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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001

OR

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

Commission File No. 0-23556

INHALE THERAPEUTIC SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

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

150 Industrial Road, San Carlos, CA 94070
(Address of principal executive offices and zip code)

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

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

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, $0.0001 par value**

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

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. o

The approximate aggregate market value of voting stock held by non-affiliates of the Registrant, based upon the last sale price of the Company's Common Stock on March 1, 2002, as reported on the Nasdaq National Market was approximately $703,929,685. This calculation excludes approximately 958,902 shares held by directors and executive officers of the Company. Exclusion of these shares should not be construed to indicate that such person controls, is controlled by or is under common control with the Registrant. This calculation does not exclude shares held by organizations whose ownership exceeds 5% of the Registrant's outstanding Common Stock as of March 1, 2002 that have represented to the Company that they are registered investment advisers or investment companies registered under section 8 of the Investment Company Act of 1940. Determination of affiliate status for the purposes of this calculation is not necessarily a conclusive determination for any other purpose.

55,149,024
(Number of shares of common stock outstanding as of March 1, 2002)

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PART I

Item 1. Business

Overview

We are working to become the world's leading drug delivery company by providing a portfolio of technologies and expertise that will enable our pharmaceutical partners to improve drug performance throughout the drug development process. Historically, drug delivery was focused on life cycle management of older products facing patent expiration, or seeking product line extensions. The advent of newer technologies, including high-throughput screening, combinatorial chemistry, genomics and proteomics, has led to an increase in the number of molecular leads. This has led pharmaceutical companies to focus earlier in development on molecular characteristics such as toxicity, solubility and immunogenicity to improve clinical safety and efficacy of drugs. It is now recognized that drug delivery spans the entire development process, with an earlier need to rescue or optimize drug candidates, and a premium on faster and more efficient drug development.

In an effort to capitalize on what we believe is a growing market need for performance-enabling drug delivery technologies, we moved to expand our technology offerings by acquiring Shearwater Corporation and Bradford Particle Design Ltd. These acquisitions have added two additional technologies, advanced PEGylation and Solution Enhanced Dispersion by Supercritical Fluids ("SEDS™") to our portfolio. With these technologies, and our Inhance™ inhaleables technology, we are now positioned to address the development needs of molecules and improve drug characteristics to enable our partners to expand their pipelines.

Our latest stage technology, advanced PEGylation, has been approved for use in three products. Advanced PEGylation is designed to enhance the efficacy and performance of most major drug classes, including macromolecules such as peptides and proteins, smaller sized molecular compounds, and other drugs. Our next most advanced technology, the Inhance™ inhaleable platform, enables inhalation for delivery of a range of drugs, including peptides, proteins and small molecules for treatment of systemic and respiratory diseases. Our latest-stage inhaleables product, Exubera™ inhaled insulin, is partnered with Pfizer Inc. and has completed initial Phase III trials. Our third platform, the SEDS™ technology uses a proprietary particle engineering method to develop drug formulations for multiple types of drug delivery and improvement. Overall, we currently have or are developing 19 therapeutic drugs and one compound used as a diagnostic agent incorporating our technologies that are either approved for use, in the process of being reviewed for approval by the appropriate regulatory agency, or in clinical trials. In addition, we have more than 50 projects underway in feasibility or preclinical development across the three platforms.

Opportunities for Improved Drug Delivery and Performance

Innovations in biotechnology and the drug discovery process have led to a large increase in the number of protein therapeutics, other macromolecule and small molecule drugs over the last several years. With this increase in leads comes an increase in development issues facing drug developers. Delivery routes, dosing schedules, solubility issues, bioavailability, and stability issues are just a small number of the issues faced by drug developers. We believe there is an opportunity to apply new technologies to the development of new therapeutic compounds to increase efficacy, reduce toxicity and increase patient acceptance of drugs and address these issues.

Currently, approximately 84 macromolecule drugs are approved for marketing in the United States and approximately 350 additional biotechnology macromolecule drugs are in human clinical trials, many for chronic and acute diseases. Sales of genetically engineered protein drugs were estimated to be at least $15.0 billion worldwide in 2000. In addition, advances in chemistry, such as combinatorial chemistry plus high-throughput screening have led to an increasing number of opportunities to develop small molecule therapeutic drugs, many of which have traditionally been difficult to formulate due to low solubility.

While a protein, macromolecule or other molecule's absorption into the bloodstream can be improved by optimizing the route of the drug's delivery, the effectiveness of the drug is still dependent on various factors including the amount of time it takes for an active molecule to be cleared through the bloodstream (i.e. its rate of circulation), the rate at which the protein or other molecule degrades and the ability of the body to produce an immune response.

Unmodified proteins may be less effective if they are quickly cleared from the bloodstream or degraded by other enzymes in the body. In addition, the human body has a natural immune response to proteins that cause them to lose potency over time. Any one of these variables can cause a particular protein to be

less effective or necessitate frequent dosing, thereby increasing the cost of the therapy and decreasing patient compliance. We believe there is a significant market opportunity to apply technology to the modification of therapeutic proteins and for addressing these variables and improving the overall therapeutic effect of these drugs. Likewise, other molecular compounds such as small molecules may be limited by poor solubility and rapid clearance from the body that could be improved by drug delivery.

We believe that an application of advanced PEGylation technology to link PEG chains of higher molecular weight to active drug compounds represents a significant commercial opportunity. Such a system could enhance the efficacy of current therapeutic proteins and other molecular compounds while increasing patient acceptance of drug therapies and compliance with prescribed regimens through reduced dosing. Additionally, advanced PEGylation technology may result in the development of new therapeutic protein compounds that in unmodified forms are ineffective due to high toxicity, low solubility or significant immunogenicity.

We also believe there is substantial opportunity for improving the efficacy and patient acceptance of protein therapeutics and macromolecule drugs by improving the method by which many of these drugs are introduced into the body. Drugs typically enter the body through one of five routes of delivery. The four natural routes are through the digestive tract (oral), the skin (transdermal), the mucosal surfaces (for example, nasal and sublingual), and the lung (inhalation). Drugs are also commonly delivered by injection (subcutaneous, intramuscular or intravenous), bypassing the natural barrier to entry provided by the skin.

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

We believe that an efficient and reproducible deep lung delivery system for systemic macromolecule drugs used in the treatment of chronic and subchronic diseases represents a significant commercial opportunity due to certain less efficient or effective alternative forms of delivery such as patches, oral delivery or nasal delivery. 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.

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

We also believe a significant commercial opportunity exists for the application of technology to the engineering and formulation of drug particles to address particular development challenges. We believe that the use of our SEDS™ supercritical fluids technology to produce drug particles of uniform size, regular shape and smooth crystalline surfaces can significantly improve drug efficacy as these properties can be critical in controlling absorption and dissolution of the active drug compound into and within the bloodstream. Additionally, we believe a significant opportunity exists to apply our SEDS™ technology to the improved development of therapeutic drugs as our SEDS™ technology permits the production of multiple forms of drugs in a reproducible manner and may simplify the application of polymer chains, including PEG, to improve the solubility of drug compounds. Lastly, we believe that the use of our SEDS™ technology will benefit the manufacturing process. There has been little change in the past half-century to the traditional milling processes utilized in both conventional particle-formation and particle-size reduction. The traditional manufacturing process involves multiple stages of production in which proteins or other active drug compounds are exposed to multiple stresses such as variations in temperature. Consequently, the traditional manufacturing process provides only limited control over the particle size. In addition to the development issues SEDS™ can address, the technology can reduce the number of manufacturing steps required to produce particles.

Our Strategy

Our goal is to become the pre-eminent provider of drug delivery solutions. While we initially focused on inhaleable macromolecules because of the need for non-invasive delivery of these drugs, our recent acquisitions of Shearwater Corporation and Bradford Particle Design have expanded our focus beyond the means of drug delivery to meet expanding drug development needs. Our growth strategy is to continue to build on our leadership position in these fields, while at the same time leveraging our strengths in inhalation, drug formulation, and powder and particle engineering technologies to enter large opportunity, non-commodity markets in these areas. Our approach is to pick technologies and markets where we can build leadership positions through developing or acquiring platform technologies with broad applications.

Our strategy incorporates the following principal elements:

- *Develop Broadly Applicable Drug Formulation Systems*. We are developing our proprietary advanced PEGylation and SEDS™ technologies to improve the formulation of drug compounds so as to make them more effective through multiple delivery applications. We intend to focus our drug formulation technologies on drug compounds where we can substantially improve the performance of the active drug compound or improve the drug development or manufacturing process and to seek out additional formulation technology platforms that are consistent with this focus.

- *Develop a Broadly Applicable Deep Lung Drug Delivery System*. We are developing our non-invasive deep lung drug delivery system to be applicable to a wide range of peptides, proteins and other molecules currently delivered by injection or poorly delivered by inhalation or other routes. We intend to develop effective non-invasive delivery alternatives that can: (1) expand market penetration for existing therapeutics currently delivered by injection, infusion or other routes; (2) commercialize new indications by using deep lung delivery as a new route of administration; and (3) extend existing patents or seek new patents to gain important competitive advantages for ourselves and our partners. In addition, we are expanding the use of our Inhance™ platform to apply to small molecules and for local lung disease applications.

- *Build Competitive Advantage Through Expertise in Multiple Disciplines*. In developing our PEGylation, SEDS™, and Inhance™ technology platforms, we have used and expanded our expertise in molecule engineering, chemistry, pulmonary physiology and biology, aerosol science,

powder science, aerosol engineering, chemical engineering, mechanical engineering and product design, protein formulation, fine powder processing and filling. This expertise creates multiple

barriers to entry and multiple opportunities in certain disciplines, such as drug formulation or powder science, to additional drug delivery applications.

- *Partner with Pharmaceutical and Biotechnology Companies*. Our strategy is to market our proposed products through collaborative partners. We are seeking to work with partners that have significant clinical development and marketing resources, and currently have collaborations with several large pharmaceutical and biotechnology companies. In a typical collaboration, our partner will provide the drug, fund clinical and formulation development and market the resulting commercial product. We will supply the drug delivery approach or drug formulation, and receive revenues from drug compound manufacturing and other manufacturing activities, as well as royalties from sales of most commercial products. In addition, for products using our Inhance™ inhaleables technology, we will receive revenues from the supply of our device for the product along with any applicable drug processing. Prior to commercialization, we receive revenues from our partners for research and development and progress payments upon achievement of certain developmental milestones. We also receive revenues from catalogue sales of certain advanced PEGylation products. More than 70% of our clinical pipeline involves molecules that are already approved by the FDA in another delivery form. In addition to the 19 therapeutic drugs and one compound used as a diagnostic agent incorporating our technologies that are in, or have completed, human trials, we have more than 70 drug projects using our various technologies that are in various stages of research, feasibility, and preclinical work, many of these in conjunction with partners. We believe this partnering strategy enables us to reduce our cash requirements while developing a large and diversified potential product portfolio.

- *Utilize our Technology to Develop Proprietary Products with an Eye Toward Partnering.* In addition to our partner-funded programs, we have started applying our technology independently toward initial proprietary product development efforts. We believe that there are many off-patent/near-term patent expiration compounds that would benefit from the application of our technology to improve their performance and delivery. For these programs, we may perform initial feasibility screening work, formulations development and early stage clinical trials before entering into a partner relationship for further development. It is our belief that we will be able to gain a greater share of product sales as a result of undertaking product development efforts.

Drug Delivery and Performance Technology Platforms

Advanced PEGylation Technology

In June 2001, we completed the acquisition of Shearwater Corporation for which we paid consideration of approximately $72.5 million in cash and an aggregate of approximately 4.0 million shares and options to purchase our common stock. Through our acquisition of Shearwater Corporation we have extended our portfolio of technologies to include advanced PEGylation technology for enhancing the efficacy and performance of most major drug classes including macromolecules such as peptides and proteins and small molecules and other drugs. PEGylation is one of the leading methods for improving drug formulations through the modification of proteins and other molecular compounds accomplished through the attachment of polyethlene glycol ("PEG") to the active therapeutic molecule. The chemical attachment of PEG chains to a broad range of drug substances results in effectively increasing the drug's molecular weight. The advantages of PEGylation include improving drug solubility and stability, reducing immune responses, and in certain instances improving efficacy and/or safety of a molecule.

PEG is a neutral, water soluble, non-toxic polymer that is one of the few synthetic polymers approved for internal use by the FDA in a variety of foods, cosmetics, personal care products and pharmaceuticals. When dissolved in water, the long chain-like PEG molecule is heavily "hydrated" (meaning water molecules are bound to it) and is put in a state of rapid motion. This rapid motion leads to the PEG molecule sweeping out a large volume and prevents the approach of other molecules. Although PEG is

largely invisible to biological systems, due to its unique properties it can improve stability and solubility of the drug compound, reduce the natural immune response to proteins and degradation by other enzymes, and increase concentration and circulation of the active compound throughout the system. As a result, the effectiveness of the active drug compound may be increased and the dosing frequency of the drug may be decreased.

First generation PEG chemistry has been generally restricted to the use of PEG chains with low molecular weight because of the poor solubility characteristics traditionally observed with PEG chains of higher molecular weight. The attachment of low molecular weight PEG chains to proteins has been limited by the inherently unstable linkages of PEG chains to the molecular compound. Attachment of low molecular weigh PEG chains can cause the modified compound to quickly degrade in a manner which may trigger an immune response to the active drug compound or otherwise hinder its effectiveness. The effectiveness of such PEG derivatives is also limited by the ability of the relatively small PEG to penetrate poorly accessible regions on the surface of a protein resulting in degradation of the active drug compound or undesired side effects.

Characteristics of our Advanced PEGylation Technology

Our advanced PEGylation technologies are designed to improve the issues of first generation technology of therapeutic pharmaceutical products. The attachment of our activated PEG derivatives is designed to yield one or more of the following benefits:

- Improved solubility and stability of the active drug compound;
- Reduced immunogenicity and degradation of the drug compound;
- Slower clearance from the body; and
- Improved efficacy and/or safety.

As a result of these benefits, less frequent dosing may be possible due to increased circulation time, more of the administered dose may be available to reach its intended target, and the efficacy of a particular dose may be improved due to increased concentration of the drug and longer dwell time at the site of action by the active drug compound.

Our advanced PEGylation technology is also designed to optimize the efficacy of the attached therapeutic compounds and is characterized by the following features:

- Activated high-molecular weight PEGs that can be linked stably and site specifically to drugs, allowing prolonged performance of the drug in its PEGylated form;
- Stable linkage chemistry of the PEG to the drug compound to avoid problems associated with rapid degradation or clearance of the active drug compound;
- The availability of site-specific PEGylation in which the PEG is linked with the drug compound at a specific site on the compound to produce desired effects;
- Controlled release of the drug from the PEG-drug conjugated compound; and
- The availability of bi-functional PEG to facilitate targeting of the active drug compound.

We believe these features are substantially superior to the characteristics associated with first-generation PEGylation chemistry and may significantly enhance the therapeutic value of new drugs or chemical entities already marketed by others and off-patent drugs with otherwise limited utility.

Advanced PEGylation Applications

We believe our advanced PEGylation technology can be of critical importance in facilitating a substantial number of emerging biopharmaceutical technologies, including the following:

- *PEG-Proteins for Pharmaceutical Use.* Our principal market strategy for our advanced PEGylation technology is to demonstrate and assist in developing drug compounds, particularly proteins that substantially enhance the therapeutic value of the active drug over unmodified forms. It has been demonstrated that the proteins with PEG attached remain active and have a greatly diminished or negligible immune response. As a result these PEG-proteins have substantially increased plasma lifetimes. In addition, active drugs attached to PEG result in making proteins or other compounds much larger and thus reduces their rate of clearance through the kidney, thereby allowing the active drug to remain active in the system for longer periods of time.
- *PEG-Surfaces*. In addition to molecular modifications, PEG can also be attached to surfaces to form protective, biocompatible coatings. A variety of applications may result, including PEG-coatings for arterial replacements, diagnostic apparatus and blood contacting devices. Similarly, capillary zone electrophoresis has emerged as an analytical technique in biochemistry, and PEG coatings on capillaries have been demonstrated to prevent absorption and provide critical control of electro-osmosis.
- *PEG-Liposomes*. Recent research has shown that incorporation of PEG into the outer coating of liposomes, which are particular membranes the biopharmaceutical industry is investigating as a means to provide controlled and specific delivery of drugs, can greatly increase serum lifetime, thereby potentially facilitating the use of liposomes for these purposes.
- *Molecule-Molecule and Molecule-Surface Coupling*. The nature of PEGs and their well-defined chemistry make them attractive for coupling or tethering molecules to molecules or molecules to surfaces. We believe this attribute could be critical to the next generation of drugs and biomaterials as developers seek to take advantage of unique properties resulting from binding particular molecules to other molecules or surfaces.
- *Biological Purification*. As biotechnology has continued to succeed in producing a variety of physiologically active proteins, a need has been created for improved methods for isolation of the proteins produced. We believe that PEG may provide a useful approach in this area by using its binding qualities to extract the desired protein in a method of purification that partitions in an aqueous two-phase system.
- *Solubilization of Insoluble Materials*. PEG is soluble in both water and many organic solvents and through PEG attachment water-insoluble materials may become water-soluble. This characteristic of PEGs may be critical to the effectiveness of pharmaceuticals as well as to include in various other products such as dyes, flavors, substrates for enzymes and cofactors.

Clinical Status Summary of our Advanced PEGylation Technology Applications

As with our other drug delivery and drug formulation technologies, we typically develop new products using our advanced PEGylation technology through collaborations with corporate partners. We maintain a catalog of clinically proven PEG reagents for coupling to active pharmaceutical agents for use in our customers' internal drug development programs. More typically, however, our collaborative research personnel will work closely with our partners to choose the proper PEG derivative for the particular application and to optimize the PEG attachment. In a typical research collaboration, we derive revenue from milestone payments during research and development and will derive additional royalties on net sales of approved drugs or other PEG applications. We also derive revenue from manufacturing the PEG reagent.

We have also initiated internal development of several proprietary PEG drugs with the expectation that we will fund this activity through the early stages of clinical trials before establishing a collaborative effort to market the final product. We believe that, in certain circumstances, this process may result in higher royalty payments for marketed products than collaborations initiated at earlier stages of development.

Our advanced PEGylation technology platform is currently being used in the manufacture and development of 15 drugs that are either currently in clinical trials or have either been approved or submitted for approval to the U.S. Food and Drug Administration. Three products using our advanced PEGylation technology, including two therapeutic drug compounds and one compound used as a diagnostic agent, have been approved for use by the FDA and two products have been submitted for approval to the FDA. In addition we have announced supply and/or collaboration agreements with an additional nine pharmaceutical companies with respect to products in various stages of research, feasibility, and development including collaborations with Regeneron Pharmaceuticals, Inc., Maxygen, Inc. and United Therapeutics Corporation.

The following table summarizes our publicly announced partner development programs and the products currently in development using our advanced PEGylation technology, the indication(s) for the particular drug or other product, its present stage of clinical development and, with respect to our announced partner development programs, the identity of the corporate partner for such drug.

