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, 1996 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.)

1060 EAST MEADOW CIRCLE, PALO ALTO, CA 94303
(Address of principal executive offices and zip code)

(415) 354-0700
(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 10, 1997 as reported by Nasdaq National Market was approximately $211,702,383. Determination of affiliate status for this purpose is not a determination of affiliate status for any other purpose.

13,642,004
(Number of shares of common stock outstanding as of March 28, 1997)

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's definitive Proxy Statement to be filed for its 1997 Annual Meeting of Shareholders are incorporated by reference into Part III hereof.

INHALE THERAPEUTIC SYSTEMS
1996 ANNUAL REPORT ON FORM 10-K
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PART I

ITEM 1. BUSINESS

OVERVIEW

Inhale Therapeutic Systems ("Inhale" or the "Company") 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 including existing inhalation systems. As an alternative to invasive delivery techniques, a pulmonary delivery system potentially could 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.

Inhale has created a system that integrates customized formulation and proprietary fine-powder processing and packaging technologies with a proprietary inhalation device for efficient, reproducible, deep-lung drug delivery. The Company has developed and completed the initial scale-up needed for production of pulmonary products for major clinical trials. As of February 28, 1997 Inhale had 15 programs in various stages of feasibility, pre-clinical and clinical development. Ten of the 15 programs are sponsored by partners and four of the 15 programs are in human clinical trials. The insulin program with Pfizer Inc. ("Pfizer") is in a multi-site Phase IIb trial with up to 240 people.

Inhale approaches pulmonary drug delivery with the objective of maximizing overall system efficiency while addressing commercial requirements for reproducibility, formulations stability, safety and convenience. Inhale is designing its delivery system to integrate customized formulations and proprietary fine dry powder processing and packaging technology with a proprietary inhalation device for efficient, reproducible lung delivery of macromolecule powders. To achieve this goal, Inhale is combining an understanding of lung biology, aerosol science, chemical engineering, mechanical engineering, and protein formulations in its system development efforts. Inhale intends to take bulk drugs supplied by collaborative pharmaceutical and biotechnology partners, formulate and process these drugs into fine powders and fill and package the powders into individual dosing units (blisters). The blisters are designed to be loaded into Inhale's device, which patients then activate to inhale the aerosolized drugs.

Inhale's strategy is to work with collaborative partners to develop and commercialize macromolecule drugs for systemic and local lung indications using its pulmonary delivery system. As part of this strategy, Inhale is engaged in early stage feasibility, research or development collaborations with Pfizer, Baxter Healthcare Corporation (a subsidiary of Baxter International, "Baxter"), Immunex Corporation ("Immunex"), Centeon L.L.C. (a joint venture of Hoechst AG and Rhone-Poulenc Rorer, Inc.) ("Centeon"), Asahi Chemical Industry Co., Ltd. ("Asahi"), Genzyme Corporation ("Genzyme"), and Eli Lilly & Company ("Eli Lilly" or "Lilly"). In addition to its collaborations, Inhale has initiated projects with several macromolecule drugs including calcitonin, heparin, interferon-beta, interferon alpha and follicle stimulating hormone ("FSH"). The Company anticipates that any product that may be developed would be commercialized through a collaborative partner and believes its partnering strategy will enable it to reduce its cash requirements while developing a large and diversified potential product portfolio.

During 1996 and early 1997, Inhale made progress toward its goals of broadening its partner base and moving products toward commercialization. The Company entered into strategic relationships with four new collaborative partners, moved the pulmonary insulin product development program into a Phase IIb clinical trial and two additional product development programs into Phase I testing, strengthened its balance sheet by adding $25 million of equity financing from corporate partners, completed a $32.4 million private placement of its common stock, and expanded its technology and manufacturing development activities as well as its management team.

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. 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.

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 therapeutics, which are identical or similar to the body's natural molecules, are enabling new therapies for many previously untreated or poorly treated diseases and serve as the bases for most biotechnology therapeutic products. Some 30 macromolecule drugs are approved for marketing in the United States and more than 130 additional macromolecule drugs are in human clinical trials, many for chronic and sub-chronic diseases. Sales of genetically engineered protein drugs were estimated at $10.7 billion worldwide in 1995 with projections of sales of macromolecule drugs predicted to reach or exceed $20 billion by 2000. Worldwide sales of insulin, for example, were estimated at $2.1 billion in 1996.

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 sub-chronic diseases meet with varying degrees of patient acceptance and compliance with the prescribed regimens. Poor acceptance and compliance can lead to increased incidents 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 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 sub-chronic 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.

Since the skin is even less naturally permeable to macromolecules than the gastrointestinal tract, passive transdermal delivery using "patch" technology has not been successful to date and 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, in general, these devices have not been well accepted.

The nasal route has been shown to have low natural bioavailability for many peptides and proteins. The natural bioavailability of peptides and proteins, such as insulin and growth hormones, delivered nasally is generally less than 2%. As a result, to achieve higher bioavailability and thus higher system efficiency, penetration enhancers may be required, which may cause local irritation or may result in long-term safety concerns. Only four small peptide drugs have been approved for marketing in the United States utilizing nasal delivery. There are no nasal-delivered products being marketed for larger peptides and proteins in the United States.

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 20 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 generally is 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 to the deep lung the inter-patient 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 sub-chronic diseases may provide significant potential commercial opportunities. Such a system could improve patient acceptance of systemic macromolecule drug therapy and compliance with prescribed regimens, thereby improving therapeutic outcome and reducing the costs of administration and overall disease treatment. Additionally, pulmonary delivery may enable new therapeutic uses of certain macromolecule drugs.

Inhale 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, very low efficiency, low drug payload per puff, poor moisture barrier and, in the case of wet systems, long dosing time and microbial growth.

Inhale believes that its technology could be used to address these problems through: 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, e.g., 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 major market advantages. The Company's strategy incorporates the following principal elements:

- - CREATE 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 or infusion; (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.

- - USE AN INTEGRATED SYSTEM APPROACH. The Company intends to develop a commercially viable pulmonary delivery system through an integrated systems solution. Inhale is combining 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.

- - FOCUS INITIAL EFFORTS 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.

- - PURSUE COLLABORATIONS WITH PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES. Inhale is building a drug delivery company and currently does not intend to market its own pharmaceutical products. The Company is seeking to work with partners that have significant clinical development and marketing resources, and

currently has early stage collaborations with several large pharmaceutical and biotechnology companies. For drug products that are covered by third-party patents, Inhale intends to work with partners 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 will enable it to reduce its cash requirements while developing a large and diversified potential product portfolio.

- - 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 help it to achieve a proprietary position in the manufacture of dry powder drug formulations for pulmonary delivery and provide manufacturing economies of scale across a range of therapeutic products.

- - LEVERAGE TECHNOLOGY BASE FOR OTHER APPLICATIONS. Inhale intends to leverage its core technologies over a targeted group of molecules where the Company views the use of pulmonary delivery systems a significant advantage.

