

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, 1998 OR
/ / TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934.

COMMISSION FILE NO. 0-23556

INHALE THERAPEUTIC SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark whether the Registrant (1) has filed all reports
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of
1934 during the preceding 12 months (or for such shorter period that the
Registrant was required to file such reports), and (2) has been subject to such
filing requirements for the past 90 days. Yes /X/ No / /

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

The approximate aggregate market value of voting stock held by
non-affiliates of the Registrant, based upon the last sale price of the Common
Stock on March 1, 1999 as reported by Nasdaq National Market was approximately
\$428,798,342. Determination of affiliate status for this purpose is not a
determination of affiliate status for any other purpose.

16,925,375

(Number of shares of common stock outstanding as of March 1, 1999)

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's definitive Proxy Statement to be filed for its 1999
Annual Meeting of Shareholders are incorporated by reference into Part III
hereof.

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ITEM 1. BUSINESS

OVERVIEW

Inhale Therapeutic Systems, Inc. ("Inhale" or the "Company") is creating an inhalation drug delivery system to deliver a wide range of drugs, including peptides, proteins and other macromolecule drugs to the deep lung. Inhale is using this system principally to enable non-invasive delivery of macromolecule drugs currently administered by injection. Inhale's lead program is inhaled insulin sponsored by Pfizer Inc. ("Pfizer") Pfizer initiated Phase III trials with an investigators meeting held November 7-9, 1998 to be followed with recruitment, enrollment and dosing of patients. Inhale has a variety of drug delivery programs in development and has tested six drugs in human clinical trials.

Currently there are approximately 30 macromolecule drugs marketed in the United States and about 120 others in human clinical trials. Sales of the top 15 genetically engineered protein drugs which are a subject of macromolecule drugs, were estimated at \$14 billion worldwide in 1997. Most of these drugs are currently delivered by injection. Injections are undesirable for numerous reasons including patient discomfort, inconvenience and risk of infection. Poor patient acceptance of, and compliance with, injectable therapies can lead to increased incidence of medical complications and higher disease management costs. Alternatives to injection such as oral, transdermal and nasal delivery have to date been shown generally to be commercially unattractive due to low natural bioavailability--the amount of drug absorbed from the delivery site into the bloodstream. As an alternative to the invasiveness of injection, Inhale believes a pulmonary delivery system could expand the market for macromolecule drug therapies and may enable new therapeutic uses of certain macromolecule drugs.

Inhale is creating a proprietary platform integrating customized formulation, fine-powder processing and packaging with a novel inhalation device to enable efficient, reproducible delivery of macromolecule drugs for systemic and local lung indications. For specific drug products, Inhale formulates and processes bulk drugs supplied by collaborative partners into fine powders which are packaged into individual dosing units referred to as blisters. The blisters are designed to be loaded into Inhale's device, which patients then activate to inhale the aerosolized drugs. Inhale has developed a prototype inhalation device that has been used several times per day, for several months in outpatient trials for insulin. In addition, Inhale has demonstrated room temperature stability of a year or more for a number of macromolecule drugs, and has scaled-up its powder processing and packaging for late stage clinical trials and small-scale production for certain drugs.

As an alternative to invasive delivery techniques, Inhale believes that a pulmonary delivery system could potentially expand the market for macromolecule drug therapies by increasing patient acceptance and improving compliance, which in turn could decrease medical complications and the associated costs of disease management. Additionally, pulmonary delivery may enable new therapeutic uses of certain macromolecule drugs. Inhale is focusing development efforts on applying its pulmonary delivery system primarily to drugs for systemic and local lung diseases that either have proven efficacy and are approved for delivery by injection or are in late stage human clinical trials.

Inhale's business strategy is to work with collaborative partners to develop and commercialize macromolecule drugs for pulmonary delivery. In a typical collaboration, Inhale's partner provides the drug, funds clinical development, and will market the resulting commercial product. Inhale supplies the delivery system and receives research and development and progress payments during development, and will receive revenue from powder manufacturing, device supply, and royalties from sales of any commercial products.

In addition to Pfizer's sponsorship of inhaled insulin, Inhale has alliances with a series of corporate partners. The Company's most recent agreement is with Biogen, Inc. ("Biogen") for pulmonary delivery of AVONEX-Registered Trademark-, a drug used in the treatment of multiple sclerosis. Inhale is also engaged in early stage

feasibility and preclinical research and development collaborations with Centeon L.L.C. ("Centeon") (a joint venture of Hoechst AG and Rhone-Poulenc Rorer, Inc.) on alpha-1 proteinase inhibitor for genetic emphysema; Genzyme Corporation on gene vectors for lung diseases; two projects with Eli Lilly and Company ("Lilly") and projects with Baxter Healthcare Corp. ("Baxter"), a subsidiary of Baxter International. Inhale anticipates that any product that may be developed would be commercialized with a collaborative partner and believes its partnering strategy will enable it to reduce the investment required to develop a large and diversified potential product portfolio.

While Inhale 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 Inhale'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 Inhale 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 Inhale's potential products will prove safe and effective in clinical trials, meet applicable regulatory standards, be capable of being produced in commercial quantities at acceptable cost or be successfully marketed to health care providers, payors or patients. In addition, there can be no assurance that Inhale's strategic relations with any and all of its partners will continue in the future. Any failure by Inhale to maintain or continue its partner relations, achieve technical feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or, together with partners, successfully market products, would have a material adverse effect on Inhale's business, financial condition and results of operations. See "Risk Factors" beginning on page 19.

OPPORTUNITY FOR PULMONARY DRUG DELIVERY

MACROMOLECULES

Innovations in biotechnology and recombinant techniques have led to a large increase in the number of macromolecule drugs over the last several years. These drugs, which are identical or similar to the body's natural molecules, are enabling new therapies for many previously untreated or poorly treated diseases. Approximately 30 macromolecule drugs are approved for marketing in the United States and approximately 120 additional macromolecule drugs are in human clinical trials, many for chronic and subchronic diseases. Sales of genetically engineered protein drugs were estimated at \$14 billion worldwide in 1997.

Due principally to their large size, most macromolecules typically have been delivered by injection. Drug injections administered in hospitals or doctors' offices can be expensive and inconvenient to patients. Many patients find self-injectable therapies unpleasant. As a result, such therapies for many chronic and subchronic diseases meet with varying degrees of patient acceptance and compliance with the prescribed regimens. Poor acceptance and compliance can lead to increased incidence of medical complications and potentially higher disease management costs. In addition, some elderly, infirm or pediatric patients cannot administer their own injections and require assistance, thereby increasing both inconvenience to these patients and the cost of therapy.

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

Oral delivery is a common method of delivery for many small molecule drugs. However, drug delivery scientists generally believe that oral delivery provides extremely low delivery system efficiency for most macromolecules. In addition, Inhale believes that dosage reproducibility for oral delivery of macromolecules may be very poor because of their low oral bioavailability. While several companies are

working on oral delivery for macromolecule drugs, no commercially viable system is currently being marketed.

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

The nasal route has been shown to have low and variable bioavailability for proteins and peptides, which is a major limitation for the nasal administration of such drugs. As a result of these limitations, penetration enhancers are often used with nasal delivery to achieve higher bioavailability; these enhancers may cause local irritation to the nasal tissue and result in safety concerns with long-term use. Only four peptides have been approved for marketing in the United States utilizing nasal delivery.

Pulmonary drug delivery systems, such as MDIs, existing dry powder inhalers and nebulizers, are used primarily to deliver drugs to the airways of the lung for local lung applications. Approximately 30 drugs are approved for marketing by the United States Federal Drug Administration ("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, Inhale believes that the total efficiency of such systems is generally not high enough to be commercially feasible for systemic delivery of most macromolecule drugs.

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

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

Inhale also believes that opportunities for a 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 for leveraging its technology for small molecules where there is a clear, demonstrable need for an alternative drug delivery system and where Inhale's existing technology can be applied without significant modification. Examples include molecules that require rapid systemic absorption for efficacy, i.e., analgesics and antiemetics, molecules that undergo massive first pass metabolism by the oral route or molecules used for local lung delivery for diseases such as asthma that are currently delivered by sub-optimal aerosol systems.

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

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

STRATEGY

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

- DEVELOP A BROADLY APPLICABLE PULMONARY DELIVERY SYSTEM. Inhale is developing its non-invasive pulmonary drug delivery system to be applicable to a wide range of peptides, proteins and other molecules currently delivered by injection or poorly delivered by inhalation or other routes. Inhale intends to develop an effective non-invasive delivery alternative that can: (i) expand market penetration for existing therapeutics currently delivered by injection, infusion or other routes; (ii) commercialize new indications by using pulmonary delivery as a new route of administration; and (iii) extend existing patents or seek new patents to gain important competitive advantages for Inhale and its partners.
- BUILD COMPETITIVE ADVANTAGE THROUGH AN INTEGRATED SYSTEMS APPROACH. Inhale is developing a commercially viable pulmonary delivery system through an integrated systems solution. Inhale combines its expertise in aerosol engineering, chemical engineering, mechanical engineering, aerosol science, protein formulations, fine powder processing and powder filling, and pulmonary physiology and biology to build a proprietary, fully-integrated system for pulmonary delivery of therapeutic drugs. Inhale believes that building expertise in technology across several disciplines provides it with a significant competitive advantage.
- PARTNER WITH PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES. Inhale's strategy is to market its proposed products through collaborative partners. Inhale is seeking to work with partners that have significant clinical development and marketing resources, and currently has collaborations with several large pharmaceutical and biotechnology companies. For patented drug products, Inhale intends to partner with owners or licensees from the outset of the project. For drugs that are off-patent or licensed-in, Inhale may perform initial feasibility screening work, formulations development and early stage human clinical trials before entering into a partner relationship for further

development. Inhale believes this partnering strategy enables it to reduce its cash requirements while developing a large and diversified potential product portfolio.

- FOCUS ON APPROVED OR LATE STAGE DRUGS. To date, Inhale has focused primarily on drugs that either have proven efficacy and are approved for marketing or are in late stage clinical trials. Inhale believes that working primarily with drugs with demonstrated efficacy reduces the technical risk of its projects. In the future, Inhale anticipates working on drugs at earlier stages of development.
- EXPAND MANUFACTURING CAPABILITY. Inhale intends to formulate, manufacture and package dry powders for most of its drugs and to subcontract manufacturing of its device. Inhale believes that this strategy will provide manufacturing economies of scale across a range of therapeutic products and expand capacity for additional partnerships and commercial scale production.

INHALE'S PULMONARY DELIVERY SYSTEM

Inhale believes that the following criteria are necessary for a commercially viable non-invasive drug delivery system:

- SYSTEM EFFICIENCY/COST: The system must attain a certain minimum efficiency in delivering a drug to the bloodstream as compared to injection. Bioavailability--the percentage of drug absorbed into the bloodstream from the lungs relative to that absorbed from injection is the most important element of system efficiency. Total system efficiency is critical due to the high cost of macromolecule drugs. Total delivery system efficiency is determined by the amount of drug loss during manufacture, in the delivery device, in reaching the site of absorption, and during absorption from that site into the bloodstream. Inhale believes that for most systemic macromolecule drugs, a non-invasive delivery system must show total delivery system efficiency of at least 5% to 25% compared to injection for the system to be commercially viable.
- REPRODUCIBILITY: The system must deliver a consistent and predictable amount of drug to the lung and into the bloodstream.
- FORMULATION STABILITY: Formulations used in the system must remain physically and chemically stable over time and under a range of storage conditions.
- SAFETY: The system should not introduce local toxicity problems during chronic or subchronic use by a wide patient population.
- CONVENIENCE: The system must be convenient to the patient in terms of comfort, ease of operation, transportability and required dosage time.

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

Inhale has chosen to base its pulmonary delivery system on dry powders for several reasons. Many proteins are more stable in dry powders than in liquids. In addition, dry powder aerosols can carry approximately five times more drug in a single breath than MDIs and, for many drugs, at least 25 times more than currently marketed liquid or nebulizer systems. Inhale believes that a dry powder system for drugs requiring higher doses, such as insulin, 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 Inhale's products will ever be successfully commercialized.

FORMULATIONS.