PARTNER DEVELOPMENT PROGRAMS (PEGylation)

Product	Indication(s)	Clinical Status(1)	Partner
Diagnostic	Undisclosed	Approved	Undisclosed
PEG Interferon Alpha	Hepatitis C	Approved	Schering-Plough(2)
PEG-G-CSF	Neutropenia	Approved	Amgen
PEG Interferon Alpha	Hepatitis C	NDA Filed	Roche
PEG-hGHRa	Acromegaly	NDA Filed	Pharmacia
PEG Interferon Alpha	Hepatitis B	Phase III	Roche
PEG-hydrogel	Post-surgical adhesions	Phase II/III	Confluent
PEG-Aptamer	Macular degeneration	Phase II/III	Eyetech
PEG CDP870	Rheumatoid arthritis	Phase II (Complete)	Pharmacia
PEG (undisclosed)	Undisclosed	Phase II	Undisclosed
PEG (undisclosed)	Undisclosed	Phase II	Undisclosed
PEG (undisclosed)	Undisclosed	Phase II	Undisclosed
PEG (undisclosed)	Undisclosed	Phase II	Undisclosed
PEG (undisclosed)	Undisclosed	Phase I	Undisclosed
PEG Interferon Beta	Hepatitis C	Phase I	Serono
PEG AXOKINE	Obesity	Preclinical	Regeneron
PEG-UT-15	Pulmonary Hypertension	Preclinical	United Therapeutics
PEG-Proteins	Multiple	Preclinical	Maxygen
3DP-3534	Thrombocytopenia	Preclinical	3-Dimensional Pharmaceuticals

(1) Clinical Status means:

Approved—regulatory approval to market and sell product obtained.

NDA filed—clinical trials completed and new drug application filed with the FDA.

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

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

Phase I—clinical trials typically in healthy subjects to test safety.

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

(2) This is Enzon's proprietary PEG manufactured by Shearwater. (See Patents and Proprietary Rights for Enzon agreement.)

In general, our collaborative arrangements with respect to our advanced PEGylation technology provides funding for development, payments upon the achievement of certain milestones and royalty and manufacturing revenues upon the commencement of commercial sales.

Selected Partner Development Programs

PEG-INTRON™ Program (PEG Interferon Alpha)

On February 1, 2000, Shearwater entered into a manufacturing agreement with Schering-Plough Corporation ("Schering-Plough") in connection with the PEG reagent used in PEG-INTRON™ (PEG-interferon alpha) for use in the treatment of the hepatitis C virus. Under the terms of this agreement, we manufacture the PEG reagent and Schering-Plough holds an exclusive worldwide license to PEG-INTRON, the first and only PEGylated interferon product approved for marketing in the United States and worldwide.

PEG-INTRON is a recombinant interferon alpha-2b linked to a 12,000 Dalton PEG molecule and is a longer-acting form of INTRON A that uses proprietary PEG technology developed by Enzon. PEG-INTRON is approved for dosing according to patient body weight and is a once-weekly therapy designed to optimize the balance between antiviral activity and elimination of half-life.

Chronic hepatitis C is estimated to affect some 10 million people in major world markets. The Centers for Disease Control and Prevention ("CDC") estimate that between 2.7 and 4 million Americans are chronically infected with the hepatitis C virus with 70 percent of infected patients going on to develop chronic liver disease. Hepatitis C infection contributes to the deaths of an estimated 8,000 to 10,000 Americans each year and this toll is expected to triple by the year 2010, according to the CDC.

Neulasta™ Program (PEG-G-CSF)

On July 25, 1995, Shearwater announced that it had entered into a license, manufacturing and supply agreement with Amgen Inc. to supply its proprietary 20kDa PEG derivative, which is utilized in the manufacture of pegfilgrastim for Amgen's Neulasta™ product. Neulasta™ was approved for marketing in the United States by the FDA in late January 2002.

Neulasta™ is indicated for decreasing the incidence of infection, as manifested by febrile neutropenia (fever associated with a severe drop in infection-fighting white blood cells) in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs. Neulasta™ is a protein that stimulates the production of infection-fighting white blood cells (neutrophils) that are depleted by cytotoxic chemotherapy. Amgen's first generation drug, NEUPOGEN® (Filgrastim), requires up to 2 weeks of daily injections following each cycle of chemotherapy due to the relatively short time it remains circulating in the blood. Almost half of chemotherapy patients who receive NEUPOGEN® require ten or more injections per chemotherapy cycle. With Neulasta™, a PEG unit is added to enlarge the Filgrastim molecule, thereby extending its half-life and causing it to be removed more slowly from the body. This allows for administration in a single dose per chemotherapy cycle. Self-regulation (neutrophil-mediated clearance) of Neulasta™ allows the drug to remain in the blood throughout the time during which a patient is neutropenic (when it is needed) and then be cleared rapidly when it is no longer needed (as neutrophils recover toward normal levels).

Febrile neutropenia is a serious and common complication of many cancer chemotherapies. Up to half of cancer chemotherapy patients develop severe neutropenia, potentially placing them at risk for life-threatening infections. On average, less than 10% of these patients receive proactive protection from

neutropenia and studies have shown that 30% to 40% of patients receiving certain types of chemotherapy who do not get a white blood cell booster will experience neutropenia with fever. Thousands of patients are hospitalized for neutropenia and its complications each year, in an age when most chemotherapy patients are treated in the outpatient setting.

PEGASYS™ Program (PEG Interferon Alpha)

On November 9, 1998 Shearwater announced that it had entered into a license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd. ("Roche") whereby we license to Roche the PEG reagent used in Roche's PEGASYS™ product for the treatment of chronic hepatitis C. This agreement provides us with milestone payments, rights to manufacture the PEG reagent and a share of future revenues related to our PEGASYS™ product. On April 5, 1999, Shearwater entered into a subsequent agreement with Roche related to further collaborative work on PEGASYS™, a PEGylated interferon alpha-2a product.

PEGASYS™ was filed for approval with the FDA for a hepatitis C indication on May 22, 2000. Under the terms of the collaborative arrangement with Roche, the FDA filing triggered a $1.0 million milestone payment to Shearwater by Roche. According to the CDC, chronic hepatitis C is estimated to affect some 10 million people in major world markets. Only a small percentage of the people estimated to be infected with hepatitis C now use interferon alpha because of its low success rate in treating the disease. In Phase III trials, the efficacy and safety of PEG modified interferon alpha-2a (PEGASYS) was compared with unmodified interferon alpha-2a (Roferon-A) for treatment of hepatitis-C in 531 patients. The results reported that sustained viral clearance was observed in 39% of patients receiving PEGASYS compared with 19% of patients receiving Roferon-A. In May 2001, Shearwater announced the latest clinical trial data from the first large efficacy and safety study to directly compare PEGASYS™ in combination with the antiviral drug ribavirin, against Rebetron™ (interferon alpha-2b plus rivavirin). The study results suggested that the combination of PEGASYS™ and ribavirin may yield significantly increased sustained virologic responses compared to combination therapy with Rebetron™.

We are also developing a PEGASYS™ program to be used in the treatment of hepatitis B. A recently completed Phase II study for our PEG interferon alpha indication showed positive results at dosages of 180mg when compared to similar dosages of standard Roferon. Phase III studies in both antigen negative and positive hepatitis B have now begun with approximately 1,000 patients being treated. These trials will compare PEGASYS™ mono-therapy and PEGASYS™ combination therapy (with Lamivudine) vs. Lamivudine.

Somavert™ Program (PEG-hGHRa)

On April 4, 2000, Shearwater entered into a license, manufacturing and supply agreement with Sensus Drug Development Corporation for the PEGylation of Sensus' Somavert™ (pegvisomant for injection), a human growth hormone receptor antagonist. The agreement provides us with milestone payments, rights to manufacture the PEG reagent and a share of future revenues. In March 2001, Sensus was acquired by Pharmacia Corp.

Somavert™ is a genetically modified form of human growth hormone and an investigational drug designed to block the binding of growth hormone produced by the pituitary. Our patented PEG reagent is covalently bound to the molecule to increase the circulating life of the drug in the blood stream and potentially reduce the immune reaction to the drug. Pharmacia completed Phase III clinical trials for the use of Somavert™ in the treatment of acromegaly, a serious, debilitating disease that often requires lifelong therapy. Patients with acromegaly often suffer from headache, excessive sweating, soft-tissue swelling, joint disorders and a progressive coarsening of facial features and enlargement of the hands, feet and jaw. In acromegaly, excess production of growth hormone is usually caused by a pituitary tumor, affecting an estimated 40,000 patients in the U.S., Europe and Japan. Following the completion of

Phase III clinical trials in 111 patients in the U.S. and Europe, an application to market Somavert™ in the U.S. and Europe was filed in February 2001 and is awaiting regulatory response.

SprayGel™ Program (PEG-hydrogel)

On August 6, 1999, Shearwater entered into a license, supply and manufacturing agreement with Confluent Surgical, Inc. for Shearwater's PEG-hydrogel for use in the SprayGel™ adhesion barrier system. Under the terms of this arrangement, we manufacture and supply PEG components used in the SprayGel™ system and receive royalty payments and manufacturing supply fees from Confluent. SprayGel™ was approved for commercial distribution in Europe, receiving product certification by European regulatory authorities in November 2001.

SprayGel™ is a bio-degradable, water-based, coating material designed to prevent post-operative adhesion formation. This material is formed from two water-based PEG solutions that mix at the site of an injury. The solutions are sprayed using an applicator that is designed for minimally invasive surgery. As internal wounds heal following surgery, a type of scar tissue or adhesion can form, connecting two organs or surfaces that are normally separate in the body. SprayGel™ is sprayed onto the internal surfaces most at risk for adhesions and creates a thin, flexible hydrogel coating that acts as an internal bandage as the wound heals.

The sterile polymer kit manufactured and supplied to Confluent consists of two separate aqueous PEG-containing liquid precursors (clear and blue) that polymerize to form the hydrogel when mixed. The blue precursor also contains a small amount of methylene blue, a colorant added to facilitate visualization during hydrogel application. The hydrogel barrier is formulated to remain adherent to the site of application for 5-7 days during the critical window period when fibrin deposition, fibrinolysis and adhesion formation is believed to occur. It is then completely hydrolyzed, absorbed and excreted by the kidneys within 3-4 weeks.

Adhesions can be responsible for severe pain and discomfort as well as small bowel obstructions and are the leading cause of infertility in women following gynecological surgery. Approximately 500,000 surgical procedures are performed annually to remove adhesions.

PEG-Aptamer Program

On February 26, 2002, we announced a long-term commercial supply agreement with Eyetech Pharmaceuticals, Inc., a privately held biopharmaceutical company based in New York City. Eyetech is currently conducting a Phase II/III pivotal clinical trial to evaluate the safety and efficacy of EYE001, a PEGylated aptamer, for the treatment of age-related macular degeneration. .

Under the agreement, we will provide Eyetech with PEGylation technology for use in the development of EYE001 and we will receive milestone payments, royalties and exclusive manufacturing of the PEGylated derivative.

Age-related macular degeneration is a leading cause of blindness in the adult population. Studies suggest that Vascular Endothelial Growth Factor (VEGF) causes the abnormal blood vessel growth and/or leakage that lead to age-related macular degeneration. EYE001, an anti-VEGF aptamer, may inhibit the biological pathway that causes vision loss. Aptamers are chemically synthesized molecules created to either mimic or prevent specific molecules from binding to their receptors much like antibodies. If successful, Eyetech's compound may result in stabilized or improved vision and an enhanced quality of life for patients suffering from age-related macular degeneration, diabetic macular edema and other related retinal diseases.

PEG CDP870 Program

On February 26, 2002, we announced a collaboration with Pharmacia Corporation to provide proprietary PEGylation technology for Pharmacia's investigational new therapy for the treatment of rheumatoid arthritis, CDP870. This is a humanized antibody fragment that binds with high affinity to tumor necrosis factor-alpha, a key mediator responsible for the inflammation of rheumatoid arthritis. It is chemically modified to enable slow elimination from the body by coupling a branched PEG reagent to the antibody fragment. CDP870 has completed Phase II clinical testing.

Shearwater entered into a license, manufacturing and supply agreement with Celltech Group plc in 2000 which was subsequently assigned to Pharmacia. Under the agreement, we receive milestone payments, royalties and PEG manufacturing revenues if the product is commercialized. Pharmacia will manage further clinical development and market the product for rheumatoid arthritis. CDP870 is also being assessed in Phase II studies as a treatment for Crohn's disease.

Rheumatoid arthritis affects an estimated 2.1 million Americans. This systemic autoimmune disease is characterized by inflammation of the lining of the joint. Current therapies are directed at treating the symptoms of rheumatoid arthritis or at modifying the disease, or a combination of the two, requiring daily or weekly administration.

Cross Platform Strategic Alliance

In January 2002, we announced a strategic alliance with Enzon, Inc. ("Enzon") that includes an agreement making us solely responsible for licensing Enzon's PEGylation patents, an option for Enzon to license our PEGylation patents, an agreement to explore the development of non-invasive delivery of single-chain antibody products via the pulmonary route and settlement of a patent infringement litigation originally filed by Enzon against Shearwater. We will have the option to license Enzon's PEG patents for use in our proprietary products. Enzon will receive a royalty or a share of profits on final product sales of any products that use Enzon's patented PEG technology, including branched PEG. As part of this broad alliance, we entered into a collaboration to develop three products using our Inhance™ inhaleables technology and/or SEDS™ technology. Under the terms of this collaboration, we will be responsible for the development of drug formulations for the agreed upon pharmaceutical agents as well as clinical and commercial manufacturing of the drug formulation and device combination. Enzon will be responsible for the clinical development and worldwide commercialization of such combination. We will receive research and development funding, milestone payments as the program progresses through further clinical testing, and royalty payments once the product is commercialized. As part of this alliance, Enzon made a $40.0 million equity investment in Inhale in the form of preferred convertible stock.

Inhance™ Inhaleables Technology

Historically, we focused on the non-injectible delivery of peptides and proteins to the body through the lungs. Our inhaleables technology platform, known as Inhance™, would enable such non-invasive delivery of certain large sized molecular compounds now administered by injection. Currently there are approximately 84 of these macromolecule drugs marketed in the United States and about 350 other such drugs in clinical trials. Most of these drugs are currently delivered by frequent injection. Frequent injections are undesirable for numerous reasons including patient discomfort, inconvenience and risk of infection that

can lead to non-compliance. The failure by patients to comply with current requirements for frequent injections can lead to increased incidence of medical complications and higher disease management costs. Alternatives to injection such as oral, nasal and transdermal, or "skinpatch," delivery approaches generally have been commercially unattractive for macromolecules due to the low natural amount of drug absorbed from the delivery site into the bloodstream relative to injection. As an alternative to the invasiveness of frequent injections, we believe our inhaleables technology could expand the market for macromolecule drug therapies and may enable new therapeutic uses of certain macromolecule drugs.

Characteristics of Inhance™ Inhaleables Technology

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

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

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

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

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

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

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

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

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

Components of the Integrated Inhance™ Deep Lung Drug Delivery System

The Inhance™ inhaleable platform integrates several technologies including customized formulation of drug compounds, dry powder processing and packaging along with proprietary inhalation devices to enable efficient and consistent delivery of both macromolecule and small molecule drugs for systemic and local lung diseases. For specific drug products, we formulate and process bulk drugs supplied by collaborative partners into dry powders, that are packaged into individual dosing units referred to as

"blisters." The blisters are designed to be loaded into our device, which patients then activate to inhale the aerosolized drugs that have been formulated to a particle size that permits deep lung delivery.

Dry Powder Formulations for Delivery to the Deep Lung. Each macromolecule drug poses different formulation challenges due to differing chemical and physical characteristics and dosing requirements. This requires significant optimization work for each specific drug. We have assembled a team with expertise in protein formulation, powder science and aerosol science, and we are applying this expertise to develop proprietary techniques and methods that we believe will produce stable, fillable, shippable and dispersible dry powder drug formulations. We have developed several protein powders which remain stable at room temperature in excess of one year. Through our work with numerous macromolecules, we are developing an extensive body of knowledge on aerosol dry powder formulations, including knowledge relating to the physiochemical properties of particles that make up powders and the resulting characteristics such as flowability, dispersability and solubility within the lung, as well as the related properties and influences of various excipients. We have filed and expect to continue to file patent applications on several of our formulations and, through strategic acquisitions, have acquired rights to certain U.S. and foreign patents and patent applications relating to stabilization of macromolecule drugs in dry powder formulations.

Powder Processing. We are modifying standard powder processing equipment and developing custom techniques to enable us to produce fine dry powders with particle aerosol diameters of between one and five microns without significant drug degradation or significant loss. We have scaled up powder processing to levels sufficient for producing candidate powders for late stage clinical trials. It is expected that production at these levels will be more than sufficient to satisfy the needs of small volume commercial products. We are also in the process of further scaling up our powder processing systems in order to produce quantities

sufficient for commercial production of products we believe we will need to supply in high volumes, such as insulin. However, there can be no assurance that we will be successful in further scaling up our powder processing on a timely basis or at a reasonable cost, or that the powder processing system will be applicable for every drug.

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

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

- *Effectively Disperse Fine Particles into an Aerosol Cloud.* Fine powders have different dispersion requirements or characteristics than large powders. Most current dry powder inhalers use larger powders and are not efficient in dispersing powders with aerosol diameters of one to five microns. We have developed and are refining the dispersion system for our device specifically for fine powders. Our device has been designed to efficiently remove powders from the packaging, effectively break up the powder particles and create an aerosol cloud while maintaining the integrity of the drug.

- *Efficiently and Reproducibly Deliver the Aerosol Cloud to the Deep Lung.* We are developing a proprietary aerosol cloud handling system in our device that is intended to facilitate deep lung powder deposition and reproducible patient dosing. The handling system design is intended to enable the aerosolized particles to be transported from the device to the deep lung during a patient's breath, reducing losses in the throat and upper airways. In addition, the aerosol cloud handling system, in conjunction with the dispersion mechanism and materials used in the device, is designed to reduce powder loss in the device itself.

- *Eliminate the Use of Propellants to Avoid Associated Environmental Concerns and Formulation Difficulties.* Our device does not use propellants. The oily surfactants required to stabilize propellant formulations used in many MDI formulations can cause aggregation of macromolecules. In addition, current chlorofluorocarbon propellants are being phased out in many countries due to environmental concerns.

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

Clinical Status Summary of our Inhance™ Inhaleables Technology

The following table sets forth, for our partner development programs, the drugs currently in development using our Inhance™ inhaleables technology, the indication(s) for the particular drug, its present stage of clinical development and the identity of the corporate partner for such drug. We also have early stage feasibility and research collaborations involving our inhaleables technology with several other companies and have tested approximately 12 inhaleable drugs in clinical trials. We have also developed internal programs with respect to certain drugs or undertaken subsequent development with respect to certain drugs formerly the subject of particular collaborations. We are also developing next generation inhaleable powders and inhalation devices to further facilitate the delivery of small molecules and macromolecules both to, and through, the lung.