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 with 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 because of 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 in being absorbed 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 a 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 with chronic or sub-chronic use by a wide patient population.

CONVENIENCE: The system must be convenient to the patient in terms of 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 is designing its delivery system to integrate customized formulations with its proprietary inhalation device specifically designed for efficient, reproducible lung delivery of macromolecule powders. Inhale is combining an understanding of lung biology, aerosol science, chemical engineering, mechanical engineering and protein formulations

in its system development efforts. Finally, the Company believes that this interdisciplinary capability provides it with an important competitive advantage.

Inhale has chosen to base its pulmonary delivery system on dry powders for several reasons. First, 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 at least 25 times more than 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 will be able to successfully commercialize and market its delivery system.

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 substantial 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 addition, in July 1994 Inhale entered into an agreement with Pafra Limited under which the Company obtained an exclusive license to certain proprietary technologies for use in the respiratory delivery of macromolecules covering protein powder compositions with enhanced room temperature stability and methods for their production.

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 at the scale-level necessary for late stage clinical trials and small volume marketed products. Inhale is in the process of scaling up its powder processing systems in order to produce quantities sufficient for Phase III clinical trials and initial commercial production. However, there can be no assurance that the Company will be successful in scaling up its powder processing at all, on a timely basis or at a reasonable cost or that the 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 accurately finer particles 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 for 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 U.S. in October 1995 (see "Patents and Proprietary Rights"). To achieve this goal, Inhale has designed a prototype of its pulmonary delivery device to:

- - 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. Its 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 combination with the dispersion mechanism and materials used in the device, is designed to decrease 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. A prototype is currently being used in Phase II insulin trials and Phase I trials for calcitonin and several other drugs. Inhale's insulin project with Pfizer has now moved into take-home trials where diabetics will be using the Inhale system for several months.

The commercial viability 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. Reproducibility (the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups) will require, among other things, the inhalation device to consistently deliver predictable amounts of dry powder formulations to the deep lung.

The Company's integrated approach to systems development relies upon several different but related technologies, and its business strategy depends upon collaborations with corporate partners. 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 development of a prototype automated packaging system will need to be accomplished before commercialization of a product using the Company's system and subsequent commercialization of its delivery system.

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, 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 not experience delays in the various aspects of product and business development. Any such delays would cause delays in overall product development. The failure to demonstrate pulmonary bioavailability, achieve total system efficiency, provide safe, reproducible dosages of stable formulations or advance timely the various aspects of product and business development would have a material adverse effect on the Company.

THERAPEUTIC PRODUCTS UNDER DEVELOPMENT

DRUG	POTENTIAL INDICATIONS	STATUS	PARTNER
Human insulin	Type I and II diabetes	Completed Phase I(1) , IIa(2) Clinical Trials; Started Phase IIb(3) Clinical Trial	Pfizer
*	Osteoporosis	IND Filed; One Phase I trial completed(4)	Alza completed Phase I; Eli Lilly will take trials to next step
Calcitonin	Osteoporosis, Bone pain, Paget's Disease	In Phase I clinical trial(1)	
Interleukin-1 Receptor	Asthma	Phase I/II Clinical Trial(1)(2)	Immunex
Alpha-1 proteinase inhibitor	Alpha-1 antitrypsin deficiency (leads to emphysema)	Pre-clinical	Centeon
*	Osteoporosis	Formulation Development(5)	Asahi
Gene Vectors	Lung diseases	Research(6)	Genzyme
Heparin	Blood clotting	Formulation Development(5)	
Interferon Alpha	Hepatitis B and C	Feasibility(7)	
Interferon Beta	Multiple Sclerosis	Formulation Development(5)	
Follicle Stimulating Hormone (FSH)	Infertility and Reproductive Diseases	Feasibility(7)	
Four molecules	*	Feasibility/Formulation(5)(6)	Baxter

DEFINITION OF DEVELOPMENT STATUS:

(1) PHASE I CLINICAL TRIAL - TESTS SAFETY AND COMPARES BIOAVAILABILITY AND BIOACTIVITY IN PULMONARY DELIVERY VERSUS SUBCUTANEOUS INJECTION IN HEALTHY SUBJECTS.
(2) PHASE II CLINICAL TRIAL - TESTS BIOAVAILABILITY AND BIOACTIVITY IN PULMONARY DELIVERY VERSUS SUBCUTANEOUS INJECTION.
(3) PHASE IIB CLINICAL TRIAL - OUT-PATIENT CLINICAL TRIALS OF PULMONARY INSULIN USING INHALE'S PULMONARY DELIVERY SYSTEM WITH UP TO 240 PATIENTS.
(4) COMPLETED SINGLE-DOSE BIOAVAILABILITY STUDY THAT COMPARED SUBCUTANEOUS INJECTION OF THE DRUG WITH PULMONARY DELIVERY USING THE INHALE AEROSOLIZED DELIVERY. SHOWED THAT DRUG WAS SYSTEMICALLY ABSORBED.
(5) FORMULATION DEVELOPMENT - DEVELOPING DRY POWDER AEROSOL FORMULATION FOR DRUG.
(6) RESEARCH - EARLY STAGE WORK TO DETERMINE APPLICABILITY OF INHALE SYSTEM; PRODUCT NOT YET ON PATH TO CLINICAL DEVELOPMENT.
(7) FEASIBILITY - WORK TO DETERMINE PULMONARY BIOAVAILABILITY.

* DRUG, PARTNER NAME OR INDICATION WITHHELD AT PARTNER'S REQUEST.

INHALE PULMONARY DRUG DELIVERY PROGRAMS IN PROGRESS

Inhale is in various stages of development or research on potential products for several indications. The Company has 15 programs in various stages of feasibility, formulation, pre-clinical and clinical development. Ten of the 15 programs are sponsored by partners. Four are in human clinical trials; and insulin is in a Phase IIb trial with Pfizer with up to 240 patients.

PFIZER PROGRAM (INSULIN). 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 $2.1 billion in 1996. 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 seven million diagnosed Type I (juvenile onset) and Type II (adult onset) diabetics in the United States. They estimate an additional seven million who have not been diagnosed. All Type I diabetics, estimated at about 10% 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 generally is supposed to be administered 30 minutes before mealtimes and generally is given only twice a day. A ten-year study by the National Institute 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 injectors have been available for many years, however, they have not gained wide acceptance in the United States.

Inhale is developing a regular insulin that can be administered in one to three doses 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, and could yield medical advantages by providing a more rapid acting insulin than current injectable products.

Through its collaboration with Inhale, Pfizer conducted additional Phase I and Phase IIa clinical trials. The Phase I and IIa trial data indicated that pulmonary insulin was absorbed systemically and lowered glucose levels. In late October 1996 Pfizer initiated a multi-site Phase IIb outpatient trial to include up to 240 patients. The trial is designed to test the effectiveness of pulmonary-delivered insulin using Inhale's system in controlling blood glucose levels following chronic administration in diabetics over several months of use. In connection with the collaboration, Pfizer made two $5 million equity investments in Inhale at a 25% premium to the market price of Inhale stock at the time of each investment.

