- ---
- ---

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

/X/

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 1997 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

(Exact name of registrant as specified in its charter)

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

150 INDUSTRIAL ROAD, SAN CARLOS, CA 94070

(Address of principal executive offices and zip code)

(650) 631-3100

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: COMMON STOCK, NO 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 9, 1998 as reported by Nasdaq National Market was approximately $394,332,870. Determination of affiliate status for this purpose is not a determination of affiliate status for any other purpose.

15,580,145

(Number of shares of common stock outstanding as of March 9, 1998)

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's definitive Proxy Statement to be filed for its 1998 Annual Meeting of Shareholders are incorporated by reference into Part III hereof.

- ---
- ---

INHALE THERAPEUTIC SYSTEMS
1997 ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS

OVERVIEW

Inhale Therapeutic Systems ("Inhale" or the "Company") is creating an inhalation drug delivery system to deliver a wide range of drugs, including peptides, proteins and other macromolecule drugs to the deep lung. Inhale is using this system principally to enable non-invasive delivery of macromolecule drugs currently administered by injection. The Company's insulin program, sponsored by Pfizer Inc. ("Pfizer"), is in a multi-site Phase IIb in-home trial with up to 240 diabetics. Baxter Healthcare Corporation (a subsidiary of Baxter International, Inc.) ("Baxter") is sponsoring four non-peptide or protein drugs for inhalation delivery, one of which is in a Phase II clinical trial and one of which is in a Phase I clinical trial. Eli Lilly & Company ("Lilly") is sponsoring two projects: an osteoporosis drug in a Phase I clinical trial and an undisclosed protein. In total, Inhale has 14 programs in development, ten of which are sponsored by collaborative partners. Six programs are in human clinical trials.

Currently there are approximately 30 macromolecule drugs marketed in the United States and about 120 others in human clinical trials. Sales of genetically engineered protein drugs were estimated at $7.6 billion worldwide in 1995. 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 shown generally to be commercially unattractive due to low natural bioavailability (the amount of drug absorbed from the delivery site into the bloodstream). As an alternative to the invasiveness of injection, Inhale believes a pulmonary delivery system could expand the market for macromolecule drug therapies and may enable new therapeutic uses of certain macromolecule drugs.

Inhale is creating a proprietary platform integrating customized formulation, fine-powder processing and packaging with a novel inhalation device to enable efficient, reproducible delivery of macromolecule drugs for systemic and local lung indications. For specific drug products, Inhale formulates and processes bulk drugs supplied by collaborative partners into fine 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 a prototype inhalation device that is being used several times per day for several months in outpatient trials for insulin. In addition, the Company has demonstrated room temperature stability of a year or more for a number of macromolecule drugs, and has scaled-up its powder processing and packaging for late stage clinical trials and small-scale production for certain drugs.

Inhale's development strategy is to focus efforts on applying its pulmonary delivery system primarily to drugs that either have proven efficacy and are approved for delivery by injection or are in late stage human clinical trials. Inhale's business strategy is to work with collaborative partners to develop and commercialize macromolecule drugs for pulmonary delivery. Generally, these partners have rights to the drugs, seek regulatory approvals and supply the drugs to Inhale for formulation. In addition to Pfizer, Baxter and Lilly, the Company is engaged in early stage feasibility and preclinical research and development collaborations with Centeon L.L.C. (a joint venture of Hoechst AG and Rhone-Poulenc Rorer, Inc.) on alpha-1 proteinase inhibitor for genetic emphysema and Genzyme Corporation on gene vectors for lung diseases. In addition to collaborations, Inhale has initiated projects with several macromolecule drugs including calcitonin, heparin, interferon beta, interferon alpha and follicle stimulating hormone. One of these drugs is currently partnered with Lilly. The Company 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 amount of cash required to develop a large and diversified potential product portfolio.

Inhale is developing a pulmonary drug delivery system applicable to a wide range of peptides, proteins and other macromolecules currently delivered by injection or by other routes. As an alternative to invasive delivery techniques, a pulmonary delivery system could potentially expand the market for macromolecule drug therapies by increasing patient acceptance and improving compliance, which in turn could decrease medical complications and the associated costs of disease management. Additionally, pulmonary delivery may enable new therapeutic uses of certain macromolecule 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 human clinical trials.

During 1997 and early 1998, Inhale continued to make progress toward its goals of broadening its partner base and moving products toward commercialization. The Company completed three new partnering agreements to develop products using its pulmonary delivery system, moved the pulmonary insulin product development program through a Phase IIb clinical trial, entered two new drugs into clinical trials, completed Phase I testing for two product development programs, strengthened its balance sheet by completing a $30.5 million private placement as well as a $40.0 million public offering of its common stock, and expanded its technology and manufacturing development activities.

While the Company believes its pulmonary delivery system will provide a unique delivery alternative for a wide range of drugs, development and testing are still ongoing and there can be no assurance that the Company's pulmonary delivery technology will prove to be technically feasible or commercially applicable to a range of drugs. Although many of the underlying drug compounds with which the Company is working have been tested in humans by others using alternative delivery routes, Inhale's potential products will require extensive research, development, pre-clinical and clinical testing, and may involve lengthy regulatory review. There can be no assurance that any of the Company's potential products will prove safe and effective in clinical trials, meet applicable regulatory standards, be capable of being produced in commercial quantities at acceptable cost or be successfully marketed to health care providers, payors or patients. In addition, there can be no assurance that the Company's strategic relations with any and all of its partners will continue in the future. Any failure by the Company to maintain or continue its partner relations, achieve technical feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or, together with partners, successfully market products, would have a material adverse effect on the Company.

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. Approximately 30 macromolecule drugs are approved for marketing in the United States and approximately 120 additional macromolecule drugs are in human clinical trials, many for chronic and subchronic diseases. Sales of genetically engineered protein drugs were estimated at $7.6 billion worldwide in 1995. Worldwide sales of insulin, for example, were estimated at $2.5 billion in 1995.

Due principally to their large size, most macromolecules typically have been delivered by injection. Drug injections performed 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.

Medical science, health care providers and consumers have been searching for alternatives to injection as a means of delivery of macromolecules used in the systemic treatment of chronic and subchronic diseases. Several non-invasive routes of delivery are being explored for macromolecule drugs, including oral, transdermal, nasal and pulmonary, such as metered-dose inhalers (MDIs).

Oral delivery is a common method of delivery for many small molecule drugs. However, drug delivery scientists generally believe that oral delivery provides extremely low delivery system efficiency for most macromolecules. In addition, the Company 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.

Passive transdermal delivery using "patch" technology has not been successful to date since the skin is even 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, the Company believes these devices have not been well accepted due to patient discomfort and relatively high cost.

The nasal route has been shown to have low and variable bioavailability for proteins and peptides, which is a major limitation for the nasal administration of such drugs. 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 four peptides have been approved for marketing in the United States utilizing nasal delivery.

Pulmonary drug delivery systems, such as MDIs, existing dry powder inhalers and nebulizers, are used primarily to deliver drugs to the airways of the lung for local lung applications. Approximately 30 drugs are approved for marketing by the FDA for delivery into the lung, but none of these delivery devices was designed to optimize drug delivery to the deep lung for absorption into the bloodstream. Current 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, the Company 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, current pulmonary drug delivery devices do not provide the dosage reproducibility and formulation stability generally needed for commercially viable systemic macromolecule drug delivery. The Company 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, the Company 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, reproducible pulmonary 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 overall disease treatment. Additionally, pulmonary delivery may enable new therapeutic uses of certain macromolecule drugs.

Inhale also believes that opportunities for an integrated pulmonary 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 much smaller amounts of certain drugs generally are needed than for systemic administration and the drug can be applied directly to the site of action, thereby potentially reducing systemic side effects.

OTHER MOLECULES

In addition to developing a pulmonary delivery system for macromolecules, Inhale is investigating opportunities of leveraging its technology for small molecules where there is a clear, demonstrable need for an alternative drug delivery system and where the Company'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 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 microbial growth.

Inhale is applying its technology to the delivery of small molecules where there is a clear, demonstrable need for an alternative drug delivery system and where the Company's existing technology can be applied without significant modification. Examples include molecules that require rapid systemic absorption for efficacy such as 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.

Inhale believes that its technology could be used to address these problems through the following: efficient dispersion of the drug into the lungs, reproducible delivery of a consistent and predictable amount of drug into the bloodstream, and a strong moisture barrier in the blister packs. The Company further believes its technology could potentially be applied economically in market segments where it is essential that significant drug doses reach the lung, such as severe asthma cases where nebulizers are used today. Large amounts of drugs taken orally or through inefficient inhalers can result in side effects which could be avoided or reduced through more efficient pulmonary delivery.

STRATEGY

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

- DEVELOP A BROADLY APPLICABLE PULMONARY DELIVERY SYSTEM. Inhale is developing its non-invasive pulmonary 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 an effective non-invasive delivery alternative that can: (i) expand market penetration for existing therapeutics currently delivered by injection, infusion or other routes; (ii) commercialize new indications by using pulmonary delivery as a new route of administration; and (iii) 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. The Company is developing a commercially viable pulmonary delivery system through an integrated systems solution. Inhale

combines its expertise in aerosol engineering, chemical engineering, mechanical engineering, aerosol science, protein formulations, fine powder processing and powder filling, and pulmonary physiology and biology to build a proprietary, fully-integrated system for pulmonary delivery of therapeutic drugs. The Company 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. The Company 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 human clinical trials before entering into a partner relationship for further development. The Company believes this partnering strategy enables it to reduce its cash requirements while developing a large and diversified potential product portfolio.

- FOCUS ON APPROVED 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. The Company 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 the manufacture of its device. The Company 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 PULMONARY DELIVERY SYSTEM

Inhale believes that the following criteria are necessary for a commercially viable non-invasive 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 since it cannot be increased without enhancing the natural permeability of the delivery site. Total system efficiency is critical due to the high cost of macromolecule drugs. 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. 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 conditions.

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

- 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 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. The Company believes that this interdisciplinary capability provides an important competitive advantage.

Inhale has chosen to base its pulmonary 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 MDI systems and, for many drugs, at least 25 times more than currently marketed liquid or nebulizer systems. The Company believes that a dry powder system for drugs requiring higher doses, such as insulin, alpha-1 antitrypsin and heparin, 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 the Company's products will ever be successfully commercialized.

FORMULATIONS. Each macromolecule drug poses different formulation challenges due to varying chemical and physical characteristics and dosing requirements, which therefore requires significant optimization work for each specific drug. Inhale has assembled a team with expertise in protein formulations, 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 several protein powders with on-going room temperature stability (both chemical and physical) of more than 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, and has filed and expects to continue to file patent applications on several of its formulations. In June 1997, the Company acquired the intellectual property portfolio of the BioPreservation Division of Pafra Limited ("Pafra") of Basildon, England. This portfolio includes issued U.S. and foreign Letters Patent and pending applications relating to the stabilization of macromolecule drugs in dry formulations. See "Risk Factors -- Dependence upon Proprietary Technology; Uncertainty of Obtaining Licenses or Developing Technology."

POWDER PROCESSING. Inhale is modifying standard powder processing equipment and developing custom techniques to enable it to produce fine dry powders consistently with particle diameters of between one and five microns without drug degradation or significant loss of expensive bulk drug. The Company has scaled up powder processing to sufficient levels for producing test powders for late stage clinical trials and small volume marketed products, if any. Inhale is in the process of scaling up its powder processing systems in order to produce quantities sufficient for commercial production of products the Company believes it will need to supply in high volumes, such as insulin. However, there can be no assurance that the Company 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 PACKAGING. Fine particle powders have special handling requirements that are different from those for larger particles. Current commercial filling and packaging systems are designed for filling larger particle powders and therefore must be modified to dispense finer particles more accurately and in the small quantities required. Initially, powder filling was performed manually. Inhale has since developed and qualified a proprietary automated filling system suitable for use in clinical trials and initial production

quantities for certain products. Inhale is also developing with Pfizer a proprietary, high capacity system for production use.

INHALATION 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. See "Business -- Patents and Proprietary Rights." To achieve this goal, Inhale has designed a prototype of its pulmonary delivery device to perform the following:

- EFFECTIVELY DISPERSE FINE PARTICLES INTO AN AEROSOL CLOUD. Fine powders have different dispersion requirements than large powders. Most current dry powder inhalers use larger powders and are not efficient in dispersing powders with diameters of one to five microns. Inhale has developed and is refining its dispersion system for its prototype 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 macromolecule drug.

- EFFICIENTLY AND REPRODUCIBLY DELIVER THE AEROSOL CLOUD TO THE DEEP LUNG. Inhale has developed a proprietary aerosol cloud handling system in its device that facilitates 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.