Each macromolecule drug poses different formulation challenges due to varying chemical and physical characteristics and dosing requirements. This requires significant optimization work for each specific drug. Inhale has assembled a team with expertise in protein formulations, powder science and aerosol science and is applying this expertise to develop proprietary techniques and methods that it believes will produce stable, fillable and dispersible dry powder drug formulations. Inhale has several protein powders with on-going room temperature stability (both chemical and physical) of more than one year. Through its work with numerous macromolecules, Inhale is developing an extensive body of knowledge on aerosol dry powder formulations, including knowledge relating to powder flow characteristics and solubility within the lung, as well as physical and chemical properties of various excipients. The Company has filed and expects to continue to file patent applications on several of its formulations. In June 1997, Inhale acquired the intellectual property portfolio of the BioPreservation Division of Pafra Limited ("Pafra") of Basildon, England. This portfolio included issued U.S. and foreign Letters Patent and pending applications relating to the stabilization of macromolecule drugs in dry formulations.

POWDER PROCESSING.

Inhale is modifying standard powder processing equipment and developing custom techniques to enable it to produce fine dry powders consistently with particle diameters of between one and five microns without drug degradation or significant loss of expensive bulk drug. Inhale has scaled up powder processing to sufficient levels for producing test powders for late stage clinical trials and small volume marketed products, if any. Inhale is in the process of scaling up its powder processing systems in order to produce quantities sufficient for commercial production of products Inhale believes it will need to supply in high volumes, such as insulin. However, there can be no assurance that Inhale will be successful in further scaling up its powder processing on a timely basis or at a reasonable cost, or that the powder processing system will be applicable for every drug.

POWDER PACKAGING.

Fine particle powders have special handling requirements that are different from those for larger particles. Current commercial filling and packaging systems are designed for filling larger particle powders and therefore must be modified to dispense finer particles more accurately and in the small quantities required. Initially, powder filling was performed manually. Inhale has since developed and qualified a proprietary automated filling system suitable for use in clinical trials and initial production quantities for certain products. Inhale is also developing with Pfizer a proprietary, high capacity system for production use.

INHALATION DEVICE.

Inhale's proprietary pulmonary delivery device is designed to provide deep lung delivery of therapeutic powders in a reproducible, safe and efficient manner. The first of a series of patents covering the device was granted in the United States in October 1995. See "Business--Patents and Proprietary Rights." To achieve this goal, Inhale has designed a prototype of its pulmonary delivery device to perform the following:

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

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

- EFFICIENTLY AND REPRODUCIBLY DELIVER THE AEROSOL CLOUD TO THE DEEP LUNG. Inhale has developed a proprietary aerosol cloud handling system in its device that facilitates deep lung powder deposition and reproducible patient dosing. The handling system design is intended to enable the aerosolized particles to be transported from the device to the deep lung during a patient's breath, reducing losses in the throat and upper airways. In addition, the aerosol cloud handling system, in conjunction with the dispersion mechanism and materials used in the device, is designed to reduce powder loss in the device itself.
- ELIMINATE THE USE OF PROPELLANTS TO AVOID ASSOCIATED ENVIRONMENTAL CONCERNS AND FORMULATION DIFFICULTIES. Unlike MDIs, the Inhale device does not use propellants. The oily surfactants required to stabilize propellant formulations can cause aggregation of macromolecules. Current chlorofluorocarbon propellants, which are used in most commercial MDI systems, are being phased out in many countries due to environmental concerns.

The success of Inhale's pulmonary drug delivery system for any drug will depend upon Inhale 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 that administered by injection for systemic indications, or the amount of drug delivered to the lung tissue for local lung indications. The initial screening factor for the feasibility of pulmonary delivery of any systemic macromolecule drug is pulmonary bioavailability, which measures the percentage of the drug absorbed into the bloodstream when delivered directly to the lungs. In addition, a certain percentage of each drug dose may be lost at various stages of the manufacturing and pulmonary delivery process in drug formulation, dry powder processing, packaging, and in moving the drug from a delivery device into the lungs. Excessive drug loss at any one stage or cumulatively in the manufacturing and delivery process would render a drug commercially unfeasible for pulmonary delivery. Formulation stability--the physical and chemical stability of the formulated drug over time and under various storage conditions and safety will vary with each macromolecule and the type and amount of excipients that are used in the formulation. Reproducible dosing--the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups requires the development of an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung, accurate unit dose packaging of dry powder formulations and moisture resistant packaging. There can be no assurance that Inhale will be able to successfully develop such an inhalation device or overcome such other obstacles to reproducible dosing.

CLINICAL STATUS SUMMARY

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

DRUG	INDICATIONS	CLINICAL STATUS	PARTNER STATUS
Human insulin.....	Type 1 and 2 diabetes	Phase III (patient recruitment)	Pfizer--active
Non-protein, non-peptide.....	Not released	Phase II	Baxter--on hold due to Baxter re-focus
Non-protein, non-peptide.....	Not released	Phase I	Baxter--minimum work while looking for new partner
PTH.....	Osteoporosis	Phase I	Lilly--minimum work while Lilly investigates problem with injectable version
Calcitonin.....	Osteoporosis, bone pain, Paget's disease	Phase I	Looking for partner
Interleukin-1 Receptor....	Asthma	Phase I/II	Immunex--on hold; waiting for partner activity
Alpha-1 Antitrypsin proteinase inhibitor....	Genetic emphysema	Preclinical	Centeon--active
Interferon beta.....	Multiple sclerosis	Preclinical	Biogen--active
Non-protein, non-peptide.....	Not released	Preclinical	Baxter--on hold due to Baxter re-focus

Definition of Clinical Status:

Phase III--broad out-patient clinical trials conducted to obtain information regarding specific patient groups conducted following encouraging safety and efficacy trials.

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

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

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

INHALE'S PULMONARY DRUG DELIVERY PROGRAMS IN PROGRESS

Inhale has a variety of programs in development, six of which have been tested in human clinical trials. In general, Inhale's partnership arrangements provide funding for development, payments upon the achievement of certain milestones and royalty and manufacturing revenues upon the commencement of commercial sales. The arrangements are cancelable by the partner at any time without significant penalty.

PFIZER PROGRAM.

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

According to the Centers for Disease Control and Prevention, more than 16 million people in the United States have diabetes--10.3 million are diagnosed with diabetes, another 5.4 million have undiagnosed diabetes, and 798,000 new cases are diagnosed each year. All Type 1 diabetics, estimated at between 5% and 15% of all diabetics, require insulin therapy. Type 1 diabetics generally require both a baseline treatment of long-acting insulin and multiple treatments of regular insulin throughout the day. Type 2

diabetics, depending on the severity of their case, may or may not require insulin therapy. Type 2 diabetics who use insulin are best treated with regular insulin and sometimes require long-acting insulin as well. Many Type 2 patients who do not require insulin to survive but would benefit from it are reluctant to start treatment because of the inconvenience and unpleasantness of injections.

Regular insulin is generally administered 30 minutes before mealtimes and generally is given only twice a day. A ten-year study by the National Institutes of Health ("NIH"), (the DCCT Research Group, published in the New England Journal of Medicine in Sept. 1993) 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.

Inhale and Pfizer are developing a regular insulin that can be administered in one to three blisters using its pulmonary delivery system. Inhale believes that its pulmonary delivery system could provide increased user convenience and result in greater patient compliance by eliminating some injections for Type 1 and Type 2 patients and all injections for some Type II patients. In addition, Inhale believes that pulmonary delivery could yield medical advantages by providing a more rapid acting insulin than certain current injectable products.

Through its collaboration with Inhale, Pfizer conducted Phase I and Phase IIa clinical trials which indicated that pulmonary insulin was absorbed systemically and reduced glucose levels and provides the same control of diabetes as does injected insulin. In October 1996, Pfizer initiated a multi-site Phase IIb outpatient trial to include up to 240 patients with diabetes mellitus. In June 1998, Pfizer announced the results of Phase IIb trials. In 70 Type 1 diabetics treated with either inhaled or conventional injected insulin therapy for three months, the levels of hemoglobin A1c, the best index of blood glucose control, were statistically equivalent. Virtually identical results were obtained in a group of Type 2 diabetics. In September 1998 Pfizer released additional Phase IIb data from the inhaled insulin trials which indicated that results from 56 of 69 patients in a three-month trial showed that individuals with Type 2 diabetes can markedly improve their glycemic control without insulin injections by combining Inhale's pulmonary insulin with oral diabetes agents.

In November 1998, Pfizer and Hoechst Marion Roussel AG announced that they entered into worldwide agreements to manufacture insulin, co-develop and co-promote inhaled insulin. Under the terms of the agreement, Pfizer and Hoechst Marion Roussel said they will construct a jointly owned manufacturing plant--one of the world's largest insulin production facilities of its kind in Frankfurt, Germany. Until its completion, Hoechst Marion Roussel will provide biosynthetic recombinant insulin from its existing plant to Inhale for powder processing. Inhale will continue to have responsibility for manufacturing powders and supplying devices and will receive a royalty on inhaled insulin products marketed jointly by Pfizer and Hoechst. Later in the same month, Pfizer held a meeting for 117 Phase III sites of the inhaled insulin trials to be followed by patient recruitment, enrollment and dosing.

Inhale has begun initial research funded by Pfizer on a long-acting inhaled insulin. Some diabetic patients require a long-acting insulin to maintain baseline insulin levels. A long-acting, inhalable form of insulin could be used by these patients as a supplement to short-acting, mealtime inhaled insulin. This program is part of a broader sustained release program announced by Inhale in January 1999.

In January 1995 and October 1996, Pfizer made two \$5 million equity investments in Inhale at a 25% premium to the market price of Inhale stock at the time of each investment. See "Risk Factors" beginning on page 19.

BAXTER PROGRAM.

In March 1996, Inhale entered into a collaboration agreement with Baxter to use Inhale's dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In connection with the collaboration, Baxter made a \$20 million equity investment in Inhale at a 25% premium to the market price of Inhale stock at the time of the investment. Baxter received worldwide commercialization rights for four non-protein/peptide drugs in exchange for up to an estimated \$60 million in research and development funding and progress payments. In April 1998 Inhale announced that the first two compounds from its collaboration with Baxter had successfully completed Phase I and Phase II trials respectively. In addition, it was announced that the program would focus on the product that had completed Phase I as it was the product with the most commercial potential. The technology from one of the three remaining products was returned to Inhale, leaving the development of the other two compounds on hold. In October 1998, Inhale announced that it had reached an agreement with Baxter to amend their collaborative agreement to facilitate signing a new corporate partner to fund further development and commercialization of the undisclosed compound that had been their focus since April 1998. Baxter will continue to provide development funding for this compound in preparation for Phase II trials while the two companies are seeking a new partner. See "Risk Factors" beginning on page 19.

ELI LILLY & COMPANY PROGRAMS.

In January 1997 Inhale entered into a collaborative agreement with Lilly to develop pulmonary delivery for a selected Lilly osteoporosis drug, parathyroid hormone (PTH 1-34). Osteoporosis is estimated to affect approximately 25 million Americans, mostly women. If not prevented or left untreated, osteoporosis can progress painlessly until a bone breaks. As many as 35,000 people die each year from a cause associated with hip fractures, primarily due to complications that result from surgery or from being confined to bed.

Under the terms of its agreement with Lilly, Inhale will receive up to an estimated \$20 million in initial fees, funding for research and progress payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products, with Inhale receiving royalties on any marketed products. Inhale will manufacture and package product with bulk drug supplied by Lilly and supply the inhalation devices.

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

In late 1998, unexpected observations from a long-term test in rats of the injectable version of this osteoporosis drug, parathyroid hormone, led Lilly to suspend further clinical development of the injectable and pulmonary versions of PTH pending further analysis. Inhale is maintaining a minimum development effort in its pulmonary program pending further direction from Lilly. Depending on the continued evaluations by Lilly, this inhalation program could be re-initiated, suspended for an extended period, or possibly terminated.

In January 1998 Lilly and Inhale entered into a second collaborative agreement to develop pulmonary delivery for an unspecified protein product based on Inhale's deep-lung delivery system for macromolecules. Under the terms of the agreement, Inhale will receive funding of up to \$20 million in research, development and milestone payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. Inhale will manufacture packaged powders for and supply inhalation devices to Lilly. See "Risk Factors" beginning on page 19.