BAXTER PROGRAM (FOUR MOLECULES). 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 the first 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 also will be managed by Inhale. Baxter will be responsible for the worldwide commercialization of the products resulting from the collaboration.

OSTEOPOROSIS PROGRAMS. Osteoporosis, the thinning of bones, is estimated to affect approximately 150 million people worldwide, including 25 million Americans, mostly women. If not prevented or left untreated, osteoporosis can progress painlessly until a bone breaks. As many as 50,000 people die each year as a result of hip fractures - usually because of complications that result from surgery or from being confined to bed. Associated medical costs of the estimated 1.3 million bone fractures caused annually by osteoporosis are estimated to be about $10 billion per year in the United States. Inhale has three programs underway to develop a pulmonary delivered product for drugs used to treat osteoporosis: one with Eli Lilly, one being performed by the Company, and one with Asahi.

ELI LILLY PROGRAM. In January 1997, Inhale entered into a collaborative agreement with Eli Lilly to develop pulmonary delivery for a selected osteoporosis product. Under the terms of the agreement, Inhale will receive up to an estimated $20 million in initial fees and 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 with Alza Corporation ("Alza") indicated that the drug was systemically absorbed when delivered with Inhale's pulmonary system. The single-dose bioavailability study compared subcutaneous injection of the drug with pulmonary delivery using the Inhale aerosolized delivery system in 18 fasted, normal volunteers. The results indicated that the drug was systemically absorbed when delivered with Inhale's system.

Alza collaborated with Inhale on development and funding for the Phase I trial of the pulmonary product. As previously reported, the two companies agreed that they would seek a new corporate partner to fund further development and commercialization of the osteoporosis product following successful completion of the Phase I trial. Lilly will be taking the clinical trials to the next step and will receive worldwide commercialization rights.

CALCITONIN PROGRAM. 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 40 have Paget's disease. Hypercalcemia occurs as a result of excessive serum calcium levels caused by hyperparathyroidism and malignancy. It occurs in approximately 5-10% of cancer patients.

The worldwide calcitonin market is dominated by fish calcitonins, including salmon and eel, which are thought to be about ten times more potent than human calcitonin. The calcitonin markets are supplied by various manufacturers, including Rhone-Poulenc Rorer, Sandoz and Asahi. In addition to its injectable formulation, salmon calcitonin is available in several countries, including the United States, as a non-invasive nasal spray.

Osteoporosis is by far the most important potential clinical indication for calcitonin. It has been shown 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. Oral and transdermal estrogens (and progestins) are also prescribed for osteoporosis and currently are the dominant therapies in the United States. While long term estrogen therapy may cause vaginal bleeding in some women, calcitonins have exhibited no such side effect. In addition, clinical evidence suggests that calcitonin may provide superior efficacy to estrogens in cases of rapid turnover osteoporosis.

Considerable work has been done on non-invasive delivery of calcitonin. While oral bioavailabilities of several percent have been reported, 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.

Inhale has shown in animal tests that calcitonin is well absorbed from the lung. The Company announced the start of a Phase I clinical trial of an aerosolized form of salmon calcitonin in late July 1996. The study is being performed in the United Kingdom using Inhale's pulmonary delivery system for macromolecules. Pulmonary calcitonin was Inhale's fourth product to enter human clinical trials.

ASAHI PROGRAM. Inhale is developing a dry powder formulation of a proprietary drug for osteoporosis for use in the Inhale delivery system with Asahi Chemical Industry Co., Ltd., Tokyo, Japan. With Asahi, Inhale will test that formulation in initial human clinical studies.

CENTEON PROGRAM (ALPHA-1 ANTITRYPSIN DEFICIENCY). 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. The deficiency was first identified in 1963 and is usually found in individuals of Northern European descent. In infants, it causes neonatal cirrhosis which is often fatal. In adults, it can lead to pulmonary emphysema. It is estimated that as many as 100,000 people in the U.S. were born with alpha-1 antitrypsin deficiency and potentially 28,000 in Northern Europe. Of these, emphysema resulting from the deficiency afflicts up to 40,000 people in the U.S. alone.

Alpha-1 antitrypsin normally provides one type of protection against enzymes which are part of white blood cells that clean up wounds and perform other valuable, healthy functions. If, due to the lack of alpha-1 antitrypsin, the activities of these substances are not controlled, they can attack normal tissues in the body. In the lung, they can damage the tiny air sacs. 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. In addition, alpha-1 antitrypsin deficiency can cause a mild strain on the liver, leading to occasional liver problems. Every person inherits two alpha-1 antitrypsin genes, one from each parent. A person has alpha-1 antitrypsin deficiency only if he or she inherits a combination of abnormal genes or none at all.

Early symptoms of related alpha-1 antitrypsin deficiency emphysema often appear between ages of 30 and 40 and consist of shortness of breath following activity, as well as decreased exercise capacity and wheezing. Both the early age at which the disease is present and the fact that the disease most frequently appears in the lower rather than the upper lung regions help distinguish genetic emphysema from other types of emphysema.

Alpha-1 proteinase inhibitor is approved in the United States and several European countries for augmentation treatment of alpha-1 antitrypsin deficiency. Current treatment is given by systemic intravenous infusion on a weekly basis. Infusion therapy can take about 45 minutes. This "replacement therapy" consists of a concentrated form of alpha-

1 proteinase inhibitor derived from human plasma. It increases the alpha-1 antitrypsin in the blood to levels that should help to protect the lungs.

In January 1997, Inhale and Centeon entered into a collaboration to develop a pulmonary formulation of alpha-1 proteinase inhibitor 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 deep-lung delivery device for macromolecules. 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 proteinase inhibitor has the potential to significantly improve the efficiency of delivery compared to current infusion therapy. A pulmonary-delivered therapy could be a significant improvement in therapeutic efficiency and delivery convenience over weekly infusion therapy. A pulmonary delivery system could significantly reduce the amount of drug needed for genetic emphysema therapy since alpha-1 proteinase inhibitor could be delivered directly to the lung. In addition, the companies believe that pulmonary delivery would be more convenient and less invasive than intravenous infusion, thereby providing increased patient convenience and potentially improving the patient's quality of life.

GENZYME PROGRAM (GENE VECTORS). 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 products. Early stage research has shown that Inhale's dry powder formulations and powder processing technology can be used to make powders containing gene vectors that retain their activity.

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.

IMMUNEX PROGRAM (INTERLEUKIN-1 RECEPTOR). Interleukin-1 is a cytokine that helps initiate the inflammatory response to foreign pathogens. Inhale collaborated with Immunex for the development of a pulmonary delivery system potentially for the treatment of 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.

HEPARIN AND LOW MOLECULAR WEIGHT HEPARIN (LMWHS) (ANTICOAGULANT). 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 1994 were estimated to be approximately $400 million. Major suppliers in the United States include The Upjohn Company, Wyeth-Ayerst Laboratories Division of American Home Products, Inc. and Eli Lilly. There are also indications that heparin may have local lung applications. Heparin has been shown in a study reported in the NEW ENGLAND JOURNAL OF MEDICINE to have efficacy in treating asthma. Others have also suggested that it possesses anti-protease activity, similar to alpha-1 antitrypsin, and could be used to treat lung diseases.