Inhale believes that its device will be capable of achieving deep lung delivery with commercially feasible efficiencies for many macromolecule drugs. An early prototype of the device was used in Inhale's insulin Phase I clinical trial and in Immunex's IL-1 human clinical trial. Another prototype is currently being used in several Phase I and II trials, including the outpatient Phase II insulin trial with Pfizer, in which diabetics have been using the Inhale system for several months.

The success of Inhale's pulmonary drug delivery system for any drug will depend upon the Company achieving sufficient formulation stability, safety dosage reproducibility and 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 screening determinant for the feasibility of pulmonary delivery of any systemic macromolecule 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 and pulmonary delivery process in drug formulation, dry powder processing, 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 conditions) and safety will vary with each macromolecule and the type and amount of excipients that are used in the formulation. Reproducible dosing (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 the Company will be able to successfully develop such an inhalation device or overcome such other obstacles to reproducible dosing. See "Risk Factors -- Uncertainties Related to Technology and Product Development."

THERAPEUTIC PRODUCTS UNDER DEVELOPMENT

The following table sets forth the type of product currently in development, the application(s) for the particular product, its present stage of development and the identity of the Company's corporate partner, if any, for such product application.

	DRUG	POTENTIAL INDICATIONS	STATUS	PARTNER
1)	Human Insulin	Type I and II Diabetes	Phase IIb	Pfizer
2)	*	*	Phase II	Baxter
3)	*	*	Phase I	Baxter
4)	*	Osteoporosis	Phase I	Lilly
5)	Calcitonin	Osteoporosis, Bone Pain, Paget's Disease	Phase I	**
6)	Interleukin-1 Receptor	Asthma	Phase I/II	Immunex+
7)	*	*	Preclinical	Baxter
8)	*	*	Feasibility	Baxter
9)	Alpha-1 Antitrypsin	Genetic Emphysema	Preclinical	Centeon
10)	Follicle Stimulating Hormone	Infertility and Reproductive Diseases	Feasibility	**#
11)	Gene Vectors	Lung Diseases	Feasibility	Genzyme
12)	Heparin	Blood Clotting	Feasibility	**#
13)	Interferon Alpha	Hepatitis B and C	Feasibility	**#
14)	Interferon Beta	Multiple Sclerosis	Feasibility	**#

STATUS:

PHASE IIb -- OUT-PATIENT CLINICAL TRIALS TO ESTABLISH SAFETY AND EFFICACY.

PHASE II -- HUMAN CLINICAL TRIALS TO ESTABLISH DOSING AND EFFICACY IN PATIENTS.

PHASE I -- HUMAN CLINICAL TRIALS TO TEST SAFETY, AND FOR DRUGS WITH SYSTEMIC APPLICATIONS, ALSO TESTS BIOAVAILABILITY COMPARED WITH INJECTION IN HEALTHY SUBJECTS.

PRECLINICAL -- FORMULATION DEVELOPMENT AND ANIMAL TESTING IN PREPARATION FOR HUMAN CLINICAL TRIALS.

FEASIBILITY -- STUDIES TO ESTABLISH VIABILITY OF PULMONARY DELIVERY WITH INHALE'S SYSTEM INCLUDING ANIMAL BIOAVAILABILITY STUDIES OR INITIAL FORMULATION DEVELOPMENT.

* DRUG OR POTENTIAL INDICATIONS WITHHELD AT PARTNER'S REQUEST.

** NOT CURRENTLY PARTNERED.

+ THIS PROGRAM IS AWAITING FURTHER WORK AND/OR LICENSING FROM IMMUNEX.

ONE OF THESE FOUR IS PARTNERED WITH LILLY.

INHALE'S PULMONARY DRUG DELIVERY PROGRAMS IN PROGRESS

Inhale has 14 programs in development, six of which are in human clinical trials and ten of which are sponsored by collaborative partners. In general, the Company'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.

PFIZER 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 regulate properly blood glucose levels, is caused by insufficient production of insulin by the pancreas or insufficient use of the insulin that is secreted. Over time, high blood glucose levels can lead to failure of the microvascular system, which may lead to blindness, loss of circulation, kidney failure, heart disease or stroke. Insulin currently is marketed only in injectable form. Worldwide sales of insulin were estimated at $2.5 billion in 1995. Insulin is supplied by various manufacturers, including Eli Lilly and Novo-Nordisk A/S.

The American Diabetes Association estimates that in 1995 there were approximately eight million diagnosed Type I (juvenile onset) and Type II (adult onset) diabetics in the United States. They estimate an additional eight million who have not been diagnosed. All Type I diabetics, estimated at between 5% and 15% of all diabetics, require insulin therapy. Type I diabetics generally require both a baseline treatment of long-acting insulin and multiple treatments of regular insulin throughout the day. Type II diabetics, depending on the severity of their case, may or may not require insulin therapy. Type II diabetics who use insulin are best treated with regular insulin and sometimes require long-acting insulin as well. Many Type II patients who do not require insulin to survive but would benefit from it are reluctant to start treatment because of the inconvenience and unpleasantness of injections.

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. However, many patients are reluctant to increase their number of doses because they find injections unpleasant and inconvenient.

Although non-invasive routes of insulin delivery have been sought, the only commercially viable way to deliver insulin to date has been by subcutaneous injection. Subcutaneous injections are generally given with a syringe and needle, although high pressure needle-less injection devices are also available. Needle-less injection devices, which inject proteins like insulin through the skin into the body, have been available for many years. However, the Company believes these devices have not been well accepted due to patient discomfort and relatively high cost.

Inhale is developing a regular insulin that can be administered in one to three blisters using its pulmonary delivery system. The Company believes that its pulmonary delivery system could provide increased user convenience and result in greater patient compliance by eliminating some injections for Type I and Type II patients and all injections for some Type II patients. In addition, the Company believes that pulmonary delivery could yield medical advantages by providing a more rapid acting insulin than certain current injectable products.

Through its collaboration with Inhale, Pfizer conducted Phase I and Phase IIa clinical trials which indicated that pulmonary insulin was absorbed systemically and reduced glucose levels. In late October 1996, Pfizer initiated a multi-site Phase IIb outpatient trial to include up to 240 patients with diabetes mellitus. In late October 1997, Pfizer announced the results of current Phase II testing. In 70 Type I diabetics treated with either inhaled or conventional injected insulin therapy for three months, the levels of hemoglobin A1c, the best index of blood glucose control, were statistically equivalent. Virtually identical results were obtained in a group of Type II diabetics. Pfizer also announced that it intends to continue the

insulin project with a Phase III study. In connection with the collaboration with Inhale, Pfizer has 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.

BAXTER PROGRAM. In March 1996, Inhale entered into a collaboration agreement with 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 will receive worldwide commercialization rights in exchange for up to an estimated $60 million in research and development funding and milestone payments for four molecules, assuming successful development and continuation of the program by Baxter. Baxter also has an option to add other molecules to the collaboration that could result in additional funding and milestone payments to Inhale. Inhale will receive royalties and manufacturing payments on sales of products developed through the collaboration. Inhale has primary responsibility for development of the selected therapeutics. Inhale will develop dry powder formulations for use with its portable inhalation device and will process and package powders for clinical supplies and marketed products. Clinical trials will also be managed by Inhale. Baxter will be responsible for the worldwide commercialization of the products resulting from the collaboration.

In September 1997 Inhale announced that the first compound from its collaboration with Baxter has entered Phase II clinical testing using Inhale's pulmonary delivery system. On November 11, 1997 the Company announced that the second compound from this collaboration has entered clinical testing in a Phase I study. Inhale is currently renegotiating with Baxter certain terms of their collaboration agreement to address concerns raised by both parties about the overall scope and cost of the collaborative arrangement. As of February 1998 no formal renegotiation has been agreed to, and there can be no assurance that the parties will be able to reach an agreement or that the collaborative arrangement between Inhale and Baxter will be continued. See "Risk Factors -- Dependence on Collaborative Partners."

ELI LILLY & CO. PROGRAMS. In January 1997 Inhale entered into a collaborative agreement with Lilly to develop pulmonary delivery for a selected osteoporosis product. Osteoporosis is 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 as a result of hip fractures, primarily due to complications that result from surgery or from being confined to bed. Associated medical costs of the estimated 1.5 million bone fractures caused annually by osteoporosis are estimated to be about $10 billion per year in the United States.

Under the terms of its agreement with Lilly, Inhale will receive up to an estimated $20 million in initial fees, funding for research and milestone 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 and supply inhalation devices for Lilly.

Phase I clinical trials of this osteoporosis drug, completed in collaboration with Alza Corporation ("Alza") indicated that the drug was systemically absorbed when delivered with Inhale's pulmonary system. Under an agreement between Alza and Inhale, Alza has agreed not to participate in the future development and commercialization of the osteoporosis product. Subsequently, the Company entered into an agreement with Lilly, pursuant to which Lilly has agreed to conduct future clinical trials and will receive worldwide commercialization rights.

In January 1998 Lilly and Inhale entered into a second collaborative agreement to develop pulmonary delivery for an unspecified protein product based on Inhale's deep-lung delivery system for macromolecules. 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 any marketed products. Inhale will manufacture packaged powders for and supply inhalation devices to Lilly.

CALCITONIN PROGRAM. Inhale is funding a proprietary program to develop pulmonary delivery 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.

Osteoporosis is by far the most important potential clinical indication for calcitonin. It has been demonstrated in clinical trials to reduce the incidence of bone fractures in osteoporosis patients. While there is some evidence that calcitonin can restore bone, its primary benefit appears to be the retardation of bone loss. In addition, clinical evidence suggests that calcitonin may provide superior efficacy to estrogens in cases of rapid turnover osteoporosis. While considerable work has been done on non-invasive delivery of calcitonin, to date only salmon calcitonin for nasal delivery has been marketed. Nasally-delivered calcitonin, however, is sometimes characterized, depending upon the formulation used, by low bioavailability, irritation caused by enhancers and poor reproducibility. Inhale believes that pulmonary calcitonin could be more efficient, more reproducible and less irritating than nasal calcitonin.

In April 1997 the Company announced the successful completion of Phase I clinical trials to determine the safety 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 normal volunteers indicated that the drug was systemically absorbed through the pulmonary route when delivered with Inhale's system. The Company is seeking a partner for further clinical development.

IMMUNEX PROGRAM. Interleukin-1 is a cytokine that helps initiate the inflammatory response to foreign pathogens. Inhale collaborated with Immunex to develop pulmonary delivery of 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.

CENTEON PROGRAM. Alpha-1 antitrypsin deficiency results from a patient's liver producing insufficient alpha-1 antitrypsin, a protein that circulates in the blood and inhibits the activity of elastase enzyme. It is estimated that as many as 100,000 people in the United States were born with alpha-1 antitrypsin deficiency and potentially 28,000 in Northern Europe. Of this group, emphysema resulting from the deficiency afflicts up to 40,000 people in the United States alone.

If not treated, alpha-1 antitrypsin deficiency leads to the breakdown of the intricate protein fiber network in the adult lung which provides support for the millions of tiny airsacs which make up the lung (the alveoli). The degradation of these fibers leads to a gradual loss of surface area for gas exchange, which can cause the inability to breathe properly and ultimately premature death.

Alpha-1 antitrypsin 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 antitrypsin derived from human plasma.

In January 1997 Inhale and Centeon entered into a collaboration to develop a pulmonary formulation of alpha-1 antitrypsin to treat patients with alpha-1 antitrypsin deficiency. Under the terms of the collaboration, Centeon 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. Centeon 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 Centeon for commercialization and marketing.

The two companies completed pre-clinical work that indicates Inhale's dry powder formulation of Centeon's alpha-1 antitrypsin has the potential to significantly improve the efficiency of delivery compared with current infusion therapy. The Company believes its pulmonary delivery system could significantly reduce the amount of drug needed for genetic emphysema therapy since alpha-1 antitrypsin could be delivered directly to the lung.

Centeon is currently negotiating with multiple partners to secure rights under patents that have been granted in the United States and Europe directed to aerosol formulations for the treatment of the lung containing alpha-1 antitrypsin (U.S.) and serine protease inhibitors including alpha-1 antitrypsin (Europe). The failure by Centeon to secure rights under these patents could result in the termination of the program. See "Risk Factors -- Dependence on Proprietary Technology; Uncertainty of Obtaining Licenses or Developing Technology."

GENZYME PROGRAM. In July 1996 the Company signed an agreement with Genzyme Corporation to examine the feasibility of developing dry powder formulations of gene vectors for pulmonary applications. Gene vectors are currently being investigated by several companies and academic institutions for use in treating lung diseases such as cystic fibrosis. Inhale believes that its delivery system is well suited for the delivery of gene therapies to treat lung disease because its system could provide efficiency, reproducibility, stability and containment advantages relative to alternative pulmonary delivery methods. Early stage research has shown that Inhale's dry powder formulations and powder processing technology can be used to make powders containing active gene vectors.