CALCITONIN PROGRAM.

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

In April 1997 Inhale announced the successful completion of Phase I clinical trials to determine the safety and bioavailability of pulmonary delivery of a dry powder, aerosolized form of salmon calcitonin as a potential treatment for osteoporosis, Paget's disease, hypercalcemia and other bone diseases. The single-dose study conducted in the United Kingdom with a total of 36 fasted normal volunteers indicated that the drug was systemically absorbed through the pulmonary route when delivered with Inhale's system. Inhale is seeking a partner for further clinical development. Inhale is continuing work on this program. See "Risk Factors" beginning on page 19.

IMMUNEX PROGRAM.

Interleukin-1 is a cytokine that helps initiate the inflammatory response to foreign pathogens. Inhale collaborated with Immunex to develop pulmonary delivery of a therapeutic product for asthma. Initial formulation development and animal toxicology have been completed, and the two companies successfully completed Phase I/II trials demonstrating pulmonary delivery. This program is awaiting further work and/or licensing by Immunex. See "Risk Factors" beginning on page 19.

CENTEON PROGRAM.

In January 1997 Inhale and Centeon entered into a collaboration to develop a pulmonary formulation of alpha-1 antitrypsin to treat patients with alpha-1 antitrypsin deficiency. Alpha-1 antitrypsin is approved in the United States and several European countries for augmentation treatment of alpha-1 antitrypsin deficiency. Current treatment is given by systemic intravenous infusion on a weekly basis. This "replacement therapy" consists of a concentrated form of alpha-1 antitrypsin derived from human plasma. Under the terms of the collaboration, Centeon will receive commercialization rights worldwide excluding Japan and Inhale will receive royalties on product sales, an up-front signing fee and up to an estimated \$15 million in research and development funding and milestone payments. Centeon will manufacture the active ingredient for use in Inhale's delivery device. Inhale will manufacture and package the dry powder and supply inhalation devices to Centeon for commercialization and marketing.

The two companies have completed pre-clinical work that indicates Inhale's dry powder formulation of Centeon's alpha-1 antitrypsin has the potential to significantly improve the efficiency of delivery compared with current infusion therapy. Inhale believes its pulmonary delivery system could significantly reduce the amount of drug needed for genetic emphysema therapy since alpha-1 antitrypsin could be delivered directly to the lung. Centeon is currently negotiating to secure rights under patents that have been granted in Europe directed to aerosol formulations for the treatment of the lung containing serine protease inhibitors including alpha-1 antitrypsin. See "Risk Factors" beginning on page 19.

BIOGEN PROGRAM.

In February 1999 Inhale entered into a collaborative agreement with Biogen to develop pulmonary delivery for Biogen's AVONEX-Registered Trademark-. Under the terms of the agreement, Inhale will receive royalties on product sales, an up front signing fee, and up to an estimated \$25 million in research and development funding and potential progress payments. Biogen will provide bulk AVONEX-Registered Trademark- to Inhale for formulation into a room-temperature stable dry powder. Inhale will manufacture and package the dry powder and supply inhalation devices. Biogen will be responsible for clinical trials, marketing and commercialization. See "Risk Factors" beginning on page 19.

FOLLICLE STIMULATING HORMONE (FSH) PROGRAM.

FSH, a glycoprotein hormone secreted by the pituitary gland, has been utilized since the 1960s for treatment of infertility. In female reproduction, FSH is responsible for ovarian follicular growth and development. Therapeutic use of FSH has expanded since the 1970s. It is currently administered in a series of daily injections over one to three weeks to enhance follicle growth and ovum production. Inhale has demonstrated the feasibility of pulmonary FSH in an animal model and continues to work on this project.

GENZYME PROGRAM.

In July 1996 Inhale signed an agreement with Genzyme Corporation to examine the feasibility of developing dry powder formulations of gene vectors for pulmonary applications. Gene vectors are currently being investigated by several companies and academic institutions for use in treating lung diseases such as cystic fibrosis. Inhale believes that its delivery system is well suited for the delivery of gene therapies to treat lung disease because its system could provide efficiency, reproducibility, stability and containment advantages relative to alternative pulmonary delivery methods. Early stage research has shown that Inhale's dry powder formulations and powder processing technology can be used to make powders containing active gene vectors. The Company continues to do research on this project. See "Risk Factors" beginning on page 19.

INTERFERON ALPHA PROGRAM.

Interferon alpha is produced by a number of cell types in the body and serves to turn on an array of genes in cells for fighting viral infections. It has been approved for Hepatitis B and C (inflammatory viral diseases of the liver), hairy cell leukemia (a blood cancer), and AIDS-related Kaposi's sarcoma (a skin cancer prevalent in AIDS patients). There are at least five companies competing in the interferon alpha market, including Schering-Plough Corporation, Hoffmann-La Roche, Inc., Sumitomo Corp. and Otsuka Pharmaceutical Co., Ltd. Interferon alpha is currently given in all indications three times per week by subcutaneous injection. Inhale believes that a pulmonary delivery system could provide a competitive advantage in what is now an exclusively injectable market and could reduce the cost of treatment by enabling more home therapy. Inhale has completed feasibility testing, including animal studies, showing that interferon alpha is well absorbed systemically following pulmonary administration. Inhale continues to work on this project. See "Risk Factors" beginning on page 19.

There can be no assurance that Inhale will be able to enter into additional collaborations or that its feasibility agreements will lead to collaborations. There also can be no assurance that Inhale 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 Inhale to enter into or maintain such collaborative arrangements and feasibility agreements would have a material adverse effect on Inhale. See "Risk Factors," beginning on page 19.

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, Inhale must build and have validated a powder processing and packaging facility. Inhale must also select and have validated a device manufacturer. Inhale believes its manufacturing strategy will enable it to achieve the following: (i) provide economies of scale by utilizing manufacturing capacity for multiple products; (ii) improve its ability to retain any manufacturing know-how; and (iii) allow its customers to bring pulmonary delivery products to market faster.

Inhale has built a powder manufacturing and packaging facility in San Carlos, California capable of producing powders in quantities sufficient for human clinical trials and commercial launch. This facility has been inspected and licensed by the State of California and is used to manufacture and package powders under Good Manufacturing Practices ("GMP"). Inhale intends to expand the facility to meet its future commercial manufacturing commitments.

Inhale is working to further scale up its powder processing to a larger production scale system and to further develop the necessary powder packaging technologies. Fine particle powders and small quantity powder packaging (such as those to be used in Inhale's delivery system) require special handling. Current commercial packaging systems are designed for filling larger quantities of larger particle powders and therefore must be modified to dispense finer particles in the small quantities required by Inhale. Inhale has developed and validated a proprietary small scale prototype automated filling system which Inhale believes is capable of supporting its requirements through Phase III trials and into commercial production for some products. Inhale is developing a higher capacity automated filling unit capable of filling blisters on a production scale for moderate and large volume products. Inhale faces significant technical challenges in developing an automated, commercial-scale filling system that can accurately and economically handle the small dose and particle sizes of its powders. There can be no assurance that Inhale will be able to develop or acquire the technology necessary to develop successfully any such system in a timely manner or at commercially reasonable cost. Any failure or delay in developing such technology would delay product development or bar commercialization of Inhale's products and would have a material adverse effect on Inhale. See "Risk Factors" beginning page 19.

A new prototype inhalation device has been developed for commercial use and will be used in the Phase III insulin and other trials in 1999. Inhale plans to subcontract the manufacture of its pulmonary delivery devices before commercial production of its first product. Inhale has identified contract manufacturers that it believes have the technical capabilities and production capacity to manufacture its devices and which can meet the requirements of 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. Inhale's dependence upon third parties for the manufacture of its potential inhalation device may adversely affect Inhale's cost of goods and its ability to develop and commercialize products on a timely and competitive basis.

GOVERNMENT REGULATION

The research and development, manufacture and marketing of pulmonary drug delivery systems are subject to regulation by the FDA in the United States and by comparable regulatory agencies in other countries. These national agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of Inhale's products.

The process required by the FDA before a pulmonary drug delivery system may be marketed in the United States depends on whether the compound has existing approval for use in other dosage forms. If

the drug is a new chemical entity that has not been approved, the process includes the following: (i) pre-clinical laboratory and animal tests; (ii) the filing of an Investigational New Drug application ("IND"); (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug in its intended indication; and (iv) submission to the FDA for approval of a New Drug Application ("NDA") with respect to drugs or a Biological License Application ("BLA") with respect to biologics. If the drug has been previously approved, the approval process is similar, except that certain toxicity tests normally required for the IND and NDA/BLA application may not be necessary.

Pre-clinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulation. Pulmonary systems must be formulated according to GMP, and pre-clinical safety tests must be conducted by laboratories that comply with FDA Good Laboratory Practices regulations. The results of the pre-clinical tests are submitted to the FDA as part of an IND application and are reviewed by the FDA before human clinical trials begin. The IND application becomes effective 30 days after receipt by the FDA, unless the FDA raises objections.

Clinical trials involve the administration of the drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. Each clinical study is conducted under the auspices of an independent Institutional Review Board ("IRB"). The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into healthy human subjects, the product generally is tested for safety, dosage tolerance, pharmacokinetics, absorption, metabolism and excretion. Phase II involves studies in a limited patient population to (i) determine the efficacy of the product for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage, and (iii) identify possible adverse effects and safety risks. When Phase II evaluations demonstrate that dosing the drug by the pulmonary system is effective and has an acceptable safety profile, Phase III trials are undertaken to evaluate further clinical efficacy and safety within an expanded patient population at geographically dispersed clinical study sites. The FDA, the clinical trial sponsor, the investigator or the IRB may suspend clinical trials at any time if it believes that clinical subjects are being exposed to an unacceptable health risk.

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

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

Many of the drugs with which Inhale is working are already approved for marketing by the FDA. Inhale believes that when working with approved drugs, the approval process for delivery by pulmonary

delivery may require less time and fewer tests than for new chemical entities. However, Inhale expects that its formulations often will use excipients not currently approved for pulmonary use. Use of these excipients will require additional toxicological testing that may increase the costs of, or lengthen the time in, gaining regulatory approval. In addition, regulatory procedures applicable to Inhale's products may change as regulators gain experience in the area of macromolecules, and any such changes may delay or increase the cost of regulatory approval.

Inhale's device will not be developed as an independent product but will be an inseparable part of the pulmonary drug delivery system for each specific molecule. Prior to or at the time of submission of the IND, the FDA Center and division within the Center will be identified to be responsible for the review of the IND and NDA/BLA. In the case of Inhale's products, either the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research, in consultation with the Center for Devices and Radiological Health, will be involved in the review. However, one Center is designated as the Center which has the lead responsibility for regulating the product. The jurisdiction within the FDA is based on the primary mode of action of the drug and is identified in the FDA's intercenter agreement.

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

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

PATENTS AND PROPRIETARY RIGHTS

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

Inhale expects that its integrated system for 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 Inhale's strategy to build proprietary positions in each of its technological areas. Inhale's success will depend in part upon its ability to protect its proprietary technology from infringement, misappropriation, duplication and discovery. Inhale has filed patent applications covering certain aspects of its device and powder processing technology and powder formulations and pulmonary route of delivery for certain molecules, and plans to file additional patent applications. On October 17, 1995, Inhale received United States Patent No. 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, Inhale received United States Patent No. 5,607,915 from the United States Patent Trademark Office for pulmonary delivery of active fragments of parathyroid hormone (PTH) 1-34. On October 17, 1997, Inhale was granted United States Patent No. 5,654,007 covering a system and methods for processing fine dispersible powders for easier processing. There can be no assurance that any of the patents applied for by Inhale will issue, or that any patents that issue will be valid and enforceable. Even if such patents are enforceable, Inhale anticipates that any attempt to enforce its patents could be time consuming and costly.