PARTNER DEVELOPMENT PROGRAMS (Inhaleables)

Drug	*Indication(s)*	*Clinical Status(1)*	*Partner*
Insulin	Type 1 and 2 Diabetes	Phase III	Pfizer
Alpha-1 Proteinase Inhibitor	Hereditary Emphysema	Phase I	Aventis Behring
Tobramycin	Cystic Fibrosis	Phase I	Chiron
Fortéo™	Osteoporosis	Phase I(2)	Lilly
Leuprolide	Prostate Cancer, Endometriosis	Phase I	Unpartnered
Multiple Drugs TBD	TBD	N/A	Johnson & Johnson

Multiple Drugs TBD	Lung Infections	N/A	Chiron
Dronabinol (THC)	Multiple-pain	N/A	Unimed

(1) Clinical Status means:

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

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

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

(2) Clinical activities on hold; on-going stability work.

In general, our partnership arrangements with respect to our Inhance™ inhaleables technology 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.

Partner Development Programs

Insulin Program

Insulin is a protein hormone naturally secreted by the pancreas to induce the removal of glucose from the blood into cells. Diabetes, the inability of the body to regulate properly blood glucose levels, is caused by insufficient production of insulin by the pancreas or resistance to the insulin produced. 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, in its injectible form, is supplied by various manufacturers, including Lilly, Novo-Nordisk A/S and Aventis Pharma.

According to the United States Centers for Disease Control and Prevention, approximately 16 million people in the United States have diabetes, 10.3 million of which are diagnosed with diabetes and another 5.4 million of which have undiagnosed diabetes. There are approximately 798,000 new cases of diabetes diagnosed each year. All Type 1 diabetics, estimated at between 5% and 15% of all diabetics, require insulin therapy. Type 1 diabetics require both basal insulin in the form of long-acting insulin and multiple treatments of regular, or short acting, insulin throughout the day. Type 2 diabetics, depending on the severity of their disease, may or may not require insulin therapy. Because of the inconvenience and unpleasantness of injections, many Type 2 patients who do not require insulin to survive, despite the fact that they would benefit from it, are reluctant to start treatment.

Insulin therapy in Type 2 patients is generally given twice daily and is a combination of a short and long acting insulin. A ten-year study by the National Institutes of Health, however, demonstrated that the side effects of diabetes could be significantly reduced by dosing more frequently. The NIH study

recommended dosing regular insulin three to four times per day, a regimen which would more closely mirror the action of naturally produced insulin in non-diabetics. Because of the risk of severe hypoglycemia, this course of treatment is not recommended for children, older adults, people with heart disease or with a history of frequent severe hypoglycemia. In addition, many patients are reluctant to increase their number of daily doses because they find injections unpleasant and inconvenient. Similar results were demonstrated in Type 2 patients in a UK trial.

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

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

In November 1998, Pfizer and Aventis Pharma announced that they entered into a worldwide agreement to manufacture insulin and to co-develop and co-promote inhaleable insulin. Under the terms of the agreement, Pfizer and Aventis Pharma agreed to construct a jointly owned, state-of-the-art insulin manufacturing plant in Frankfurt, Germany. Pfizer and Aventis Pharma have reported plans to invest over $160 million in this new plant which is projected to be the largest of its kind worldwide and would employ approximately 200 people. We will continue to have responsibility for manufacturing powders and supplying delivery devices and will receive a royalty on inhaleable insulin products marketed jointly by Pfizer and Aventis Pharma.

In June 1999, Pfizer began dosing in Phase III clinical trials. In June 2000, Pfizer reported new data on patients using inhaleable insulin therapy from a Phase II continuation, or extension, study being conducted by Pfizer and Aventis Pharma. The goal of the extension study was to determine if safety and efficacy results from previously reported short-term Phase II clinical trials could be maintained in the long term. These data showed that HbAlc, the long-term measurement of blood glucose control, remained stable in patients for up to 30 months of therapy. At the time that this data was compiled, 83 patients had completed 24 months of inhaleable therapy. Further data presented indicated similar results for patients who completed 30 months of therapy. Additionally, the results of four different lung function tests showed that lung function was sustained during the course of treatment.

In June 2001, Pfizer reported on data released from Phase III studies showing that more patients with Type 2 diabetes who were treated with inhaled insulin achieved the recommended blood glucose levels than patients who received only insulin injections. In addition the frequency and nature of adverse events were

comparable between groups. Patients who used inhaled insulin developed increased insulin antibody serum binding, but there did not appear to be any related clinical significance. Additional data released from these Phase III studies suggested that patients with Type 1 diabetes using inhale insulin multiple times a day with one bedtime long acting injection achieved comparable control of blood glucose to that seen in patients receiving multiple daily injections. An additional Phase III study indicated that Type 2

diabetic patients who were poorly controlled on a combination of two oral diabetes therapies demonstrated improved glycemic control and greater overall satisfaction and acceptance of therapy when inhaled insulin was added to their treatment regimen or when it replaced oral therapies.

In December 2001, Pfizer announced that it had decided to include an increased level of controlled, long-term safety data in its proposed NDA with respect to inhaled insulin and that it expected to complete this additional study in 2002.

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

Alpha-1 Proteinase Inhibitor Program

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

We and Aventis Behring have completed preclinical work and Phase I clinical trials that indicate our dry powder formulation of Aventis Behring's alpha-1 proteinase inhibitor has the potential to improve significantly the efficiency of delivery compared with current infusion therapy. We believe our pulmonary delivery system could significantly reduce the amount of drug needed for genetic emphysema therapy since alpha-1 proteinase inhibitor could be delivered directly to the lung where it acts. Aventis Behring is currently negotiating to secure rights under patents that have been granted in Europe directed to aerosol formulations for the treatment of the lung containing serine protease inhibitors, including alpha-1 proteinase inhibitor. Although originally planning to initiate pivotal clinical trials in the first half of 2002, Aventis Behring has not decided yet when they plan to conduct more advanced clinical trials based on their need to re-examine the type of endpoint measurement to be used.

Tobramycin Program

In December 2001, we entered into a collaboration with Chiron Corporation to develop a next-generation inhaleable formulation of tobramycin for the treatment of *Pseudomonas aeruginosa* in cystic fibrosis patients and to explore the development of other inhaled antibiotics using our Inhance™ inhaleables technology. Cystic fibrosis is a hereditary disease that primarily affects people of Caucasian origin. About 30,000 people in the United States and about 70,000 people worldwide have cystic fibrosis. Cystic fibrosis is caused by genetic mutation that prevents cells from building a protein required for normal movement of sodium and chloride in and out of cells lining the lungs and other organs. Patients with cystic fibrosis typically suffer from chronic respiratory infections, digestive disorders, reduced male fertility and other problems. Chiron's existing tobramycin product, TOBI®, was introduced in 1998 as the first inhaled antibiotic approved for treating *Pseudomonas aeruginosa* lung infections in cystic fibrosis patients.

Under the terms of the tobramycin collaboration, we will be responsible for the development of the next generation formulation of tobramycin as well as clinical and commercial manufacturing of the drug formulation and device combination. Chiron will be responsible for the clinical development and worldwide commercialization of the system. We will receive research and development funding, milestone payments as the program progresses through further clinical testing, and royalty payments once the product is commercialized. It is expected that the additional drug formulations to be investigated will also relate to antibiotic products for the treatment of lung infections.

Fortéo™ Program

In January 1997, we entered into a collaborative agreement with Eli Lilly and Company ("Lilly") to develop an inhaleable formulation of Fortéo™, a version of parathyroid hormone, PTH 1-34, used in the treatment of osteoporosis. Under the terms of the agreement we were to receive up to an estimated $20.0 million in research, development and milestone payments. Lilly was to receive global commercialization rights for the pulmonary delivery of the products and we were to receive royalties on any marketed products.

In late 1998, unexpected observations from a long-term test in rats of the injectible version of this osteoporosis drug led Lilly to suspend further clinical development of the injectible and pulmonary versions of Fortéo™ pending further analysis. In September 2000, we announced the reinitiation of the Fortéo™ development program with Lilly. In October 2001, Lilly informed us that inhaled Fortéo™ would not be funded in 2002 and that other than on-going stability work, other activities were to be suspended. It was our understanding that this suspension is a result of Lilly's decision on funding priorities for the next year, not due to any technical issues.

Collaborations for other drug compounds

In October 2001, we entered into a collaboration with the R.W. Johnson Pharmaceutical Research Institute and the Janssen Research Foundation, subsidiaries of Johnson & Johnson, for the development of multiple small molecule compounds using our inhaleables technology. Under the terms of the collaboration, we will be responsible for developing the formulations of inhaleable small molecule compounds up to proof-of-concept, and our partners will be responsible for the evaluation and clinical development of selected formulations. We will receive research and development funding, milestone payments based on progress in clinical trials and royalty payments if products are commercialized.

Marinol® Program

In February 2002, we entered into a collaboration with Unimed Pharmaceuticals, Inc., a wholly owned subsidiary of Solvay Pharmaceuticals, Inc., ("Unimed") to develop an MDI of dronabinol (synthetic delta-9-tetrahydrocannabinol) to be used for multiple indications. Dronabinol is the active ingredient in Unimed's product MARINOL® Capsules. MARINOL® Capsules is synthetic delta-9-tetrahydrocannabinol. MARINOL® is approved in the U.S. and is indicated for the treatment of anorexia associated with weight loss in patients with AIDS and for the treatment of refractory nausea and vomiting associated with cancer chemotherapy.

Under the terms of the collaboration, we will be responsible for development of the formulation, as well as clinical and commercial manufacturing of the drug formulation and inhaler combination. Unimed will be responsible for the clinical development and worldwide commercialization of the system. We will receive research and development funding, milestone payments as the program progresses through further clinical testing, and royalty payments and manufacturing revenues when the product is commercialized.

Avonex® Program

In February 1999, we entered into a collaborative agreement with Biogen to develop an inhaleable formulation of Biogen's proprietary Interferon-Beta-la, marketed as Avonex®, for the treatment of multiple sclerosis. Under the terms of the collaboration agreement, Biogen was to provide us with bulk Avonex® for formulation into a dry powder for inhalation into the deep lung. We were to manufacture and package the dry powder and supply inhalation devices. Biogen was responsible for clinical development, commercialization and worldwide marketing of inhaleable Avonex®. In return for developing inhaleable Avonex®, we were to receive royalties on product sales, milestone payments and research and development funding.

Dosing for the Phase IA clinical trial of inhaleable Avonex® began in April 2000 and is now complete. In January 2002, Biogen announced that it does not plan to further develop inhaleable Avonex® for multiple sclerosis at this time, but is working with us to evaluate other opportunities for collaboration.

Feasibility Studies

In addition to the active partners mentioned above and other development programs, we have conducted and continue to conduct feasibility studies of additional drug formulations both on our own account and in cooperation with potential partners. We will continue to pursue these and other feasibility programs to determine the potential for collaborative development programs with respect to these drugs.

Supplemental Agreement with Alliance Pharmaceutical Corp.

In March 2002, we announced the expansion of our agreement with Alliance Pharmaceutical Corp. ("Alliance") regarding the PulmoSphere® particle and particle processing technology, aspects of which we initially acquired from Alliance in November, 1999. The PulmoSphere® technology is a particle formation method designed to enhance the performance of drugs delivered via the lung in propellant-based metered-dose inhalers and dry powder inhalers. As a result of the supplemental agreement, Inhale has paid to Alliance $5.25 million in exchange for rights beyond inhaleable applications and other considerations. Under the terms of the supplemental agreement, Inhale has the right to use the PulmoSphere® technology for alternative methods of delivery in addition to inhaleable applications. Further, Alliance assigned five new patent applications covering methods of producing microparticles to Inhale. Alliance retains the rights to use the technology on products to be instilled directly into the lung, and obtains the rights to commercialize up to four products administered with inhalers, two of which will be royalty-free. Inhale will pay Alliance future milestone or royalty payments on a reduced number of products developed by Inhale or its licensees utilizing the technology.

SEDS™ Technology

In January 2001, we completed our acquisition of all the outstanding share capital of Bradford Particle Design for which we paid consideration of approximately $20.4 million in cash and an aggregate of approximately 3.75 million shares and options to purchase our common stock. Through this acquisition, we acquired additional technology and collaborations relating to the development of drug compounds using a technology known as Solution Enhanced Dispersion by Supercritical Fluids ("SEDS™"). This technique uses gases at elevated temperatures and pressures as alternative solvents and non-solvents in the formation of dry powder particles used in the manufacture of pharmaceuticals. Our SEDS™ technology is designed to reduce to a single step the current multi-stage powder manufacturing process for drug powders, while at the same time improving product purity and consistency. It offers an alternative to typical crystallization processes for many small molecules with the potential benefits of better control over particle size, form, structure and surface characteristics resulting in the potential for improved drug absorption, easier and more efficient formulation of drug compounds and lower manufacturing costs. We believe this technology can also be used in connection with technology designed for taste masking and controlled release of drug compounds.

Over 80% of pharmaceutical products contain powder particles, either in the final form or at some point during the manufacturing process. Specific particle characteristics are fundamental to the effectiveness of drug delivery but precision and consistency in particle formation are difficult to achieve using conventional multi-stage methods of production. SEDS™ is designed to control the formation of powder particles in a wide variety of chemical substances. A supercritical fluid is any material held above a critical pressure and temperature. Supercritical fluids have attractive chemical properties for processing and preparing drug substances. Carbon dioxide is the widest commercially used supercritical fluid.

In the SEDS™ process, the supercritical fluid disperses and mixes a stream of drug solution while simultaneously extracting the organic solvent and rapidly forming dry particles. This is achieved by metering the solution and the supercritical fluid into a particle formation vessel held under controlled conditions of temperature and pressure above the critical point of the supercritical fluid-solvent mixture. Dry, solvent free particles are then recovered from the particle formation vessel.

As a single-stage manufacturing process, SEDS™ provides greater control over batch to batch consistency, particle size, particle shape, powder flow, dissolution rate and residual solvent levels than traditional manufacturing methods. As a result, we believe that SEDS™ can deliver the following benefits:

- Cost efficiency through greater consistency of product from batch to batch and simplicity in initial development of desired particle characteristics;
- Lower risk of product recalls by ensuring stability, purity and consistent concentration of active ingredients; and
- Reduced complexity and increased speed in drug development due to the reduced number of process standards and controls involved in single-stage manufacturing.

SEDS™ Applications

We believe our SEDS™ technology can serve as a platform technology for a diverse range of therapeutic areas, including the following:

- *Polymorph Separation.* The SEDS™ process offers the ability to prepare separate polymorphic forms of drugs in a manner that is easily reproducible.
- *Water Solubility*. The SEDS™ process helps to provide enhanced dissolution of sparingly water-soluble drugs, by producing sub-micron sized particles or through coformulation with water soluble polymers.
- *Controlled Release*. The SEDS™ process can support the application of a wide range of polymers and other materials to modify drug dissolution and release profiles.
- *Improved Powders for Inhaleable Drugs.* We believe that particles designed with appropriate size and low cohesion deliver more drug to the deep lung from a range of dry powder inhalation devices. By allowing greater control over the formation of particles during manufacture, SEDS™ technology can assist in the development of dry powders with these preferred characteristics.
- *Taste Masking.* We believe that the SEDS™ process can be used to minimize the taste of many oral drugs, particularly small organic molecules.
- *Biologicals*. The typical method for particle formation of peptides, proteins, nucleic acids and other biologicals involves freeze-drying and spray-drying, which may lead to significant batch variation and problems in downstream processing and manufacture. We believe that SEDS™ offers a potentially valuable alternative to this method of particle formation for biologicals.

Clinical Status Summary of our SEDS™ Technology Applications

We typically develop new products using our SEDS™ technology through collaborations with corporate partners. As with our other technologies, our collaborative research personnel will work closely with our partners in designing the preferred characteristics of the particle to be formulated and in applying the technology to achieve these characteristics consistently. In a typical research collaboration, we derive revenue from milestone payments and additional royalties on net sales of approved drugs. We will also derive revenue from the manufacturing of the drug powders.

We have 18 feasibility or collaboration agreements with biotechnology and pharmaceutical companies to apply our SEDS™ technology to approximately 25 drugs. Most of our collaborations with respect to our SEDS™ technology are in the preclinical feasibility stage with one product having been tested in humans.

Almost all of our collaborations with corporate partners are at the feasibility stage and involve mostly new chemical entities. We are currently confidentially collaborating with eight pharmaceutical companies worldwide with respect to our SEDS™ technology. At this time, we have publicly announced partner development programs for the development of new products using our SEDS™ technology with the following corporate partners:

AstraZeneca UK Limited has been carrying out feasibility studies on specific compounds using SEDS™ technology. AstraZeneca is continuing to evaluate our supercritical fluid technology and holds a license in certain of our patents.

Bristol-Myers Squibb Company is funding a program of feasibility studies to evaluate the utility of supercritical fluid technology for a number of applications for its proprietary molecules. In 2000, Bradford Particle Design entered into a license agreement with Bristol-Myers Squibb to carry out further in-house research on our SEDS™ technology.

GlaxoSmithKline plc is collaborating with Bradford Particle Design on supercritical fluid processes for particle formation. GlaxoSmithKline holds a license in this technology and continues to evaluate its potential.

Manufacturing

We believe our manufacturing strategy will enable us to achieve the following:

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

With respect to products using our Inhance™ inhaleables technology we generally plan to formulate, manufacture and package the powders for our deep lung delivery products and to subcontract the manufacture of our proprietary pulmonary delivery devices. Our device is still in clinical testing and production scale-up work is underway. Further design and development work is underway to enable commercial manufacturing and additional work may be required to optimize the device for regulatory approval, field reliability or other issues that may be important to its commercial success. Additional design and development work may lead to a delay in regulatory approval, efforts to seek regulatory approval for any product that incorporates the device or the time the device could be ready for commercial launch. Under our collaborative agreement with Pfizer to develop inhaleable insulin, we will manufacture insulin powders and Pfizer will

be primarily responsible for filling blisters. The terms of the collaborative agreement with Pfizer provide that prior to the commercialization of its first products, we must build and have validated a powder processing facility and must have validated a device manufacturer or manufacturers. We will be the commercial powder manufacturer at launch. Pfizer has the right to manufacture a portion of the powder requirement post-launch.

We have built a powder manufacturing and packaging facility in San Carlos, California capable of producing powders in quantities sufficient for clinical trials of drugs using our inhaleables technology. This facility has been inspected and licensed by the State of California and is used to manufacture and package powders under current good manufacturing practices. We are expanding our facility to meet our future commercial manufacturing commitments and expansion and scale-up is expected to be completed in time for commercial operations.

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

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

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

With respect to products using our advanced PEGylation technology, we maintain two facilities in Huntsville, Alabama for the manufacture of PEG-derivatives in batch sizes of 100 grams to 10 kilograms. Our PEG manufacturing facilities include four separate production suites qualified to produce activated PEG derivatives. We are in the process of constructing two additional clean rooms to be qualified to produce bulk small molecule and peptide active pharmaceutical ingredients. Upon completion of this facility, we believe that our manufacturing capacity will be sufficient to produce PEG derivatives and bulk final PEG-drug substances in quantities sufficient to support commercial sale of these products.

With respect to products using our SEDS™ technology, we currently have one facility in Bradford, England which allows for the production of 100 to 250 kilograms annually of dry powder material depending on the attributes of the compound. We believe this capacity is sufficient for the production of materials necessary to complete a substantial portion of early-stage clinical trials undertaken by our collaborative partners. With further optimization we would expect this capacity to rise. We currently are in the early planning stages for the development of a full-scale manufacturing facility that will enable us to produce products using the SEDS™ technology on a commercial scale. We expect such facility to be completed within the next 18 months.