Thromboembolitic diseases such as deep vein thrombosis, pulmonary embolism, heart attacks and restenosis are caused by blood clots. Warfarin, a small molecule oral anticoagulant, is the most widely used non-invasively delivered alternative to heparin. The most serious risks associated with warfarin are 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. The Company anticipates that any product that might be developed would be commercialized through a marketing partner.

INTERFERON ALPHA (HEPATITIS). 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 $1.3 billion. One of the largest markets for interferon alpha is in Japan where an estimated three million people suffer from Hepatitis B and C, as compared to an estimated 300,000 people in the United States. 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.

Early attempts to use high doses of nasally-delivered interferon alpha for the common cold demonstrated limited success, but were accompanied by nasal irritation. Some companies are exploring sustained release interferon alpha injections.

Inhale believes that a pulmonary delivery system could provide a competitive advantage in what is now an exclusively injectable market. A pulmonary interferon alpha could reduce the cost of treatment by enabling more home therapy. Inhale has shown in animal studies that interferon alpha is well absorbed systemically following pulmonary administration. Inhale has completed feasibility testing and may seek a partner for further development.

INTERFERON-BETA (MULTIPLE SCLEROSIS). Interferon is a protein with anti-viral activity formed by mammalian cells in response to infection by viruses. The structure of interferons was not known until recombinant DNA techniques were used to clone the mammalian genes in bacteria. Interferons are synthesized as a more rapid response to viral infection than the formation of serum antibodies and are associated with the body's protective mechanism against and recovery from viral infection. This has led to an interest in interferons as potential therapeutic agents against viral diseases, some forms of cancer, and other diseases of suspected viral or unknown etiology.

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. In 1996, analysts estimated this market to be approximately $300 million. There are an estimated 700,000 cases in North America and Europe in total with 75% being female. The disorder affects mostly upper and middle class female Caucasians.

Two companies have gained FDA approval for interferon beta for relapsing and remitting multiple sclerosis. The first drug is Betaseron, which is interferon-beta 1b, and is sold by Berlex Laboratories Inc., of Wayne, N.J. and manufactured by Chiron Corp., of Emeryville, Calif. Worldwide sales of Betaseron were $277 million in 1995. Berlex is a subsidiary of Schering AG, of Berlin. Betaseron has been shown to reduce relapses, but not to slow the disorder's deteriorating march. Biogen markets Avonex, or Interferon-beta-1a. Biogen has demonstrated in clinical trials that Avonex can slow progression of the disease and reduce flare-ups. Avonex is taken weekly compared with daily injections of Betaseron.

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 and may seek a partner for further development.

FOLLICLE STIMULATING HORMONE (FSH) (INFERTILITY). 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 given in a series of daily injections over two weeks to enhance follicle growth and ovum production. Analysts estimate the female infertility market to be approximately $400 million. Inhale has demonstrated the feasibility of pulmonary FSH in an animal model and now seeks a pharmaceutical partner for development.

There can be no assurance that Inhale will be able to demonstrate pulmonary bioavailability for any drug or that its pulmonary delivery system will provide safe, reproducible dosages of stable formulations. There also can be no assurance that Inhale will be able to scale-up its manufacturing, obtain marketing approval for, or successfully market, any drug for pulmonary delivery. Further, there can be no assurance that any of the Company's collaborative partners will complete product development and commercialization. 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 approval and commercialize certain products. 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.")

The Company's existing partners have the right 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 also will have 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, or over the pricing of any such products. There can be no assurance 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.

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 million for all current human clinical trials, and intends to obtain insurance for future clinical trials of insulin and other products under development. However, there can be no assurance 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.

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 manufacturing facility. The Company also must select and have validated a device manufacturer. Inhale believes its manufacturing strategy will: (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 and packaging manufacturing facility capable of producing powders in quantities sufficient for Phase I, Phase II, and early 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 trial, Immunex's IL-IR 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 on scaling-up its powder processing to a production scale system and is developing 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 trails and into commercial production for some products. Inhale plans to develop a higher capacity automated filling unit, which would be capable of filling its powders 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")

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 a Phase II insulin trial and a Phase I clinical trial for another project. 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.

The Company has no experience manufacturing products for large scale clinical testing or commercial purposes. To date, the Company has performed powder processing only on the small scale needed for clinical trials and for testing formulations of certain other potential therapeutic products. There can be no assurance that manufacturing and control problems will not arise as the Company attempts to 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 yields in powder processing will be sufficient 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.

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. To date, the Company has used small machine shops for production of its prototype inhalation devices. 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 satisfactory contract manufacturing 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")

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: (i) pre-clinical laboratory and animal tests; (ii) the filing of an Investigational New Drug application ("IND") (iii) adequate and 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 Product License Application ("PLA") and an Establishment License Application 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/PLA 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 or the investigator 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/PLA for approval of the marketing and commercial shipment of the pulmonary system. The FDA may deny an

NDA/PLA 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/PLA 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.

The Company's research and development involve 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.

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/PLA. 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 the 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 completing 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.

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 development of a prototype 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 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.

Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental change. Although Congress has failed to pass comprehensive health care reform legislation to date, the Company anticipates that Congress, state legislatures and the private sector will continue to review and assess alternative health care delivery and payment systems. Potential approaches that have been considered include mandated basic health care 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 may cause Inhale's collaborative partners or potential partners to limit or eliminate spending on collaborative drug development projects. Legislative debate is expected to continue in the future, market forces are expected to demand reduced costs, and Inhale cannot predict what impact the adoption of any federal or state health care reform measures or future private sector reform may have on its business.

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.

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. There can be no assurance that any of the other 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 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. There can be no assurance that the Company's patents, if issued, would be held valid by a court of competent jurisdiction. 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 United States and foreign patent rights and other proprietary rights owned by third parties that relate to aerosol devices and delivery, pharmaceutical formulations, dry powder processing technology and the pulmonary route of delivery for certain powder formulations of macromolecules. The Company cannot predict with any certainty which, if any, patent references 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 the 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. 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.

The Company also relies upon trade secret protection for its confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to the Company's trade secrets or disclose such technology, or that the Company can meaningfully protect its trade secrets.

Third parties from time to time have asserted or may assert that the Company is infringing their proprietary rights based upon issued patents, trade secrets or know-how that they believe cover the Company's technology. 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 assurance 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 required 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 biopharmaceutical drugs, including some of those 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, a patent has been granted in Europe which is directed to aerosol formulations of serine protease inhibitors, including alpha-1 antitrypsin, for the treatment of the lung. 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, however, 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.

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.

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. Under the terms of the license, Genentech has exclusive rights to work with Inhale on certain molecules until August 1, 1997.