In 1998 Inhale was granted an additional six patents by the PTO. United States Patent No. 5,775,320 issued July 7, 1998, covers the method and means for dispersing a dry-powder or liquid drug, and transferring the drug in its aerosolized "cloud" form to a holding chamber where it is held until a patient is ready to inhale. The patent also covers a way to pull in atmospheric "chase" air following the initial inhalation to help push the drug into the deep lung. United States Patent No. 5,740,794, issued April 21, 1998, covers a method and means to access a packaged drug, to break up a dry powder drug into particles with compressed air (aerosolize), and to transport the aerosolized drug into a holding chamber. United States Patent No. 5,785,049, issued July 28, 1998, contains 50 claims directed to methods and means for aerosolizing dry powders through use of a high pressure gas stream to draw dry powder from a receptacle such as a blister. Inhale utilizes the design described in this patent to enable efficient aerosolization of fine dry powders to enable deep lung delivery for systemic absorption. United States Patent No. 5,780,014 issued July 14, 1998, covers methods and means for pulmonary delivery of dry powder alpha-1 antitrypsin for administration to a patient. United States Patent No. 5,814,607, issued September 29, 1998, extends Inhale's coverage of pulmonary delivery of active fragments of parathyroid hormone (PTH), a macromolecule being developed by pharmaceutical companies to treat osteoporosis. United States Patent No. 5,826,633 covers Inhale's powder handling technologies. Included under the patent is the process of transferring fine powder particles into blister packs in an un-compacted state so that they can be easily dispersed in Inhale's pulmonary delivery system.

In April 1998 Inhale and Initiatech Inc. signed an agreement under which Inhale will license technology, intellectual property, and patents for protecting biologically active compounds in the dry state. Inhale plans to use this technology to expand its current technology base in stabilizing dry powder aerosol formulations for peptides, proteins, and other macromolecules at room temperature. Inhale's license will be exclusive for the fields of respiratory delivery of pharmaceutical products and for any delivery form of insulin. The license includes rights to two issued United States patents and a pending foreign application covering the protection of biological materials from degradation. Initiatech has exclusive rights to this technology from the Boyce Thompson Institute for Plant Research Inc., (BTI) including the right to sub-license.

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

In June 1997 Inhale acquired the intellectual property portfolio of the BioPreservation Division of Pafra. This portfolio includes issued U.S. and foreign Letters Patent and pending applications relating to the stabilization of macromolecule drugs in dry formulations. A granted European patent included in this portfolio is currently the subject of an opposition proceeding before the European Patent Office and Inhale is continuing the defense of this patent, the opposition to which was initiated prior to the

acquisition. There can be no assurance that Inhale will be successful in the defense of this opposition proceeding. In addition, there can be no assurance that any of the Pafra patent applications will issue, or that any Pafra patents will be valid and enforceable. The loss of the opposition proceeding or the inability to obtain or defend the Pafra patents could have a material adverse effect on Inhale. See "Risk Factors" beginning on page 19.

Inhale has obtained license rights to certain know-how and patent applications owned by Genentech, Inc. covering formulations and powder processing and pulmonary delivery of certain molecules, which it believes could be important to the development of its business. These license rights are worldwide, nonexclusive, sublicensable and royalty free. Recently, Genentech successfully defended an opposition proceeding involving a pending European patent licensed to Inhale. This decision is currently on appeal. The pending patent covers the pulmonary delivery of cytokines and growth factors.

SCIENTIFIC ADVISORS

Inhale has assembled scientific and development advisors that provide Inhale expertise in critical scientific, development, engineering, manufacturing and business issues facing Inhale. The scientific advisory group assists Inhale on issues related to pulmonary delivery, pulmonary toxicology, aerosol science, government regulation, product selection and clinical trial design. Its members are called upon individually as needed and include:

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

EMPLOYEES AND CONSULTANTS

As of December 31, 1998, Inhale had 205 full time employees, of which 168 were engaged in research and development (including manufacturing) activities and 37 in general administration and business development. Eighty-nine of the employees hold advanced degrees, of which 44 are Ph.D.s. Inhale employs scientists and engineers with expertise in the areas of pulmonary biology, aerosol science, mechanical engineering, protein chemistry and chemical engineering. None of Inhale's employees are covered by a collective bargaining agreement and Inhale has experienced no work stoppages. Inhale believes that it maintains good relations with its employees.

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

RESEARCH AND DEVELOPMENT

Research and development expenditures totaled \$35.4 million, \$23.6 million, \$14.4 million for the years ended December 31, 1998, 1997 and 1996 respectively. Research and development expenditures funded by partners were approximately \$21.8 million, \$16.2 million and \$6.9 million for the years ended December 31, 1998, 1997 and 1996 respectively.

THIRD-PARTY REIMBURSEMENT

In both domestic and foreign markets, sales of Inhale'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 Inhale'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 Inhale's proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services. See "Risk Factors" beginning on page 19.

RISK FACTORS

THE FOLLOWING RISK FACTORS SHOULD BE READ CAREFULLY IN CONNECTION WITH EVALUATING INHALE'S BUSINESS. ANY OF THE FOLLOWING RISKS COULD MATERIALLY ADVERSELY AFFECT INHALE'S BUSINESS, OPERATING RESULTS OF FINANCIAL CONDITION.

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

We are in an early stage of development. There is a risk that our deep lung delivery technology will not be technically feasible. Even if our deep lung delivery technology is technically feasible, it may not be commercially accepted across a range of large and small molecule drugs. We have tested six of our thirteen deep lung delivery formulations in humans. The deep lung formulations tested in humans are insulin, interleukin-1 receptor, salmon calcitonin, an osteoporosis drug and two small molecules.

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

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

We may not be able to achieve the total system efficiency needed to be competitive with alternative routes of delivery. System efficiency is the product of the deep lung bioavailability of a potential product and the percentage of each drug dose lost at various stages of the manufacturing and deep lung delivery process. Deep lung bioavailability is the percentage of a drug that is absorbed into the bloodstream when that drug is delivered directly to the lungs. This is the initial screen for whether deep lung delivery of any systemic drug is feasible.

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

We may not be able to identify and produce powdered versions of drugs that retain the physical and chemical properties needed to work with our delivery device. Formulation stability is the physical and chemical stability of the drug over time and under various storage conditions. Formulation stability will vary with each deep lung formulation and the type and amount of ingredients that are used in the formulation. We would not consider a drug as a good candidate for development and commercialization if its dose loss is excessive at any one stage or cumulatively in the manufacturing and delivery process or if its deep lung bioavailability is too low. Problems with powdered drug stability would seriously impact our ability to develop and market our potential products.

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

We may not be able to prove potential products to be safe.

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

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

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

- an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung;
- accurate unit dose packaging of dry powder formulations; and
- moisture resistant packaging.

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

WE DO NOT KNOW IF OUR TECHNOLOGIES CAN BE INTEGRATED IN TIME TO BRING PRODUCT TO MARKET.

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

- dry powder formulations;
- dry powder processing technology;
- dry powder packaging technology; and
- deep lung delivery devices.

At the same time we must:

- establish collaborations with partners;
- perform laboratory and clinical testing of potential products; and
- scale-up our manufacturing processes.

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

OUR DEEP LUNG DELIVERY SYSTEM MAY NOT BE COMMERCIALY ACCEPTED.

We may not be able to achieve commercial viability of our deep lung delivery system. In order to sell any potential product, we must make it commercially acceptable to the market. This means that we must:

- further refine our device prototype;
- complete scale-up of our powder processing system; and
- complete scale-up of our automated packaging system.

The failure to demonstrate deep lung bioavailability, achieve total system efficiency, provide safe, reproducible dosages of stable formulations or advance on a timely basis the numerous aspects of product and business development will seriously impact the amounts of our revenues and our results of operations.

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

We have never been profitable and, through December 31, 1998, have incurred a cumulative deficit of approximately \$56.0 million. We expect to continue to incur substantial and increasing losses over at least the next several years as we expand our research and development efforts, testing activities and manufacturing operations, and as we complete our late stage clinical and early commercial production facility. All of our potential products are in research or in the early stages of development except for our insulin collaboration. We have generated no revenues from approved product sales. Our revenues to date have consisted primarily of payments under short-term research and feasibility agreements and development contracts. To achieve and sustain profitable operations, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products using our deep lung drug delivery system. There is a risk that we will not generate sufficient product or contract research revenue to become profitable or to sustain profitability.

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

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

- make bulk drugs to be used as medicines;
- design and carry out large scale clinical studies;
- prepare and file documents necessary to obtain government approval to sell a given drug product; and
- market and sell our products when and if they are approved.

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

WE DO NOT KNOW IF WE WILL BE ABLE TO PRODUCE OUR PRODUCTS IN COMMERCIAL QUANTITIES.

We must scale-up our current powder processing and filling facilities and comply with the good manufacturing practice standards prescribed by the United States Food and Drug Administration and other standards prescribed by other regulatory agencies to achieve drug production levels that are adequate to support late stage human clinical testing and early commercial sales.

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

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

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

We face many technical challenges in further developing our inhalation device to work with a broad range of drugs, to produce such a device in sufficient quantities and to adapt the device to different powder formulations. There is a risk that we will not successfully achieve any of these things. Our failure to overcome any of these challenges will impact our revenues and results of operations.

For late stage clinical trials and initial commercial production, we intend to use one or more contract manufacturers to produce our device. There is a risk that we will not be able to enter into or maintain arrangements with any potential contract manufacturers, and that the failure to do so will impact our revenues and results of operations.

WE DO NOT KNOW IF THE MARKET WILL ACCEPT INHALE'S DEEP LUNG DELIVERY SYSTEM.

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

- the safety and efficacy results of our clinical trials;
- favorable regulatory approval and product labeling;
- the frequency of product use;
- the availability of third-party reimbursement;
- the availability of alternative technologies; and
- the price of our products relative to alternative technologies.

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

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

Inhale has filed patent applications covering certain aspects of our device, powder processing technology, and powder formulations and deep lung route of delivery for certain molecules, and we plan to file additional patent applications. Currently we have 27 issued U.S. and foreign patents that cover certain aspects of our technology and we have a number of patent applications pending. There is a risk that any of the patents applied for will not issue, or that any patents that issue or have issued will not be valid and enforceable. Enforcing our patent rights would be time consuming and costly.

We are aware of an alternate dry powder processing technology that we are not using for our current products under development but may desire to use for certain products in the future. The ownership of this powder processing technology is unclear. We are aware that multiple parties, including Inhale, claim patent, trade secret and other rights in the technology. If we determine that this alternate powder processing technology is relevant to the development of future products and further determine that a license to this alternate powder processing technology is needed, we cannot be certain that we can obtain a license from the relevant party or parties on commercially reasonable terms, if at all.

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

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

WE MAY NOT OBTAIN REGULATORY APPROVAL.

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

In addition, we may encounter delays or rejections based upon changes in the United States Food and Drug Administration policy, including policy relating to good manufacturing practice compliance, during the period of product development. We may encounter similar delays in other countries.

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

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

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

OUR COMPETITORS MAY DEVELOP AND SELL BETTER DRUG DELIVERY SYSTEMS.

We are aware of other companies engaged in developing and commercializing pulmonary drug delivery systems and enhanced injectable drug delivery systems. Many of these companies have greater

research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do and represent significant competition for us. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' financial, marketing and other resources. Accordingly, our competitors may succeed in developing competing technologies, obtaining United States Food and Drug Administration approval for products or gain market acceptance before us. We cannot assure that developments by others will not make our products or technologies uncompetitive or obsolete.

WE EXPECT OUR STOCK PRICE TO REMAIN VOLATILE.

Our stock price is volatile. In the last twelve months our stock price ranged from \$20 1/8 to \$36 1/2 and we expect it to remain volatile. A variety of factors may have a significant effect on the market price of our common stock, including:

- fluctuations in our operating results;
- announcements of technological innovations or new therapeutic products;
- announcement or termination of collaborative relationships by Inhale or our competitors;
- governmental regulation;
- clinical trial results;
- developments in patent or other proprietary rights;
- public concern as to the safety of drug formulations developed by Inhale or others; and
- general market conditions.

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

INVESTORS SHOULD BE AWARE OF INDUSTRY-WIDE RISKS.

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

- handling of hazardous materials;
- hiring and retaining qualified people; and
- insuring against product liability claims.

ITEM 2. PROPERTIES

Inhale currently leases approximately 140,000 square feet in San Carlos, California and 20,000 square feet in Palo Alto, California. The Palo Alto facility is used for research, development and administration. The lease has a five year term, and expires on May 31, 2003.

