STOCKHOLDERS' EQUITY (CONTINUED) STOCK COMPENSATION

Inhale recorded deferred compensation of approximately \$964,000 during the year ended December 31, 1999. Deferred compensation of \$576,000 had been recorded in the year ended December 31, 1998. These amounts represent the difference between the exercise price and the deemed fair market value of certain of Inhale's 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 5,830,108 shares of common stock have been reserved for issuance at December 31, 1999 for Inhale's equity incentive plans and the warrants.

NOTE 6--INCOME TAXES

As of December 31, 1999, Inhale had federal and state net operating loss carryforwards of approximately \$82,000,000 and \$10,600,000, respectively. Inhale also had federal and state research and other tax credit carryforwards of approximately \$2,000,000 and \$2,100,000, respectively. The federal and state net operating loss and credit carryforwards will expire at various dates beginning in 2000 through 2019 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 Inhale's deferred tax assets for federal and state income taxes as of December 31 are as follows:

	1999	1998
	(IN THOU	JSANDS)
Deferred tax assets:	^ 00 500	A 16 200
Net operating loss carryforwards Research and other credits	\$ 28,500 3,700	\$ 16,300 2,200
Capitalized research expenses	1,600	1,900
Deferred revenue Depreciation	1,900 1,300	1,700
Other	2,100	2,500
Total deferred tax assets	39,100	24,600
Valuation allowance for deferred tax assets	(39,100)	(24,600)
Net deferred tax assets	\$	\$

Because of Inhale's lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$14,500,000 and \$8,900,000 during the years ended December 31, 1999 and 1998, respectively.

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1999

NOTE 7--STATEMENT OF CASH FLOWS DATA

YEARS ENDED

		DECEMBER 31,	
	1999	1998	1997
		(IN THOUSANDS)	
Supplemental disclosure of cash flows information:			
Interest paid	\$ 470	\$270	\$ 66
	======	====	====
Supplemental schedule of non-cash investing and financing activities:			
Deferred compensation related to the issuance of certain			
stock options	\$ 964	\$576	\$551
	======	====	====
Issuance of common stock to Alliance	\$5,000	\$	\$
	======	====	====
Issuance of common stock and options in connection with			
licensing agreement	\$	\$284	\$600
	=====	====	====

NOTE 8--SUBSEQUENT EVENTS (UNAUDITED)

In February 2000, Inhale received \$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 accrues at a rate of 5% per year, subject to adjustment in certain circumstances. The notes will mature in 2007 and are convertible into shares of Inhale's common stock at a conversion price of \$76.71 per share, subject to adjustment in certain circumstances.

In February 2000, Inhale entered into privately negotiated agreements with certain holders of its outstanding 6 3/4% convertible subordinated debentures privately placed in October and November 1999, providing for the conversion of approximately \$94.2 million aggregate principal amount of the outstanding debentures in exchange for cash payments of approximately \$16.2 million in the aggregate. As a result of these transactions, the \$94.2 million of convertible debentures were converted into approximately 2.9 million shares of Inhale common stock. Inhale will no longer have interest payment obligations on the debentures that were converted.

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-8 No. 333-07969, Form S-8 No. 333-59735, Form S-8 No. 333-65919 and Form S-8 No. 333-74669) pertaining to the Employee Stock Purchase Plan, the 1994 Equity Incentive Stock Option Plan, the Non-Employee Directors Stock Option Plan, the 1994 Equity Incentive Plan and the 1998 Non-Officer Equity Incentive Plan of Inhale Therapeutic Systems, Inc., the Registration Statement (Form S-3 No. 333-20787) and related Prospectus of Inhale Therapeutic Systems, Inc. for the registration of 1,800,000 shares of its common stock, the Registration Statement (Form S-3 No. 333-68897) and related Prospectus of Inhale Therapeutic Systems, Inc. for the registration of 1,200,000 shares of its common stock and the Registration Statement (Form S-3/A No. 333-94161) and related Prospectus of Inhale Therapeutic Systems, Inc. for the registration of 3,388,268 shares of its common stock and \$108,450,000 of 6.75% Convertible Subordinated Debentures due October 13, 2006, of our report dated January 24, 2000, with respect to the financial statements of Inhale Therapeutic Systems, Inc. included in this amendment to the Annual Report on Form 10-K/A for the year ended December 31, 1999.

/s/ Ernst & Young

Palo Alto, California March 9, 2000

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE ANNUAL FINANCIAL STATEMENTS OF INHALE THERAPUETIC SYSTEMS, INC. AS FILED ON FORM 10-K/A FOR THE PERIOD ENDED DECEMBER 31, 1999. AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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