COMPETITION

The Company believes that products developed using Inhale's technology will compete on the basis of system efficiency, dosage reproducibility, safety, patient convenience and cost. There is intense competition to develop a solution to the non-invasive delivery of drugs from several drug delivery and pharmaceutical companies, many of which are much larger and have far greater resources than Inhale. These include companies working on developing systems for other non-invasive routes of delivery, such as oral, transdermal, bucal, nasal, and needle-less injections, as well as companies working on pulmonary delivery systems. In addition, several companies are working on sustained release injectable systems. While these latter systems involve injections, the lower number of injections could be competitive

with Inhale's pulmonary delivery technology in certain applications. The Company believes its technology and integrated pulmonary delivery systems approach provides it with important competitive advantages in the delivery of drugs compared with currently known alternatives. However, new drugs or further developments in alternative drug delivery methods may provide greater therapeutic benefits for a specific drug or indication, or may offer comparable performance at lower cost than the Company's proprietary pulmonary delivery system.

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

The Company's success depends upon maintaining a competitive advantage in the development of products and technologies for pulmonary delivery of macromolecules. 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 macromolecule drugs to the deep lung, a non-invasive drug delivery system which is more attractive for the delivery of macromolecule drugs than pulmonary delivery, or an invasive delivery system which overcomes some of the drawbacks of current invasive systems for chronic or sub-chronic indications (such as sustained release system), the Company's business would 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, bucal and colonic absorption systems. Several of these companies may have or be developing dry powder devices that could be used for pulmonary delivery of macromolecules. The Company also is 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 more rapidly than the Company and gaining market acceptance. There can be no assurance that developments by others will not render the Company's products or technologies noncompetitive or obsolete.

SCIENTIFIC ADVISORS

The Company has assembled scientific 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:

SCIENTIFIC ADVISORS

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 February 28, 1997, Inhale had 92 employees, 76 engaged in research and development activities and 16 in general administration and business development. Sixty-two of the employees hold advanced degrees, of which 18 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 uses 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 $14.4 million, $9.0 million, and $4.9 million for the years ended December 31, 1996, 1995, and 1994 respectively. Research and development expenditures funded by partners were approximately $6.9 million, $3.4 million, and $1.7 million for the years ended December 31, 1996, 1995, and 1994 respectively.

THIRD-PARTY REIMBURSEMENT

Successful commercialization of certain of the Company's products will depend in part on the availability of reimbursement from third-party health care payors, such as private insurance plans and the government. There can be no assurance that such reimbursement will be available. Third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic and diagnostic products. (See "Government Regulation.")

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 macromolecule and other drugs. Only four of the Company's pulmonary delivery formulations, insulin, Interleukin-1 Receptor, salmon calcitonin and a peptide for the treatment of osteoporosis 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, preclinical 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. Moreover, even if the Company's products prove to be safe and effective and are approved for marketing by the United States Food and Drug Administration ("FDA") and other regulatory authorities, there can be no assurance that health care providers, payors or patients will accept the Company's products. 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 Health Care Reform and Third-Party Reimbursement."

NO ASSURANCE OF SUCCESSFUL DEVELOPMENT OR COMMERCIALIZATION OF DRUGS FOR PULMONARY DELIVERY. The commercial viability 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 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. Too much 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. Reproducibility (the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups) will require, among other things, the development of an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung.

The Company's integrated approach to systems development relies upon several different but related technologies, and its business strategy depends upon collaborations with corporate partners. 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 later 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, 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 various aspects of product and business development on a timely basis

that does not cause delays in overall product development. The failure to demonstrate pulmonary bioavailability, achieve total system efficiency, provide safe, reproducible dosages of stable formulations or advance timely the various aspects of product and business development would have a material adverse effect on the Company. See "Risk Factors Dependence Upon Partners" and " Government Regulation; Uncertainty of Obtaining Regulatory Approval."

HISTORY OF OPERATING LOSSES; UNCERTAINTY OF FUTURE PROFITABILITY. The Company has not been profitable since inception and, through December 31, 1996, had incurred a cumulative deficit of approximately $27.7 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, development contracts and interest income. 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.

DEPENDENCE UPON PARTNERS. The Company currently does not possess the resources necessary to develop, complete the FDA approval process for, 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 approval and commercialize certain products. 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.

The Company's existing partners have the 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 arrangements with companies whose products compete with products sold by its partners. The Company also will have 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. 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, 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."

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, plan and build a late stage clinical and early commercial production facility, and comply with the good manufacturing practices ("GMP") prescribed by the 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 only on the small scale needed for early stage trials and for testing formulations of certain other potential therapeutic products and scaled-up 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."

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 the costly and time-consuming research and preclinical and clinical testing activities necessary to develop early commercial production facility and to 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.

The Company expects that its existing capital resources, contract research revenues from collaborations and the net proceeds of this offering and interest thereon, will enable the Company to maintain its current and planned operations at least through 1998. 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.

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 United States Patent and Trademark Office ("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. There can be no assurance that the Company's patents, if issued, would be held valid by a court of competent jurisdiction. 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 United States 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. 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.

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, a patent has been granted in Europe which is directed to aerosol formulations of serine protease inhibitors, including alpha-1 antitrypsin, for the treatment of the lung. 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.

The PTO has recently adopted changes to the United States patent law which change 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 Partners," " Government Regulation; Uncertainty of Obtaining Regulatory Approval."

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. This 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 experiences 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 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 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.

UNCERTAINTY RELATED TO HEALTH CARE REFORM AND THIRD-PARTY REIMBURSEMENT. Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental change. Although Congress has failed to pass comprehensive health care reform legislation to date, the Company anticipates that Congress, state legislatures and the private sector will continue to review and assess alternative health care delivery and payment systems. Potential approaches that have been considered include mandated basic health care benefits, controls on health care 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 Inhale's collaborative partners or potential partners to limit or eliminate spending on collaborative drug development projects. Legislative debate is expected to continue in the future, market forces are expected to demand reduced costs and Inhale cannot predict what impact the adoption of any federal or state health care reform measures or future private sector reform may have on its business.

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 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 and any such changes could further limit reimbursement for medical products and services.

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 would 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 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 more rapidly than the Company and gaining market acceptance. 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 for certain clinical trials and intends to obtain insurance for future clinical trials of insulin and other products under development. However, there can be no assurance 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 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 such 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 technology 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 securities are subject to a high degree of risk and volatility.

ITEM 2. PROPERTIES

Inhale currently leases approximately 35,000 square feet in two buildings in Palo Alto, California. This space is used for research, development, administration and manufacturing of drugs for early stage clinical trials. This 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 through May 31, 2003.

In October 1996, the Company entered into a 15-year lease agreement on a third facility totaling approximately 110,000 square feet. The Company plans to consolidate its operations into this facility over the next eighteen months and intends to use the facility as its initial commercial manufacturing site.

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, 1996.

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	40	President, Chief Executive Officer and Director
Ajit S. Gill	48	Senior Vice President, Chief Operating Officer
Stephen L. Hurst	41	Vice President, Intellectual Property and Licensing
Judi R. Lum	36	Vice President, Finance and Administration and Chief Financial Officer
John S. Patton, Ph.D.	50	Vice President, Research and Director
Robert M. Platz	45	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, Senior Vice President and 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.