FOLLICLE STIMULATING HORMONE (FSH) PROGRAM. FSH, a glycoprotein hormone secreted by the pituitary gland, has been utilized since the 1960s for treatment of infertility. In female reproduction, FSH is responsible for ovarian follicular growth and development. Therapeutic use of FSH has expanded since the 1970s. It is currently administered in a series of daily injections over one to three weeks to enhance follicle growth and ovum production. According to industry sources, the female infertility market was approximately $600 million in 1996. Inhale has demonstrated the feasibility of pulmonary FSH in an animal model.

HEPARIN AND LOW MOLECULAR WEIGHT HEPARIN (LMWHS) PROGRAM. Heparin is a low cost mucopolysaccharide anticoagulant isolated from the lungs and intestines of pigs and cows. Heparin, which is delivered by subcutaneous or intravenous injection, is approved for many applications pertaining to blood clotting, including prophylaxis and treatment of deep vein thrombosis, pulmonary embolism and prevention of other thromboembolitic indications. Worldwide sales in 1996 were estimated to be approximately one billion dollars. Research studies have indicated that heparin may have additional, non-antithrombotic properties, including anti inflammatory properties which are useful in treating local lung diseases such as asthma. Others have also suggested that it possesses antiprotease activity, similar to alpha-1 antitrypsin, and could be used to treat lung diseases.

Warfarin, a small molecule oral anticoagulant, is the most widely used non-invasively delivered alternative to heparin. Warfarin, however, has some serious associated risks which include hemorrhaging and, less frequently, necrosis or gangrene of the skin or other tissues.

Inhale believes that a non-invasive heparin or LMWH could expand the drug's use for preoperative, postoperative and prophylactic use at home. A number of human studies on pulmonary-delivered heparin suggest that it is safe and efficacious as an inhaled systemic anticoagulant. Inhale has developed an initial dry powder formulation for heparin and conducted animal absorption screening studies.

INTERFERON ALPHA PROGRAM. Interferon alpha is produced by a number of cell types in the body and serves to turn on an array of genes in cells for fighting viral infections. It has been approved for Hepatitis B and C (inflammatory viral diseases of the liver), hairy cell leukemia (a blood cancer), and AIDS-related Kaposi's sarcoma (a skin cancer prevalent in AIDS patients). The global market for all interferon alpha agents was estimated to be approximately $700 million in 1995. There are at least five companies competing in the interferon alpha market, including Schering-Plough Corporation, Hoffmann-La Roche, Inc., Sumitomo Corp. and Otsuka Pharmaceutical Co., Ltd. Interferon alpha is currently given in all indications three times per week by subcutaneous injection. Inhale believes that a pulmonary delivery system could provide a competitive advantage in what is now an exclusively injectable market and could reduce the cost of treatment by enabling more home therapy. Inhale has completed feasibility testing, including animal studies, showing that interferon alpha is well absorbed systemically following pulmonary administration.

INTERFERON BETA PROGRAM. Interferon beta has been approved for treatment of multiple sclerosis, an immunological disorder in which the immune system attacks the myelin sheath that coats the nerves. Analysts estimate this market at approximately $300 million. There are an estimated 700,000 cases in North America and Europe.

Two interferon beta products are FDA approved for chronic treatment of multiple sclerosis (Betaseron by Berlex and Avonex by Biogen). Betaseron is administered as daily injections and Avonex is administered as a weekly injection. Inhale believes that a pulmonary drug delivery system could provide a competitive advantage in this exclusively injectable market. The Company has successfully completed formulation feasibility testing of Interferon-beta.

There can be no assurance that the Company will be able to enter into additional collaborations or that its feasibility agreements will lead to collaborations. There also can be no assurance that the Company will be able to maintain any such collaborative arrangements or feasibility agreements or that any such collaborative arrangements or feasibility agreements will be successful. The failure of the Company to enter into or maintain such collaborative arrangements and feasibility agreements would have a material adverse effect on the Company. See "Risk Factors -- Dependence on Collaborative Partners."

MANUFACTURING

Inhale generally plans to formulate, manufacture and package the powders for its pulmonary delivery products and to subcontract the manufacture of its proprietary pulmonary delivery devices. Under its collaborative agreement with Pfizer to develop insulin powders, Inhale will be the primary manufacturer of powders and Pfizer will be primarily responsible for filling blisters. Prior to the commercialization of its first products, the Company must build and have validated a powder processing and packaging facility. The Company must also select and have validated a device manufacturer. Inhale believes its manufacturing strategy will enable it to achieve the following: (i) provide economies of scale by utilizing manufacturing capacity for multiple products; (ii) improve its ability to retain any manufacturing know-how; and (iii) allow its customers to bring pulmonary delivery products to market faster than if they established their own powder processing and packaging facilities.

The Company has built a powder manufacturing and packaging facility capable of producing powders in quantities sufficient for Phase I, Phase II, and the initiation of Phase III human clinical trials. This facility has been inspected and licensed by the State of California and was used to manufacture and package powders under Good Manufacturing Practices ("GMP") for Inhale's Phase I and Phase II human insulin trials, Phase I and II trials with Baxter, Immunex's IL-1 receptor Phase I/II clinical trial, Phase I calcitonin, and a Phase I clinical trial for another project. Inhale intends to build a facility capable of manufacturing and packaging powders in quantities sufficient for registration batches and initial commercial production.

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 the Company'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 the Company. Inhale has developed and validated a proprietary small scale prototype automated filling system which the Company 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. The Company 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 the Company 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 the Company's products and would have a material adverse effect on the Company. See "Risk Factors -- Limited Manufacturing Experience; Risk of Scale-Up."

Inhale used a prototype of its inhalation device in its Phase I human insulin trial and in Immunex's Phase I/II clinical trial. Inhale has completed development of a prototype take-home device which is being used in several Phase I and II trials, including a Phase IIb insulin trial. Additionally, Inhale is refining the device design for use in later-stage clinical trials and commercial products.

Inhale plans to subcontract the manufacture of its pulmonary delivery devices before commercial production of its first product. The Company 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 GMP. There can be no assurance that Inhale will be able to obtain and maintain satisfactory contract manufacturing on commercially acceptable terms, if at all. The Company's dependence upon third parties for the manufacture of its potential inhalation device may adversely affect the Company'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 the Company'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: (i) pre-clinical laboratory and animal tests; (ii) the filing of an Investigational New Drug application ("IND"); (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug in its intended indication; and (iv) 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 toxicity tests normally required for the IND and NDA/BLA application may not be necessary.

Pre-clinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulation. Pulmonary systems must be formulated according to GMP, 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 human clinical trials begin. The IND application becomes effective 30 days after receipt by the FDA, unless the FDA raises objections.

Clinical trials involve the administration of the drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy 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 safety of human subjects 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 safety, dosage tolerance, pharmacokinetics, absorption, metabolism and excretion. Phase II involves studies in a limited patient population to (i) determine the efficacy of the product for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage, and (iii) identify possible adverse effects and safety risks. When Phase II evaluations demonstrate that dosing the drug by the pulmonary system 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 investigator or the IRB may suspend clinical trials at any time if it believes that clinical subjects 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 system. 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 problems occur after the product reaches the market. The FDA may require testing and surveillance programs to monitor the effect of pulmonary systems that have been commercialized, and has the power to prevent or limit future marketing of the product based on the results of these post-marketing 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 GMP compliance. Inhale is also subject to United States federal, state and local regulations regarding workplace safety, environmental protection and hazardous and controlled substance controls, among others.

Many of the drugs with which the Company is working are already approved for marketing by the FDA. The Company believes that when working with approved drugs, the approval process for delivery by pulmonary delivery may require less time and fewer tests than for new chemical entities. However, the Company 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 the Company'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.

The Company's device will not be developed as an independent product but will be an inseparable part of the pulmonary drug delivery system for each specific molecule. Prior to or at the time of submission of the IND, the FDA Center and division within the Center will be identified to be responsible for the review of the IND and NDA/BLA. 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, will 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 or to each partner portions of the Drug Master File being developed and to be maintained by Inhale which contains data concerning the manufacturing processes for the product. The 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. The Company's business strategy contemplates performing more of these studies in the future.

Sales of the Company's products outside the United States are subject to regulatory requirements governing human 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 the Company's pulmonary drug delivery system, whether or not such drug was already approved for marketing in another dosage form, the product must undergo rigorous pre-clinical and clinical testing and an extensive review process mandated by the FDA and equivalent foreign authorities. These processes generally take a number of years and require the expenditure of substantial resources. None of the Company's proposed products has been submitted to the FDA for marketing approval. The Company 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. The Company also relies upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and further develop its competitive position. The Company plans to defend aggressively its proprietary technology and any issued patents.

Inhale expects that its integrated system for the development of pulmonary delivery technology for macromolecule drugs will yield innovations in dry powder formulations, powder processing, powder packaging and device design. It is the Company's strategy to build proprietary positions in each of its technological areas. The Company'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. On October 17, 1995, the Company received United States Patent Number 5,458,135 from the United States Patent and Trademark Office (the "PTO") for certain claims covering the use of its device in a method for delivering powder formulations of drugs to the lung. On March 4, 1997, the Company received United States Patent Number 5,607,915 from the United States Patent Trademark Office for pulmonary delivery of active fragments of parathyroid hormone (PTH) 1-34. On October 17, 1997, Inhale was granted United States patent No. 5,654,007 covering a system and methods for processing fine dispersible powders for easier processing. There can be no assurance that any of the patents applied for by the Company will issue, or that any patents that issue will be valid and enforceable. Even if such patents are enforceable, the Company anticipates that any attempt to enforce its patents could be time consuming and costly.

It is the Company's policy to require its employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from the Company to

execute confidentiality agreements upon the commencement of employment or consulting relationships with the Company. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with the Company 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 the Company. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for the Company's trade secrets in the event of unauthorized use or disclosure of such information.

In June 1997 the Company 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. A granted European patent included in this portfolio is currently the subject of an opposition proceeding before the European Patent Office and the Company is continuing the defense of this patent, the opposition to which was initiated prior to the acquisition. There can be no assurance that the Company will be successful in the defense of this opposition proceeding. In addition, there can be no assurance that any of the Pafra patent applications will issue, or that any Pafra patents will be valid and enforceable. The loss of the opposition proceeding or the inability to obtain or defend the Pafra patents could have a material adverse effect on the Company. See "Risk Factors -- Dependence Upon Proprietary Technology; Uncertainty of Obtaining Licenses or Developing Technology."

The Company has obtained license rights to certain know-how and patent applications owned by Genentech, Inc. covering formulations and 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. Recently, Genentech successfully defended an opposition proceeding involving a pending European patent licensed to Inhale. This decision is currently on appeal. The pending patent covers the pulmonary delivery of cytokines and growth factors.

SCIENTIFIC ADVISORS

The Company has assembled scientific and development advisors that provide Inhale expertise in critical scientific, development, engineering, manufacturing and business issues facing the Company. The scientific advisory group assists Inhale 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:

NAME	AFFILIATION	AREA OF EXPERTISE
Joseph Brain, Ph.D.	Professor, Harvard School of Public Health Chairman, Department of Environmental Health Director, Physiology Program	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

EMPLOYEES AND CONSULTANTS

As of December 31, 1997, Inhale had 147 employees, of which 119 were engaged in research and development (including manufacturing) activities and 28 in general administration and business development. Seventy-six of the employees hold advanced degrees, of which 35 are Ph.D.s. The Company employs scientists and engineers with expertise in the areas of pulmonary biology, aerosol science, mechanical engineering, protein chemistry and chemical engineering. None of the Company's employees are covered by a collective bargaining agreement and the Company 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 the Company's scientific advisors as well as independent consultants.

RESEARCH AND DEVELOPMENT

Research and development expenditures totaled $23.6 million, $14.4 million, and $9.0 million for the years ended December 31, 1997, 1996, and 1995 respectively. Research and development expenditures funded by partners were approximately $16.2 million, $6.9 million, and $3.4 million for the years ended December 31, 1997, 1996, and 1995 respectively.

THIRD-PARTY REIMBURSEMENT

In both domestic and foreign markets, sales of the Company's potential products, if any, will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. 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. There can be no assurance that the Company's proposed products will be considered cost effective or that adequate third-party reimbursement will be available to enable Inhale to maintain price levels sufficient to realize an appropriate return on investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before the Company's proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services. (See "Risk Factors -- Uncertainty Related to Health Care Reform and Third-Party Reimbursement")

RISK FACTORS

In addition to the other information in this Report, the following risk factors should be considered carefully in evaluating the Company and its business.