Government Regulation

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

The process required by the FDA before a product using our drug delivery and drug formulation technologies may be marketed in the United States depends on whether the compound has existing

approval for use in other dosage forms. If the drug is a new chemical entity that has not been approved, the process includes the following:

- extensive preclinical laboratory and animal testing;
- submission of an Investigational New Drug application, or IND;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for the intended indication; and
- submission to the FDA for approval of a New Drug Application, or NDA, with respect to drugs or a Biological License Application, or BLA, with respect to biological products.

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

Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulation. Drug products must be formulated according to current good manufacturing practices, and preclinical safety tests must be conducted by laboratories

that comply with FDA good laboratory practices regulations. The results of the preclinical tests are submitted to the FDA as part of an IND application and are reviewed by the FDA before clinical trials can begin. Clinical trials may begin 30 days after receipt of the IND by the FDA, unless the FDA raises objections during that period.

Clinical trials involve the administration of the drug to healthy volunteers or to patients under the supervision of a qualified medical investigator according to an approval protocol. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor participant safety and efficacy or other criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. Each clinical study is conducted under the auspices of an independent Institutional Review Board, or IRB. The IRB considers, among other things, ethical factors, the potential risks to subjects participating in the trial and the possible liability of the institution. The IRB also approves the consent form signed by the trial participants.

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

- determine the efficacy of the product for specific targeted indications;
- determine dosage tolerance and optimal dosage and regimen of administration; and
- identify possible adverse effects and safety risks.

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

The results of product development, preclinical studies and clinical studies are submitted to the FDA as an NDA/BLA for approval of the marketing and commercial shipment of the pulmonary drug product. The FDA may deny an NDA/BLA if applicable regulatory criteria are not satisfied or may require additional clinical testing. Even if such data are submitted, the FDA may ultimately decide that the NDA/ BLA does not satisfy the criteria for approval. Product approvals, once obtained, may be withdrawn if compliance with regulatory standards are not maintained or if safety concerns arise after the product

reaches the market. The FDA may require post-marketing testing and surveillance programs to monitor the effect of pulmonary drug products that have been commercialized and has the power to prevent or limit future marketing of the product based on the results of such programs.

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

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

For products currently under development using our inhaleables technology, our inhalation device is considered to be part of a drug/device combination for deep lung delivery of each specific molecule. Prior to submission of an IND, the FDA Center and division within the FDA Center responsible for the review of the IND and NDA/BLA will be identified. In the case of our products, either the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research, in consultation with the Center for Devices and Radiological Health, could be involved in the review. However, one center is designated as having the lead responsibility for regulating the product. The jurisdiction within the FDA is based on the primary mode of action of the drug and is identified in the FDA's intercenter agreement.

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

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

Prior to marketing a new dosage form of any drug, the product must undergo rigorous preclinical and clinical testing and an extensive review process mandated by the FDA and equivalent foreign authorities regardless of whether or not such drug was already approved for marketing in another dosage form. These processes generally take a number of years and require the expenditure of substantial resources. We primarily intend to rely on our partners to fund clinical testing and to obtain product approvals.

In developing the device component for our inhaleables technology, we have sought to develop our quality systems and design engineering function in adherence to the principles of design control for medical devices as set out in the applicable regulatory guidance. Although hybrid drug/device products are

typically reviewed as a drug, we have sought to adhere to the design control approach both as a good business practice, and because it is clear that the drug and biologic centers of the FDA and other worldwide agencies are moving in this direction. In the EU, this has already taken place and delivery devices are viewed as separate entities and are subject to review as such under the Medical Device Directive. In the U.S., although not yet formally required, it is our intention to comply with the FDA regulations for devices and develop our device technology in compliance with design control principles. There can be no assurance that products designed by us and built by our contract manufacturers will be approved, or meet approval requirements on a timely basis.

Patents and Proprietary Rights

Our policy is to apply for patent protection for the technology, inventions and improvements deemed important to the success of our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and further develop our competitive position. Through our acquisitions of Shearwater and Bradford Particle Design, our patent portfolio has expanded in size and scope to encompass our SEDS™ and PEGylation technologies in addition to our pulmonary delivery systems technologies. We plan to defend aggressively our proprietary technologies and any issued patents.

Our recently expanded patent portfolio contains patents and patent applications related to our advanced PEGylation technology. These patents and patent applications cover reactive polyethylene glycol (PEG) derivatives, PEG-drug conjugates, PEG-based prodrugs, hydrogels, and unimolecular micelles. We have filed patent applications directed to activated PEG reagents having a variety of structures (branched or multi-armed PEGs, forked PEGs, linear PEGs, etc.) and reactive groups, methods of producing highly pure polymer reagents, PEG prodrugs having hydrolysable linkages, PEG-based hydrogels and alternative gel systems and PEG conjugates of certain molecules. Patents or patent applications have issued or have been published in many of these areas and include: U.S. Patent No. 5,446,090 directed to heterofunctional PEGs having a terminal vinylsulfone group for reaction with sulfhydryl groups and U.S. Patent No. 6,214,966, directed to PEG derivatives having a weak, hydrolytically unstable linkage near the reactive terminus of the polymer. U.S. Patent No. 5,672,662 covering monosubstituted PEG derivatives, U.S. Patent No. 5,990,237 directed to PEG-aldehyde hydrates and U.S. Patent No. 5,932,462 directed to branched or multi-armed PEGs.

We expect that our integrated system for pulmonary delivery of both large and small molecule drugs will continue to yield innovations in dry powder formulations, powder processing, powder packaging and device design. It is our strategy to build proprietary positions in each of these technological areas. Our success will depend in part upon our ability to protect our proprietary technology from infringement, misappropriation, duplication and discovery. We have filed patent applications covering certain aspects of our inhalation device, powder processing technology, powder formulations and pulmonary route of delivery for certain molecules, and plan to file additional patent applications in these and other innovative areas. Patents that have issued in these areas cover many facets of these technologies. For example, U.S. Patent Nos. 5,458,135 and 6,138,668 cover pulmonary delivery devices for delivering aerosolized (including powder) formulations of drugs to the lungs. U.S. Patent Nos. 5,826,633 and 6,051,256 cover methods and apparatus for preparing and handling our dry powder formulations. A further group of issued U.S. patents, which include U.S. Patent Nos. 5,997,848 and 6,080,721 cover particular active agent formulations for delivery via the respiratory tract.

Our SEDS™ patent portfolio is related to compositions and apparatuses for preparing particles using our proprietary supercritical fluid process. The particle formation technique involves contacting an active agent solution or suspension with a supercritical fluid to precipitate active agent particles from the solution or suspension. There are patents and patent applications that cover both the method of forming the particles and apparatuses for carrying out the method. These patents and patent applications are not

limited by the particular product made. Further applications cover formulations made by the process described above.

As a result of our acquisition of Shearwater, we became a party to litigation with Enzon, Inc. whereby Enzon alleged infringement of its patents related to branched polymers and their conjugates. In a complaint originally filed in December 1998 and amended in December 2000, Enzon sued Shearwater asserting infringement of certain Enzon patents by certain Shearwater PEG-2 reagents and certain other advanced PEGylation products. In January 2002, we announced a strategic alliance with Enzon that includes a collaboration to develop three products using our Inhance™ inhaleables technology or SEDS™ technology, an agreement making Inhale solely responsible for licensing Enzon's PEG patents, an option for Enzon to license Inhale's PEGylation patents, and an agreement to explore the development of non-invasive delivery of single-chain antibody products via the pulmonary route. In connection with this agreement, the patent infringement litigation was settled. We made a one-time payment of $3.0 million to Enzon in connection with the settlement of the litigation. Also as part of this transaction, Enzon made a $40.0 million investment in our convertible preferred stock.

In November 1999, we acquired Alliance Pharmaceutical Corp.'s PulmoSphere® technology and other related assets for particle formulation and powder processing, subject to the terms and conditions of an asset purchase agreement. The PulmoSphere® technology utilizes an emulsification process to produce a powder having characteristics that we believe may improve efficiency and reproducibility for drugs delivered to the lung through alternative technologies such as MDIs as well as potentially improve drug delivery through our proprietary deep lung drug delivery system. The assets acquired included Alliance's intellectual property portfolio for the PulmoSphere® technology consisting of, among other things, several patent applications. With respect to applications of the PulmoSphere® technology outside the respiratory field, we have licensed the technology back to Alliance. While Alliance has made several representations in its agreement with us regarding its ownership rights of the PulmoSphere® technology, it is possible that third parties might assert claims challenging Alliance's rights, and thus our rights. Even if we can defend our rights successfully, the uncertainty regarding the status of our rights during the time any such litigation is pending may prevent us from using the underlying technology. We concluded a further agreement with Alliance in March 2002 for further rights to the technology.

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

In June 1997, we acquired the intellectual property portfolio of the BioPreservation Division of Pafra. This portfolio includes issued U.S. and foreign Letters Patent and pending applications relating to the stabilization of macromolecule drugs in dry formulations. An application for reissue of the original U.S. patent

included in this portfolio is pending in the Patent and Trademark Office ("PTO"). There can be no assurance that we will be successful in obtaining a reissued patent. A second U.S. patent from this portfolio issued to us on July 27, 1999. A granted European patent included in this portfolio was the subject of an opposition proceeding before the European Patent office. The opposition hearing was held on December 16, 1999. We successfully defended the patent and our method claims relating to glass stabilization technology against four opposing parties. In addition, in late 1999, based on claims of this granted European patent, we filed an infringement action in the courts of the United Kingdom against Quadrant Healthcare plc. Quadrant challenged the validity of this patent as part of its defense of the infringement suit and in June 2001, the English High Court of Justice ruled the patent invalid in the United Kingdom. The revocation has no effect outside the United Kingdom and does not invalidate the

European patent in other European countries. There can be no assurance that any of the other Pafra patent applications will be held to be valid and enforceable. The inability to obtain or defend the Pafra patents could have a material adverse effect on us.

We have obtained license rights to certain know-how and patent applications owned by Genentech, Inc. covering formulations, powder processing and pulmonary delivery of certain molecules, which we believe could be important to the development of our business. These license rights are worldwide, nonexclusive, sublicensable and royalty free. In 1997, Genentech successfully defended an opposition proceeding involving a pending European patent licensed to us and this decision was upheld on appeal in October 1999. The patent issued in the United States as Patent No. 6,099,517 and covers the pulmonary delivery of cytokines and growth factors.

The patent positions of pharmaceutical, biotechnology and drug delivery companies, including ours, are uncertain and involve complex legal and factual issues. There can be no assurance that any of the patents applied for by us will issue, or that any patents that issue will be valid and enforceable. Even if such patents are enforceable, we anticipate that any attempt to enforce our patents could be time consuming and costly. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued. As a consequence, we do not know whether any of our patent applications will be granted with broad coverage or whether the claims that eventually issue will be circumvented. Since publication of discoveries in scientific or patent literature often lag behind actual discoveries, we cannot be certain that we were the first inventor of inventions covered by our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. Moreover, we may have to participate in interference proceedings declared by the PTO to determine priority of invention, which could result in substantial cost to us, even if the eventual outcome is favorable. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute.

We are aware of numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties that relate to aerosol devices and delivery, pharmaceutical formulations, dry powder processing technology, the pulmonary route of delivery for certain powder formulations of macromolecules, the attachment of polymer chains to active molecules and the use of supercritical fluids in particle formation.

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

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

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

Defense of any lawsuit or failure to obtain any such required license could have a material adverse effect on us.

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

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

Competition

We believe that products developed using our technology will compete on the basis of system efficiency, dosage reproducibility, safety, patient convenience and cost. There is intense competition to develop a solution to the non-invasive delivery of drugs and to develop more efficient and effective drug formulations from several drug delivery and pharmaceutical companies, many of which are much larger and have far greater resources than we do. These include companies working on developing systems for other non-invasive routes of delivery, such as oral, transdermal, buccal, nasal, and needle-less injections, as well as companies working on pulmonary delivery systems. Several companies are also working on sustained release injectible systems. While these latter systems involve injections, the lower number of injections could be competitive with our pulmonary delivery technology in certain applications. We also face significant competition in the development of technologies to effectively modify active molecules using polymers as well as more effectively manufacture drug powders.

We believe our technologies provides us with important competitive advantages in the delivery and performance of drugs compared with currently known alternatives. However, new drugs or further developments in alternative drug delivery methods may provide greater therapeutic benefits for a specific drug or indication, or may offer comparable performance at lower cost than our proprietary technologies.

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

competitive advantage. If a device or system is developed that is superior to ours for certain applications, we may seek to obtain a license to allow our partners to use such device with our developed powders, although there can be no assurance that we would be able to do so.

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

With respect to our advanced PEGylation technology we are currently in competition with Mountain View Pharmaceuticals, Inc., Valentis, Inc. and SunBio PEGShop, who are also developing PEGylation technologies. Also there are internal programs at various pharmaceutical and biotechnology companies. In addition to our competitors in the PEGylation field, numerous other companies and technologies are focused on improving the dosing duration and efficacy of drug products. We intend to monitor these companies and if a technology developed is superior to PEGylation, we may seek to obtain a license to allow our partners access to this technology.

With regard to our SEDS™ technology, we compete primarily with Lavipharm SA, Crititech, Inc. and certain other smaller companies in the U.S. and Europe focusing on particle formation technologies. Some of our other competitors include Alkermes, Battelle Memorial Institute, Ethypharm SA, Ferro Corp., Phasex Corporation and RxKinetics. Certain pharmaceutical companies are also beginning to set up in-house research and development groups in this area. A key part of our competitive strategy with respect to our SEDS™ technology is to drive the scale-up studies of this technology as rapidly as possible such that we maintain a leadership position. We also intend to continue to maintain our competitive position with an active patenting and licensing strategy.

All aspects of our business are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems, drug formulation technology, or new drug research and testing, as well as with entities producing and developing drugs using current delivery and formulation technologies. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do and represent significant competition for us. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance competitors' financial, marketing and other resources. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than us. Developments by others may render our products or technologies noncompetitive or obsolete.

Employees and Consultants

As of December 31, 2001, we had 694 employees, of which 580 were engaged in research and development, including manufacturing and quality activities and 114 in general administration and business development. Two hundred thirty-two of our employees hold advanced degrees, of which 110 are Ph.D.s. We employ scientists and engineers with expertise in the areas of chemical engineering, pulmonary biology, aerosol science, powder technology, mechanical engineering and protein chemistry. None of our employees are covered by a collective bargaining agreement and we have experienced no work stoppages. We believe that we maintain good relations with our employees.

To complement our own expertise, we utilize specialists in regulatory affairs, pulmonary toxicology, process engineering, manufacturing, quality assurance, device design, clinical trial design and business

development. These individuals include certain of our scientific advisors as well as independent consultants. See Item 10 "Directors and Executive Officers of the Registrant."

RISK FACTORS

The following risk factors should be read carefully in connection with evaluating our business. Any of the following risks could materially and adversely affect our business, operating results or financial condition.

If our drug delivery technologies are not commercially feasible, then our revenues and results of operations will be impacted negatively.

We are in an early stage of development. There is a risk that our drug delivery technologies will not be commercially feasible. Even if our drug delivery technologies are commercially feasible, they may not be commercially accepted across a range of large and small molecule drugs. We have tested 12 drug formulations using our inhaleables technology in humans, but many of our potential formulations have not been tested in clinical trials. We are currently using the advanced PEGylation technology platform we recently acquired through our acquisition of Shearwater in the development of 15 drugs. While we have incorporated our PEGylation technology in three products that the FDA approved for use and in two products that our partners have submitted for approval to the FDA through a NDA, many of the drug formulations with which we are incorporating this technology are in the early stages of feasibility testing or human clinical trials. We recently acquired our SEDS™ supercritical fluids technology through our acquisition of Bradford Particle Design, which is also primarily in an early stage of feasibility. This technology represents a new method of manufacturing drug particles and is still in research and development, with only one formulation having entered human clinical testing.

Other companies have tested many of the underlying drug compounds contained in our drug formulations in humans using alternative delivery routes or technologies. Our potential products require extensive research, development and preclinical and clinical testing. Our potential products also may involve lengthy regulatory reviews 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, accomplish the objectives that we and our collaborative partners are seeking through the use of our technologies, meet regulatory standards or continue to meet such standards if already approved. There is a risk that we and our collaborative partners may not be able to produce any of our potential products in commercial quantities at acceptable cost or marketed successfully. Failure to achieve commercial feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or, together with partners, successfully market products will negatively impact our revenues and results of operations.

If our research and development efforts are delayed or unsuccessful, then we may be delayed or unsuccessful in commercializing our products and our business will suffer.

Except for our products that have already been approved by the FDA or submitted for approval by the FDA, our product candidates are still in research and development, including preclinical testing and clinical trials. Preclinical testing and clinical trials are long, expensive and uncertain processes. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage in the process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in later stage clinical trials, even after promising results in earlier trials.

Any clinical trial may fail to produce results satisfactory to us, our collaborative partners or the FDA. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be repeated or a program to be terminated. We typically

rely on collaborative partners and third-party clinical investigators to conduct our clinical trials and, as a result, we may face additional delaying factors outside our control.

We do not know if any of our research and development efforts, including preclinical testing or clinical trials will adhere to our planned schedules or be completed on a timely basis or at all. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials. If our research and development efforts are unsuccessful or substantially delayed, our results of operations will be adversely affected.

If our drug delivery technologies are not efficient, then our products may not be competitive.

We may not be able to achieve the total system efficiency needed to be competitive with alternative routes of delivery or formulation technologies. We determine total system efficiency by the amount of drug loss during manufacture, in the delivery device, in reaching the site at which the drug is absorbed into the bloodstream, and during absorption from that site into the bloodstream.

Deep lung bioavailability is the percentage of a drug that is absorbed into the bloodstream when that drug is delivered directly to the lungs as compared to when the drug is delivered by injection. Relative bioavailability is the initial screen for whether deep lung delivery using our inhaleables technology of any drug is commercially feasible. We would not consider a drug to be a good candidate for development and commercialization using our inhaleables technology if drug loss is excessive at any one stage or cumulatively in the manufacturing and delivery process.

Our ability to efficiently attach PEG polymer chains to a drug molecule is the initial screen as to whether drug formulations using our advanced PEGylation technology are commercially feasible. We would not consider a drug formulation using our advanced PEGylation technology if we could not efficiently attach a PEG polymer chain to such drug without destroying or impairing the drug's activity.

For our supercritical fluids technology, solubility characteristics of a drug and the solvents which maybe incorporated in the manufacturing process provide the initial screen for whether drug formulations using this technology are commercially feasible. We would not consider a drug to be a good candidate for this technology if its solubility characteristics were such that the application of our technology results in very low efficiency in manufacturing of drug powders.

If our drug formulations are not stable, then we will not be able to commercialize our products.

We may not be able to identify and produce powdered or other formulations of drugs that retain the physical and chemical properties needed to work effectively with our delivery device for deep lung delivery using our inhaleables technology or through other methods of drug delivery using our other drug delivery technologies. Formulation stability is the physical and chemical stability of the drug over time and under various storage, shipping and usage conditions. Formulation stability will vary with each drug formulation and the type and amount of ingredients that are used in the formulation. Since our drug formulation technology is new and largely unproven, we do not know if our drug formulations will retain the physical and chemical properties of injected drugs. Problems with powdered drug stability in particular would negatively impact our ability to develop and market products using our inhaleables or SEDS™ technologies or obtain regulatory approval of such products.