The San Carlos facility is leased pursuant to a 15-year lease agreement. The San Carlos facility serves as the Company's corporate headquarters and is used for research and development, manufacturing and administration. The lease provides Inhale with an option to lease approximately 80,000 additional square feet in the same facility. This manufacturing facility operates under Good Manufacturing Practices and has been approved and licensed by the State of California to manufacture clinical supplies for use in human clinical trials.

In October 1998 the Company acquired 4.7 acres of land adjacent to its San Carlos facility. The Company intends to use this property to expand future operations.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

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

No matters were submitted to a vote of Inhale's stockholders in the quarter ended December 31, 1998.

EXECUTIVE OFFICERS OF THE REGISTRANT

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

NAME	AGE	POSITION
Robert B. Chess.....	42	Co-Chief Executive Officer and Director
Ajit S. Gill.....	50	Co-Chief Executive Officer and Director
Stephen L. Hurst.....	43	General Counsel
John S. Patton, Ph.D.....	52	Vice President, Research and Director
Robert M. Platz.....	47	Vice President, Technology

ROBERT B. CHESS has served as Co-Chief Executive Officer since August 1998. Mr. Chess served as President of Inhale from December 1991 to August 1998 and as Chief Executive Officer from May 1992 to September 1998. Mr. Chess was also elected a Director of Inhale in May 1992. From September 1990 until October 1991, he was an Associate Deputy Director in the White House Office of Policy Development. In March 1987, Mr. Chess co-founded Penederm Incorporated ("Penederm"), a topical dermatological drug delivery company, and served as its President until February 1989. He left Penederm in October 1989. Prior to co-founding Penederm, Mr. Chess held management positions at Intel Corp., a semiconductor manufacturer, and Metaphor, a computer software company (acquired by International Business Machines). Mr. Chess holds a BS in Engineering from the California Institute of Technology and an MBA from the Harvard Business School.

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

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

JOHN S. PATTON, PH.D., a co-founder of Inhale, has been Vice President, Research since December 1991 and a Director of Inhale since July 1990. He served as President of Inhale from its incorporation in July 1990 to December 1991. From 1985 to 1990, Dr. Patton was a Project Team Leader with Genentech, Inc., a biotechnology company, where he headed their non-invasive drug delivery activities.

Dr. Patton was on the faculty of the Marine Science and Microbiology Departments at the University of Georgia from 1979 through 1985, where he was granted tenure in 1984. Dr. Patton received a BS in Zoology and Biochemistry from Pennsylvania State University, an MS from the University of Rhode Island, a Ph.D. in Biology from the University of California, San Diego and received post doctorate fellowships from Harvard Medical School and the University of Lund, Sweden both in biomedicine.

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

PART II

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

PRICE RANGE OF COMMON STOCK

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

	PRICE RANGE OF COMMON STOCK	
	HIGH	LOW
YEAR ENDED DECEMBER 31, 1997:		
1st Quarter.....	\$ 22.625	\$ 15.125
2nd Quarter.....	25.000	18.375
3rd Quarter.....	33.625	18.750
4th Quarter.....	36.500	25.000
YEAR ENDED DECEMBER 31, 1998:		
1st Quarter.....	\$ 34.250	\$ 25.250
2nd Quarter.....	34.000	23.125
3rd Quarter.....	29.750	21.750
4th Quarter.....	33.375	21.500

As of December 31, 1998, there were approximately 184 holders of record of Inhale's Common Stock. Inhale has not paid any cash dividends since its inception and does not intend to pay any cash dividends in the foreseeable future.

On December 11, 1998, Inhale sold 1,200,000 shares of its common stock to funds affiliated with Capital Research and Management Company, an accredited investor, for aggregate cash consideration of \$37,200,000 pursuant to the exemption from registration provided by 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				
	1998	1997	1996	1995	1994
STATEMENT OF OPERATIONS DATA:					
Contract revenue.....	\$ 21,795	\$ 16,249	\$ 6,890	\$ 3,445	\$ 1,651
Operating costs and expenses:					
Research and development.....	35,398	23,645	14,376	9,041	4,934
General and administrative.....	8,387	6,328	4,004	3,232	2,465
Total operating costs and expenses.....	43,785	29,973	18,380	12,273	7,399
Loss from operations.....	(21,990)	(13,724)	(11,490)	(8,828)	(5,748)
Net loss.....	\$ (18,356)	\$ (9,983)	\$ (9,909)	\$ (7,662)	\$ (5,279)
Net loss per share.....	\$ (1.17)	\$ (0.72)	\$ (0.88)	\$ (0.78)	\$ (0.86)
Shares used in computation of net loss per share (1).....	15,719	13,792	11,207	9,837	6,103

	DECEMBER 31,				
	1998	1997	1996	1995	1994
(IN THOUSANDS)					
BALANCE SHEET DATA:					
Working capital.....	\$ 71,784	\$ 83,811	\$ 31,304	\$ 17,701	\$ 13,451
Total assets.....	134,496	119,762	41,492	23,248	17,249
Equipment financing obligations, less current portion.....	9	135	187	353	460
Tenant improvement loan, less current portion.....	4,931	4,967	--	--	--
Accumulated deficit.....	(56,018)	(37,662)	(27,679)	(17,770)	(10,108)
Stockholders' equity.....	115,881	97,093	35,061	20,182	15,427

No cash dividends have been paid.

(1) Basic and diluted net loss per share is based upon the weighted average number of common shares outstanding. All share amounts have been adjusted to reflect the implementation of FASB Statement No. 128 and Staff Accounting Bulletin No. 98. See Note 1 of Notes to Financial Statements.

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

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

OVERVIEW

Since its inception in July 1990, Inhale has been engaged in the development of a pulmonary system for the delivery of macromolecules and other drugs for systemic and local lung applications. Inhale has been unprofitable since inception and expects to incur significant and increasing additional operating

losses over the next several years primarily due to increasing research and development expenditures and expansion of manufacturing facilities. To date, Inhale has not sold any products and does not anticipate receiving revenue from product sales or royalties for at least the next several years. For the period from inception through December 31, 1998, Inhale incurred a cumulative net loss of approximately \$56.0 million. Inhale's sources of working capital have been equity financings, financings of equipment acquisitions and tenant improvements, interest earned on investments of cash, and revenues from short term research and feasibility agreements and development contracts.

Inhale typically has been compensated for research and development expenses incurred during initial feasibility work as well as for work performed under collaborative arrangements. Partners that enter into collaborative agreements generally pay for research and development expenses and make additional payments to Inhale as Inhale achieves certain key milestones. These additional payments are intended to fund the continued development of the Company's technology. Inhale expects to receive royalties from its partners based on revenues received from product sales, and to receive revenue from the manufacturing of powders and the supply of devices. In certain cases, Inhale may enter into collaborative agreements under which Inhale's partners would manufacture powders or supply inhalation devices, thereby potentially limiting one or more sources of revenue for Inhale. To achieve and sustain profitable operations, Inhale, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products utilizing its pulmonary drug delivery system. There can be no assurance that Inhale will be able to generate revenue from commercial products or generate sufficient product or contract research revenue to become profitable or to sustain profitability.

RESULTS OF OPERATIONS

YEARS ENDED DECEMBER 31, 1998, 1997 AND 1996

Contract research revenue was \$21.8 million for the year ended December 31, 1998 compared to \$16.2 million and \$6.9 million for the years ended December 31, 1997 and 1996, respectively. Revenue increased 34% in 1998 from 1997 levels and 136% in 1997 from 1996 levels. Costs of contract research revenue approximate such revenue and are included in operating costs and expenses.

The 34% increase in revenue for the year ended December 31, 1998 as compared to December 31, 1997 was primarily due to the increase in activities under Inhale's existing collaborative agreement with Pfizer. The increase in activity under the Pfizer collaboration was primarily related to manufacturing scale-up and clinical supply production. Contract revenues are expected to fluctuate from year to year, and future contract revenues cannot be predicted accurately. The level of contract revenues depends in part upon future success in obtaining new collaborative agreements, timely completion of feasibility studies, the continuation of existing collaborations and achievement of milestones under current and future agreements.

Research and development expenses were \$35.4 million for the year ended December 31, 1998, as compared to \$23.6 million and \$14.4 million for the years ended December 31, 1997 and 1996, 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, clinical manufacturing costs, laboratory supplies, consulting services, facilities, costs of obtaining intellectual property protection for Inhale's technologies and expenses associated with the development of manufacturing processes. The \$11.8 million increase in research and development expenses in 1998 from 1997 was primarily attributable to the development of infrastructure necessary to manufacture the Company's products on a late stage clinical scale. The \$9.3 million increase in research and development expenses in 1997 from 1996 was primarily attributed to continued expansion of research activities resulting from an increase in the number of projects and the hiring of additional scientific personnel required to support the increased number of projects. Inhale expects research and development spending to increase over the next few years as Inhale

expands its development efforts under collaborative agreements and plans, builds and scales up a late stage clinical and early commercial manufacturing facility.

General and administrative expenses were \$8.4 million for the year ended December 31, 1998 as compared to \$6.3 million and \$4.0 million for the years ended December 31, 1997 and 1996, respectively. The \$2.1 million increase in general and administrative expenses in 1998 from 1997 and the \$2.3 million increase in 1997 from 1996 were due primarily to costs associated with supporting Inhale's increased research efforts including administrative staffing, business development activities and marketing activities. General and administrative expenses are expected to continue to increase over the next few years as Inhale expands its research, development and manufacturing activities.

Interest income was \$3.9 million for the year ended December 31, 1998 as compared to \$3.8 million and \$1.6 million for the years ended December 31, 1997 and 1996, respectively. The 3% increase in interest income in 1998 from 1997 was due to Inhale maintaining larger cash and investment balances. The 132% increase in interest income in 1997 from 1996 was primarily a result of Inhale receiving research funding and milestone payments from collaborative partners, the completion of a private placement of Inhale's Common Stock in February 1997 which raised net proceeds of \$30.5 million as well as the completion of a public offering of Inhale's Common Stock in November 1997 which raised net proceeds of \$40.0 million.

At December 31, 1998, Inhale had federal net operating loss carryforwards of approximately \$47.2 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

Inhale 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, Inhale raised net proceeds of approximately \$14.4 million and raised additional net proceeds of \$7.2 million in its public offering completed in March 1995. On February 7, 1997 Inhale completed a private placement of its Common Stock, selling 1.8 million newly issued shares for net proceeds of \$30.5 million. In November 1997 Inhale completed a public offering of its Common Stock, selling 1.725 million newly issued shares for net proceeds of \$40.0 million. In May 1997, Inhale obtained a \$10 million line of credit which may be drawn upon to finance the purchases of equipment and facility improvements. As of December 31, 1998, Inhale had not drawn on this line of credit. The line of credit expires in May 1999. Inhale secured a \$5 million loan in November 1997 to also finance the purchases of equipment and facility improvements. In December 1998, Inhale completed a private placement of its Common Stock, selling 1.2 million newly issued shares for net proceeds of \$35.2 million. At December 31, 1998, Inhale had cash, cash equivalents and short-term investments of approximately \$82.9 million.

Inhale's operations used cash of \$19.2 million, provided cash of \$5.0 million and used cash of \$5.8 million in the years ended December 31, 1998, 1997 and 1996, respectively. These amounts differed from Inhale's net operating losses in these periods principally due to increases in accounts payable and accrued liabilities, depreciation expenses and deferred revenue. Additionally, in 1998 Inhale recorded a non-cash transaction of \$284,000 in connection with the completion of two licensing agreements.

Inhale purchased property and equipment of approximately \$34.6 million, \$17.3 million and \$2.2 million during the years ended December 31, 1998, 1997 and 1996, respectively. The increase for the year ended December 31, 1998 is primarily due to the build out of Inhale's manufacturing facility and corporate headquarters located in San Carlos, California. In addition, the Company acquired land adjacent to the current facility for approximately \$7.4 million which will be used to support future expansion.

Inhale expects its cash requirements to increase due to expected increases in expenses related to the further research and development of its technologies resulting from a larger number of projects, development of drug formulations, process development for the manufacture and filling of powders and devices, marketing and general and administrative costs. These expenses include, but are not limited to, increases in personnel and personnel related costs, purchases of capital equipment, inhalation device prototype construction and facilities expansion, including the planning and building of a late stage clinical and early stage commercial manufacturing facility.