EARLY STAGE COMPANY. Inhale is in an early stage of development. There can be no assurance that the Company's pulmonary delivery technology will prove to be technically feasible or commercially applicable to a range of macromolecules and small molecule drugs. Only six of the Company's fourteen pulmonary delivery formulations, insulin, interleukin-1 receptor, salmon calcitonin, the Lilly osteoporosis drug and two small molecules have been subject to any human clinical testing. Although many of the underlying drug compounds with which the Company is working have been tested in humans by others using alternative delivery routes, Inhale's potential products will require extensive research, development, pre-clinical and clinical testing, and may involve lengthy regulatory review. There can be no assurance that any of the Company's potential products will prove to be safe and effective in clinical trials, meet applicable regulatory standards, be capable of being produced in commercial quantities at acceptable cost or be marketed successfully. Any failure of the Company to achieve technical feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or, together with partners, successfully market products, would have a material adverse effect on the Company. See "Risk Factors - -- No Assurance of

Successful Development or Commercialization of Drugs for Pulmonary Delivery," "-- Government Regulation; Uncertainty of Obtaining Regulatory Approval" and "-Uncertainty Related to the Health Care Industry and Third-Party Reimbursement."

UNCERTAINTIES RELATED TO TECHNOLOGY AND PRODUCT DEVELOPMENT. The success of Inhale's pulmonary drug delivery system for any drugs will depend upon the Company achieving sufficient 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), formulation stability, safety and dosage reproducibility.

The initial screening determinant for the feasibility of pulmonary delivery of any systemic drug is pulmonary bioavailability, which measures the percentage of the drug absorbed into the bloodstream when delivered directly to the lungs. In addition, a certain percentage of each drug dose is lost at various stages of the manufacturing and pulmonary delivery process in drug formulation, dry powder processing, packaging, and in moving the drug from a delivery device into the lungs. Excessive drug loss at any one stage or cumulatively in the manufacturing and delivery process could render a drug commercially unfeasible for pulmonary delivery.

Formulation stability (the physical and chemical stability of the formulated drug over time and under various storage conditions) and safety will vary with each drug and the type and amount of excipients that are used in the formulation. Reproducible dosing (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 the Company will be able to develop successfully such an inhalation device or overcome such other obstacles to reproducible dosing.

The Company's integrated approach to systems development relies upon several different but related technologies. Development of powder formulations, processing and packaging technology and the delivery device, establishing collaborations with partners, laboratory and clinical testing, and manufacturing scale-up must proceed contemporaneously so as not to delay any aspect of systems development. Any delay in one component of product or business development could cause consequential delays in the Company's ability to develop, obtain approval of or market therapeutic products using its system. Further refinement of the Company's device prototype, further scale-up of the powder processing system and automated packaging system will need to be accomplished before initiation of late stage clinical trials.

There can be no assurance that Inhale will be able to demonstrate pulmonary bioavailability for the drug candidates it has identified or may identify, will be able to achieve commercial viability of its pulmonary delivery system or will achieve the total system efficiency needed to be competitive with alternative routes of delivery. Further, there can be no assurance that the Company's pulmonary delivery system will prove to be safe or provide reproducible dosages of stable formulations sufficient to achieve clinical efficacy, regulatory approval or market acceptance. In addition, there can be no assurance that Inhale will advance the numerous aspects of product and business development such that delays in overall product development do not occur. The failure to demonstrate pulmonary bioavailability, achieve total system efficiency, provide safe, reproducible dosages of stable formulations or advance on a timely basis the numerous aspects of product and business development would have a material adverse effect on the Company. See "Risk Factors -- Dependence Upon Collaborative Partners" and "-- Government Regulation; Uncertainty of Obtaining Regulatory Approval;" "Business -- Inhale's Pulmonary Device System" and "-- Government Regulation."

UNCERTAINTIES RELATED TO CLINICAL TRIALS. The Company has limited experience in conducting clinical trials and intends to rely primarily on the pharmaceutical companies with which it collaborates, including Pfizer and Lilly. The Company is responsible for managing the clinical trials in its collaboration with Baxter. Before seeking regulatory approvals for the commercial sale of products under development, the

Company must demonstrate through pre-clinical studies and clinical trials that such products are safe and effective for use in the target indications. The results from pre-clinical studies and early clinical trials may not be indicative of results that will be obtained in large-scale testing, and there can be no assurance that the Company's clinical trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or will result in marketable products. Clinical trials are also often conducted with patients having advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless affect clinical trial results. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Clinical trials for products being developed by the Company and its partners may be delayed by many factors, including enrolling a sufficient number of patients fitting the appropriate trial profile. If any of the Company's products under development are not shown to be safe and effective in clinical trials, the resulting delays in developing other compounds and conducting related pre-clinical testing and clinical trials, as well as the need for additional financing, would have a material adverse effect on the Company.

HISTORY OF OPERATING LOSSES; UNCERTAINTY OF FUTURE PROFITABILITY. The Company has not been profitable since inception and, through December 31, 1997, has incurred a cumulative deficit of approximately $37.6 million. The Company expects to continue to incur substantial and increasing losses over at least the next several years as the Company's research and development efforts, preclinical and clinical testing activities and manufacturing scale-up efforts expand and as the Company plans and builds its late stage clinical and early commercial production facility. All of the Company's potential products are in research or in the early stages of development, and no revenues have been generated from approved product sales. The Company's revenues to date have consisted primarily of payments under short-term research and feasibility agreements and development contracts. To achieve and sustain profitable operations, the Company, 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 the Company can generate sufficient product or contract research revenue to become profitable or to sustain profitability. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

DEPENDENCE UPON COLLABORATIVE PARTNERS. The Company currently does not possess the resources necessary to develop, obtain regulatory approvals, or commercialize any of its potential therapeutic products. The Company's ability to apply its pulmonary delivery system to a broad range of drugs will depend upon its ability to establish and maintain collaborative arrangements since many of the drugs currently approved for sale or in clinical testing are covered by third-party patents. The Company has entered into collaborative arrangements with certain of its partners to fund clinical trials, assist in obtaining regulatory approvals, supply drugs for formulation and market and distribute products. While Inhale has also entered into agreements with partners to test the feasibility of its pulmonary delivery system with certain of their proprietary molecules, there can be no assurance that the Company will be able to enter into additional collaborations or that its feasibility agreements will lead to collaborations. There also can be no assurance that the Company will be able to maintain any such collaborative arrangements or feasibility agreements or that any such collaborative arrangements or feasibility agreements will be successful. The failure of the Company to enter into or maintain such collaborative arrangements and feasibility agreements would have a material adverse effect on the Company. Moreover, the inability of the Company to enter into a collaborative arrangement with the owner of any patented drug may preclude the Company from working with such drug. Beginning in October 1997, Inhale announced that it plans to renegotiate with Baxter certain terms of their collaboration agreement to address concerns raised by both parties about the overall scope and cost of the collaborative arrangement. There can be no assurance that the parties will be able to reach agreement or that the collaborative arrangement between Inhale and Baxter will be continued. See "Business -- Inhale's Pulmonary Drug Delivery Programs in Progress."

The Company's existing partners have rights to pursue parallel development of other drug delivery systems which may compete with the Company's pulmonary drug delivery system and to terminate their agreements with the Company at any time without significant penalty. The Company anticipates that any future partners would have similar rights. Although the Company intends generally to formulate and manufacture powders for partners and to supply inhalation devices for such powders, certain partners may choose to formulate or manufacture their own powders, or to develop or supply their own device, thereby limiting one or more potential sources of revenue for Inhale. In addition, the Company anticipates that it may be precluded from entering into new arrangements with companies whose products compete with those of its existing partners. The Company also has limited or no control over the resources that any partner may devote to the Company's products, over partners' development efforts, including the design and conduct of clinical trials, and over the pricing of any such products. The pharmaceutical and biotechnology industries are consolidating, and acquisitions by, or of, the Company's existing or potential collaborative partners may affect the initiation or continuation of any such collaborations. There can be no assurances that any of the Company's present or future collaborative partners will perform their obligations as expected, will devote sufficient resources to the development, clinical testing or marketing of the Company's potential products or will not terminate their agreements with the Company prematurely or renegotiate such agreements. Any parallel development by a partner of alternate drug delivery systems, development by a partner rather than by Inhale of components of the delivery system, preclusion from entering into competitive arrangements, failure to obtain timely regulatory approvals, premature termination of an agreement, renegotiation of an agreement, or failure by a partner to devote sufficient resources to the development and commercialization of the Company's products would have a material adverse effect on the Company. See "Risk Factors -- Dependence Upon Proprietary Technology; Uncertainty of Obtaining Licenses or Developing Technology;" and "Business -- Inhale's Pulmonary Drug Delivery Programs in Progress."

LIMITED MANUFACTURING EXPERIENCE; RISK OF SCALE-UP. To achieve the levels of production of Inhale's dry powder drug formulations necessary to support late stage human clinical trials and for early commercialization of any of such products, the Company will need to scale-up its current powder processing facilities and automated filling, build a late stage clinical and early commercial production facility, and comply with the good manufacturing practice ("GMP") standards prescribed by the United States Food and Drug Administration ("FDA") and other standards prescribed by various federal, state and local regulatory agencies in the United States and any other country of use.

The Company has no experience manufacturing products for large scale clinical testing or commercial purposes. To date, the Company has performed powder processing on the small scale needed for early stage trials and for testing formulations of certain other potential therapeutic products and scaled-up powder processing for larger clinical trials. There can be no assurance that manufacturing and control problems will not arise as the Company attempts to further scale-up its powder processing facilities or that such scale-up can be achieved in a timely manner or at a commercially reasonable cost. Any failure to surmount such problems could delay or prevent late stage clinical testing and commercialization of the Company's products and would have a material adverse effect on the Company. To date, the Company has relied on a particular method of powder processing. There can be no assurance that this technology will be applicable to all drugs or that the drug losses in powder processing will not be too high for commercial viability for certain drugs. In the event that the Company decides to pursue alternative powder processing methods for some or all of its drugs, there can be no assurance that these methods will prove commercially practical for aerosol drugs or that the Company will have or be able to acquire rights to use such alternative methods. See "Risk Factors -- Dependence Upon Proprietary Technology; Uncertainty of Obtaining Licenses or Developing Technology."

Fine particle powders and small quantity packaging (such as those to be used in the Company's delivery system) require special handling. The Company has designed and qualified small scale automated filling equipment for small quantity packaging of fine powders. The Company faces significant technical

challenges scaling-up an automated filling system that can accurately and economically handle the small dose and particle sizes of its powders in commercial quantities. There can be no assurances that the Company will be able to scale-up its 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 the Company's products and would have a material adverse effect on the Company.

The Company also faces technical challenges in further developing its inhalation device to achieve the efficiency necessary to deliver a broad range of drugs, to produce such a device in quantities sufficient for later stage clinical trials and early commercialization, and to adapt the device as may be required for different powder formulations. There can be no assurance that Inhale will successfully achieve such efficiencies, will be able to produce such quantities or will be able to adapt the device as required. The failure of the Company to overcome any such challenges would have a material adverse effect on the Company. For late stage clinical trials and initial commercial production, the Company intends to use one or more contract manufacturers to produce its device. There can be no assurance that Inhale will be able to enter into or maintain such arrangements. The failure of the Company to enter into and maintain such arrangements would have a material adverse effect on the Company. See "Risk Factors -- No Assurance of Successful Development or Commercialization of Drugs for Pulmonary Delivery;" and "Business -- Manufacturing."

UNCERTAINTY OF MARKET ACCEPTANCE. The commercial success of the Company's pulmonary drug delivery system will depend upon market acceptance by health care providers, payors and patients. The Company's products under development use a new method of drug delivery, and there can be no assurance that any of the Company's products under development will ever achieve market acceptance. Market acceptance will depend on many factors, including the safety and efficacy results of the Company's clinical trials, favorable regulatory approval and product labeling, the frequency of administration, the availability of third-party reimbursement, the availability of alternative technologies and the price of the Company's products relative to alternative technologies. There can be no assurance that health care providers, patients or third-party payors will accept the Company's pulmonary drug delivery system and the failure to do so would have a material adverse effect on the Company.

FUTURE CAPITAL NEEDS; UNCERTAINTY OF ADDITIONAL FUNDING. The Company's operations to date have consumed substantial and increasing amounts of cash. The negative cash flow from operations is expected to continue and to accelerate in the foreseeable future. The development of the Company's technology and proposed products will require a commitment of substantial funds to conduct costly and time-consuming research, preclinical and clinical testing, establish an early commercial production facility and bring any such products to market. The Company's future capital requirements will depend on many factors, including continued progress in the research and development of the Company's technology and drug delivery system, the ability of the Company to establish and maintain collaborative arrangements with others and the terms thereof, payments received from partners under research and development agreements, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of development and the rate of scale-up of the Company's powder processing and packaging technologies, the timing and costs of its late stage clinical and early commercial production facility, the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technology and the status of competitive products. See "Risk Factors -- Dependence Upon Collaborative Partners."

The Company expects that its existing capital resources, contract research revenues from collaborations and the net proceeds from the November 1997 public offering and the interest thereon, will enable the Company to maintain its current and planned operations at least through 1999. Thereafter, the Company may need to raise substantial additional capital to fund its operations. The Company intends to seek such additional funding through collaborative or partnering arrangements, the extension of existing arrangements, or through public or private equity or debt financings. There can be no assurance that additional financing will be available on acceptable terms or at all. If additional funds are raised by issuing

equity securities, further dilution to shareholders may result. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its research or development programs or obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop or commercialize. See "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Use of Proceeds."