If our drug delivery technologies are not safe, then we may not obtain regulatory approval of our products or adequately develop or market our products.

We may not be able to prove potential products using our drug delivery technologies to be safe. Our products require lengthy laboratory, animal and human testing. Most of our products are in preclinical testing or the early stage of human testing. Since most of our products are in an early stage of testing and have not completed clinical trials we cannot be certain that these products, and our technology that

developed these products, are safe or will not produce unacceptable adverse side effects. The safety of our formulations will vary with each drug and the ingredients used in our formulation. If we find that any product is not safe, we will not be able to commercialize the product.

If our drug delivery technologies do not provide consistent doses of medicine, then we will not be able to develop and commercialize our products.

We may not be able to provide reproducible dosing of stable formulations of drug compounds. 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 of drugs using our inhaleables technology requires the development of:

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

Compound stability, development of appropriate delivery devices, accuracy in measurement of doses, and appropriate packaging may also effect our ability to provide reproducible dosing of drugs using our other drug delivery technologies. Since all of our technologies are still in development and, for the most part, are yet to be commercialized, we cannot be certain that we will be able to develop reproducible dosing of any potential product. The failure to do so means that we would not consider such a product as a good candidate for development and commercialization.

If our collaborative partners that we depend on to obtain regulatory approvals and commercialization of our products are not successful, and if such collaboration fails, then our product development or commercialization of our products may be delayed or unsuccessful.

Because we are in the business of developing technology for delivering drugs to the lungs, producing improved drug formulations for other routes of delivery and licensing these technologies to companies that make and sell drugs, we do not have the people and other resources to do the following things:

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

When we sign a collaborative development agreement or license agreement to develop a product with a drug company, the drug company agrees to do some or all of the things described above.

Reliance on collaborative relationships poses a number of risks, including:

- we will not be able to control whether our corporate partners will devote sufficient resources to our programs or products;
- disputes may arise in the future with respect to the ownership of rights to technology developed with corporate partners;
- disagreements with corporate partners could lead to delays in or termination of the research, development or commercialization of product candidates, or result in litigation or arbitration;
- contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform; corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may

pursue alternative technologies or products either on their own or in collaboration with our competitors;

- corporate partners with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products of their own development; and
- there are risks related to the ability of our distributors and corporate partners to pay us.

Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. In October 2001, Eli Lilly and Company, our collaborative partner with respect to a Phase I program for an inhaleable product for the treatment of osteoporosis, Fortéo™, notified us that the program will not be funded in 2002. Lilly further informed us that other than on-going stability work, additional activities with respect to the program will be suspended. In January 2002, Biogen, our collaborative partner with respect to a Phase I program for an inhaleable product for the treatment of multiple sclerosis,

announced that it does not plan to further develop inhaleable Avonex® for multiple sclerosis at this time. If the collaborative programs with Lilly or Biogen are not reinitiated, or other significant collaborations are suspended or terminated, our ability to successfully commercialize certain of our proposed products would be significantly and negatively impacted. If these efforts fail, our product development or commercialization of products could be delayed.

If we fail to establish future successful collaborative relationships, then our financial results may suffer and our product development efforts may be delayed or unsuccessful.

We intend to seek future collaborative relationships with corporate partners to fund some of our research and development expenses and to develop and commercialize potential products. Further, we anticipate that the timing of drug development programs under existing collaborative agreements with our corporate partners will continue to affect our revenues from such agreements. We may not be able to negotiate acceptable collaborative arrangements in the future, and any arrangements we do negotiate may not be successful. If we fail to establish additional collaborative relationships, we will be required to undertake research, development, marketing and manufacturing of our proposed products at our own expense or discontinue or reduce these activities.

If we do not obtain regulatory approval for our products on a timely basis, then our revenues and results of operations may be affected negatively.

There is a risk that we will not obtain regulatory approval for our unapproved products on a timely basis, or at all. Our unapproved products must undergo rigorous animal and human testing and an extensive FDA mandated or equivalent foreign authorities review process. This process generally takes a number of years and requires the expenditure of substantial resources and the time required for completing such testing and obtaining such approvals is uncertain. The FDA and other U.S. and foreign regulatory agencies also have substantial discretion to terminate clinical trials, require additional testing, delay or withhold registration and marketing approval and mandate product withdrawals. The FDA has approved two products using our advanced PEGylation technology for specific use in the United States. In addition, our partners have submitted for approval to the FDA three NDAs using our PEGylation technology and we plan to manufacture and market other potential products. Even though we have obtained regulatory approval for two products, these products and our manufacturing processes are subject to continued review by the FDA and other regulatory authorities. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which we may market our product. In addition, our marketed product, our manufacturing facilities and we, as the manufacturer in certain instances, 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 products from the market. The failure to obtain timely regulatory approval of our products, any product marketing limitations or a product withdrawal would negatively impact our revenues and results of operations.

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

In July 2001, Pfizer, our collaborative partner in the development of inhaleable insulin for the treatment of Type 1 and Type 2 diabetes announced that based upon its active discussions with the FDA regarding the requirements for a NDA for this product, it had decided to include an increased level of controlled, long-term safety data in its proposed NDA with respect to inhaled insulin and that it expected to complete this additional study in 2002. Any delay in the filing of this NDA may result in a delay in the approval of the NDA by the FDA, if such approval is received at all. Any material delay in the regulatory approval of this product or failure to receive regulatory approval of this product would negatively impact our results of operations.

If our technologies cannot be integrated successfully to bring products to market, then our ability to develop, obtain approval of or market our products may be delayed or unsuccessful.

We may not be able to integrate all of the relevant technologies to provide complete drug delivery and formulation systems. In particular, our development of drugs using our inhaleables technology relies upon several different but related technologies:

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

Our other drug delivery development efforts may face similar challenges relating to the integration of drug formulation, processing, packaging and delivery device technologies. 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 products using our delivery and formulation technologies.

If we are not able to manufacture our products in commercially feasible quantities, then we will not be able to successfully commercialize our products.

Advanced PEGylation and SEDS™ Technologies

We recently acquired our advanced PEGylation and supercritical fluids technologies through our acquisitions of Shearwater and Bradford Particle Design, respectively. Except for our approved products or products pending approval using our advanced PEGylation technology, all of the drug formulations with which we are incorporating these technologies are in the early stages of feasibility testing or human clinical trials. At this time, our existing facilities are large enough

for most commercial scale manufacturing to meet current demand. In the future, we may have to expand our facilities if we are not able to scale-up to large clinical trials or commercial manufacturing for products incorporating either of these technologies in a timely manner or at a commercially reasonable cost. Our failure to solve any of these problems could delay or prevent late stage clinical testing and commercialization of our products and could negatively impact our revenues and results of operations.

Inhaleables Technology

Powder Processing. We have no experience manufacturing powder processing products for commercial purposes. With respect to drugs using our inhaleables technology, we have only performed powder processing on the 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 some late stage clinical testing and commercialization of our products and could negatively impact our revenues and results of operations.

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

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

Inhalation Device. We face many technical challenges in developing our inhalation devices 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. Our device is still in clinical testing and production scale-up work is underway. Further design and development work is underway to enable commercial manufacturing and additional work may be required to optimize the device for regulatory approval, field reliability or other issues that may be important to its commercial success. Additional design and development work may lead to a delay in regulatory approval, efforts to seek regulatory approval for any product that incorporates the device or the time the device could be ready for commercial launch. In addition, we are attempting to develop a smaller inhalation device, which presents particular technical challenges. There is a risk that we will not successfully achieve any of these challenges. Our failure to overcome any of these challenges would negatively impact our revenues and results of operations.

For late stage clinical trials and initial commercial production, we intend to use one or more contract manufacturers to produce our drug delivery devices. There is a risk that we will not be able to maintain arrangements with our contract manufacturers or effectively scale-up production of our drug delivery devices through contract manufacturers. Our failure to do so would negatively impact our revenues and results of operations. Because our manufacturing processes and those of our contract manufacturers are very complex and subject to lengthy governmental approval processes, alternative qualified production sources or capacity may not be available on a timely basis or at all. Disruptions or delays in our manufacturing processes or those of our contract manufacturers for existing or new products could result in increased costs, loss of revenues or market share, or damage to our reputation.

We depend on sole or exclusive suppliers for our inhalation device, bulk drugs and PEG polymer chains and if such suppliers fail to provide when required, then our product development efforts may be delayed or unsuccessful.

We have agreed to subcontract the manufacture of our inhalation device before commercial production of our first inhaleable technology product. We have identified contract manufacturers that we

believe have the technical capabilities and production capacity to manufacture our inhalation device and which can meet the requirements of cGMP. We are not certain that we will be able to maintain satisfactory contract manufacturing on commercially acceptable terms, if at all. Our dependence on third parties for the manufacture of our inhalation devices may negatively impact our cost of goods and our ability to develop and commercialize products using our inhaleables technology on a timely and competitive basis.

We obtain the bulk drugs we use to manufacture the drugs using our drug delivery and formulation technologies from sole or exclusive sources of supply. For example, with respect to our source of bulk insulin, we have entered into a collaborative agreement with Pfizer which has, in turn, entered into an agreement with Aventis Pharma to manufacture biosynthetic recombinant insulin. Under the terms of their agreement, Pfizer and Aventis Pharma agreed to construct a jointly owned manufacturing plant in Frankfurt, Germany. Until its completion, Pfizer will provide us with insulin from Aventis Pharma's existing plant.

We have also entered into an exclusive agreement with one supplier for a significant portion of the PEG polymer chains we use in our products that incorporate PEGylation technology. NOF Corporation is our predominate supplier of pharmaceutical grade PEGylation materials pursuant to an exclusive supply agreement with NOF that provides for the supply of these materials. If our sole or exclusive source suppliers fail to provide either bulk drugs or PEGylation materials in sufficient quantities when required, our revenues and results of operations will be negatively impacted.

If the market does not accept products using our drug delivery technologies, then our revenues and results of operations will be adversely affected.

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 new drug delivery technologies and there is a risk that our potential products will not be accepted by the market. Market acceptance will depend on many factors, including:

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

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

If our products are not cost effective, then government and private insurance plans may not pay for them.

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

If our competitors develop and sell better drug delivery and formulation technologies, then our products or technologies may be uncompetitive or obsolete and our revenues and results of operations will be adversely affected.

We are aware of other companies engaged in developing and commercializing pulmonary drug delivery and formulation systems, as well as drug delivery technologies similar to the SEDS™ technology and the advanced PEGylation technology we are developing through our acquisitions of Bradford Particle Design and Shearwater, respectively. Some of our competitors with regard to inhaleables technology include AeroGen, Inc., Alkermes, Inc. and Aradigm Corporation. Aerogen and Aradigm are working on liquid drug delivery systems, and Alkermes is working on a dry powder delivery system. Our competitors with regard to advanced PEGylation technology include Valentis, Inc., Mountain View Pharmaceuticals, Inc. and SunBio PEG-SHOP, as well as several pharmaceutical and biotechnology companies with in-house PEGylation expertise. Some of our competitors with regard to SEDS™ technology include Alkermes, Battelle Memorial Institute, Ethypharm SA, Ferro Corp., Lavipharm SA, Phasex Corporation and RxKinetics. Some of these companies license or provide the technology to other companies, while others are developing the technology for internal use. Many of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do and represent significant competition for us. Acquisitions of or collaborations with competing drug delivery companies by large pharmaceutical companies could enhance our competitors' financial, marketing and other resources. Accordingly, our competitors may succeed in developing competing technologies, obtaining regulatory approval for products or gaining market acceptance before us. Developments by others could make our products or technologies uncompetitive or obsolete. Our competitors may introduce products or processes competitive with or superior to ours.

If any of our patents are invalid or pending patents are not valid, then we may lose key intellectual property right protection. If our products infringe on third-party's rights, then we will suffer adverse effects on our ability to develop and commercialize products as well as our revenues and results of operations.

We have filed patent applications covering certain aspects of our inhalation device, powder processing technology, powder formulations and deep lung route of delivery for certain molecules as well as for our advanced PEGylation and SEDS™ supercritical fluids technologies, and we plan to file additional patent applications. We currently have 275 issued U.S. and foreign patents that cover certain aspects of our technology and we have a number of patent applications pending. There is a risk that many of the patents applied for will not issue, or that any patents that issue or have issued will not be valid and enforceable. Enforcing our patent rights would be time consuming and costly.

Our access or our partners' access to the drugs to be formulated using our technologies 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, and our drug formulation technologies are subject to issued and pending U.S. and foreign patents that may be owned by competitors. We know that there are issued patents and pending patent applications relating to the formulation and delivery of large and small molecule drugs, including several for which we are developing deep lung or other delivery formulations using our various technologies. This situation is highly complex, and the ability of any one company, including us, to commercialize a particular drug is unpredictable.

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

We may incur material litigation costs which may adversely affect our business and results of operations.

Substantially all of the litigation to which we are currently subjected to or have been subjected to relates to our patent and intellectual property rights. We cannot predict with certainty the eventual outcome of any pending litigation or potential future litigation, and we might have to incur substantial expense in defending this or future lawsuits or indemnifying third parties with respect to the results of such litigation.

If earthquakes and other catastrophic events strike, our business may be negatively affected.

Our corporate headquarters, including a substantial portion of our research and development operations, are located in the Silicon Valley area of Northern California, a region known for seismic activity. A significant natural disaster such as an earthquake could have a material adverse impact on our business, operating results, and financial condition.

The recent energy crisis in California could disrupt our business and the businesses of our suppliers, contract manufacturers and collaborative partners, and could increase our expenses.

Over the past year, the western United States (and California in particular) has experienced episodes of diminished electrical power supply, and it is possible that this situation could worsen in the near future. As a result of these episodes, certain of our operations or facilities may continue to be subject to "rolling blackouts" or other unscheduled interruptions of electrical power. The prospect of such unscheduled interruptions may continue for the foreseeable future, and we are unable to predict their occurrence or duration. Certain of our contract manufacturers and collaborative partners are also located in this area and their operations may also be materially and adversely affected by such interruptions, which in turn could have a material adverse effect on our business or results of operations.

Investors should be aware of industry-wide risks which are applicable to us and may affect our revenues and results of operations.

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

- changes in and compliance with government regulations;
- handling of hazardous materials;
- hiring and retaining qualified people; and
- insuring against product liability claims.

If we fail to manage our growth effectively, our business may suffer.

Our ability to commercialize our products, achieve our expansion objectives, manage our growth effectively and satisfy our commitments under our collaboration agreements depends on a variety of factors, all of which must be successfully managed. Key factors include our ability to develop products internally, enter into strategic partnerships with collaborators, attract and retain skilled employees and effectively expand our internal organization to accommodate anticipated growth including integration of any potential businesses that we may acquire. If we are unable to manage some or all of these factors effectively, our business could grow too slowly or too quickly to be successfully sustained, thereby resulting in material adverse effects on our business, financial condition and results of operations.

If we do not effectively integrate personnel and operations relating to our acquisitions of Bradford Particle Design and Shearwater, our business and management may suffer disruptions.

Our acquisitions of Bradford Particle Design and Shearwater may present unique risks related to our business. We may not be able to successfully assimilate the additional personnel, operations, acquired technology and products into our business. In particular, we need to assimilate and retain key management, research and engineering personnel. Key personnel from acquired companies such as Bradford Particle Design and Shearwater often decide to pursue other opportunities. In addition, there may be complications if we attempt to integrate any of the technology acquired from these companies with our other technologies, and it is uncertain whether we may accomplish this easily or at all. These integration difficulties could disrupt our ongoing business, distract management and employees or increase expenses. Acquisitions are inherently risky, and we may also face unexpected costs, which may adversely affect operating results in any quarter. Additionally, because Bradford Particle Design is a UK company, we will face additional risks related to cross-border acquisitions and international operations, including foreign legal and regulatory restrictions and potential economic instability. Due diligence conducted in connection with either acquisition may not uncover all the potential problems or liabilities we may have assumed in these transactions. Any of these risks could have a significant impact on our ability to continue our research and development efforts on a competitive and timely basis.

We cannot predict the impact of recent actions and comments by the Securities and Exchange Commission regarding valuation methodologies related to business combinations and as such, we may need to restate our financial statements which may alter our operating results.

The Securities and Exchange Commission has been reviewing registrants' valuation methodologies of in-process research and development related to business combinations. The valuations we placed on Bradford Particle Design and Shearwater included certain assumptions about the technology, development and future operations of these businesses. These assumptions also determined in large part how we reflected these acquisitions in our financial statements. While we believe that we are in compliance with all of the existing rules and related guidance applicable to our business operations, if the SEC does not agree with our valuation methodologies, or if the assumptions taken at the time of the valuation are not achieved, we may be required to restate our financial statements. In addition, the SEC may change these rules or issue new guidance applicable to our business in the future. There can be no assurance that the SEC will not seek to reduce the amount of in-process research and development previously expensed by us or require us to make an adjustment related to our valuation assumptions. This would result in the restatement of our previously filed financial statements and could have a material adverse effect on our operating results and financial condition for periods subsequent to the acquisitions.

If we acquire additional companies, products or technologies, we may face risks similar to those faced in our other acquisitions.

We may continue to acquire or make investments in complementary companies, products or technologies. We may not realize the anticipated benefits of any other acquisition or investment. If we acquire another company, we will likely face some or all of the same risks, uncertainties, earnings and disruptions as discussed above with respect to the Bradford Particle Design and Shearwater acquisitions. We may face risks relating to difficult integrations of personnel, technology and operations, uncertainty whether any integration will be successful and whether earnings will be negatively affected, and potential distractions to our management with respect to these acquisitions. In addition, our earnings may suffer because of acquisition-related costs.

We expect to continue to lose money for the next few years and may not reach profitability if our products do not generate sufficient revenue.

We have never been profitable and, through December 31, 2001, we have an accumulated deficit of approximately $441.9 million. We expect to continue to incur substantial and potentially increasing losses

over at least the next few years as we expand our research and development efforts, testing activities and manufacturing operations, and as we further expand our late stage clinical and early commercial production facility. Many of our potential products are in the early stages of development except for our three approved products using our PEGylation technology. Except for our approved advanced PEGylation technology products, 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 and other drug delivery systems. There is a risk that we will not generate sufficient product or contract research revenue to become profitable or to sustain profitability.

If we cannot raise additional capital our financial condition may suffer.

We anticipate that our existing capital resources will enable us to maintain currently planned operations through the next 30 months. However, this expectation is based on our current operating plan, which may change as a result of certain factors, and may result in additional funding requirements sooner than anticipated. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in dilution to our stockholders.

We have no material credit facility or other material committed sources of capital. To the extent operating and capital resources are insufficient to meet future requirements, we will have to raise additional funds to continue the development and commercialization of our technologies. Such funds may not be available on favorable terms, or at all. In particular, our substantial leverage may limit our ability to obtain additional financing. In addition, as an early stage biotechnology company, we do not qualify to issue investment grade debt and therefore any financing we do undertake will likely involve the issuance of equity, convertible debt instruments or high-yield debt. These sources of capital may not be available to us in the event additional financing is required. If adequate funds are not available on reasonable terms, we may be required to curtail operations significantly or to obtain funds by entering into financing, supply or collaboration agreements on unattractive terms. Our inability to raise capital could negatively impact our business.