Inhale believes that its cash, cash equivalents and short-term investments as of December 31, 1998 together with interest income and possible additional equipment financing, will be sufficient to meet its operating expense and capital expenditure requirements at least through the first half of 2000. However, Inhale's capital needs will depend on many factors, including continued scientific progress in its research and development arrangements, progress with pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of developing and the rate of scale-up of Inhale's powder processing and packaging technologies, the timing and cost of its late-stage clinical and early commercial production facility, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technologies and the status of competitive products. To satisfy its long-term needs, Inhale intends to seek additional funding, as necessary, from corporate partners and from the sale of securities. There can be no assurance that additional funds, if and when required, will be available to Inhale on favorable terms, if at all.

YEAR 2000 COMPLIANCE

The Company is aware of the issues associated with the programming code in existing computer systems as the millennium (Year 2000) approaches. The Year 2000 ("Y2K") problem is pervasive and complex as virtually every computer operation may be affected in some way by the rollover of the two digit year value to "00". The issue is whether systems will properly recognize date sensitive information when the year changes to 2000. If the Company's software and firmware with date-sensitive functions are not Y2K compliant, they may recognize a date with "00" as the year 1900 rather than the year 2000. This could result in a system failure or miscalculations causing disruptions of operations, including, among other things, interruptions in manufacturing operations, a temporary inability to process transactions, or engage in similar normal business activities.

The Company is utilizing both internal and external resources to conduct a comprehensive review of its systems to identify those systems that could be affected by the Y2K problem and has developed an implementation plan to resolve the issue by the end of 1999. The scope of the Y2K effort includes information technology ("IT") such as software and hardware, non-IT systems or embedded technology such as microcontrollers contained in various manufacturing and lab equipment, environmental and safety systems, facilities and utilities, and the Y2K readiness of key third parties such as suppliers and financial institutions. A multi-step Y2K readiness plan has been developed for its internal systems. This plan includes the following elements: 1) Awareness - raising the Company's awareness of the Y2K issue; 2) Discovery - keeping an inventory and monitoring the compliance status of key financial, informational and operations systems subject to Y2K issues; 3) Assessment - determining both the business impact of noncompliance and the likelihood of noncompliance from each of the entities in the inventory; 4) Validation Remediation - the process of validating entities to ascertain compliance and remediate non-compliant entities. As of December 1998, the Company had completed the Awareness, Discovery and Assessment phases of the plan.

The Company has initiated formal communication with significant vendors and suppliers to determine the extent to which the Company's operations are vulnerable to those third parties' failure to remediate their own Y2K issues. Suppliers of hardware, software or other products that might contain embedded processors were requested to provide information regarding Y2K compliance status of their products. The Company will continue to seek information from non-responsive suppliers and plans to contact replacement vendors and suppliers through the second quarter of 1999 and then implement appropriate

contingency plans. In addition, in order to protect against the acquisition of additional non-compliant products, the Company now requires suppliers to warrant that products sold or licensed to the Company are Y2K compliant. In the event that any of the Company's significant suppliers do not successfully achieve Y2K compliance in a timely manner, the Company's business or operations could be adversely affected. There can be no assurance that the systems of other companies on which the Company's systems rely will be converted on a timely basis and would not have an adverse effect on the Company's operations.

The Company has not yet fully developed a comprehensive contingency plan to address situations that may result if the Company is unable to achieve Y2K readiness of its critical operations. Development of contingency plans are in progress and will be completed by the end of first quarter of 1999. There can be no assurance that the Company will be able to develop a contingency plan that will adequately address issues that may arise in the year 2000. The failure of the Company to develop and implement, if necessary, an appropriate contingency plan could have a material impact on the operations of the Company. Finally, the Company is also vulnerable to external forces that might generally affect industry and commerce, such as utility and transportation company Y2K compliance failures and related service interruptions.

The Company anticipates completing the mission critical, high impact Y2K issues by the first half of 1999, which is prior to any anticipated impact on its operating systems and expects the Y2K project to continue beyond the year 2000 with respect to the upgrading, replacement and testing of non-critical systems. These dates are contingent upon the timeliness and accuracy of software and hardware upgrades from vendors, adequacy and quality of resources available to work on completion of the project and any other unforeseen factors. The total expense of the Y2K project is currently estimated at approximately \$750,000, of which approximately \$250,000 has been spent through December 31, 1998, which is not material to the Company's business operations or financial condition. The expenses of the Y2K project are being funded through operating cash flows.

The costs of the project and the date on which the Company believes it will complete the Y2K modifications are based on management's best estimates, which were derived utilizing numerous assumptions of future events, including the continued availability of certain resources, third-party modification plans and other factors. There can be no assurance that these estimates will be achieved and actual results could differ materially from those anticipated.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of the Company's investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, the Company invests in highly liquid and high quality debt securities. The Company's investments in debt securities are subject to interest rate risk. To minimize the exposure due to adverse shift in the interest rates the Company invests in short term securities and maintains an average maturity of one year or less. A hypothetical 50 basis point increase in interest rates would result in an approximate \$150,000 decrease (less than 0.185% in the fair value of the Company's available-for-sale securities).

The potential change noted above is based on sensitivity analyses performed on the Company's financial positions at December 31, 1998. Actual results may differ materially.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements for the years ended December 31, 1998, 1997 and 1996 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 1999 Annual Meeting of Stockholders.

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 Inhale's definitive Proxy Statement to be filed for its 1999 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Inhale incorporates by reference the information set forth under the heading "Security Ownership of Certain Beneficial Owners and Management" in Inhale's definitive Proxy Statement to be filed for its 1999 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Inhale incorporates by reference the information set forth under the heading "Certain Transactions" in Inhale's definitive Proxy Statement to be filed for its 1998 Annual Meeting for Stockholders.

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)	Certificate of Incorporation of the Registrant.
3.2 (3)	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.
4.3 (5)	Stock Purchase Agreement between the Registrant and Baxter World Trade Corporation, dated March 1, 1996.
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.

EXHIBIT

EXHIBIT TITLE

-
- 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.
- 10.9 (1) Sublicense Agreement between the Registrant and John S. Patton, dated September 13, 1991.
- 10.11(2) Addendum to Lease dated September 17, 1992, between the Registrant and W.F. Batton & 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.
- 10.17(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 the signature page.
- 27.1 Financial Data Schedule

-
- (1) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement (No. 33-75942), as amended.
- (2) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement (No. 33-89502), as amended.
- (3) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998
- (4) Incorporated by reference to Inhale's Registration Statement on Form S-8 (No. 333-07969).
- (5) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.
- (6) Incorporated by reference to the indicated exhibit in Inhale's Annual Report on Form 10-K for the year ended December 31, 1995.
- (7) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.

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

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

(b) Reports on Form 8-K.

No Reports on Form 8-K were filed during the quarter ended December 31, 1998.

(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 29th day of March 1999.

INHALE THERAPEUTIC SYSTEMS, INC.

By: /s/ ROBERT B. CHESS

Robert B. Chess
CO-CHIEF EXECUTIVE OFFICER AND DIRECTOR

By: /s/ AJIT S. GILL

Ajit S. Gill
CO-CHIEF EXECUTIVE OFFICER AND DIRECTOR

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, Ajit S. Gill and Robert B. Chess, and each of them, as his attorney-in-fact for him in any and all capacities, to sign any and all amendments to this report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that the said attorney-in-fact, or his substitutes, may do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ ROBERT B. CHESS ----- Robert B. Chess	Co-Chief Executive Officer and Director (CO-PRINCIPAL EXECUTIVE OFFICER)	March 29, 1999
/s/ AJIT S. GILL ----- Ajit S. Gill	Co-Chief Executive Officer and Director (CO-PRINCIPAL EXECUTIVE OFFICER)	March 29, 1999
/s/ CHRISTIAN O. HENRY ----- Christian O. Henry	Corporate Controller (PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER)	March 29, 1999
/s/ JOHN S. PATTON ----- John S. Patton	Vice President and Director	March 29, 1999
/s/ MARK J. GABRIELSON ----- Mark J. Gabrielson	Director	March 29, 1999
/s/ JAMES B. GLAVIN ----- James B. Glavin	Director	March 29, 1999
/s/ MELVIN PERELMAN ----- Melvin Perelman	Director	March 29, 1999
/s/ TERRY L. OPDENDYK ----- Terry L. Opdendyk	Chairman of the Board	March 29, 1999

INHALE THERAPEUTIC SYSTEMS, INC.

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders of

Inhale Therapeutic Systems, Inc.

We have audited the accompanying balance sheets of Inhale Therapeutic Systems, Inc. as of December 31, 1998 and 1997, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1998. 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, 1998 and 1997, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1998 in conformity with generally accepted accounting principles.

ERNST & YOUNG LLP

Palo Alto, California
January 22, 1999

INHALE THERAPEUTIC SYSTEMS, INC.

BALANCE SHEETS

(IN THOUSANDS, EXCEPT PAR VALUE PER SHARE INFORMATION)

	DECEMBER 31,	
	1998	1997
	-----	-----
ASSETS		
Current assets:		
Cash and cash equivalents.....	\$ 24,916	\$ 14,104
Short-term investments.....	57,946	86,069
Other current assets.....	1,678	752
	-----	-----
Total current assets.....	84,540	100,925
Property and equipment, net.....	49,863	18,694
Deposits and other assets.....	93	143
	-----	-----
	\$ 134,496	\$ 119,762
	-----	-----
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable.....	\$ 3,678	\$ 5,975
Accrued liabilities.....	4,655	4,370
Deferred revenue.....	4,359	6,686
Equipment financing obligations--current portion.....	30	52
Tenant improvement loan--current portion.....	34	31
	-----	-----
Total current liabilities.....	12,756	17,114
Equipment financing obligations.....	9	135
Tenant improvement loan.....	4,931	4,967
Accrued rent.....	919	453
Commitments (See Note 3)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized, no shares issued or outstanding.....	--	--
Common stock, \$0.0001 par value; 50,000 shares authorized; 16,924 shares and 15,542 shares issued and outstanding at December 31, 1998 and 1997, respectively.....	2	2
Capital in excess of par value.....	172,847	135,271
Deferred compensation.....	(931)	(538)
Accumulated deficit.....	(56,018)	(37,662)
Accumulated other comprehensive income/(loss).....	(19)	20
	-----	-----
Total stockholders' equity.....	115,881	97,093
	-----	-----
	\$ 134,496	\$ 119,762
	-----	-----

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.

STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)

	YEAR ENDED DECEMBER 31,		
	1998	1997	1996
Contract research revenue.....	\$ 21,795	\$ 16,249	\$ 6,890
Operating costs and expenses:			
Research and development.....	35,398	23,645	14,376
General and administrative.....	8,387	6,328	4,004
Total operating costs and expenses.....	43,785	29,973	18,380
Loss from operations.....	(21,990)	(13,724)	(11,490)
Interest income.....	3,904	3,807	1,638
Interest expense.....	(270)	(66)	(57)
Net loss.....	\$ (18,356)	\$ (9,983)	\$ (9,909)
Basic and diluted net loss per share.....	\$ (1.17)	\$ (0.72)	\$ (0.88)
Shares used in basic and diluted net loss per share calculation.....	15,719	13,792	11,207

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.