JUDI R. LUM has served as Vice President, Finance and Administration and Chief Financial Officer since October 1996. She brings a diversity of experience in finance, business development, and operations. She most recently served as Vice President of Finance and Administration for an ophthalmics start-up company and previously was Director of Corporate Development for GenPharm International, Inc.. She also served as Director of Finance for the Industrial Sector of Raychem Corporation, Pilot Operations Manager for Advanced Cardiovascular Systems, and Assistant Vice President of Crocker National Bank. She received her BA and MBA degrees from Stanford University.

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, 1995:	HIGH	LOW
1st Quarter	$11.375	$7.250
2nd Quarter	8.000	7.000
3rd Quarter	14.750	7.625
4th Quarter	11.500	7.250
YEAR ENDED DECEMBER 31, 1996:		
1st Quarter	$16.750	$9.750
2nd Quarter	21.500	15.000
3rd Quarter	18.625	12.625
4th Quarter	17.625	12.875

As of December 31, 1996, there were approximately 114 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.

On October 23, 1996 the Company sold 272,456 shares of Common Stock to Pfizer, Inc. for aggregate consideration of $5,000,000 in cash pursuant to Section 4(2) of the Securities Act of 1933, as amended.

ITEM 6. SELECTED FINANCIAL DATA

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

	YEARS ENDED DECEMBER 31				
	1996	1995	1994	1993	1992
STATEMENT OF OPERATIONS DATA:					
Contract revenue	$6,890	$3,445	$1,651	$708	$98
Operating costs and expenses:					
Research and development	14,376	9,041	4,934	2,765	1,259
General and administrative	4,004	3,232	2,465	856	580
Total operating costs and expenses	18,380	12,273	7,399	3,621	1,839
Loss from operations	(11,490)	(8,828)	(5,748)	(2,913)	(1,741)
Net lo	$(9,909)	$(7,662)	$(5,279)	$(2,861)	$(1,681)
Net loss per share (1)	$(0.88)	$(0.78)	$(0.86)	$(1.03)	$(0.61)
Shares used in computation of loss per share (1)	11,207	9,837	6,103	2,787	2,777

	DECEMBER 31,				
	1996	1995	1994	1993	1992
	(IN THOUSANDS)				
BALANCE SHEET DATA:					
Working capital	$31,304	$17,701	$13,451	$4,954	$3,345
Total assets	41,492	23,248	17,249	7,190	4,376
Equipment financing obligations, less current portion	187	353	460	652	229
Accumulated deficit	(27,691)	(17,770)	(10,108)	(4,829)	(1,968)
Shareholders' equity	35,061	20,182	15,427	5,891	3,742

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

(1) Net loss per share is based upon the weighted average number of common and certain common equivalent shares outstanding. 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 macromolecule 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, 1996, the Company incurred a cumulative net loss of approximately $27.7 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 during initial feasibility work performed under collaborative arrangements. Inhale's strategy is to enter into development contracts with pharmaceutical and biotechnology corporate partners after feasibility is demonstrated. Inhale expects that such partners will pay for research and development expenses and will make payments to Inhale as it achieves certain key milestones. Inhale intends to receive a royalty 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.

RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 1996, 1995 AND 1994

Contract research revenue was $6.9 million for the year ended December 31, 1996 compared to $3.4 million and $1.7 million for the years ended December 31, 1995 and 1994, respectively. Revenue increased 100% in 1996 from 1995 levels and 109% in 1995 from 1994 levels. The year to year increases resulted from an increase in the number of research feasibility agreements with partners and development contracts as well as revenue earned in 1996 and 1995 by the Company under its existing development agreements. Costs of contract research revenue approximate such revenue and are included in research and development expense.

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. Nevertheless, the Company expects higher contract revenues in 1997 as it performs its development activities under its collaborative development agreements.

Research and development expenses were $14.4 million for the year ended December 31, 1996, as compared to $9.0 million and $4.9 million for the years ended December 31, 1995 and 1994, 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 $5.3 million increase in research and development expenses in 1996 from 1995 and the $4.1 million increase in research and development expenses in 1995 from 1994 were primarily due to the hiring of additional research personnel and increased expenses associated with expanding laboratory and clinical manufacturing facilities. The Company expects research and development and process development spending to increase significantly over the next few years as the Company expands its proprietary 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 $4.0 million for the year ended December 31, 1996 as compared to $3.2 million and $2.5 million for the years ended December 31, 1995 and 1994, respectively. The $772,000 increase in general and administrative expenses in 1996 from 1995 and the $767,000 increase in 1995 from 1994 was due primarily to costs associated with supporting the Company's increased research and development programs and accelerated business

development efforts. The Company expects general and administrative spending to increase over the next few years as the Company expands its operations.

Interest income was $1.6 million for the year ended December 31, 1996 as compared to $1.3 million and $592,000 for the years ended December 31, 1995 and 1994, respectively. The $386,000 increase in interest income in 1996 from 1995 was due primarily to interest earned on higher average cash balances as a result of Baxter World Trade Corporation ("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 Inc. ("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. The increase of $660,000 in interest income in 1995 from 1994 was due primarily to higher cash balances as a result of the $7.2 million net proceeds received from the Company's follow-on public offering of Common Stock in March 1995. In addition, in February 1995 Pfizer made a $5.0 million equity investment in Inhale at a 25% premium-to-market price in conjunction with the January 1995 agreement between the Company and Pfizer.

At December 31, 1996, the Company had federal net operating loss carryforwards of approximately $23.0 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. At December 31, 1996, the Company had cash, cash equivalents and short-term investments of approximately $36.3 million.

The Company's operations used cash of $5.8 million, $5.3 million and $4.0 million in the years ended December 31, 1996, 1995 and 1994, respectively. These amounts differed from the Company's net operating losses in these periods due principally to depreciation expenses and increases in accounts payable, accrued liabilities and deferred revenue. Additionally, in 1994, non-cash amortization of deferred compensation expense of approximately $350,000 contributed to the difference between the net operating losses and cash used by operations.

The Company added property and equipment of approximately $2.1 million, $1.3 million and $1.4 million during the years ended December 31, 1996, 1995 and 1994, respectively. The Company financed approximately $151,000 of these additions through lease agreements during the year ended December 31, 1995. The Company did not finance additions through equipment financing agreements in 1996 or 1994.

In February 1997 the Company raised an additional $30.4 million in net proceeds by completing a private placement of its common stock to a number of institutional investors. Under the agreements, the investors purchased 1.8 million newly-issued shares of Inhale common stock, no par value, at a price of $18 per share.

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, acquisition 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 existing cash, cash equivalents and short-term investments of approximately $66.7 million (including net proceeds from the private placement completed in February 1997) , when coupled with future contract revenues from collaborative development arrangements, future equity investments, interest income and possible additional equipment financings, will be sufficient to meet its operating expense and capital expenditure requirements at least through 1998.