We expect our stock price to remain volatile.

Our stock price is volatile. In the last twelve-month period ending March 1, 2002, based on closing prices on the Nasdaq National Market, our stock price ranged from $11.01 to $35.47. 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 us or our competitors;
- governmental regulation;
- clinical trial results or product development delays;
- developments in patent or other proprietary rights;
- public concern as to the safety of drug formulations developed by Inhale or others; and
- general market conditions.

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

If we do not generate sufficient cash flow through increased revenues or raising additional capital, then we may not be able to meet our debt obligations.

As of December 31, 2001, we had approximately $336.3 million in long-term obligations. Our substantial indebtedness has and will continue to impact us by:

-

increasing our interest expense and related debt service costs;

- making it more difficult to obtain additional financing; and
- constraining our ability to react quickly in an unfavorable economic climate.

Currently, we are not generating sufficient cash flow to satisfy the annual debt service payments on our outstanding subordinated convertible debentures and subordinated convertible notes. This may require us to use a portion of the proceeds from the sales of these securities to pay interest or borrow additional funds or sell additional equity to meet our debt service obligations. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result, which would negatively impact our future prospects. As of December 31, 2001, we had cash, cash equivalents and short-term investments valued at approximately $344.4 million.

Anti-takeover provisions in our charter documents and under Delaware law may make it more difficult to remove our management. Further, these provisions may make it more difficult to acquire a large portion of our securities, to initiate a tender offer or a proxy contest or to acquire us, even though such events may be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws could make it more difficult for a third party to remove our management. Further, these provisions may make it more difficult to acquire a large portion of our securities, to initiate a tender offer or a proxy contest or acquire us, even if doing so would benefit our stockholders. Among other things, these provisions:

- authorize the issuance of "blank check" preferred stock that could be issued by our Board of Directors to increase the number of outstanding shares and thwart a takeover attempt; and
- limit who may call a special meeting of stockholders.

On June 1, 2001, our Board of Directors adopted a preferred share purchase rights plan, commonly known as a "poison pill." The provisions described above, our preferred share purchase rights plan and provisions of the Delaware General Corporation Law relating to business combinations with interested stockholders may discourage, delay or prevent a third party from removing our management. Further, they may discourage, delay or prevent a third party from acquiring a large portion of our securities, initiating a tender offer or proxy contest or acquiring us, even if our stockholders might receive a premium for their shares in the acquisition over then current market prices.

This report includes forward-looking statements and if these statements are incorrect or inaccurate, our actual results may differ.

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact are "forward-looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will,"

"expects," "plans," "anticipates," "estimates," "potential," or "continue," or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below and for the reasons described elsewhere in this prospectus. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and we do not intend to update any forward-looking statements except as required by law or applicable regulations.

Item 2. Properties

We currently lease facilities in San Carlos and Palo Alto, California, two facilities in Huntsville, Alabama and a complex in Bradford, England.

We currently occupy a facility in San Carlos that covers approximately 173,000 square feet and is leased pursuant to a 15-year lease agreement. This facility serves as our corporate headquarters and is used for research and development, manufacturing and administration. The lease provides us with an option to lease approximately 57,000 additional square feet in the same facility. This manufacturing facility operates under cGMP and has been approved and licensed by the State of California to manufacture clinical supplies for use in human clinical trials.

In October 1999, we commenced construction of a second San Carlos facility on a 4.7 acre parcel of land that we had acquired in October 1998, in order to expand our administrative offices and research and development capacity. This facility consists of approximately 80,000 square feet. In October 2000, we leased back the facility pursuant to a build-to-suit lease agreement for a 16-year term, with a 10-year option and a second 8-year option to extend the lease. In November 2000 we began occupancy of this facility. In October 2001, we leased an additional 45,600 square feet in this facility and declined an option to lease an additional 46,500 square feet.

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

We have two locations in Huntsville, Alabama for research and administration for our advanced PEGylation technology. The Church Street location is the pilot plant for the manufacture of PEG derivatives and is approximately 35,000 square feet with a lease term expiring in June 2009. The Discovery Drive location has not been qualified, is approximately 50,000 square feet and is owned by us.

We currently occupy a complex in Bradford, England that covers approximately 17,500 square feet, consisting of several units with varying lease terms through 2009. This facility is used for research and development, clinical research and administration.

Item 3. Legal Proceedings

Not applicable.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of our shareholders in the quarter ended December 31, 2001.

PART II

Item 5. Market for Registrant's Common Stock and Related Stockholder Matters

PRICE RANGE OF COMMON STOCK

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

	Price Range of Common Stock	
	High	Low
Year Ended December 31, 2000:		
1st Quarter	$ 63.313	$ 20.844
2nd Quarter	54.344	23.156
3rd Quarter	56.375	40.594
4th Quarter	55.188	38.500
Year Ended December 31, 2001:		
1st Quarter	$ 48.250	$ 17.125
2nd Quarter	35.470	18.375
3rd Quarter	23.910	11.010
4th Quarter	19.470	13.130
Year Ended December 31, 2002:		
1st Quarter (through March 1, 2002)	$ 18.220	$ 12.450

As of December 31, 2001, there were approximately 335 holders of record of our Common Stock. We have not paid any cash dividends since our inception and do not intend to pay any cash dividends in the foreseeable future.

Sales of Unregistered Securities

On January 25, 2002, we filed a Schedule TO with the SEC announcing our offer to certain Inhale employees to exchange certain options to purchase shares of the Company's Common Stock granted prior to July 24, 2001 with exercise prices greater than or equal to $25.00 per share currently outstanding under the Company's 2000 Non-Officer Equity Incentive Plan, as amended (the "Eligible Options"), for replacement options (the "Replacement Options") to purchase shares of the Common Stock to be granted under the 2000 Non-Officer Plan Equity Incentive Plan (the "2000 Non-Officer Plan"). The Company conducted the exchange with respect to the Eligible Options on a one-for-two (1:2) basis. If an employee accepted this offer with respect to any Eligible Option, such employee also was obligated to exchange all options to acquire Common Stock of the Company granted to such employee on or after July 24, 2001 (the "Mandatory Exchange Options"). The Company conducted the exchange with respect to Mandatory Exchange Options on a one-for-one (1:1) basis. On March 18, 2002, the Company filed an Amendment No. 2 to Schedule TO announcing that 90 employees participated in the exchange offer, exchanging 1,217,500 Eligible Options and 78,170 Mandatory Exchange Options to purchase shares of Common Stock of the Company. The Company intends to issue Replacement Options to purchase 686,920 shares of Common Stock on August 26, 2002 at an exercise price equal to the closing price of the Company's Common Stock as reported on the Nasdaq National Market on the last market trading day prior to the date of grant.

In January 2002, we announced a strategic alliance with Enzon that includes an agreement making Inhale solely responsible for licensing Enzon's PEG patents, an option for Enzon to license Inhale's PEGylation patents, an agreement to explore the development of non-invasive delivery of single-chain antibody

products via the pulmonary route and settlement of a patent infringement litigation originally filed by Enzon against Shearwater. As part of this alliance, we also entered into a preferred stock purchase agreement with Enzon in which Enzon purchased 40,000 shares of Series B Convertible Preferred Stock (the "Preferred Stock") of Inhale at a purchase price of $1,000 per share for an aggregate purchase price of $40.0 million. The Preferred Stock is convertible, in whole or in part, into that number of shares of common stock (the "Conversion Shares") equal to the quotient of $1,000 per share divided by the Conversion Price. The "Conversion Price" is initially equal to $22.79 per share or 125% of the average of the Company's closing bid prices as listed on the Nasdaq National Market for the twenty (20) trading days preceding the date of the closing of the transaction (the "Closing Price"). The Preferred Stock is convertible at the option of the holder after the first anniversary of the original issuance of the Preferred Stock (the "Original Issue Date") or, if earlier, upon a change in control. Except with respect to an automatic conversion, the Conversion Price is equal to 125% of the Closing Price until the third anniversary of the Original Issue Date. Upon the third anniversary of the Original Issue Date, the Conversion Price shall be adjusted to be equal to either (i) the Closing Price, in the event that the average of the closing bid prices of Inhale's Common Stock as quoted on the Nasdaq National Market for the twenty (20) trading days preceding the third anniversary of the original issuance (the "Future Price") is less than or equal to the Closing Price; (ii) the Future Price (as defined above) if the Future Price is greater than the Closing Price but less than 125% of the Closing Price; or (iii) 125% of the Closing Price if the Future Price is equal to or greater than 125% of the Closing Price. To the extent not previously converted, the Preferred Stock will automatically convert into shares of Inhale Common Stock, based on the then effective Conversion Price, upon the earliest of (i) the fourth anniversary of the Original Issue Date; (ii) immediately prior to a change in control; or (iii) with the consent of the holders of a majority of the then outstanding Series B Preferred Stock immediately prior to a liquidation, dissolution or winding up of Inhale. In the event of an automatic conversion pursuant to a change in control, the adjustment mechanism described above will be applied immediately prior to the automatic conversion. We issued these shares in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, pursuant to Regulation D promulgated under the Act. Under the terms of the agreement, Inhale has agreed to use reasonable commercial efforts to prepare and file a registration statement on Form S-3 (or Form S-1 in the event that Form S-3 registration is not available), at any time prior to the earlier of 60 days prior to the first anniversary of the closing of the transaction, or upon the conversion of the preferred stock into common stock of the Company.

In June 2001, we entered into an agreement to acquire Shearwater in which cash was paid in the amount of approximately $56.4 million and 3,112,603 shares of common stock were to be issued to the holders of all the outstanding common stock of Shearwater in consideration for the acquisition of Shearwater through its merger with and into a wholly owned subsidiary of Inhale. We issued these shares in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, pursuant to Regulation D promulgated under the Act. For each share of Shearwater common stock, we issued approximately 3.09 new shares of our common stock and paid Shearwater stockholders cash in the amount of $55.94 per share. In addition, we assumed all of the outstanding options to acquire Shearwater common stock which were converted into options to acquire approximately 887,343 shares of our common stock and the holders thereof were also paid in cash an aggregate amount of $16.1 million at closing. Each outstanding option to purchase Shearwater common stock was converted into the right to receive approximately 3.09 shares of our common stock upon exercise and option holders were paid cash in the amount of $55.94 per share of Shearwater common stock issuable upon exercise of such options. No fractional shares of our common stock were issued in connection with the acquisition. In lieu thereof, any holder of Shearwater common stock was paid cash based on the value of such fractional share. The SEC

declared a registration statement on Form S-3, as amended (File No. 333-67340), registering the resale of these shares of common stock effective on November 9, 2001.

In January 2001 we issued 3,752,456 shares of our common stock to the holders of all of the existing issued ordinary share capital of Bradford Particle Design, a United Kingdom company. We issued these shares as consideration for the acquisition of the outstanding share capital of Bradford Particle Design in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended (the "Act") and/or Regulation D or Regulation S promulgated under the Act. For each share of Bradford Particle Design common stock outstanding we issued 1.8354 new shares of our common stock and paid approximately $9.80 cash, for an aggregate cash payment of approximately $20.4 million. The acquirers relying upon the exemption from registration afforded by Regulation S signed forms of acceptances indicating respectively their intent to acquire the securities for investment only and not with a view to distribution, and also indicated that if they were an individual, then they were residents of the United Kingdom, or if they were a corporation, limited liability company or other entity, then the offices of the Bradford Particle Design shareholder in which its investment decision was made was located in the United Kingdom. The acquirers relying upon the exemption from registration afforded by Regulation D signed forms of acceptances indicating respectively their intent to acquire the securities for investment only and not with a view to distribution, and also represented that they were "accredited investors" as that term is defined under Rule 501 of Regulation D. Appropriate legends are affixed to the shares issued in this transaction. Cazenove & Co. served as financial advisor and broker to the Company in connection with the acquisition of Bradford Particle Design and received $650,000 in payment of certain fees. The SEC declared a registration statement on Form S-3, as amended (File No. 333-54080), registering the resale of these shares of common stock effective on February 5, 2001.

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

In October 2000, we issued $230 million in aggregate principal amount of 3.5% convertible subordinated notes, which are convertible at the option of the holder, at any time on or prior to maturity into shares of our common stock. The October 2000 notes were sold only in the United States to certain qualified institutional buyers under an exemption from registration provided by Rule 144A of the Act. The October 2000 notes are convertible at a conversion price of $50.46 per share, which is equal to a conversion rate of approximately 19.8177 shares per $1,000 principal amount of notes, subject to adjustment. Interest on the October 2000 notes will accrue at a rate of 3.5% per year subject to adjustment in certain circumstances. We pay interest on the October 2000 notes on April 17 and October 17 of each year, beginning April 17, 2001. The October 2000 notes mature on October 17, 2007. We may redeem some or all of the October 2000 notes at any time before October 17, 2003 at a redemption price equal to $1,000 per $1,000 principal amount of notes, if the closing price of our common stock has exceeded 150% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days ending on the trading day before the date of mailing of the provisional redemption notice. Upon any such provisional redemption, we will make additional payment in cash or shares of our common stock, at our option, to compensate investors for interest payments not yet received through the provisional redemption

date. This additional payment will be equal to $105.00 per $1,000 principal amount of notes, less the amount of any interest actually paid on the October 2000 notes before the call for redemption. We may redeem some or all of the October 2000 notes at any time after October 17, 2003 at certain redemption prices dependent upon the date of redemption if the closing price of our common stock has exceeded 120% of the conversion price then in effect for at least 20 trading days within a period of 30 connective days. The October 2000 notes are unsecured and subordinated to our existing and future senior indebtedness. The initial purchasers of the 3.5% convertible notes, Merrill Lynch & Co., Deutsche Banc Alex Brown, Lehman Brothers, and U. S. Bancorp Piper Jaffray, received an aggregate of $6.9 million in the form of discounts to the offering price of these notes. The SEC declared a registration statement on Form S-3, as amended (File No. 333-53678), registering the resale of these shares of common stock effective in February 2001.

In February 2000, we issued $230 million in aggregate principal amount of 5.0% convertible subordinated notes, which are convertible at the option of the holder, at any time on or prior to maturity into shares of our common stock. The February 2000 notes were sold only in the United States to certain qualified institutional buyers under an exemption from registration provided by Rule 144A of the Act. The February 2000 notes are convertible at a conversion price of $38.355 per share, which is equal to a conversion rate of approximately 26.074 shares per $1,000 principal amount of notes, subject to adjustment. Interest on the February 2000 notes will accrue at a rate of 5.0% per year subject to adjustment in certain circumstances. We pay interest on the February 2000 notes on February 8 and August 8 of each year, beginning August 8, 2000. The February 2000 notes mature on February 8, 2007. We may redeem some or all of the February 2000 notes at any time before February 8, 2003 at a redemption price equal to $1,000 per $1,000 principal amount of notes, if the closing price of our common stock has exceeded 150% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days ending on the trading day before the date of mailing of the provisional redemption notice. Upon any such provisional redemption, we will make additional payment in cash or shares of our common stock, at our option, to compensate investors for interest payments not yet received through the provisional redemption date. This additional payment will be equal to $137.93 per $1,000 principal amount of notes, less the amount of any interest actually paid on the February 2000 notes before the call for redemption. We may redeem some or all of the February 2000 notes at any time after February 8, 2003 at certain redemption prices dependent upon the date of redemption if the closing price of our common stock has exceeded 120% of the conversion price then in effect for at least 20 trading days within a period of 30 connective days. The February 2000 notes are unsecured and subordinated to our existing and future senior indebtedness. The initial purchasers of the 5.0% convertible notes, Merrill Lynch & Co., Deutsche Banc Alex Brown, Lehman Brothers, and U. S. Bancorp Piper Jaffray, received an aggregate of $6.25 million in the form of discounts to the offering price of these notes. The SEC declared a registration statement on Form S-3, as amended (File No. 333-36152), registering the resale of these shares of common stock effective in May 2000.

Item 6. Selected Consolidated Financial Data

SELECTED CONSOLIDATED FINANCIAL INFORMATION
(In thousands, except per share information)

	Years Ended December 31,				
	2001	2000	1999	1998	1997
Statement of Operations Data:					
Revenue:					
Contract research revenue	$ 68,899	$ 51,629	$ 41,358	$ 21,795	$ 16,249
Product sales	8,569	—	—	—	—
Total revenue	77,468	51,629	41,358	21,795	16,249
Operating costs and expenses:					
Cost of goods sold	4,169	—	—	—	—
Research and development	139,651	100,779	64,035	35,398	23,645
General and administrative	18,861	13,932	7,869	8,387	6,328
Purchased in-process research and development	146,260	2,292	9,890	—	—
Amortization of goodwill & other intangible assets	25,490	765	48	—	—
Total operating costs and expenses	334,431	117,768	81,842	43,785	29,973
Loss from operations	(256,963)	(66,139)	(40,484)	(21,990)	(13,724)
Debt conversion premium, net	—	(40,687)	—	—	—
Interest and other income (expense), net	6,955	9,423	2,036	3,634	3,741
Net loss	$ (250,008)	$ (97,403)	$ (38,448)	$ (18,356)	$ (9,983)
Basic and diluted net loss per share	$ (4.71)	$ (2.32)	$ (1.13)	$ (0.58)	$ (0.36)
Shares used in computation of basic and diluted net loss per share(1)	53,136	41,998	34,016	31,438	27,584

	Years Ended December 31,				
	2001	2000	1999	1998	1997
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 344,356	$ 484,841	$ 138,185	$ 82,862	$ 100,173

Working capital	301,642	462,840	122,239	71,784	83,811
Total assets	667,241	629,540	226,806	134,496	119,762
Long-term debt (excluding current portion)	37,130	20,118	4,895	4,940	5,102
Convertible subordinated notes and debentures	299,149	299,149	108,450	—	—
Accumulated deficit	(441,877)	(191,869)	(94,466)	(56,018)	(37,662)
Total stockholders' equity	270,313	277,883	86,629	115,881	97,093

Quarterly Financial Data (unaudited)

The following table sets forth certain unaudited quarterly financial data for the eight quarters ended December 31, 2001. In our opinion, the unaudited information set forth below has been prepared on the same basis as the audited information and includes all adjustments necessary to present fairly the

information set forth herein. The operating results for any quarter are not indicative of results for any future period. All data is in thousands except per share information.

	Fiscal Year 2001				Fiscal Year 2000			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Contract research revenue	$ 14,097	$ 16,799	$ 17,236	$ 20,767	$ 10,633	$ 13,789	$ 14,061	$ 13,146
Product sales	$ —	$ —	$ 5,169	$ 3,400	$ —	$ —	$ —	$ —
Gross margin from product sales	$ —	$ —	$ 3,190	$ 1,210	$ —	$ —	$ —	$ —
Net loss	$ (81,041)	$ (105,794)	$ (26,921)	$ (36,252)	$ (28,832)	$ (15,747)	$ (13,215)	$ (39,609)
Basic and diluted net loss per share	$ (1.59)	$ (2.05)	$ (0.49)	$ (0.66)	$ (0.76)	$ (0.38)	$ (0.31)	$ (0.87)

We have experienced fluctuations in our quarterly results. Our results have included costs associated with the conversion of convertible notes and debentures in 2000, acquisitions of various technologies, increases in research and development expenditures, expansion of late stage clinical and early stage commercial manufacturing facilities. We expect these fluctuations to continue into the future. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of our critical accounting policies.