STATEMENT OF STOCKHOLDERS' EQUITY

(IN THOUSANDS)

	COMMON STOCK		CAPITAL IN EXCESS OF PAR VALUE	DEFERRED COMPENSATION	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME/ (LOSS)	TOTAL STOCKHOLDERS' EQUITY
	SHARES	PAR VALUE					
Balance at December 31, 1995.....	10,142	\$1	\$ 38,201	\$ (250)	\$ (17,770)	--	\$20,182
Issuance of common stock in connection with collaborative agreements, net of issuance costs of \$806.....	1,608	--	24,196	--	--	--	24,196
Amortization of deferred compensation.....	--	--	--	162	--	--	162
Common stock issued upon exercise of stock options.....	85	--	442	--	--	--	442
Unrealized loss on securities held as available-for-sale.....	--	--	--	--	--	(12)	(12)
Net loss for the year ended December 31, 1996.....	--	--	--	--	(9,909)	--	(9,909)
Comprehensive loss.....	--	--	--	--	--	--	(9,921)
Balance at December 31, 1996.....	11,835	1	62,839	(88)	(27,679)	(12)	35,061
Issuance of common stock in private placement, net of issuance costs of \$1,940.....	1,800	1	30,459	--	--	--	30,460
Issuance of common stock in connection with licensing agreement.....	28	--	600	--	--	--	600
Issuance of common stock in public offering, net of issuance costs of \$2,885.....	1,725	--	40,024	--	--	--	40,024
Common stock issued upon exercise of stock options.....	125	--	798	--	--	--	798
Issuance of common stock in connection with exercise of warrant.....	29	--	--	--	--	--	--
Deferred compensation.....	--	--	551	(551)	--	--	--
Amortization of deferred compensation.....	--	--	--	101	--	--	101
Unrealized gain on securities held as available-for-sale.....	--	--	--	--	--	32	32
Net loss for the year ended December 31, 1997.....	--	--	--	--	(9,983)	--	(9,983)
Comprehensive loss.....	--	--	--	--	--	--	(9,951)
Balance at December 31, 1997.....	15,542	2	135,271	(538)	(37,662)	20	97,093
Issuance of common stock in private placement, net of issuance costs of \$1,997.....	1,200	--	35,202	--	--	--	35,202
Issuance of common stock in connection with licensing agreement.....	6	--	159	--	--	--	159
Issuance of stock options in connection with licensing agreement.....	--	--	125	--	--	--	125
Common stock issued upon exercise of stock options.....	176	--	1,514	--	--	--	1,514
Deferred compensation.....	--	--	576	(576)	--	--	--
Amortization of deferred compensation.....	--	--	--	183	--	--	183
Unrealized loss on securities held as available-for-sale.....	--	--	--	--	--	(39)	(39)
Net loss for the year ended December 31, 1998.....	--	--	--	--	(18,356)	--	(18,356)
Comprehensive loss.....	--	--	--	--	--	--	(18,395)
Balance at December 31, 1998.....	16,924	\$2	\$172,847	\$ (931)	\$ (56,018)	(19)	\$115,881

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.

STATEMENTS OF CASH FLOWS

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS

(IN THOUSANDS)

	YEAR ENDED DECEMBER 31,		
	1998	1997	1996
CASH FLOWS FROM (USED IN) OPERATING ACTIVITIES			
Net loss.....	\$ (18,356)	\$ (9,983)	\$ (9,909)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization.....	3,415	2,337	1,071
Amortization of deferred compensation.....	183	101	162
Issuance of common stock and stock options in connection with licensing agreements.....	284	600	--
Decrease (increase) in other current assets, deposits and other assets.....	(876)	518	(752)
Increase (decrease) in accounts payable and accrued liabilities.....	(1,546)	7,443	1,465
Increase (decrease) in deferred revenue.....	(2,327)	3,963	2,145
Net cash (used in) provided by operating activities.....	(19,223)	4,979	(5,818)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchases of short-term investments.....	(219,414)	(483,247)	(58,993)
Sales of short-term investments.....	65,189	80,662	2,020
Maturities of short-term investments.....	182,309	334,289	55,313
Purchases of property and equipment, net.....	(34,584)	(17,261)	(2,181)
Net cash used in investing activities.....	(6,500)	(85,557)	(3,841)
CASH FLOWS FROM FINANCING ACTIVITIES			
Payments of equipment financing obligations.....	(150)	(83)	(52)
Payments of tenant improvement loan obligations.....	(31)	(2)	--
Payments of capital lease obligations.....	--	(83)	(193)
Proceeds from tenant improvement loan.....	--	5,000	--
Issuance of common stock, net of issuance costs.....	36,716	71,282	24,638
Net cash provided by financing activities.....	36,535	76,114	24,393
Net increase (decrease) in cash and cash equivalents.....	10,812	(4,464)	14,734
Cash and cash equivalents at beginning of period.....	14,104	18,568	3,834
Cash and cash equivalents at end of period.....	\$ 24,916	\$ 14,104	\$ 18,568

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.

NOTES TO FINANCIAL STATEMENTS

DECEMBER 31, 1998

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION AND BASIS OF PRESENTATION

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

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

Inhale considers all highly liquid investments with a maturity from date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include demand deposits held in banks and interest bearing money market funds. All other liquid investments are classified as short-term investments. Short-term investments consist of federal and municipal government securities, repurchase agreements or corporate commercial paper with 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. Inhale limits its concentration of risk by diversifying its investments among a variety of industries and issuers. Inhale has experienced no material losses on its investments.

At December 31, 1998, all short-term investments are designated as available-for-sale and are carried at fair value, with material unrealized gains and losses, if any, reported in stockholders' equity. The amortized cost of securities is adjusted for amortization of material premiums and accretion of discounts to maturity. Such amortization, if any, is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

DECEMBER 31, 1998

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)
CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS (CONTINUED)

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

AVAILABLE-FOR-SALE SECURITIES				
	COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
(IN THOUSANDS)				
Obligations of U.S. government agencies.....	\$ 20,758	\$ --	\$ --	\$ 20,758
U.S. corporate commercial paper.....	42,773	--	(19)	42,754
Repurchase agreements, secured by U.S. Government securities.....	17,704	--	--	17,704
Other.....	105	--	--	105
	\$ 81,340	\$ --	\$ (19)	\$ 81,321
Amounts included in cash and cash equivalents.....	\$ 23,375	\$ --	\$ --	\$ 23,375
Amounts included in short-term investments.....	57,965	--	(19)	57,946
	\$ 81,340	\$ --	\$ (19)	\$ 81,321

The following is a summary of available-for-sale securities as of December 31, 1997:

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

The gross realized losses and gains on the sale of securities available-for-sale during the years ended December 31, 1998 and 1997, were not material. At December 31, 1998 and 1997, the average portfolio duration was approximately three months and the contractual maturity of any single investment did not exceed eleven months (nine months at December 31, 1997).

NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

DECEMBER 31, 1998

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)
CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS (CONTINUED)

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

PROPERTY AND EQUIPMENT

Property and equipment consist of the following at December 31:

	1998	1997
	-----	-----
	(IN THOUSANDS)	
Laboratory and other equipment.....	\$ 15,012	\$ 9,145
Leasehold improvements.....	36,003	14,729
Land.....	7,443	--
	-----	-----
	58,458	23,874
Less accumulated depreciation and amortization.....	(8,595)	(5,180)
	-----	-----
	\$ 49,863	\$ 18,694
	-----	-----

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

Interest is capitalized in connection with the construction of leasehold improvements to the Company's manufacturing facility in San Carlos, California. The capitalized interest is recorded as part of the asset to which it relates and is amortized over the asset's estimated useful life. In 1998, \$203,000 of interest cost was capitalized. No interest was capitalized in 1997.

COMPREHENSIVE LOSS

Effective January 1, 1998, Inhale adopted the Financial Accounting Standards Board's ("FASB") Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" ("SFAS 130"). Other comprehensive income includes only unrealized gains and losses on securities held as available-for-sale and is shown in the Statement of Stockholders' Equity.

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 in the period in which it is earned. In accordance with contract terms, upfront and progress payments from collaborative research agreements are considered to be payments to support continued research and development activities under the agreements. In accordance with the Company's revenue

DECEMBER 31, 1998

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

recognition policy, these payments are included in deferred revenue and are recognized as the related research and development expenditures are incurred.

STOCK-BASED COMPENSATION

As permitted by the provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123"), Inhale continues to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations in accounting for its employee stock option plans. Under APB 25, if the exercise price of Inhale's employee stock options equals or exceeds the fair market value of the underlying stock on the date of grant as determined by the closing price of Inhale's common stock as quoted on the Nasdaq stock market, no compensation expense is recognized. See Note 3 for pro forma disclosures required by FAS 123. Stock options and warrants issued to non-employees are accounted for based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

NET LOSS PER SHARE

In accordance with Financial Accounting Standard No. 128, basic and diluted net loss per share has been computed using the weighted average number of shares of common stock outstanding during the period. Had Inhale been in a net income position, diluted earnings per share would have included the shares used in computation of basic net loss per share as well as an additional 1,190,814, 1,098,987 and 715,918 shares for the years ended December 31, 1998, 1997, and 1996, respectively, relating to outstanding options and warrants (after the application of the treasury stock method) and stock subject to repurchase.

SEGMENT INFORMATION

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

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

NOTE 2--COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Inhale performs research and development for others pursuant to feasibility agreements and development and license agreements. Under the feasibility agreements, Inhale generally is reimbursed for the cost

DECEMBER 31, 1998

NOTE 2--COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CONTINUED)
of work performed. Feasibility agreements are designed to evaluate the applicability of Inhale's technologies to a particular molecule and therefore are generally completed in less than one year. Under Inhale's development and license agreements, the partner companies receive an exclusive license to develop, use and sell a dry powder formulation and a suitable delivery device to be developed by Inhale for one of the partner's macromolecule drugs. Under these development agreements, Inhale will be reimbursed for development costs and may also be entitled to milestone and advance royalty payments when and if certain development milestones are achieved. All of Inhale's research and development agreements are generally cancelable by the partner without significant financial penalty to the partner.

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

In January 1997, the Company executed a collaboration agreement with Lilly to develop pulmonary delivery for parathyroid hormone ("PTH") based on Inhale's deep-lung delivery system for macromolecules. Under the terms of the agreement, Inhale will receive funding up to \$20 million of initial fees, research and development and progress payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. Inhale will manufacture packaged powders for and supply devices to Lilly. Under this agreement the Company recognized revenue of \$3.8 million and \$3.4 million in 1998 and 1997, respectively. In late 1998, unexpected observations from a long-term test in rats of the injectable version of parathyroid hormone led Lilly to suspend further clinical development of the injectable and pulmonary versions of PTH pending further analysis. Inhale is maintaining a minimum development effort in its pulmonary program pending further direction from Lilly.

In December 1996, the Company executed a collaboration agreement with Centeon L.L.C. ("Centeon") to develop a pulmonary formulation of alpha-1 proteinase inhibitor to treat patients with alpha-1 antitrypsin deficiency, a genetic disorder which can lead to emphysema. Under the terms of the agreement, Inhale will receive funding up to an estimated \$15 million of research and development and progress payments. Centeon will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. Inhale will manufacture packaged powders for and supply devices to Centeon. Under this agreement, the Company recognized revenue of \$1.6 million and \$0.9 million in 1998 and 1997, respectively. No revenue was recognized under this agreement in 1996.

In March 1996, Inhale entered into a collaboration agreement with Baxter Healthcare Corporation ("Baxter") to use Inhale's dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In connection with the collaboration, Baxter made a \$20 million equity investment in Inhale at a 25% premium to the market price of Inhale stock at the time of the investment. Baxter received worldwide commercialization rights in exchange for up to an estimated

DECEMBER 31, 1998

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

\$60 million in research and development funding and milestone payments for four molecules. In October 1998, Inhale announced that it had reached an agreement with Baxter to amend their collaborative agreement to facilitate signing a new corporate partner to fund further development and commercialization of the products. Baxter will continue to provide development funding for this compound in preparation for Phase II trials while the two companies are seeking a new partner. The Company recognized revenues associated with this program of \$4.0 million, \$4.1 million and \$0.9 million in 1998, 1997 and 1996, respectively.

In January 1995, the Company entered into a collaborative development and license agreement with Pfizer Inc. ("Pfizer") to develop pulmonary delivery for inhaled insulin based on Inhale's deep-lung delivery system for macromolecules. Under the terms of the agreement, Inhale will receive funding consisting of initial fees, research and development and progress payments. Upon execution of the agreement Pfizer purchased \$5.0 million of Inhale common stock. In addition, in October 1996, Pfizer purchased an additional \$5.0 million of Inhale common stock. Pfizer will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. Inhale will manufacture inhaled insulin for, and supply devices to Pfizer. Under this agreement the Company recognized revenue of \$11.1 million, \$7.6 million and \$5.3 million in 1998, 1997 and 1996, respectively.