The Company's capital needs will depend on many factors, including continued scientific progress in the research and development of the Company's technology, the ability of the Company to establish and maintain collaborative arrangements with others and the terms thereof, the resources that the Company devotes to the development of self-funded projects, payments received from partners under research and development arrangements, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost 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 longer-term liquidity needs, the Company intends to seek additional funding, when needed, 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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements for the years ended December 31, 1996, 1995 and 1994 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 1997 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 1997 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 1997 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 1997 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.
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.

EXHIBIT	EXHIBIT TITLE
10.9(1)	Sublicense Agreement between the Registrant and John S. Patton, dated September 13, 1991.
10.10(2)	Offer Letter, dated September 16, 1994, from the Registrant to Jack M. Anthony.
10.11(2)	Addendum to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
10.12(6)	Lease dated May 31, 1995, between the Registrant and W.F. Batton & Marie A. Batton.
10.13(6)	Addendum Number One to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
10.14(6)	Addendum to Lease dated May 31, 1995 between the Registrant and W.F. Batton & Marie A. Batton.
10.15(6)	Addendum Number Two to Lease dated September 17, 1992, between the Registrant and W.F. Batton & 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 43.
27.1	Financial Data Schedule

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(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, 1996.

(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 28th day of March 1997.

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 and Judi R. Lum as his/her attorney-in-fact for him/her 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 28, 1997
/s/ Judi R. Lum Judi R. Lum	Chief Financial Officer (PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER)	March 28, 1997
/s/ JOHN S. Patton John S. Patton	Vice President and Director	March 28, 1997
/s/ Mark J. Gabrielson Mark J. Gabrielson	Director	March 28, 1997
/s/ James B. Glavin James B. Glavin	Director	March 28, 1997
/s/ Melvin Perelman Melvin Perelman	Director	March 28, 1997
/s/ Terry L. Opdendyk Terry L. Opdendyk	Chairman of the Board	March 28, 1997

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, 1996 and 1995, and the related statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 1996. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Inhale Therapeutic Systems at December 31, 1996 and 1995, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1996 in conformity with generally accepted accounting principles.

ERNST & YOUNG LLP

Palo Alto, California
February 10, 1997

INHALE THERAPEUTIC SYSTEMS
BALANCE SHEETS
(IN THOUSANDS)
ASSETS

	DECEMBER 31,	
	1996	1995
Current assets:		
Cash and cash equivalents	$ 18,568	$ 3,834
Short-term investments	17,741	16,093
Other current assets	1,239	487
Total current assets	37,548	20,414
Property and equipment, net	3,770	2,660
Deposits and other assets	174	174
	$41,492	$23,248
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,130	$ 717
Accrued liabilities	1,746	899
Accrued compensation	479	274
Deferred revenue	2,723	578
Equipment financing obligations current portion	166	245
Total current liabilities	6,244	2,713
Equipment financing obligations	187	353
Commitments		
Shareholders' equity:		
Preferred stock, 10,000 shares authorized, no shares issued or outstanding		
Common stock, no par value; 30,000 shares authorized; 11,835 shares and 10,142 shares issued and outstanding at December 31, 1996 and 1995, respectively	62,840	38,202
Deferred compensation	(88)	(250)
Accumulated deficit	(27,691)	(17,770)
Total shareholders' equity	35,061	20,182
	$41,492	$23,248

See accompanying notes

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

	YEARS ENDED DECEMBER 31,		
	1996	1995	1994
Contract research revenue	$ 6,890	$ 3,445	$ 1,651
Operating costs and expenses:			
Research and development	14,376	9,041	4,934
General and administrative	4,004	3,232	2,465
Total operating costs and expenses	18,380	12,273	7,399
Loss from operations	(11,490)	(8,828)	(5,748)
Interest income	1,638	1,252	592
Interest expense	(57)	(86)	(123)
Net loss	$(9,909)	$(7,662)	$(5,279)
Net loss per share	$(0.88)	$ (0.78)	$ (0.86)
Shares used in net loss per share calculation	11,207	9,837	6,103

See accompanying notes

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

	PREFERRED STOCK		COMMON STOCK				TOTAL
	SHARES	AMOUNT	SHARES	AMOUNT	DEFERRED COMPENSATION	ACCUMULATED DEFICIT	SHAREHOLDERS' EQUITY
Balance at December 31, 1993	2,909	$10,697	934	$ 23	$ --	$ (4,829)	$ 5,891
Conversion of Series A, B, and C convertible preferred stock to common stock	(2,909)	(10,697)	5,236	10,697	--	--	--
Issuance of common stock in initial public offering, net of issuance costs of $1,698	--	--	2,150	14,427	--	--	14,427
Deferred compensation related to the issuance of certain stock options granted to employees	--	--	--	760	(760)	--	--
Amortization of deferred compensation	--	--	--	--	348	--	348
Exercise of stock options for cash by employees and consultants	--	--	336	40	--	--	40
Net loss	--	--	--	--	--	(5,279)	(5,279)
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 follow-on offering, net of issuance costs of $757	--	--	1,000	7,243	--	--	7,243
Amortization of deferred compensation	--	--	--	--	162	--	162
Exercise of stock options for cash by employees and consultants	--	--	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
Exercise of stock options for cash by employees and consultants	--	--	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

See accompanying notes

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

	YEARS ENDED DECEMBER 31,		
	1996	1995	1994
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$(9,909)	$(7,662)	$(5,279)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,071	955	539
Amortization of deferred compensation	162	162	348
Increase in other current assets, deposits and other assets	(752)	(110)	(317)
Increase (decrease) in accounts payable and accrued liabilities	1,465	847	696
Increase in deferred revenue	2,145	483	8
Net cash used in operating activities	(5,818)	(5,325)	(4,005)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchases of available-for-sale securities	(58,993)	(49,318)	(22,786)
Sales of available-for-sale securities	2,020	7,812	4,102
Maturities of available-for-sale securities	55,313	29,326	18,601
Purchases of property and equipment, net	(2,181)	(1,340)	(1,371)
Net cash used in investing activities	(3,841)	(13,520)	(1,454)
CASH FLOWS FROM FINANCING ACTIVITIES			
Payments of equipment loan obligations	(52)	(32)	(27)
Payments of capital lease obligations	(193)	(205)	(154)
Issuance of equipment loan obligations		151	
Issuance of common stock, net of issuance costs	24,638	12,255	14,467
Net cash provided by financing activities	24,393	12,169	14,286
Net increase (decrease) in cash and cash equivalents	14,734	(6,676)	8,827
Cash and cash equivalents at beginning of period	3,834	10,510	1,683
Cash and cash equivalents at end of period	$18,568	$3,834	$10,510

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, 1996, 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 securities classified as available-for-sale are included in interest income.