DEPENDENCE UPON PROPRIETARY TECHNOLOGY; UNCERTAINTY OF OBTAINING LICENSES OR DEVELOPING TECHNOLOGY. The Company's success will depend in part upon protecting its proprietary technology from infringement, misappropriation, duplication and discovery. The Company intends to rely principally on a combination of patent law, trade secrets and contract law to protect its proprietary technology in the United States and abroad. Inhale has filed patent applications covering certain aspects of its device, powder processing technology, and powder formulations and pulmonary route of delivery for certain molecules, and plans to file additional patent applications. On October 17, 1995 the PTO issued U.S. Patent No. 5,458,135 to Inhale covering the use of its device as a method for delivering powder formulations of drugs to the lung. There can be no assurance that any of the patents applied for by the Company will issue, or that any patents that issue will be valid and enforceable. Even if such patents are enforceable, the Company anticipates that any attempt to enforce its patents could be time consuming and costly.

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, the Company does not know whether any of its patent applications will result in the issuance of patents or, if any patents issue, whether they will provide significant proprietary protection or will be circumvented or invalidated. Since patent applications in the United States are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, the Company cannot be certain that it was the first inventor of inventions covered by its pending patent applications or that it was the first to file patent applications for such inventions. Moreover, the Company may have to participate in interference proceedings declared by the PTO to determine priority of invention, which could result in substantial cost to the Company, even if the eventual outcome is favorable to the Company. An adverse outcome could subject the Company to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require the Company to cease using the technology in dispute.

The Company 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 macromolecules. The Company cannot predict with any certainty which, if any, patents and patent applications will be considered relevant to the Company's technology by authorities in the various jurisdictions where such rights exist, nor can the Company predict with certainty which, if any, of these rights will or may be asserted against it by such third parties. The Company is aware of an alternate dry powder processing technology which Inhale is not using for its current products under development but may desire to use for certain products in the future. The ownership of this powder processing technology is unclear and the Company is aware that multiple parties, including Inhale, claim patent, trade secret and other rights in the technology. If the Company determines that this alternate powder processing technology is relevant to the development of future products and further determines that a license to this alternate powder processing technology is needed, there can be no assurance that the Company can obtain a license from the relevant party or parties on commercially reasonable terms, if at all. The Company is also aware of an issued U.S. patent which covers a broad range of macromolecule drugs in dry formulations. The Company is evaluating the validity of this patent, its relevance to the Company's products and whether the license proposed by the patent owner is of interest to the Company. There can be no assurance that the Company can obtain any license to any technology that the Company determines it needs, on reasonable

terms, if at all, or that Inhale could develop or otherwise obtain alternate technology. The failure of the Company to obtain licenses if needed would have a material adverse effect on the Company.

In June 1997, the Company acquired the intellectual property portfolio of the BioPreservation Division of Pafra Limited of Basildon, England ("Pafra"). This portfolio includes issued U.S. and foreign Letters Patent and pending applications relating to the stabilization of macromolecule drugs in dry formulations. A granted European patent included in this portfolio is currently the subject of an opposition proceeding before the European Patent Office and the Company is continuing the defense of this patent, the opposition to which was initiated prior to the acquisition. There can be no assurance that the Company will be successful in the defense of this opposition proceeding. In addition, there can be no assurance that any of the Pafra patent applications will issue, or that any Pafra patents will be valid and enforceable. The loss of the opposition proceeding or the inability to obtain or defend the Pafra patents could have a material adverse effect on the Company.

Third parties from time to time have asserted and may assert that the Company is employing technology that they believe is based on issued patents, trade secrets or know-how of others. In addition, future patents may issue to third parties which the Company's technology may infringe. The Company 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 the Company'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, the Company and its partners may be required to obtain one or more licenses from third parties. There can be no assurances that the Company 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 license could have a material adverse effect on the Company.

The Company's ability to develop and commercialize its technology will be affected by the Company's or its partners' access to the drugs which are to be formulated. Many drugs, including powder formulations of certain drugs which are presently under development by the Company, 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 the Company is developing pulmonary delivery formulations. Specifically, patents have been granted in the United States and Europe directed to aerosol formulations for the treatment of the lung containing alpha-1 antitrypsin (U.S.) and serine protease inhibitors, including alpha-1 antitrypsin (Europe). The Company's development partner for alpha-1 antitrypsin, Centeon, is negotiating with multiple partners to secure rights under these patents. The failure by Centeon to secure rights under these patents could result in the termination of this program by Centeon. The resulting patent situation is highly complex, and the ability of any one company to commercialize a particular biopharmaceutical drug is highly unpredictable. The Company 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 that the Company's partners will be able to provide access to drug candidates for formulation for pulmonary delivery or that, if such access is provided, the Company 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 the Company.

The Company also will rely on trade secrets and contract law to protect certain of its proprietary technology. There can be no assurance that any such contract will not be breached, or that if breached, the Company will have adequate remedies. Furthermore, there can be no assurance that any of the Company's trade secrets will not become known or independently discovered by third parties.

In 1995 the PTO adopted changes to the United States patent law that changed the term of issued patents, subject to certain transition periods, to 20 years from the date of filing rather than 17 years from

date of issuance. Beginning in June 1995, the patent term became 20 years from the earliest effective filing date of the underlying patent application. Such change may reduce the effective term of protection for patents that are pending for more than three years in the PTO. In addition, as of January 1996, all inventors who work outside of the United States are able to establish a date of invention on the same basis as those working in the United States. Such change could adversely affect the ability of the Company to prevail in a priority of invention dispute with a third party located or doing work outside of the United States. While the Company cannot predict the effect that such changes will have on its business, such changes could have a material adverse effect on the Company's ability to protect its proprietary information and sustain the commercial viability of its products. Furthermore, the possibility of extensive delays in such process, could effectively further reduce the term during which a marketed product could be protected by patents. See "Risk Factors -- Dependence Upon Collaborative Partners," "-- Government Regulation; Uncertainty of Obtaining Regulatory Approval;" and "Business -- Patents and Proprietary Rights."

DEPENDENCE UPON AND NEED TO ATTRACT KEY PERSONNEL. The Company is highly dependent upon the principal members of its scientific and management staff. The Company does not have employment contracts with its key employees, nor does the Company have key man insurance policies on them. The Company also relies on consultants and advisors to assist the Company in formulating research and development strategy. To pursue its product development and commercialization plans, the Company will be required to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation and manufacturing. Expansion in product development and manufacturing also is expected to require the addition of management personnel and the development of additional expertise by existing management personnel. Retaining and attracting qualified personnel, consultants and advisors will be critical to the Company's success. The Company faces competition for qualified individuals from numerous pharmaceutical, biotechnology and drug delivery companies, universities and other research institutions. There can be no assurance that the Company will be able to retain its current key employees or attract and retain qualified additional personnel and management when needed and its failure to do so would have a material adverse effect on the Company's ability to develop and commercialize products.

GOVERNMENT REGULATION; UNCERTAINTY OF OBTAINING REGULATORY APPROVAL. The production and marketing of the Company's products and its ongoing research and development activities are subject to regulation by numerous governmental authorities in the United States and other countries. Prior to marketing a new dosage form of any drug, including one developed for use with the Company's pulmonary drug delivery system, whether or not such drug was already approved for marketing in another dosage form, the product must undergo rigorous preclinical and clinical testing and an extensive review process mandated by the FDA and equivalent foreign authorities. These processes generally take a number of years and require the expenditure of substantial resources. None of the Company's proposed products has been submitted to the FDA for marketing approval. The Company 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. See "Risk Factors -- Dependence Upon Collaborative Partners."

The time required for completing such testing and obtaining such approvals is uncertain. Further refinement of the device prototype, further scale-up of the powder processing system and automated powder filling and packaging system will need to be accomplished before initiation of later stage clinical trials. Any delay in any of these components of product development may delay testing. In addition, delays or rejections may be encountered based upon changes in FDA policy, including FDA policy relating to GMP compliance, during the period of product development. Similar delays may also be encountered in other countries. If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which the product may be marketed, and the marketed product, its manufacturer, and its manufacturing facilities remain subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such

product or manufacturer, including withdrawal of the product from the market. There can be no assurance that regulatory approval will be obtained for any products developed by the Company on a timely basis, or at all. The failure to obtain timely regulatory approval of its products, any product marketing limitations or a product withdrawal would have a material adverse effect on the Company. See "Business -- Government Regulation."

UNCERTAINTY RELATED TO THE HEALTH CARE INDUSTRY AND THIRD-PARTY REIMBURSEMENT. Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental change. Recent initiatives to reduce the federal deficit and to reform health care delivery are increasing cost-containment efforts. The Company anticipates that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on health care spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the health care delivery system. Any such proposed or actual changes could cause the Company or its collaborative partners to limit or eliminate spending on development projects. Legislative debate is expected to continue in the future, and market forces are expected to demand reduced costs. Inhale cannot predict what effect the adoption of any federal or state health care reform measures or future private sector reforms may have on its business.

In both domestic and foreign markets, sales of the Company's 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, other 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. There can be no assurance that the Company's proposed products will be considered cost effective or that adequate third-party reimbursement will be available to enable Inhale to maintain price levels sufficient to realize an appropriate return on its investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before the Company's proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products. If adequate coverage and reimbursement levels are not provided by the government and third-party payors for the Company's potential products, the market acceptance of these products would be adversely affected, which would have a material adverse effect on the Company.

HIGHLY COMPETITIVE INDUSTRY; RISK OF TECHNOLOGICAL OBSOLESCENCE. The biotechnology and pharmaceutical industries are highly competitive and rapidly evolving and significant developments are expected to continue at a rapid pace. The Company's success depends upon maintaining a competitive position 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 dry powder pulmonary delivery device or fine powder processing technology, a better system for efficiently and reproducibly delivering drugs to the deep lung, a non-invasive drug delivery system which is more attractive for the delivery of drugs than pulmonary delivery, or an invasive delivery system which overcomes some of the drawbacks of current invasive systems for chronic or subchronic indications (such as a sustained release system), the Company's business could be materially adversely affected.

The Company 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. The Company 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 and colonic absorption systems. Several of these companies may have developed or be developing dry powder devices that could be used for pulmonary delivery. The Company is also aware of other companies currently engaged in the development and commercialization of pulmonary drug delivery systems and enhanced injectable drug delivery systems.

Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than the Company and represent significant competition for the Company. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance competitors' financial, marketing and other resources. Accordingly, the Company's competitors may succeed in developing competing technologies, obtaining FDA approval for products or gain market acceptance more rapidly than the Company. There can be no assurance that developments by others will not render the Company's products or technologies uncompetitive or obsolete.

PRODUCT LIABILITY; AVAILABILITY OF INSURANCE. The design, development and manufacture of the Company's products involve an inherent risk of product liability claims and associated adverse publicity. Although the Company currently maintains general liability insurance, there can be no assurance that the coverage limits of the Company's insurance policies will be adequate. The Company obtained clinical trial product liability insurance of $3.0 million per event for certain clinical trials and intends to obtain insurance for future clinical trials of insulin and other products under development. There can be no assurance, however, that the Company will be able to obtain or maintain insurance for any future clinical trials. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. A successful claim brought against the Company in excess of the Company's insurance coverage would have a material adverse effect upon the Company and its financial condition.

HAZARDOUS MATERIALS. The Company's research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. Although the Company believes that its safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could exceed the resources of the Company. The Company may incur substantial costs to comply with environmental regulations.

ANTI-TAKEOVER PROVISIONS. Certain provisions of the Company's Restated Articles of Incorporation and the California General Corporation Law could discourage a third party from attempting to acquire, or make it more difficult for a third party to acquire, control of the Company without approval of the Company's Board of Directors. Such provisions could also limit the price that certain investors might be willing to pay in the future for shares of Common Stock. Certain of the provisions allow the Board of Directors to authorize the issuance of Preferred Stock with rights superior to those of the Common Stock. The Company also will be subject to the provisions of Section 1203 of the California General Corporation Law which requires a fairness opinion to be provided to the Company's shareholders in connection with their consideration of any proposed "interested party" reorganization transaction.

POTENTIAL VOLATILITY OF STOCK PRICE. The market prices for securities of early stage biotechnology companies have historically been highly volatile and the market from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in the Company's operating results, announcements of technological innovations or new therapeutic products or the announcement or termination of collaborative relationships by the Company or its competitors, governmental regulation, clinical trial results, developments in patent or other proprietary rights, public concern as to the safety of drug formulations developed by the Company or others and general market conditions may have a significant effect on the market price of the Common Stock. The Company's securities are subject to a high degree of risk and volatility. In the past, following periods of volatility in the market price of a company's securities, class action securities litigation has often been instituted against such a company. Any such litigation instigated against the Company could result in substantial costs and a diversion of management's attention and resources, which could have a material adverse effect on the Company's business, financial condition and operating results. See "Price Range of Common Stock."