(1) Basic and diluted net loss per share is based upon the weighted average number of common shares outstanding. The shares shown above retroactively reflect a two-for-one split, effective August 22, 2000. See Note 1 of Notes to Consolidated 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

We are working to become the world's leading drug delivery company by providing a portfolio of technologies and expertise that will enable our pharmaceutical partners to improve drug performance throughout the drug development process. We have been unprofitable since inception and expect to incur substantial and potentially increasing operating losses over at least the next few years as we expand our research and development efforts, testing activities and manufacturing operations, and as we further expand our late stage clinical and early commercial production facility. To date, except for sales from three products using our advanced PEGylation technology, we have not sold any commercial products and do not anticipate receiving material revenue from product sales or royalties in the near future. For the period from inception through December 31, 2001, we incurred a cumulative net loss of approximately $441.9 million. The sources of our working capital have been equity offerings and convertible debt 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. To date we have been primarily dependent upon equity and convertible debt financings to fund our working capital.

We have generally been compensated for research and development expenses during initial feasibility work performed under collaborative arrangements. In a typical collaboration, our partner will provide the drug, fund clinical and formulation development and market the resulting commercial product. We will supply the drug delivery approach or drug formulation and receive revenues from drug compound manufacturing and other manufacturing activities, as well as royalties from sales of most commercial products. In addition, for products using our Inhance™ inhaleables technology, we expect to receive revenues from the supply of our device for the product along with any applicable drug processing. Partners that enter into collaborative agreements generally fund research and development through expense

reimbursements and/or payments as we achieve certain key development and regulatory milestones. To achieve and sustain profitable operations, we, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products using our drug delivery and other drug delivery systems. There can be no assurance that we can generate sufficient product or contract research revenue to become profitable or to sustain profitability.

Recent Developments

In January 2002, we announced a strategic alliance with Enzon that includes an agreement making Inhale solely responsible for licensing Enzon's PEG patents, an option for Enzon to license Inhale's PEGylation patents, an agreement to explore the development of non-invasive delivery of single-chain antibody products via the pulmonary route and settlement of a patent infringement litigation originally filed by Enzon against Shearwater. As part of this broad alliance, we entered into a collaboration to develop three products using our Inhance™ inhaleables technology and/or SEDS™ technology. Under the terms of this

collaboration, we will be responsible for the development of drug formulations for the agreed upon pharmaceutical agents as well as clinical and commercial manufacturing of the drug formulation and device combination. Enzon will be responsible for the clinical development and worldwide commercialization of the system. Inhale will receive research and development funding, milestone payments as the program progresses through further clinical testing, and royalty payments once the product is commercialized. As part of this alliance, Enzon made a $40.0 million investment in our preferred stock.

In January 2002, Biogen announced that it does not plan to further develop inhaleable Avonex® for multiple sclerosis at this time, but is working with us to evaluate other potential indications for the inhaled formulation or other opportunities for collaboration.

In October 2001, Lilly notified us that the Fortéo™ development program that was reinitiated in September 2000, will not be funded in 2002. Lilly further informed us that other than on-going stability work, additional activities with respect to the program would be suspended.

In June 2001, our Board of Directors adopted a preferred share purchase rights plan (the "Plan"), commonly known as a "poison pill." The Plan and provisions of the Delaware General Corporation Law relating to business combinations with interested stockholders may discourage, delay or prevent a third party from removing our management. Further, they may discourage, delay or prevent a third party from acquiring a large portion of our securities, initiating a tender offer or proxy contest or acquiring us, even if our stockholders might receive a premium for their shares in the acquisition over then current market prices. Terms of the Plan provide for a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of common stock, par value $.0001 per share (the "Common Shares"), of the Company. The dividend is payable on June 22, 2001 (the "Record Date") to the stockholders of record on that date. Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock, par value $.0001 per share (the "Preferred Shares"), at a price of $225.00 per one one-hundredth of a Preferred Share (the "Purchase Price"), subject to adjustment. Each one one-hundredth of a share of Preferred Shares has designations and powers, preferences and rights, and the qualifications, limitations and restrictions which make its value approximately equal to the value of a Common Share. Initially, the Rights will be evidenced by the stock certificates representing the Common Shares then outstanding, and no separate Right Certificates, as defined, will be distributed. Until the earlier to occur of (i) the date of a public announcement that a person, entity or group of affiliated or associated persons have acquired beneficial ownership of 20% or more of the outstanding Common Shares (an "Acquiring Person") or (ii) 10 business days (or such later date as may be determined by action of the Board of Directors prior to such time as any person or entity becomes an Acquiring Person) following the commencement of, or announcement of an intention to commence, a tender offer or exchange offer the consummation of which would result in any person or entity becoming an Acquiring Person (the earlier of such dates being called the "Distribution Date"), the

Rights will be evidenced, with respect to any of the Common Share certificates outstanding as of the Record Date, by such Common Share certificate. Until the Distribution Date, the Rights are not exercisable and will be transferable with and only with the Common Shares. The Rights will expire on June 1, 2011 (the "Final Expiration Date"), unless the Rights are earlier redeemed or exchanged by the Company.

In June 2001, we entered into an agreement to acquire Shearwater in which cash was paid in the amount of approximately $56.4 million and 3,112,603 shares of common stock were to be issued to the holders of all the outstanding common stock of Shearwater in consideration for the acquisition of Shearwater through its merger with and into a wholly owned subsidiary of Inhale. We issued these shares in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, pursuant to Regulation D promulgated under the Act. For each share of Shearwater common stock, we issued approximately 3.09 new shares of our common stock and paid Shearwater stockholders cash in the amount of $55.94 per share. In addition, we assumed all of the outstanding options to acquire Shearwater common stock which were converted into options to acquire approximately 887,343 shares of our common stock and the holders thereof were also paid in cash an aggregate amount of $16.1 million at closing. Each outstanding option to purchase Shearwater common stock was converted into the right to receive approximately 3.09 shares of our common stock upon exercise and option holders were paid cash in the amount of $55.94 per share of Shearwater common stock issuable upon exercise of such options. No fractional shares of our common stock were issued in connection with the acquisition. In lieu thereof, any holder of Shearwater common stock was paid cash based on the value of such fractional share.

Our acquisition of Shearwater also expanded our development pipeline. On February 1, 2000, Shearwater entered into a manufacturing agreement with Schering-Plough Corporation in connection with the PEG reagent used in PEG-INTRON™ (PEG-interferon alpha) for use in the treatment of the hepatitis C virus. Under the terms of this agreement, we manufacture the PEG reagent and Schering-Plough holds an exclusive worldwide license to PEG-INTRON, the first and only PEGylated interferon product approved for marketing in the United States and worldwide. Shearwater also entered into a license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd. ("Roche") whereby Roche received a licensed to the PEG reagent used in Roche's PEGASYS™ product, a PEGylated interferon alpha-2a product, for the treatment of chronic hepatitis C. This agreement provides us with milestone payments, rights to manufacture the PEG reagent and a share of future revenues related to the PEGASYS™ product. On April 5, 1999, Shearwater entered into a subsequent agreement with Roche related to further collaborative work on PEGASYS™. PEGASYS™ was filed for approval with the FDA for a hepatitis C indication on May 22, 2000.

In January 2001, we issued 3,752,456 shares of our common stock to the holders of all of the existing issued ordinary share capital of Bradford Particle Design. We issued these shares in consideration for the acquisition of the outstanding share capital of Bradford Particle Design in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, pursuant to Regulation D and Regulation S promulgated under the Act. For each share of Bradford Particle Design's common stock, we issued 1.8354 new shares of our common stock and paid approximately $9.80 cash, for an aggregate cash payment of approximately $20.4 million. In addition, we assumed all outstanding options to acquire Bradford Particle Design common shares that converted into options to acquire 82,283 shares of our common stock.

In October 2000, we issued $230.0 million aggregate principal amount of 3.5% convertible subordinated notes, which are convertible at the option of the holder, at any time on or prior to maturity into shares of our common stock. The October 2000 notes were sold only in the United States to certain qualified institutional buyers under an exemption from registration provided by Rule 144A of the Act. The October 2000 notes will mature in 2007 and are convertible into shares of our common stock at a conversion price of $50.46 per share, subject to adjustment in certain circumstances.

In February 2000, we issued $230.0 million aggregate principal amount of 5.0% convertible subordinated notes, which are convertible at the option of the holder, at any time on or prior to maturity into shares of our common stock. The February 2000 notes were sold only in the United States to certain qualified institutional buyers under an exemption from registration provided by Rule 144A of the Securities Act of 1933, as amended. The February 2000 notes mature in

2007 and are convertible at a conversion price of $38.355 per share, subject to adjustment in certain circumstances. In October and November 2000 we entered into privately negotiated agreements with certain holders of these outstanding February 2000 notes to convert their notes into shares of our common stock in exchange for a cash payment made by us. To date, we have made cash payments of approximately $25.5 million in the aggregate in connection with agreements that provide for the conversion of approximately $168.6 million principal amount of outstanding February 2000 notes into approximately 4.4 million shares of our common stock.

In February 2000, we entered into privately negotiated agreements with certain holders of our outstanding 6.75% convertible subordinated debentures sold in October and November 1999, providing for the conversion of approximately $100.7 million aggregate principal amount of the outstanding debentures into approximately 6.3 million shares of common stock for net payments of approximately $15.2 million.

In November 1998, Pfizer and Aventis announced that they entered into a worldwide agreement to manufacture insulin and to co-develop and co-promote inhaleable insulin. We continue to have responsibility for manufacturing powders and supplying delivery devices in connection with this arrangement and will receive a royalty on inhaleable insulin products marketed jointly by Pfizer and Aventis Behring. Pfizer commenced dosing for its Phase III clinical trials on this program in June 1999, and completed these trials in April 2001. In December 2001, Pfizer announced that it had decided to include an increased level of controlled, long-term safety data in its proposed NDA with respect to inhaled insulin and that it expected to complete this additional study in 2002.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements which have been prepared in conformity with accounting principles generally accepted in the United States. It 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.

We consider certain accounting policies related to revenue recognition, business combinations and accrued liabilities to be critical to our business operations and the understanding of our results of operations:

Revenue Recognition

Contract revenue from collaborative research agreements is recorded when earned based on the performance requirements of the contract. Revenue from non-refundable upfront license fees and certain guaranteed payments where we continue involvement through collaborative development are deferred and recognized as revenue over the period of continued involvement. Revenue from grants and feasibility arrangements are recognized as the related costs are incurred. Our research revenue is derived primarily from clients in the pharmaceutical industry and consists of reimbursement of development costs, reimbursement of certain expenses, payment of clinical supplies and amortization of milestones. Payments received for milestones achieved are deferred and recorded as revenue over the next period of continued development.

Revenue from product sales is recorded when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collectability is reasonable assured. Allowances, if any, are established for estimated product returns and discounts. Because we have only

recently begun selling a limited number of products through the acquisition of our subsidiaries, we do not have substantial experience in establishing allowances for returns and discounts.

Business Combinations

Purchased In-Process Research and Development ("IPR&D")

IPR&D expense is determined based on an analysis using risk-adjusted cash flows expected to be generated by products that may result from in-process technologies purchased in connection with acquisitions or business combinations. This analysis includes forecasting future cash flows that are expected to result from the progress made on each in-process project prior to the purchase dates. Cash flows are estimated by first forecasting, on a product-by-product basis, net revenues expected from the sales of the first generation of each in-process project and risk adjusting these revenues to reflect the probability of advancing to the next stage of the FDA approval process. The forecast data in the analysis is based on internal product level forecast information maintained by management in the ordinary course of managing the business. The inputs used by management in analyzing IPR&D is based on assumptions, which management believes to be reasonable but which are inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur. Appropriate operating expenses are deducted from forecasted net revenues or on a product-by-product basis to establish a forecast of net returns on the completed portion of the in-process technology. Finally, net returns are discounted to a present value using discount rates that incorporate the weighted average cost of capital relative to the biotech industry and our company as well as product specific risks associated with the purchased in-process research and development products. The product specific risk factors include the products phase of development, type of molecule under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, preclinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, a discount rate is used for the purchase valuation, which represents a considerable risk premium to our weighted average cost of capital. The valuations used to estimate IPR&D require us to use significant estimates and assumptions, that if changed, may result in a different valuation for IPR&D. Valuations for our acquisitions were completed by independent third-party consulting firms in accordance with SEC guidelines and reviewed with our external audit firm.

Impairment of Goodwill and Other Intangible Assets

Goodwill and other intangible assets were amortized on a straight-line basis through December 31, 2001. In July 2001, the Financial Accounting Standards Board ("FASB") issued two statements as a result of its deliberations on the business combinations project: Statement of Financial Accounting Standards ("SFAS") No. 141 on Business Combinations and SFAS 142 on Goodwill and Other Intangible Assets. SFAS 141 will be effective for any business combinations initiated after June 30, 2001 and also includes the criteria for the recognition of intangible assets separately from goodwill. SFAS 142 will be effective for fiscal years beginning after December 15, 2001 and will require that goodwill not be amortized, but rather be subject to an impairment test at least annually. Separately identified and recognized intangible assets resulting from business combinations completed before July 1, 2001 that do not meet the new criteria for separate recognition of intangible assets will be subsumed into goodwill upon adoption. In addition, the useful lives of recognized intangible assets acquired in

transactions completed before July 1, 2001 will be reassessed and the remaining amortization periods adjusted accordingly. Effective January 1, 2002, consistent with the new business combination accounting rules, assembled workforce will be reclassified as goodwill and will be subject to an impairment assessment. Application of the nonamortization provisions of Statement 142 is expected to result in a reduction in net loss of $22.5 million ($0.42 per share based upon shares used in computing basic and diluted net loss per share in 2001) in 2002. We periodically evaluate whether changes have occurred that would require revision of the remaining estimated useful life of these assets or otherwise render the assets unrecoverable. If such an event occurred, we would

determine whether the goodwill or intangibles are impaired. To date, no such impairment losses have been recorded.

Accrued Liabilities

Certain accrued liabilities reflect management's best estimates based on our specific historical experience and understanding of industry practice. We record a reserve for these matters when an adverse outcome is probable and the amount of the potential liability is reasonably estimable.

Results of Operations

Years Ended December 31, 2001, 2000 and 1999

Revenue was $77.5 million for the year ended December 31, 2001 compared to $51.6 million and $41.4 million for the years ended December 31, 2000 and 1999, respectively. Revenue increased 50% in 2001 from 2000 levels and 25% in 2000 from 1999 levels. Allowances, if any, are established for estimated product returns and discounts. The 50% increase in revenue for the year ended December 31, 2001, as compared to December 31, 2000, and the 25% increase in revenue for the year ended December 31, 2000, as compared to December 31, 1999, were both primarily due to expansion of our existing collaborative agreement with Pfizer and revenues from our newly acquired subsidiaries in 2001. Pfizer represented approximately 66% of our revenues for the year ended December 31, 2001. Product sales through our Shearwater subsidiary accounted for 11% of revenues in 2001. Contract research revenue for 2001, 2000 and 1999 also included reimbursed research and development expenses as well as the amortization of deferred up-front signing and progress payments received from our collaborative partners. Contract revenues are expected to fluctuate from year to year, and future contract revenues cannot be predicted accurately. The level of contract revenues depends in part upon future success in obtaining new collaborative agreements, timely completion of feasibility studies, the continuation of existing collaborations and achievement of milestones under current and future agreements. Product sales are dependent upon regulatory approval of new products for sale and adoption of current products in the market and cannot be accurately predicted.

Cost of goods sold is associated with product sales and was $4.2 million for the year ended December 31, 2001 due to the inclusion of Shearwater's financial results since the date of acquisition.

Research and development expenses were $139.7 million for the year ended December 31, 2001, as compared to $100.8 million and $64.0 million for the years ended December 31, 2000 and 1999, respectively. The 39% increase in 2001 as compared to 2000 was primarily attributed to increased spending related to the development effort for both partner and internally funded programs, the scale-up of technologies and the continuing development of global manufacturing capabilities for both inhalation devices and drug powders in order to support inhaleable insulin clinical trials and preparation for commercial production, as well as the addition of Shearwater and Bradford Particle Design to our operations through acquisitions during 2001. The 57% increase in research and development expenses in 2000 from 1999 was due to increased spending related to the scale-up of technologies for current partnered projects, the continuing development of our global manufacturing operations in order to support Phase III inhaleable insulin clinical trials and commercial production, increased investment in internally funded research and development projects for next-generation products and non-cash compensation associated with stock options. We expect research, development and process development spending to increase over the next few years as we continue to expand our development efforts under collaborative agreements using our expanded technology portfolio and to scale up our commercial manufacturing facility.

Our research and development activities can be divided into research and preclinical programs, clinical development programs and commercial readiness. We estimate the costs associated with research

and preclinical programs, clinical development programs and commercial readiness over the past three years at the following (in thousands):

	2001	2000	1999
Research and preclinical programs	$ 35,376	$ 22,516	$ 12,690
Clinical development programs	79,184	62,527	47,404
Commercial readiness	25,091	15,736	3,941
Total research and development	$ 139,651	$ 100,779	$ 64,035

General and administrative expenses were $18.9 million for the year ended December 31, 2001 as compared to $13.9 million and $7.9 million for the years ended December 31, 2000 and 1999, respectively. The 35% increase in general and administrative expenses in 2001 from 2000 was due primarily to increased support associated with our manufacturing and development efforts, including administrative staffing, business development and marketing, as well the addition of Shearwater and Bradford Particle Design to our operations through acquisitions during 2001. The 77% increase in general and administrative expenses in 2000 from 1999 was due primarily to a non-cash compensation charge associated with stock options and the costs associated with supporting our increased manufacturing and development efforts, including administrative staffing and business development activities.

Amortization of goodwill and other intangible assets were $25.5 million for the year ended December 31, 2001 as compared to $0.8 million for the year ended December 31, 2000. This increase was associated with the acquisition of Bradford Particle Design Ltd. and Shearwater Corporation during 2001. Due to the adoption of new accounting standards with respect to business combinations, goodwill and certain other intangible assets will no longer be amortized and will

be subject to an impairment test at least annually beginning January 1, 2002. This is expected to result in a reduction in amortization expense of $22.5 million ($0.42 per share based upon the shares used in computing basic and diluted net loss per share in 2001). The useful lives of recognized intangible assets acquired in transactions will regularly be reassessed and the remaining amortization periods adjusted accordingly.

Other income/expense, net, was $4.2 million of expense for the year ended December 31, 2001 as compared to $1.0 million of income for the year ended December 31, 2000. In 2001, our equity investment in Alliance was determined to be impaired and a loss of $3.9 million was recorded. In 2000, we recorded a gain of $0.8 million associated with the sale of our Alliance shares.

There was no debt conversion premium, net, recorded for the year ended December 31, 2001 and December 31, 1999. For the year ended December 31, 2000, $40.7 million was recorded associated with the conversion of our October 2006 convertible subordinated debentures and February 2007 convertible subordinated notes.