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

NOTE 3--COMMITMENTS, EQUIPMENT FINANCING OBLIGATIONS AND TENANT IMPROVEMENT LOAN

Inhale leases its office and laboratory facilities under several arrangements expiring through the year 2012. Rent expense was approximately \$1,777,000, \$1,106,000 and \$416,000 for the years ended December 31, 1998, 1997 and 1996, respectively.

In November 1997, Inhale received from the landlord of its facility in San Carlos, California a loan of \$5.0 million to fund a portion of the cost of improvements made to the facility. The loan bears interest at 9.46% per annum, and principal and interest payments are payable monthly over the ten-year loan term with a balloon payment of \$4.5 million at the end of the tenth year. The loan is recorded on the balance sheet at December 31, 1998 as a tenant improvement loan.

NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

DECEMBER 31, 1998

NOTE 3--COMMITMENTS, EQUIPMENT FINANCING OBLIGATIONS AND TENANT IMPROVEMENT LOAN
(CONTINUED)

Future noncancelable commitments under operating leases and equipment financing and tenant improvement obligations at December 31, 1998 are as follows:

	OPERATING LEASES	EQUIPMENT FINANCING OBLIGATIONS	TENANT IMPROVEMENT OBLIGATIONS
	-----	-----	-----
	(IN THOUSANDS)		
Years ending December 31,			
1999.....	\$ 1,409	\$ 33	\$ 503
2000.....	1,461	8	503
2001.....	1,550	--	503
2002.....	1,639	--	503
2003 and thereafter.....	15,224	--	6,979
	-----	-----	-----
Total minimum payments required.....	\$ 21,283	\$ 41	\$ 8,991
	-----	-----	-----
Less amount representing interest.....		(2)	(4,026)
		-----	-----
Present value of future lease payments.....		39	4,965
Less current portion.....		(30)	(34)
		-----	-----
Non-current portion.....		\$ 9	\$ 4,931
		-----	-----
		-----	-----

NOTE 4--STOCKHOLDERS' EQUITY

COMMON STOCK

EMPLOYEE STOCK PURCHASE PLAN

In February 1994, Inhale's Board of Directors adopted the Employee Stock Purchase Plan (the "Purchase Plan"). Under the Purchase Plan, 150,000 shares of common stock have been reserved for purchase by Inhale's employees pursuant to section 423(b) of the Internal Revenue Code of 1986. As of December 31, 1998, no shares of common stock have been issued under the Purchase Plan.

STOCK OPTION PLANS

EQUITY INCENTIVE PLAN

Inhale's 1994 Equity Incentive Plan (the "Equity Incentive Plan") was adopted by the Board of Directors in February 1994. The Equity Incentive Plan is an amendment and restatement of Inhale's 1992 Stock Option Plan. The purpose of the Equity Incentive Plan is to attract and retain qualified personnel, to provide additional incentives to employees, officers, consultants and employee directors of Inhale and to promote the success of Inhale's business. Pursuant to the Equity Incentive Plan, Inhale may grant or issue incentive stock options to employees and officers and non-qualified stock options, restricted stock purchase awards, stock bonuses and stock appreciation rights to consultants, employees, officers and employee directors. Options granted to non-employees after December 15, 1994 are recorded at fair value based on the fair value measurement criteria of FAS 123.

DECEMBER 31, 1998

NOTE 4--STOCKHOLDERS' EQUITY (CONTINUED)
 STOCK OPTION PLANS (CONTINUED)

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

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

NON-EMPLOYEE DIRECTORS' STOCK OPTION PLAN

In February 1994, Inhale's Board of Directors adopted the Non-employee Directors' Stock Option Plan under which options to purchase up to 200,000 shares of Inhale's common stock at the then fair market value may be granted to Inhale's non-employee directors. As of December 31, 1998, options on 6,000 shares had been exercised and options to purchase 124,200 shares were exercisable.

1998 NON-OFFICER EQUITY INCENTIVE PLAN

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

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

INHALE THERAPEUTIC SYSTEMS, INC.

NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

DECEMBER 31, 1998

NOTE 4--STOCKHOLDERS' EQUITY (CONTINUED)

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

	OPTIONS AVAILABLE FOR GRANT	OPTIONS OUTSTANDING		WEIGHTED- AVERAGE EXERCISE PRICE
	NUMBER OF SHARES	NUMBER OF SHARES	EXERCISE PRICE PER SHARE	PER SHARE
(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)				
Balance at December 31, 1995.....	784	1,233	0.06-15.25	\$ 6.32
Shares authorized.....	1,500	--	--	--
Options granted.....	(620)	620	10.13-19.25	14.05
Options exercised.....	--	(85)	0.06-12.00	5.22
Options canceled.....	109	(109)	0.31-15.25	8.33
Balance at December 31, 1996.....	1,773	1,659	0.06-19.25	9.13
Options granted.....	(851)	851	0.01-35.25	20.99
Options exercised.....	--	(125)	0.06-16.13	6.41
Options canceled.....	33	(33)	0.56-22.75	15.27
Balance at December 31, 1997.....	955	2,352	0.01-35.25	13.46
Shares authorized.....	1,550	--	--	--
Options granted.....	(1,070)	1,070	0.01-34.13	28.16
Options exercised.....	--	(176)	0.06-22.75	8.69
Options canceled.....	83	(83)	5.56-35.25	23.26
Balance at December 31, 1998.....	1,518	3,163	\$0.01-35.25	\$18.45

At December 31, 1998, 1997 and 1996, options were exercisable to purchase approximately 1,077,000, 784,000 and 514,000 at weighted-average exercise prices of \$11.36, \$8.17 and \$5.83 per share, respectively.

Weighted average fair value of options granted during the year ended December 31, 1998, 1997 and 1996, was \$28.42, \$21.89 and \$14.24 per share, respectively. The following table provides information regarding Inhaled's stock option plans.

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
	NUMBER OF SHARES	WEIGHTED- AVERAGE EXERCISE PRICE PER SHARE	WEIGHTED- AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	NUMBER OF SHARES	WEIGHTED- AVERAGE EXERCISE PRICE PER SHARE
	(IN THOUSANDS)			(IN THOUSANDS)	
\$ 0.01- 9.13	737	\$ 5.46	5.68	560	\$ 4.97
10.00-17.50	662	13.27	7.32	311	13.79
18.63-22.75	656	19.93	8.28	104	20.31
25.00-29.25	667	27.88	9.40	52	2.95
30.13-35.25	441	31.50	9.47	50	31.75
\$ 0.01-35.25	3,163	\$18.45	7.88	1,077	\$11.36

DECEMBER 31, 1998

NOTE 4--STOCKHOLDERS' EQUITY (CONTINUED)

Pro forma information regarding net loss and loss per share is required by FAS 123, which also requires that the information be determined as if Inhale has accounted for its employee stock options granted subsequent to December 31, 1994 under the fair value method of that Statement. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	1998	1997	1996
Risk-free Interest Rate.....	4.8%	5.7%	6.4%
Dividend Yield.....	0.0%	0.0%	0.0%
Volatility Factor.....	0.700	0.578	0.620
Weighted Average Expected Life.....	5 years	6 years	6 years

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

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

	1998	1997	1996
Pro forma net loss.....	\$ (24,325)	\$ (13,168)	\$ (11,252)
Pro forma basic and fully diluted net loss per common share.....	\$ (1.55)	\$ (0.95)	\$ (1.00)

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

WARRANTS

In October 1996 Inhale issued two warrants ("the warrants") to purchase a total of 20,000 shares of Common Stock (10,000 shares each) at a price of \$13.125 per share in connection with a facility lease. The warrants expire in October 2006 and were outstanding and exercisable at December 31, 1998.

DECEMBER 31, 1998

NOTE 4--STOCKHOLDERS' EQUITY (CONTINUED)

STOCK COMPENSATION

Inhale recorded deferred compensation of approximately \$576,000 during the year ended December 31, 1998. Deferred compensation of \$551,000 had been recorded in the year ended December 31, 1997. These amounts represent the difference between the exercise price and the fair market value of certain of Inhale's stock options granted in these periods. Inhale recorded amortization expense of approximately \$183,000, \$101,000, and \$162,000 for the years ended December 31, 1998, 1997, and 1996, respectively.

RESERVED SHARES

A total of 4,684,090 shares of common stock have been reserved for issuance at December 31, 1998 for Inhale's equity incentive plans and the warrants.

NOTE 5--INCOME TAXES

As of December 31, 1998, Inhale had federal net operating loss carryforwards of approximately \$47,200,000. Inhale also had federal research and development tax credit carryforwards of approximately \$1,400,000. The net operating loss and credit carryforwards will expire at various dates beginning in 2006 through 2018 if not utilized.

Utilization of the net operating losses and credits may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. Significant components of Inhale's deferred tax assets for federal and state income taxes as of December 31 are as follows:

	1998	1997
	-----	-----
	(IN THOUSANDS)	
Deferred tax assets:		
Net operating loss carryforwards.....	\$ 16,300	\$ 9,400
Research credits.....	2,100	800
Manufacturing & research equipment credits.....	100	--
Capitalized research expenses.....	1,900	1,300
Deferred revenue.....	1,700	2,700
Other.....	2,500	1,500
	-----	-----
Total deferred tax assets.....	24,600	15,700
Valuation allowance for deferred tax assets.....	(24,600)	(15,700)
	-----	-----
Net deferred tax assets.....	\$ --	\$ --
	-----	-----

Because of Inhale's lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$8,900,000 and \$4,600,000 during the years ended December 31, 1998 and 1997, respectively.

INHALE THERAPEUTIC SYSTEMS, INC.

NOTES TO FINANCIAL STATEMENTS -- (CONTINUED)

DECEMBER 31, 1998

NOTE 6--STATEMENT OF CASH FLOWS DATA (IN THOUSANDS)

	YEARS ENDED DECEMBER 31,		
	1998	1997	1996
Supplemental disclosure of cash flows information:			
Interest paid.....	\$ 270	\$ 66	\$ 57
Supplemental schedule of non-cash investing and financing activities:			
Deferred compensation related to the issuance of certain stock options.....	\$ 576	\$ 551	\$ --
Issuance of common stock in connection with licensing agreement.....	\$ 159	\$ 600	\$ --
Issuance of stock options in connection with licensing agreement.....	\$ 125	\$ --	\$ --

NOTE 7--SUBSEQUENT EVENTS (UNAUDITED)

In February 1999, the Company entered into a collaboration agreement with Biogen Inc. ("Biogen") to develop pulmonary delivery for AVONEX-Registered Trademark- (Interferon Beta-1a), a drug used in the treatment of multiple sclerosis. The product under development will be based on Inhale's deep-lung delivery system for macromolecules. Under the terms of the agreement, Inhale will receive funding up to \$25 million of research, development and progress payments. Biogen will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. Inhale will manufacture packaged powders for and supply devices to Biogen.

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-8 No. 333-07069, Form S-8 No. 333-59735 and Form S-8 No. 333-65919) pertaining to the Employee Stock Purchase Plan, the 1994 Equity Incentive Stock Option Plan, the Non-Employee Directors Stock Option Plan, the 1994 Equity Incentive Plan and the 1998 Non-Officer Equity Incentive Plan of Inhale Therapeutic Systems, Inc., and the Registration Statement (Form S-3 No. 333-20787) and in the related Prospectus of Inhale Therapeutic Systems, Inc. for the registration of 1,800,000 shares of its common stock, and the Registration Statement (Form S-3 No. 333-68897) and in the related Prospectus of Inhale Therapeutic Systems, Inc. for the registration of 1,200,000 shares of its common stock of our report dated January 22, 1999, with respect to the financial statements of Inhale Therapeutic Systems, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 1998.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 29, 1999

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE FINANCIAL STATEMENTS AS FILED ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 1998, AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

1,000

YEAR			
DEC-31-1998			
JAN-01-1998			
DEC-31-1998		24,916	
	57,946		
	0		
	0		
	0		
	84,540		
		58,458	
	(8,595)		
	134,496		
12,756			0
0			0
		0	2
	172,847		
134,496			0
	21,795		0
	43,785		
	0		
	0		
	(270)		
	(18,356)		
			0
(18,356)			
	0		
	0		
			0
	(18,356)		
	(1.17)		
	0		