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

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	152	--	--	152
	$36,649	$ --	$ 12	$36,637
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 following is a summary of available-for-sale securities as of December 31, 1995:

	AVAILABLE-FOR-SALE SECURITIES			
	COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
	(IN THOUSANDS)			
Obligations of U.S. government agencies	$11,209	$ --	$ --	$11,209
U.S. corporate commercial paper	5,871	--	--	5,871
Repurchase agreements, secured by U.S. Government securities	2,487	--	--	2,487
Other	360	--	--	360
	$19,927	$ --	$ --	$19,927
Amounts included in cash and cash equivalents	$3,834	$ --	$ --	$3,834
Amounts included in short-term investments	16,093	--	--	16,093
	$19,927	$ --	$ --	$19,927

The gross realized losses and gains on the sale of securities available-for-sale during the years ended December 31, 1996 and 1995, were not material. As of December 31, 1996, the average portfolio duration was approximately three months and the contractual maturity of any single investment did not exceed nine months (six months at December 31, 1995).

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 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.

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

PROPERTY AND EQUIPMENT

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

	1996	1995
	(IN THOUSANDS)	
Laboratory and other equipment	$3,679	$1,997
Leasehold improvements	2,258	1,759
Leased equipment	677	677
	6,614	4,433
Less accumulated depreciation and amortization	(2,844)	(1,773)
	$3,770	$2,660

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, up front 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 and biotechnology industries. Contract research revenue from two partners represented 77% and 14% of the Company's revenue in 1996. Contract revenue from two partners accounted for 78% and 13% of the Company's revenue in 1995, and two partners accounted for 56% and 18% of the Company's revenue in 1994. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

STOCK-BASED COMPENSATION

In accordance with the provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123"), the Company has elected 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 options 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.

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 advanced 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" (Statement 109). Under Statement 109, the liability method is used in accounting for income taxes.

NET LOSS PER SHARE

The net loss per common share is computed based upon the weighted average number of common shares outstanding. Common equivalent shares 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 $416,000, $217,000 and $185,000 for the years ended December 31, 1996, 1995 and 1994, respectively.

Included in property and equipment at December 31, 1996 and 1995, 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 $658,000 and $541,000 at December 31, 1996 and 1995, respectively. Future noncancellable commitments under equipment financing obligations and operating leases at December 31, 1996 are as follows:

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

	OPERATING LEASES	EQUIPMENT FINANCING OBLIGATIONS
	(IN THOUSANDS)	
Years ending December 31,		
1997	$ 728	$193
1998	956	62
1999	947	60
2000	989	109
2001 and thereafter	14,627	--
Total minimum payments required	$18,247	424
Less amount representing interest		(71)
Present value of future lease payments		353
Less current portion		166
Noncurrent portion		$187

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, 1996, 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-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

NOTE 3 SHAREHOLDERS' EQUITY (CONTINUED)

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. During the year ended December 31, 1996, options to purchase a total of 60,000 shares were granted to non-employee directors of the Company at an exercise price ranging from $10.13 to $17.50 per share. As of December 31, 1996, options on 6,000 shares had been exercised and options to purchase 81,000 shares were exercisable.

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, 1993	1,212	484	$0.06-15.25	$ 0.12
Shares authorized	690	--	--	--
Options granted	(708)	708	0.22-10.25	5.43
Options exercised	--	(336)	0.06-0.56	0.12
Options canceled	8	(8)	0.22-10.25	5.39
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

NOTE 3 - SHAREHOLDERS' EQUITY (CONTINUED)

At December 31, 1996, 1995 and 1994, options were exercisable to purchase approximately 514,000, 335,000 and 157,000 at weighted-average exercise prices of $5.83, $4.31 and $1.62 per share, respectively.

Exercise prices for options outstanding as of December 31, 1996 ranged from $0.06 to $19.25 per share. The weighted-average contractual life of those options is 8.2 years.

	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 EXCEPT PER SHARE AND YEAR INFORMATION)				
$ 0.06-5.56	483	$ 3.21	6.88	244	$ 1.83
5.75-9.13	435	8.04	7.95	166	7.76
9.88-14.50	484	11.66	9.03	86	10.96
15.25-19.25	257	17.32	9.55	18	17.80
$ 0.06-19.25	1,659	$ 9.13	8.20	514	$ 5.83

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-Sholes option pricing model with the following weighted-average assumptions for 1995 and 1996: risk-free interest rate of 6.4%; a dividend yield of 0.0%; volatility factors of the expected market price of the Company's common stock of 0.62; and a weighted-average expected life of 6 years.

The Black-Sholes 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.

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):

	1996	1995
Pro forma net loss	$(11,252)	$(8,106)
Pro forma net loss per share	$(1.00)	$(0.82)

NOTE 3 - SHAREHOLDERS' EQUITY (CONTINUED)

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.

WARRANT

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 at December 31, 1996.

As of December 31, 1996, a warrant to purchase 32,727 shares of Common stock at $3.06 per share issued in connection with equipment financing arrangements was outstanding and is exercisable through September 2003.

RESERVED SHARES

A total of 4,132,727 shares of common stock have been reserved for issuance at December 31, 1996 for the various equity incentive plans and the warrants.

NOTE 4 INCOME TAXES

As of December 31, 1996, the Company had federal net operating loss carryforwards of approximately $23,000,000. The net operating loss and credit carryforwards will expire at various dates beginning in 2006 through 2011 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:

	1996	1995
	(THOUSANDS)	
Deferred tax assets:		
Net operating loss carryforwards	$7,900	$5,200
Research credits (expiring 2006-2011)	900	500
Capitalized research expenses	600	400
Deferred revenue	1,000	200
Other	700	600
Total deferred tax assets	11,100	6,900
Valuation allowance for deferred tax assets	(11,100)	(6,900)
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 $3,000,000 during the year ended December 31, 1995.

NOTE 4 - INCOME TAXES (CONTINUED)

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,		
	1996	1995	1994
Supplemental disclosure of cash flows information:			
Interest paid	$57	$86	$123
Deferred compensation related to the issuance of certain stock options	$	$	$760

NOTE 6 - SUBSEQUENT EVENTS (UNAUDITED)

In February 1997 the Company received $30.4 million in net proceeds from a private placement of 1,800,000 shares its Common Stock to a group of institutional investors at a price of $18 per share.

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 related Prospectus of Inhale Therapeutic Systems for the registration of 1,800,000 shares of its common stock, of our report dated February 10, 1997, with respect to the financial statements of Inhale Therapeutic Systems included in this Annual Report (Form 10-K) for the year ended December 31, 1996.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 27, 1997

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE BALANCE SHEETS AND STATEMENTS OF OPERATIONS FOUND ON PAGES F-3 AND F-4 OF THE COMPANY'S FORM 10K FOR THE YEAR ENDED DECEMBER 31, 1996.

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YEAR
DEC-31-1996
JAN-01-1996
DEC-31-1996
118,568
17,741
0
0
0
37,548
6,614
(2,844)
41,492
6,244
0
0
0
0
62,840
(27,779)
41,492
0
6,890
0
6,890
11,490
0
57
(9,909)
0
(9,909)
0
0
0
(9,909)
(0.88)
0