ITEM 2. PROPERTIES

Inhale currently leases approximately 121,000 square feet in San Carlos, California and 35,000 square feet in Palo Alto, California. The space in Palo Alto is used for research, development, administration and manufacturing of drugs for early stage clinical trials. This manufacturing facility operates under Good Manufacturing Practices and has been validated and licensed by the State of California to manufacture clinical supplies for use in human clinical trials. The lease is for a five year term, ending May 31, 1998, and provides Inhale with an option to renew at the then fair market value for one building at its Palo Alto facility and an option at a fixed rate for the other building at such facility, both of which expire on May 31, 2003. In October 1997, the Company exercised its option to extend the term of the lease for one building for an additional five years at the Consumer Price Index to the current rate. The Company declined to exercise its option to extend the lease term for the second building at the then fair market value.

The San Carlos facility is leased pursuant to a 15-year lease agreement. The Company intends to consolidate its operations into this facility over the next twelve months and intends to use the facility as its initial commercial manufacturing site. The lease provides Inhale with an option to lease approximately 100,000 additional square feet in the same facility.

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 the Company's shareholders in the quarter ended December 31, 1997.

EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the names, ages and positions of the executive officers of the Company:

NAME	AGE	POSITION
Robert B. Chess	41	President, Chief Executive Officer and Director
Ajit S. Gill	49	Chief Operating Officer
Stephen L. Hurst	42	Vice President, Intellectual Property and Licensing
John S. Patton, Ph.D.	51	Vice President, Research and Director
Robert M. Platz	46	Vice President, Technology

ROBERT B. CHESS has served as President of the Company since December 1991 and as Chief Executive Officer since May 1992. Mr. Chess was also elected a Director of the Company 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, Chief Operating Officer, has also served as the Company's Chief Financial Officer from January 1993 until October 1996. Mr. Gill has experience in building new businesses. 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.

STEPHEN L. HURST has been Vice President, Intellectual Property and Licensing of the Company since March 1994. 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 of the Company since July 1990. He served as President of the Company 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 of the Company since August 1990. He also served as a Director of the Company 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.

PART II

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

PRICE RANGE OF COMMON STOCK

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

	PRICE RANGE OF COMMON STOCK	
YEAR ENDED DECEMBER 31, 1996:	HIGH	LOW
1st Quarter	$ 16.750	$ 9.750
2nd Quarter	21.500	15.000
3rd Quarter	18.625	12.625
4th Quarter	17.625	12.875
YEAR ENDED DECEMBER 31, 1997:		
1st Quarter	$ 22.625	$ 15.125
2nd Quarter	25.000	18.375
3rd Quarter	33.625	18.750
4th Quarter	36.500	25.000

As of December 31, 1997, there were approximately 118 holders of record of the Company's Common Stock. The Company has not paid any cash dividends since its inception and does not intend to pay any cash dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

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

	YEARS ENDED DECEMBER 31,				
	1997	1996	1995	1994	1993
STATEMENT OF OPERATIONS DATA:					
Contract revenue	$ 16,249	$ 6,890	$ 3,445	$ 1,651	$ 708
Operating costs and expenses:					
Research and development	23,645	14,376	9,041	4,934	2,765
General and administrative	6,328	4,004	3,232	2,465	856
Total operating costs and expenses	29,973	18,380	12,273	7,399	3,621
Loss from operations	(13,724)	(11,490)	(8,828)	(5,748)	(2,913)
Net loss	$ (9,983)	$ (9,909)	$ (7,662)	$ (5,279)	$ (2,861)
Net loss per share (pro forma in 1993 and 1994) (1)	$ (0.72)	$ (0.88)	$ (0.78)	$ (0.86)	$ (0.48)
Shares used in computation of net loss per share (pro forma in 1993 and 1994) (1)	13,792	11,207	9,837	6,103	5,969

	DECEMBER 31,				
	1997	1996	1995	1994	1993
	(IN THOUSANDS)				
BALANCE SHEET DATA:					
Working capital	$ 83,811	$ 31,304	$ 17,701	$ 13,451	$ 4,954
Total assets	119,762	41,492	23,248	17,249	7,190
Equipment financing obligations, less current portion	5,102	187	353	460	652
Accumulated deficit	(37,642)	(27,691)	(17,770)	(10,108)	(4,829)
Shareholders' equity	97,093	35,061	20,182	15,427	5,891

- ------------------------

No cash dividends have been paid for any of the periods presented.

(1) Basic and diluted net loss per share is based upon the weighted average number of common and certain common equivalent 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. THE COMPANY'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. The Company 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 manufacturing facilities. To date, Inhale has not sold any products and does not anticipate receiving revenue from product sales or royalties in the near future. For the period from inception through December 31, 1997, the Company incurred a cumulative net loss of approximately $37.6 million. Inhale's sources of working capital have been equity financings, financings of equipment acquisitions, interest earned on investments of cash, and revenues from short term research and feasibility agreements and development contracts.

Inhale typically has been compensated for research and development expenses incurred during initial feasibility work as well as for work performed under collaborative arrangements. Inhale's strategy is to enter into development contracts with pharmaceutical and biotechnology corporate partners after feasibility is demonstrated. Partners that enter into collaborative agreements will pay for research and development expenses and will make payments to Inhale as it achieves certain key milestones. Inhale expects to receive royalties from its partners based on revenues received from product sales, and to receive revenue from the manufacturing of powders and the supply of devices. In certain cases, the Company may enter into collaborative agreements under which the Company's partners would manufacture powders or supply inhalation devices, thereby potentially limiting one or more sources of revenue for the Company. To achieve and sustain profitable operations, the Company, 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 the Company will be able to generate sufficient product or contract research revenue to become profitable or to sustain profitability.

The Company is aware of the issues associated with the programming code in existing computer systems as the millennium (year 2000) approaches. The "year 2000" problem is pervasive and complex as virtually every computer operation will be affected in some way by the rollover of the two digit year value to 00. The issue is whether computer systems will properly recognize date sensitive information when the year changes to 2000. Systems that do not properly recognize such information could generate erroneous data or cause a system to fail.

The Company is utilizing internal resources to conduct a comprehensive review of its computer systems to identify the systems that could be affected by the "year 2000" issue and is developing an implementation plan to resolve the issue. The Company presently believes that, with modifications to existing software and converting to new software, the "year 2000" problem will not pose significant operational problems for the Company's computer systems as so modified and converted. However, if such modifications and conversions are not completed timely, the "year 2000" problem may have a material impact on the operations of the Company.

RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 1997, 1996 AND 1995

Contract research revenue was $16.2 million for the year ended December 31, 1997 compared to $6.9 million and $3.4 million for the years ended December 31, 1996 and 1995, respectively. Revenue increased 136% in 1997 from 1996 levels and 100% in 1996 from 1995 levels. Costs of contract research revenue approximate such revenue and are included in research and development expense.

The 136% increase in revenue for the year ended December 31, 1997 as compared to December 31, 1996 was primarily due to expansion of the Company's existing collaborative agreements as well as the signing of additional corporate partners in 1997. 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 $23.6 million for the year ended December 31, 1997, as compared to $14.4 million and $9.0 million for the years ended December 31, 1996 and 1995, respectively. These expenses represent proprietary research expenses as well as the costs related to contract research revenue and include salaries and benefits of scientific and development personnel, 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 $9.3 million increase in research and development expenses in 1997 from 1996 and the $5.3 million increase in research and development expenses in 1996 from 1995 are primarily attributed to continued expansion of research activities resulting from an increase in the number of projects, hiring of additional scientific personnel, costs associated with the development of the Company's commercial manufacturing facility and increased costs of laboratory supplies and consulting services. The Company expects research and development and process development spending to increase significantly over the next few years as the Company expands its development efforts under collaborative agreements and plans, builds and scales up a late stage clinical and early commercial manufacturing facility.

General and administrative expenses were $6.3 million for the year ended December 31, 1997 as compared to $4.0 million and $3.2 million for the years ended December 31, 1996 and 1995, respectively. The $2.3 million increase in general and administrative expenses in 1997 from 1996 and the $772,000 increase in 1996 from 1995 were due primarily to costs associated with supporting the Company'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 the Company expands its research, development and manufacturing activities.

Interest income was $3.8 million for the year ended December 31, 1997 as compared to $1.6 million and $1.3 million for the years ended December 31, 1996 and 1995, respectively. The 132% increase in interest income in 1997 from 1996 was due to the Company maintaining larger cash and investment balances. The higher cash and investment balances are a result of the Company receiving research funding and milestone payments from collaborative partners, the completion of a private placement of the Company's Common Stock in February 1997 which raised net proceeds of $30.5 million as well as the completion of a public offering of the Company's Common Stock in November 1997 which raised net proceeds of $40.0 million. The 31% increase in interest income in 1996 from 1995 was due primarily to interest earned on higher average cash balances as a result of Baxter making a $20.0 million equity investment in Inhale at a 25% premium-to-market price in conjunction with the March 1996 development agreement between the Company and Baxter. In addition, in October 1996 Pfizer made an additional $5.0 million investment in Inhale pursuant to the January 1995 agreement between the Company and Pfizer to develop insulin products using Inhale's non-invasive pulmonary drug delivery system.

At December 31, 1997, the Company had federal net operating loss carryforwards of approximately $27.4 million. These carryforwards will expire beginning in the year 2006. Utilization of net operating loss carryforwards may be subject to substantial annual limitation due to the ownership change limitation provided for by the Internal Revenue Code of 1986. The annual limitation may result in the expiration of net operating loss carryforwards before utilization.

LIQUIDITY AND CAPITAL RESOURCES

The Company has financed its operations primarily through public and private placements of its equity securities, contract research revenues, interest income earned on its investments of cash and financing of equipment acquisitions. In its initial public offering completed May 1994, the Company 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. On February 7, 1997 the Company 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 the Company completed a public offering of its Common Stock, selling 1.725 million newly issued shares for net proceeds of $40.0 million. In May 1997, the Company obtained a $10 million line of credit which may be drawn upon to finance the purchases of equipment and facility improvements. As of December 31, 1997, the Company had not drawn on this line of credit. The Company secured a $5 million loan in November 1997 to also finance the purchases of equipment and facility improvements. At December 31, 1997, the Company had cash, cash equivalents and short-term investments of approximately $100.2 million.

The Company's operations provided cash of $5.0 million and used cash of $5.8 million and $5.3 million in the years ended December 31, 1997, 1996 and 1995, respectively. These amounts differed from the Company's net operating losses in these periods principally due to increases in accounts payable and accrued liabilities, depreciation expenses and deferred revenue. Additionally, in 1997 the Company recorded a non-cash transaction of $600,000 in connection with the completion of a licensing agreement.

The Company purchased property and equipment of approximately $17.3 million, $2.2 million and $1.3 million during the years ended December 31, 1997, 1996 and 1995, respectively. The increase for the year ended December 31, 1997 is primarily due to the build out of the Company's new facility in San Carlos, California as well as the acquisition of laboratory equipment to support its research activities.

The Company expects its cash requirements to increase due to expected increases in expenses related to the further research and development of its technologies resulting from a larger number of projects, 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, inhalation device prototype construction and facilities expansion, including the planning and building of a late stage clinical and early stage commercial manufacturing facility.

The Company believes that its cash, cash equivalents and short-term investments as of December 31, 1997 together with interest income and possible additional equipment financing, will be sufficient to meet its operating expense and capital expenditure requirements at least through 1999. However, the Company'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 the Company'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, the Company 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 the Company on favorable terms, if at all.

RECENT ACCOUNTING PRONOUNCEMENTS

In February 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 128 "Earnings Per Share" ("SFAS 128") which requires disclosure of basic earnings per share and diluted earnings per share and is effective for periods ending subsequent to December 15, 1997. As such, the Company adopted this standard for the year ended December 31, 1997.

In June 1997, the Financial Accounting Standards Board issued the Statement of Financial Accounting Standard No. 130 "SFAS 130", "Reporting Comprehensive Income," which the Company is required to adopt for its fiscal year ending December 31, 1998. This Statement requires that all items that are required to be recognized under accounting standards as components of comprehensive income be reported in a financial statement that is displayed with the same prominence as other financial statements.

In June 1997, the Financial Accounting Standards Board also issued the Statement of Financial Accounting Standard No. 131 "SFAS 131", "Disclosures about Segments of an Enterprise and Related Information," which the Company is required to adopt for its fiscal year ending December 31, 1998. This Statement establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and disclosures about products and services, geographic areas, and major customers. Both standards issued in June 1997 will require additional disclosures, but will not have an effect on the Company's financial position or results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements for the years ended December 31, 1997, 1996 and 1995 are submitted as a separate section of this report. See Item 14.

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

Not Applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

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 1998 Annual Meeting of Shareholders.

Information concerning Inhale's executive officers appears at the end of Part I of this report.

ITEM 11. EXECUTIVE COMPENSATION

Inhale incorporates by reference the information set forth under the heading "Executive Compensation" in the Company's definitive Proxy Statement to be filed for its 1998 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 the Company's definitive Proxy Statement to be filed for its 1998 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 the Company's definitive Proxy Statement to be filed for its 1998 Annual Meeting for Shareholders.

PART IV

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
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:

EXHIBIT		EXHIBIT TITLE
3.1	(3)	Restated Articles of Incorporation of the Registrant.
3.2	(1)	Bylaws of the Registrant.
4.1		Reference is made to Exhibits 3.1 through 3.2.
4.2	(1)	Restated Investor Rights Agreement among the Registrant and certain other persons named therein, dated April 29, 1993, as amended October 29, 1993.
4.5	(1)	Warrant to purchase 18,182 Shares of Series C Preferred Stock between the Registrant and Phoenix Leasing Incorporated, dated October 29, 1993.
4.6	(1)	Specimen stock certificate.
4.9	(2)	Stock Purchase Agreement between the Registrant and Pfizer Inc., dated January 18, 1995.
4.10	(8)	Warrant to purchase 10,000 shares of Common Stock between the Registrant and Thomas J. Peirona, dated November 1, 1996.
4.11	(8)	Warrant to purchase 10,000 shares of Common Stock between the Registrant and Kiet Nguyen, dated November 1, 1996.
4.12	(9)	Form of Stock Purchase Agreement between the Registrant and the Selling Shareholders dated January 28, 1997.
10.1	(4)	Registrant's 1994 Equity Incentive Plan (the "Equity Incentive Plan").
10.2	(1)	Form of Incentive Stock Option under the Equity Incentive Plan.
10.3	(1)	Form of Nonstatutory Stock Option under the Equity Incentive Plan.
10.4	(7)	Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended.
10.5	(1)	Registrant's 1994 Employee Stock Purchase Plan.
10.6	(1)	Standard Industrial Lease between the Registrant and W.F. Batton & Co., Inc., dated September 17, 1992, as amended September 18, 1992.

EXHIBIT		EXHIBIT TITLE
10.7	(1)	Master Equipment Lease between the Registrant and Phoenix Leasing Incorporated, dated August 15, 1992 and Schedules i to 4 thereto.
10.8	(1)	Senior Loan and Security Agreement between the Registrant and Phoenix Leasing Incorporated, dated September 15, 1993.
10.9	(1)	Sublicense Agreement between the Registrant and John S. Patton, dated September 13, 1991.
10.11	(2)	Addendum to Lease dated September 17, 1992, between the Registrant and W.F. Batton and Marie A. Batton.
10.12	(6)	Lease dated May 31, 1995, between the Registrant and W.F. Batton and Marie A. Batton.
10.13	(6)	Addendum Number One to Lease dated September 17, 1992, between the Registrant and W.F. Batton and Marie A. Batton.
10.14	(6)	Addendum to Lease dated May 31, 1995 between the Registrant and W.F. Batton and Marie A. Batton.
10.15	(6)	Addendum Number Two to Lease dated September 17, 1992, between the Registrant and W.F. Batton and Marie A. Batton.
10.16	(5)	Stock Purchase Agreement between the Registrant and Baxter World Trade Corporation, dated March 1, 1996.
10.17	(8)	Sublease and Lease Agreement, dated October 2, 1996 between the Registrant and T.M.T. Associates L.L.C.
23.1		Consent of Ernst & Young LLP, Independent Auditors
24.1		Power of Attorney. Reference is made to page 36.
27.1		Financial Data Schedule

- ------------------------

(1) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-75942), as amended.

(2) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-89502), as amended.

(3) Incorporated by reference to the indicated exhibit in the Company's Annual Report on Form 10-K for the year ended December 31, 1994.

(4) Incorporated by reference to the Company's Registration Statement on Form S-8 (No. 333-07969).

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

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

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

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

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

(b) Reports on Form 8-K.

No Reports on Form 8-K were filed during the quarter ended December 31, 1997.

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

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 23rd day of March 1998.

INHALE THERAPEUTIC SYSTEMS

By: /s/ ROBERT B. CHESS
Robert B. Chess
PRESIDENT, CHIEF EXECUTIVE OFFICER AND DIRECTOR

POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ ROBERT B. CHESS Robert B. Chess	President, Chief Executive Officer and Director (PRINCIPAL EXECUTIVE OFFICER)	March 23, 1998
/s/ CHRISTIAN O. HENRY Christian O. Henry	Corporate Controller (CHIEF ACCOUNTING OFFICER)	March 23, 1998
/s/ JOHN S. PATTON John S. Patton	Vice President and Director	March 23, 1998
/s/ MARK J. GABRIELSON Mark J. Gabrielson	Director	March 23, 1998
/s/ JAMES B. GLAVIN James B. Glavin	Director	March 23, 1998
/s/ MELVIN PERELMAN Melvin Perelman	Director	March 23, 1998
/s/ TERRY L. OPDENDYK Terry L. Opdendyk	Chairman of the Board	March 23, 1998

INHALE THERAPEUTIC SYSTEMS
INDEX TO FINANCIAL STATEMENTS

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Shareholders of
Inhale Therapeutic Systems

We have audited the accompanying balance sheets of Inhale Therapeutic Systems as of December 31, 1997 and 1996, and the related statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 1997. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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, 1997 and 1996, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1997 in conformity with generally accepted accounting principles.

ERNST & YOUNG LLP

Palo Alto, California
January 22, 1998

INHALE THERAPEUTIC SYSTEMS

BALANCE SHEETS
(IN THOUSANDS)

ASSETS

	DECEMBER 31,	
	1997	1996
Current assets:		
Cash and cash equivalents	$ 14,948	$ 18,568
Short-term investments	85,225	17,741
Other current assets	752	1,239
Total current assets	100,925	37,548
Property and equipment, net	18,694	3,770
Deposits and other assets	143	174
	$ 119,762	$ 41,492

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 5,975	$ 1,130
Accrued liabilities	3,812	1,746
Accrued compensation	558	479
Deferred revenue	6,686	2,723
Equipment financing obligations -- current portion	83	166
Total current liabilities	17,114	6,244
Equipment financing obligations	5,102	187
Accrued rent	453	--
Commitments (See Note 2)		
Shareholders' equity:		
Preferred stock, 10,000 shares authorized, no shares issued or outstanding	--	--
Common stock, no par value; 30,000 shares authorized; 15,542 shares and 11,835 shares issued and outstanding at December 31, 1997 and 1996, respectively	135,273	62,840
Deferred compensation	(538)	(88)
Accumulated deficit	(37,642)	(27,691)
Total shareholders' equity	97,093	35,061
	$ 119,762	$ 41,492

See accompanying notes

INHALE THERAPEUTIC SYSTEMS

STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)

	YEARS ENDED DECEMBER 31,		
	1997	1996	1995
Contract research revenue	$ 16,249	$ 6,890	$ 3,445
Operating costs and expenses:			
Research and development	23,645	14,376	9,041
General and administrative	6,328	4,004	3,232
Total operating costs and expenses	29,973	18,380	12,273
Loss from operations	(13,724)	(11,490)	(8,828)
Interest income	3,807	1,638	1,252
Interest expense	(66)	(57)	(86)
Net loss	$ (9,983)	$ (9,909)	$ (7,662)
Basic and diluted net loss per share	$ (0.72)	$ (0.88)	$ (0.78)
Shares used in basic and diluted net loss per share calculation	13,792	11,207	9,837

See accompanying notes

INHALE THERAPEUTIC SYSTEMS
STATEMENT OF SHAREHOLDERS' EQUITY
(IN THOUSANDS)

	SHARES	AMOUNT	DEFERRED COMPENSATION	ACCUMULATED DEFICIT	TOTAL SHAREHOLDERS' EQUITY
Balance at December 31, 1994	8,656	$ 25,947	$ (412)	$ (10,108)	$ 15,427
Issuance of common stock in connection with a collaborative agreement	453	5,000	--	--	5,000
Issuance of common stock in public offering, net of issuance costs of $757	1,000	7,243	--	--	7,243
Amortization of deferred compensation	--	--	162	--	162
Common stock issued upon exercise of stock options	33	12	--	--	12
Net loss	--	--	--	(7,662)	(7,662)
Balance at December 31, 1995	10,142	38,202	(250)	(17,770)	20,182
Issuance of common stock in connection with collaborative agreements, net of issuance costs of $806	1,608	24,196	--	--	24,196
Amortization of deferred compensation	--	--	162	--	162
Common stock issued upon exercise of stock options	85	442	--	--	442
Unrealized loss on securities held as available-for-sale	--	--	--	(12)	(12)
Net loss	--	--	--	(9,909)	(9,909)
Balance at December 31, 1996	11,835	62,840	(88)	(27,691)	35,061
Issuance of common stock in private placement, net of issuance costs of $1,940	1,800	30,460	--	--	30,460
Issuance of common stock in connection with licensing agreement	28	600	--	--	600
Issuance of common stock in public offering, net of issuance costs of $2,885	1,725	40,024	--	--	40,024
Common stock issued upon exercise of stock options	125	798	--	--	798
Issuance of common stock in connection with exercise of warrant	29	--	--	--	--
Deferred compensation	--	551	(551)	--	--
Amortization of deferred compensation	--	--	101	--	101
Unrealized gain on securities held as available-for-sale	--	--	--	32	32
Net loss	--	--	--	(9,983)	(9,983)
Balance at December 31, 1997	15,542	$ 135,273	$ (538)	$ (37,642)	$ 97,093

See accompanying notes

INHALE THERAPEUTIC SYSTEMS
STATEMENTS OF CASH FLOWS
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS
(IN THOUSANDS)

	1997	1996	1995
	YEARS ENDED DECEMBER 31,		
CASH FLOWS FROM (USED IN) OPERATING ACTIVITIES			
Net loss	$ (9,983)	$ (9,909)	$ (7,662)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,337	1,071	955
Amortization of deferred compensation	101	162	162
Issuance of common stock in connection with licensing agreement	600	--	--
Increase (decrease) in other current assets, deposits and other assets	518	(752)	(110)
Increase in accounts payable and accrued liabilities	7,443	1,465	847
Increase in deferred revenue	3,963	2,145	483
Net cash provided by (used in) operating activities	4,979	(5,818)	(5,325)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchases of short-term investments	(483,247)	(58,993)	(49,318)
Sales of short-term investments	80,662	2,020	7,812
Maturities of short-term investments	335,133	55,313	29,326
Purchases of property and equipment, net	(17,261)	(2,181)	(1,340)
Net cash used in investing activities	(84,713)	(3,841)	(13,520)
CASH FLOWS FROM FINANCING ACTIVITIES			
Payments of equipment loan obligations	(85)	(52)	(32)
Payments of capital lease obligations	(83)	(193)	(205)
Proceeds from tenant improvement loan	5,000	--	--
Issuance of equipment loan obligations	--	--	151
Issuance of common stock, net of issuance costs	71,282	24,638	12,255
Net cash provided by financing activities	76,114	24,393	12,169
Net (decrease) increase in cash and cash equivalents	(3,620)	14,734	(6,676)
Cash and cash equivalents at beginning of period	18,568	3,834	10,510
Cash and cash equivalents at end of period	$ 14,948	$ 18,568	$ 3,834

See accompanying notes

NOTE 1 -- ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION AND BASIS OF PRESENTATION

Inhale Therapeutic Systems (the "Company") was incorporated in the State of California in July 1990. Since inception, the Company has been engaged in the development of systems for the pulmonary delivery of macromolecule drug therapies for systemic and local lung applications.

The Company expects increasing losses over the next several years as research and development efforts continue, and as the Company expands its facilities for late stage clinical trials and early stage commercial manufacturing. Management plans to continue to finance the Company primarily through issuances of equity securities, research and development contract revenue, and in the longer term, revenue from product sales and royalties. If the financing arrangements contemplated by management are not consummated, the Company may have to seek other sources of capital or reevaluate its operating plans.

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 SHORT-TERM INVESTMENTS

The Company 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 A1 or P1 short-term ratings and A or better long-term ratings with remaining maturities at date of purchase of greater than 90 days and less than one year. The Company limits its concentration of risk by diversifying its investments among a variety of industries and issuers. The Company has experienced no losses on its investments.

At December 31, 1997, 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 shareholders' 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

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

securities classified as available-for-sale are included in interest income. The following is a summary of available-for-sale securities as of December 31, 1997:

	AVAILABLE-FOR-SALE SECURITIES			
	COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
	(IN THOUSANDS)			
Obligations of U.S. government agencies	$ 19,943	$ --	$ --	$ 19,943
U.S. corporate commercial paper	70,584	20	--	70,604
Repurchase agreements, secured by U.S. Government securities	7,001	--	--	7,001
Other	57	--	--	57
	$ 97,585	$ 20	$ --	$ 97,605
Amounts included in cash and cash equivalents	$ 11,536	$ --	$ --	$ 11,536
Amounts included in short-term investments	86,049	20	--	86,069
	$ 97,585	$ 20	$ --	$ 97,605

The following is a summary of available-for-sale securities as of December 31, 1996:

	AVAILABLE-FOR-SALE SECURITIES			
	COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
	(IN THOUSANDS)			
Obligations of U.S. government agencies	$ 15,812	$ --	$ --	$ 15,812
U.S. corporate commercial paper	8,874	--	12	8,862
Repurchase agreements, secured by U.S. Government securities	11,811	--	--	11,811
Other	153	--	--	153
	$ 36,650	$ --	$ 12	$ 36,638
Amounts included in cash and cash equivalents	$ 18,897	$ --	$ --	$ 18,897
Amounts included in short-term investments	17,753	--	12	17,741
	$ 36,650	$ --	$ 12	$ 36,638

The gross realized losses and gains on the sale of securities available-for-sale during the years ended December 31, 1997 and 1996, were not material. At December 31, 1997, the average portfolio duration was approximately three months (three months at December 31, 1996) and the contractual maturity of any single investment did not exceed nine months (nine months at December 31, 1996).

The estimated fair value amounts have been determined by the Company using available market information and appropriate valuation methodologies. However, market data must be interpreted to

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

develop the estimates of fair value. Accordingly, the estimates presented herein are not necessarily indicative of the amounts that the Company could realize in a current market exchange.

PROPERTY AND EQUIPMENT

Property and equipment are stated at cost and consists of the following at December 31:

	1997	1996
	(IN THOUSANDS)	
Laboratory and other equipment	$ 8,469	$ 3,679
Leasehold improvements	14,729	2,258
Leased equipment	676	677
	23,874	6,614
Less accumulated depreciation and amortization	(5,180)	(2,844)
	$ 18,694	$ 3,770

Equipment is depreciated using the straight-line method over estimated useful lives of four to seven years. Leasehold improvements and assets acquired under capital leases are amortized using the straight-line method over the shorter of the estimated useful life of the assets or the term of the lease.

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 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. The Company's research revenue is derived primarily from clients in the pharmaceutical industry. Contract research revenue from three partners represented 47%, 25% and 21% of the Company's revenue in 1997. Contract revenue from two partners accounted for 77% and 14% of the Company's revenue in 1996, and two partners accounted for 78% and 13% of the Company's revenue in 1995. 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"), the Company 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 the Company's employee stock options equals or exceeds the fair value of the underlying stock on the date of grant as determined by the Company's Board of Directors, no compensation expense is recognized. See Note 3 for pro forma disclosures required by FAS 123.

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

RESEARCH AND DEVELOPMENT AGREEMENTS

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

ACCOUNTING FOR INCOME TAXES

The Company 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.

NET LOSS PER SHARE

In 1997, the Financial Accounting Standards Board issued Statement No. 128, "Earnings Per Share" (FAS 128) which replaced the calculation of primary and fully diluted earnings per share with basic and diluted earnings per share. Unlike primary earnings per share, basic earnings per share excludes any dilutive effects of options, warrants and convertible securities. Diluted earnings per share is very similar to the previously reported fully diluted earnings per share. All earnings per share amounts for all periods have been presented, and where appropriate, restated to conform to the FAS 128 requirements.

Basic and diluted net loss per common share is computed based upon the weighted average number of common shares outstanding in accordance with FAS 128. Common equivalent shares for stock options and warrants are not included in the per share calculations where the effect of their inclusion would be antidilutive.

NOTE 2 -- COMMITMENTS AND EQUIPMENT FINANCING OBLIGATIONS

The Company leases its office and laboratory facilities under several arrangements expiring through the year 2012. Rent expense was approximately $1,106,000, $416,000 and $217,000 for the years ended December 31, 1997, 1996 and 1995, respectively.

Included in property and equipment at December 31, 1997 and 1996, are assets with costs of $677,000 acquired pursuant to capital lease obligations and equipment loans secured by the equipment with interest rates ranging from 14% to 18% per annum. Accumulated amortization of assets acquired pursuant to these equipment financing obligations was approximately $673,000 and $658,000 at December 31, 1997 and 1996, respectively.

NOTE 2 -- COMMITMENTS AND EQUIPMENT FINANCING OBLIGATIONS (CONTINUED)

In November 1997, the Company 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. The loan is recorded on the balance sheet at December 31, 1997 as an equipment financing obligation.

Future noncancelable commitments under equipment financing obligations and operating leases at December 31, 1997 are as follows:

	OPERATING LEASES	EQUIPMENT FINANCING OBLIGATIONS
	(IN THOUSANDS)	
Years ending December 31,		
1998	$ 956	$ 565
1999	947	563
2000	989	612
2001	1,062	503
2002 and thereafter	13,565	7,481
Total minimum payments required	$ 17,519	$ 9,724
Less amount representing interest		(4,539)
Present value of future lease payments		5,185
Less current portion		(83)
Non-current portion		$ 5,102

NOTE 3 -- SHAREHOLDERS' EQUITY

COMMON STOCK

EMPLOYEE STOCK PURCHASE PLAN

In February 1994, the Company'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 the Company's employees pursuant to section 423(b) of the Internal Revenue Code of 1986. As of December 31, 1997, no shares of common stock have been issued under the Purchase Plan.

STOCK OPTION PLANS

EQUITY INCENTIVE PLAN

The Company'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 the Company'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 the Company and to promote the success of the Company's business. Pursuant to the Equity Incentive Plan, the Company may grant or issue incentive stock options to employees and officers and non-

NOTE 3 -- SHAREHOLDERS' EQUITY (CONTINUED)
qualified stock options, restricted stock purchase awards, stock bonuses and stock appreciation rights to consultants, employees, officers and employee directors.

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 the Company'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 the Company'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, the Company's Board of Directors adopted the Non-employee Directors' Stock Option Plan under which options to purchase up to 200,000 shares of the Company's common stock at the then fair market value may be granted to the Company's non-employee directors. No options were granted to non-employee directors during 1997. As of December 31, 1997, options on 6,000 shares had been exercised and options to purchase 110,000 shares were exercisable.

NOTE 3 -- SHAREHOLDERS' EQUITY (CONTINUED)

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

		OPTIONS OUTSTANDING		
	OPTIONS AVAILABLE FOR GRANT	NUMBER OF SHARES	EXERCISE PRICE PER SHARE	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE
	(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)			
Balance at December 31, 1994	1,202	848	$0.06-15.25	$ 4.50
Shares authorized	--	--	--	--
Options granted	(428)	428	7.63-12.00	9.34
Options exercised	--	(33)	0.06-2.78	0.36
Options canceled	10	(10)	0.22-10.00	1.84
Balance at December 31, 1995	784	1,233	0.06-15.25	6.32
Shares authorized	1,500	--	--	--
Options granted	(620)	620	10.13-19.25	14.05
Options exercised	--	(85)	0.06-12.00	5.22
Options canceled	109	(109)	0.31-15.25	8.33
Balance at December 31, 1996	1,773	1,659	0.06-19.25	9.13
Options granted	(847)	847	0.01-35.25	20.99
Options exercised	--	(124)	0.06-16.13	6.41
Options canceled	34	(34)	0.56-22.75	15.27
Balance at December 31, 1997	960	2,348	$0.01-35.25	$ 13.46

At December 31, 1997, 1996 and 1995, options were exercisable to purchase approximately 784,000, 514,000 and 335,000 at weighted-average exercise prices of $8.17, $5.83 and $4.31 per share, respectively.

Exercise prices for options outstanding as of December 31, 1997 ranged from $0.01 to $35.25 per share. The weighted-average contractual life of those options is 8.0 years. The following table provides information regarding the Company's equity incentive plan.

	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
RANGE OF EXERCISE PRICES	NUMBER	WEIGHTED- AVERAGE EXERCISE PRICE PER SHARE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	NUMBER	WEIGHTED- AVERAGE EXERCISE PRICE PER SHARE
	(IN THOUSANDS)			(IN THOUSANDS)	
$ 0.01-5.75	483	$ 3.42	6.14	354	$ 3.09
6.25-10.13	570	8.95	7.40	201	8.59
10.25-17.50	502	14.75	8.47	193	14.87
18.63-19.63	487	18.90	8.98	31	19.20
22.25-35.25	306	27.00	9.68	5	23.27
$ 0.01-35.25	2,348	$13.46	7.99	784	$ 8.17

NOTE 3 -- SHAREHOLDERS' EQUITY (CONTINUED)

Pro forma information regarding net income and earnings per share is required by Statement 123, which also requires that the information be determined as if the Company 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 for 1997: risk-free interest rate of 5.7%; a dividend yield of 0.0%; volatility factors of the expected market price of the Company's common stock of 0.578; and a weighted-average expected life of 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 the Company'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, the Company 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. The Company's pro forma information follows (in thousands except for earnings per share):

	1997	1996
Pro forma net loss	$ (13,168)	$ (11,252)
Pro forma basic and fully diluted net loss per common share	$ (0.95)	$ (1.00)

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 the Company 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, 1997.

STOCK COMPENSATION

The Company recorded deferred compensation of approximately $551,000 during the year ended December 31, 1997. There was no deferred compensation recorded in the year ended December 31, 1996. These amounts represent the difference between the exercise price and the deemed fair value of certain of the Company's stock options granted in these periods. The Company recorded amortization expense of approximately $101,000 and $162,000 for the years ended December 31, 1997 and 1996, respectively.

NOTE 3 -- SHAREHOLDERS' EQUITY (CONTINUED)
RESERVED SHARES

A total of 4,132,727 shares of common stock have been reserved for issuance at December 31, 1997 for the various equity incentive plans and the warrants.

NOTE 4 -- INCOME TAXES

As of December 31, 1997, the Company had federal net operating loss carryforwards of approximately $27,400,000. The net operating loss and credit carryforwards will expire at various dates beginning in 2006 through 2012 if not utilized.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31 are as follows:

	1997	1996
	(IN THOUSANDS)	
Deferred tax assets:		
Net operating loss carryforwards	$ 9,400	$ 7,900
Research credits (expiring 2006-2012)	800	900
Capitalized research expenses	1,300	600
Deferred revenue	2,700	1,000
Other	1,500	700
Total deferred tax assets	15,700	11,100
Valuation allowance for deferred tax assets	(15,700)	(11,100)
Net deferred tax assets	$ --	$ --

Because of the Company's lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $4,600,000 and $4,200,000 during the years ended December 31, 1997 and 1996, respectively.

Utilization of net operating losses and credits may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986. The annual limitation may result in the expiration of net operating losses and credits before utilization.

NOTE 5 -- STATEMENT OF CASH FLOWS DATA (IN THOUSANDS)

	YEARS ENDED DECEMBER 31,		
	1997	1996	1995
Supplemental disclosure of cash flows information:			
Interest paid	$ 66	$ 57	$ 86
Supplemental schedule of non-cash investing and financing activities:			
Deferred compensation related to the issuance of certain stock options	$ 551	$ --	$ --
Issuance of common stock in connection with licensing agreement	$ 600	$ --	$ --

NOTE 6 -- SUBSEQUENT EVENTS (UNAUDITED)

In January 1998, the Company entered into a development and license agreement with Eli Lilly & Co. to develop pulmonary delivery for an unspecified protein product based on the Company's deep-lung delivery system for macromolecules. This is the second collaborative agreement between the two companies. Under the terms of this agreement, the Company 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 the Company receiving royalties on any marketed products. The Company will manufacture packaged powders for and supply inhalation devices to Lilly.

EXHIBIT 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-07069) pertaining to the Employee Stock Purchase Plan, the 1994 Equity Incentive Stock Option Plan and the Non-Employee Directors Stock Option Plan of Inhale Therapeutic Systems, and in the Registration Statement (Form S-3 No. 333-20787) and in the related Prospectus of Inhale Therapeutic Systems for the registration of 1,800,000 shares of its common stock, of our report dated January 22, 1998, with respect to the financial statements of Inhale Therapeutic Systems included in this Annual Report (Form 10-K) for the year ended December 31, 1997.

/s/ Ernst & Young LLP

ERNST & YOUNG LLP

Palo Alto, California
March 18, 1998

5

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE
FINANCIAL STATEMENTS AS FILED ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 1997,
AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

1,000

YEAR
DEC-31-1997
JAN-01-1997
DEC-31-1997
14,948
85,225
0
0
0
100,925
23,874
(5,180)
119,762
17,114
0
0
0
135,273
0
119,762
0
16,249
0
29,973
0
0
(66)
(9,983)
0
(9,983)
0
0
0
(9,983)
(0.72)
0