Interest income was $24.6 million for the year ended December 31, 2001 as compared to $20.6 million and $4.1 million for the years ended December 31, 2000 and 1999, respectively. The $4.0 million increase in interest income in 2001 from 2000 and the $16.5 million increase in interest income in 2000 from 1999 were primarily due to our maintaining larger cash and investment balances, including the proceeds of our issuance of several offerings of convertible subordinated notes and debentures and higher interest rates. Interest expense was $13.4 million for the year ended December 31, 2001, as compared to $12.1 million and $2.1 million for the years ended December 31, 2000 and 1999, respectively. The $1.3 million increase in interest expense in 2001 from 2000 primarily relates to the full year's interest expense for the 3.5% convertible subordinated notes issued in October 2000 and the full year's interest expense associated with our build-to-suit lease in 2001. The $10.0 million increase in interest expense in 2000 from 1999 primarily relates to interest paid on the various convertible subordinated notes and debentures issued.

At December 31, 2001, we had federal and state net operating loss carryforwards of approximately $219.0 million. These carryforwards will expire beginning in the year 2002. Utilization of net operating loss

carryforwards may be subject to substantial annual limitations due to the ownership change limitations provided for by the Internal Revenue Code of 1986. The annual limitations may result in the expiration of net operating loss carryforwards before utilization.

Purchased In-Process Research and Development ("IPR&D")

IPR&D represents that portion of the purchase price of an acquisition related to the research and development activities which: (i) have not demonstrated their technological feasibility, and (ii) have no alternative future uses. During the year ended December 31, 2001 our acquisitions of Bradford Particle Design and Shearwater have resulted in an aggregate total charge to IPR&D of approximately $146.3 million.

In June 2001, we completed the acquisition of Shearwater in exchange for our payment of approximately $56.4 million and 3.11 million shares of common stock to the holders of all the outstanding common stock of Shearwater. In addition, we assumed all of the outstanding options to acquire Shearwater common stock which was converted into options to acquire approximately 887,343 shares of our common stock and the holders thereof were also paid an aggregate amount of $16.1 million in cash at closing. Of the total purchase consideration of $192.2 million, $108.6 million was allocated to the assets acquired based on their fair value on the date of acquisition, including $94.6 million in goodwill and other intangible assets. Approximately $83.6 million of the purchase price was allocated to IPR&D, which was determined to have no alternative future use and was charged as an expense during the three-month period ended June 30, 2001.

In January 2001, we acquired all of the outstanding share capital of Bradford Particle Design in exchange for approximately 3.75 million in newly issued shares of our common stock and approximately $20.4 million in cash. Of the total purchase consideration of $152.1 million, $89.4 million was allocated to the assets acquired based on their fair value on the date of acquisition, including $80.1 million in goodwill and other intangible assets. Approximately $62.7 million of the purchase price was allocated to IPR&D, which was determined to have no alternative future use and was charged as an expense in the quarter ended March 31, 2001.

The amounts of IPR&D were determined based on an analysis using risk-adjusted cash flows expected to be generated by the products that may result from the in-process platform technology for Bradford Particle Design and from the in-process technology for Shearwater. The analysis included forecasted future cash flows that were expected to result from the progress made on each of the in-process projects prior to the purchase dates. These cash flows were estimated by first forecasting, on a product-by-product basis, net revenues expected from the sales of the first generation of each in-process project and risk adjusted to reflect the probability of advancing to the next stage of the FDA approval process. Appropriate operating expenses were deducted from the total forecasted net revenues for Bradford Particle Design and on a product-by-product basis from the forecast for Shearwater to establish a forecast of net returns on the completed portion of the in-process technology. Finally, these net returns were discounted to a present value using discount rates that incorporate the weighted average cost of capital relative to the biotech industry and our company as well as product specific risks associated with the purchased in-process research and development products. The product specific risk factors included the products phase of development, type of molecule under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, preclinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, an overall discount rate of 47% for Bradford Particle Design and 22% for Shearwater was used for the purchase valuation, which represents a considerable risk premium to our weighted average cost of capital.

The forecast data in the analysis was based on internal product level forecast information maintained by Inhale's management in the ordinary course of managing the business. The inputs used by management in analyzing in-process research and development was based on assumptions, which management believed

to be reasonable but which are inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur.

In the second quarter of 2000, we recorded a $2.3 million charge for acquired in-process research and development costs. The acquisition was recorded as a purchase and $2.3 million of the purchase price was allocated to IPR&D and charged as an expense in the quarter ended June 30, 2000. As of the date of the acquisition, the in-process technology had no alternative future use and did not qualify for capitalization.

In November 1999, we concluded an agreement with Alliance Pharmaceutical Corp. to acquire Alliance's PulmoSphere® particle and particle processing technology for use in respiratory drug delivery. Under the terms of the agreement, we received the rights to the PulmoSphere® technology, other related assets (including research materials, laboratory records, and certain equipment that had been used in the development of PulmoSphere® technology and the manufacturing and testing of particles using such PulmoSphere® technology), and Alliance stock valued at $5.0 million in exchange for $15.0 million in cash and $5.0 million of our stock. Additionally, we incurred approximately $400,000 of acquired costs, which were included in the total purchase consideration. Alliance also has the right to additional substantial payments upon the achievement of certain milestones and royalties on a defined number of products commercialized using the technology. Of the total purchase consideration, $15.4 million was allocated to assets acquired based on their fair value on the date of acquisition. Approximately $9.9 million of the purchase price was allocated to IPR&D and was charged as an expense in the year ended December 31, 1999. In 2001, our equity investment in Alliance was determined to be impaired and a loss on investment of $3.9 million was recorded.

Liquidity and Capital Resources

We have financed our operations primarily through public and private placements of our debt and equity securities, revenues from development contracts and short-term research and feasibility agreements, financing of equipment acquisitions and tenant improvements, and interest income earned on our investments of cash. We do not utilize off-balance sheet financing arrangements as a source of liquidity or financing. At December 31, 2001, we had cash, cash equivalents and short-term investments of approximately $344.4 million.

Our operations used cash of $50.8 million, $35.7 million and $15.3 million for the years ended December 31, 2001, 2000 and 1999, respectively. These amounts differed from our net operating losses in these periods principally due to depreciation expense and purchased IPR&D and net debt conversion premium. We recorded a $146.3 million, $2.3 million and $9.9 million of purchased IPR&D charges for the years ended December 31, 2001, 2000 and 1999, respectively.

In October 2000, we entered into a financing arrangement with a real estate partnership to complete construction of existing office facilities and provide financing for future capital improvements of up to $51.0 million. As a result of our continuing involvement and significant influence in the real estate partnership, and other provisions in the leasing transactions, the facility costs and capital lease obligations of the real estate partnership are recorded in our consolidated financial statements.

We purchased property and equipment of approximately $34.3 million, $53.9 million and $20.5 million during the years ended December 31, 2001, 2000 and 1999, respectively. The current year activity includes $28.6 million associated with our capital lease obligation with our build-to-suit lease facility. The decrease in purchased property and equipment in 2001 as compared to 2000, reflects completion of the first phase of construction of a new San Carlos lab and office facility, offset by continued investment in our commercial manufacturing facilities, including device manufacturing at third-party contract manufacturers, and expansion of our San Carlos powder processing facilities.

Also, in connection with our acquisition of Bradford Particle Design, we paid net cash of $14.8 million, which represents cash paid to Bradford Particle Design shareholders of $20.4 million, net of Bradford Particle Design's cash balance of $5.6 million. The remainder of the Bradford Particle Design acquisition was non-cash in nature. In connection with our acquisition of Shearwater, we paid net cash of $67.2 million, which represents cash paid to Shearwater shareholders of $72.5 million, net of Shearwater's cash obtained at June 30, 2001 of $5.3 million. (See "Purchased In-process Research and Development").

In October 1999, we received approximately $104.8 million in net proceeds from the sale of convertible subordinated debentures. In February 2000 and October 2000, we received approximately $222.4 million and $222.8 million, respectively, in net proceeds from the sale of convertible subordinated notes. This includes net payments of approximately $15.2 million and $25.5 million in connection with agreements that provide for the conversion of approximately $100.7 million and $168.6 million of our October 2006 and February 2007 debentures, respectively, into common stock.

The following is a summary of our contractual obligations as of December 31, 2001:

		Payments Due by Period			
Contractual Obligations (In Thousands)	**Total**	**Less than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Tenant Improvement loan	$ 7,479	$ 503	$ 1,509	$ 5,467	$ —
Build-to-suit lease	93,573	5,518	17,224	12,063	58,768
Interest Payable	69,336	11,643	34,930	22,763	—
Operating Leases	22,829	2,343	6,462	4,452	9,572
Principal Amount of Convertible Subordinated Notes and Debentures	299,149	—	—	7,760	291,389
Other Obligations	126	39	87	—	—
Total Contractual Cash Obligations	$ 492,492	$ 20,046	$ 60,212	$ 52,505	$ 359,729

In August 2000, we entered into supply agreements with two contract manufacturers to provide for the manufacturing of our inhalation device. Under the terms of the agreements, we may be obligated to reimburse both parties for the actual unamortized and unrecovered portion of any equipment procured or facilities established and the interest accrued for their capital overlay in the event that inhaleable insulin does not gain FDA approval to the extent that the contract manufacturers cannot re-deploy the assets. At the present time, it is not possible to estimate the loss that will occur should inhaleable insulin not be approved.

We expect our cash requirements to continue to grow at an accelerated rate due to expected increases in costs associated with further research and development of our technologies, development of drug formulations, process development for the manufacture and filling of powders and devices, marketing and general and administrative costs and starting up commercial operations. These expenses include, but are not limited to, increases in personnel and personnel

related costs, purchases of capital equipment, investments in technologies, inhalation device prototype construction and facilities expansion. Our planned facilities expansion includes the completion of our commercial manufacturing facility and the scale-up of device manufacturing with our third-party contract manufacturers.

Given our current cash requirements, we believe that we will have sufficient cash to meet our operating expense requirements for the next 30 months. We plan to continue to invest in our growth and the need for cash will be dependent upon the timing of these investments. Our capital needs will depend on many factors, including continued scientific progress in our research and development arrangements, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of developing and the rate of scale-up of our powder processing and packaging technologies, the timing and cost of our late stage clinical and early commercial production facility, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new

technologies and the status of competitive products. To satisfy our long-term needs, we intend to seek additional funding, as necessary, from corporate partners and from the sale of securities. Because we are an early stage biotechnology company, we do not qualify to issue investment grade debt or have access to certain credit facilities. As a result, any financing we undertake will likely involve the issuance of equity, convertible debt instruments or high-yield debt to fund our working capital. To date we have been primarily dependent upon equity and convertible debt financings for capital and have incurred substantial debt as a result of our issuances of subordinated notes and debentures convertible into our common stock. Our substantial debt, the market price of our securities and the general economic climate, among other factors, could have material consequences for the Company's financial position and could affect our sources of short-term and long-term funding. There can be no assurance that additional funds, if and when required, will be available to us on favorable terms, if at all.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality debt securities. Our investments in debt securities are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in short term securities and maintain an average maturity of one year or less. A hypothetical 50 basis point increase in interest rates would result in an approximate $1.0 million decrease (less than 0.301%) in the fair value of our available-for-sale securities at December 31, 2001.

The potential change noted above is based on sensitivity analyses performed on our financial position at December 31, 2001. Actual results may differ materially. The same hypothetical 50 basis point increase in interest rates would have resulted in an approximate $0.6 million decrease (less than 0.126%) in the fair value of our available-for-sale securities at December 31, 2000.

Increases in interest rates could adversely affect the fair market value of our convertible subordinated notes and debentures, which pay a fixed rate of interest. As of December 31, 2001, we had approximately $299.1 million in outstanding convertible subordinated notes and debentures with a fair market value of approximately $204.5 million.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements for the years ended December 31, 2001, 2000 and 1999 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

Executive Officers and Directors.

The following table sets forth the names, ages and positions of the executive officers and directors as of December 31, 2001:

Name	Age	Position
Robert B. Chess	44	Executive Chairman of the Board
Ajit S. Gill	53	Director, Chief Executive Officer and President
Brigid A. Makes	46	Vice President, Finance and Administration, Chief Financial Officer and Assistant Secretary
John S. Patton, Ph.D.	55	Director, Founder and Chief Scientific Officer
Stephen L. Hurst	46	Vice President, Human Resources
Douglas H. Altschuler	46	Vice President, General Counsel and Secretary
James B. Glavin	66	Director
Melvin Perelman, Ph.D.	71	Director
Irwin Lerner	71	Director

Roy A. Whitfield	48	Director
Christopher A. Kuebler	48	Director

Robert B. Chess has served as Executive Chairman of the Board of Directors since April 1999. Mr. Chess served as Co-Chief Executive Officer from August 1998 to April 2000, as President from December 1991 to August 1998, and as Chief Executive Officer from May 1992 to September 1998. Mr. Chess was elected as a Director in May 1992. From September 1990 until October 1991, he was an Associate Deputy Director in the White House Office of Policy Development. In March 1987, Mr. Chess co-founded Penederm Incorporated, a topical dermatological drug delivery company, and served as its President until February 1989. Prior to co-founding Penederm, Mr. Chess held management positions at Intel Corp., a semiconductor manufacturer, and Metaphor, a computer software company (acquired by International Business Machines). Mr. Chess holds a BS in Engineering from the California Institute of Technology and an MBA from the Harvard Business School. Mr. Chess is a director of Pharsight Corp., a software company, Biotechnology Industry Organization and ChemGenex, Inc., a cancer therapeutics company.

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

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

Commerce degree from McGill University in Finance and International Business and an MBA from Bentley College.

John S. Patton, Ph.D., a co-founder of Inhale, has served as Chief Scientific Officer since November 2001 and a Director of since July 1990. He served as Vice President, Research from December 1991 to November 2001. 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. Dr. Patton is also a director of David Pharmaceuticals, Inc. a biopharmaceutical company.

Stephen L. Hurst has served as Vice President of Human Resources since July 2001. Mr. Hurst served as Vice President, General Counsel and Secretary from August 1998 to July 2001 and as Vice President, Intellectual Property and Licensing from March 1994 to August 1998. From July 1990 to February 1994, Mr. Hurst was in private law practice and consulted with COR Therapeutics, Inc., a biotechnology company, on intellectual property and business development issues. From November 1987 to June 1990, he was the Campus Patent Coordinator for the University of California, San Francisco. He also worked as an Associate Counsel at Townsend & Townsend, a San Francisco based law firm. He received a BS degree in Environmental Science from the University of California at Berkeley and his JD from Golden Gate University in San Francisco.

Douglas H. Altschuler has been Vice President, General Counsel and Secretary since November 2001. Prior to joining Inhale, Mr. Altschluler served as Vice President, General Counsel and Assistant Secretary with Axys Pharmaceuticals, Inc., a pharmaceutical company, from December 2000 until November 2001. From 1996 to 2000, Mr. Altschuler was Vice President/General Counsel and Compliance Officer of Mentor Corporation, a medical device company. Prior to joining Mentor, Mr. Altschuler was in the private practice of law. Mr. Altschuler received his JD from the University of Arizona School of Law and a BS in Chemistry and Biology from the University of Arizona.

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

Melvin Perelman, Ph.D. has been a Director since January 1996. Dr. Perelman spent 36 years at Eli Lilly & Company, most recently as Executive Vice-President and President of Lilly Research Laboratories, a position, which he held from 1986 until his retirement in 1993. Dr. Perelman served as President of Lilly International from 1976 until 1986. He was a member of the Board of Directors of Lilly from 1976 until 1993. Dr. Perelman is a member of the Board of Directors of Immusol, Inc., a biopharmaceutical company, and of The Immune Response Corporation, a biotechnology company.

Irwin Lerner has been a Director since April 1999. Mr. Lerner served as Chairman of the Board of Directors and of the Executive Committee of F. Hoffmann-La Roche Inc., a pharmaceutical and health care company, from January 1993 until his retirement in September 1993, and from 1980 through December 1992, also served as President and Chief Executive Officer. Since September 1995, Mr. Lerner has served on the Board of Medarex Inc., a monoclonal antibodies products company, and became

Chairman of the Board in May 1997. He has served for 12 years on the Board of the Pharmaceutical Manufacturers' Association where he chaired the Association's FDA Issues Committee. Mr. Lerner received a B.S. and an MBA from Rutgers University. He is currently Distinguished Executive-in-Residence at Rutgers University Graduate School of Management. Mr. Lerner is also a director of Humana Inc., a health care company, Covance Inc., a contract drug development company, V.I. Technologies, Inc., a blood products company, Medarex, Inc. and Reliant Pharmaceuticals, LLC.

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

Christopher A. Kuebler has been a Director since December 2001. Mr. Kuebler is Chairman of the Board of Directors of Covance Inc., a drug development services company, and from November 1994 to present, has served as President and Chief Executive Officer. From March 1993 through November 1994, he was the Corporate Vice President, European Operations for Abbott Laboratories Inc. ("ALI"), a diversified health care company. From January 1986 until March 1993, Mr. Kuebler served in various commercial positions for ALI's Pharmaceutical Division and was that Division's Vice President, Sales and Marketing prior to taking the position of Vice President European Operations. Mr. Kuebler holds a BS degree in Biological Science from Florida State University.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires directors and executive officers, and persons who beneficially own more than 10% of a registered class of Inhale's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of the company's Common Stock and other equity securities. Officers, directors and greater than 10% stockholders are required by the SEC to furnish Inhale with copies of all Section 16(a) forms that they file.

To Inhale's knowledge, based solely on a review of the copies of such reports furnished to Inhale and written representations that no other reports were required, during the fiscal year ended December 31, 2001, all Section 16(a) filing requirements applicable to its officers, directors and principal stockholders were complied with, except that: (i) one Form 4 statement of change of beneficial ownership covering the exercise of an aggregate of 11,334 options to purchase shares of Common Stock was not filed by Mr. Hurst. The Company intends to file a Form 5 related to the exercise of these options and a Form 4 covering the sale of these shares was filed timely; (ii) one Form 4 statement of change of beneficial ownership covering the exercise and sale of an aggregate of 16,865 options to purchase shares of Common Stock was not filed by Mr. Hurst; however, a Form 5 covering the transaction was filed on February 14, 2002; and (iii) one Form 4 statement of change of beneficial ownership covering the exercise of an aggregate of 116,956 options to purchase shares of the Common Stock was filed late by Dr. Patton.

Scientific Advisory Group

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

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

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

Regulatory and Development Advisory Board

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

Name	Affiliation	Area of Expertise
Carl C. Peck, M.D.	Professor of Pharmacology and Medicine, Director, Center for Drug	Clinical and regulatory development strategy

	Development, Georgetown University Medical Center	
David Savello, Ph.D.	Executive Vice President and Chief Technology Officer, R.P. Scherer, Inc.	Pharmaceutical research and development and regulatory affairs
Phillip B. White	Director, Medical Device Consulting, AAC Consulting (Retired)	Device regulatory affairs
Allen J. Sedman, M.D., Ph.D.	Vice President, Clinical Sciences Head, Pfizer Global Research and Development, Ann Arbor, Michigan (Retired)	Clinical drug development in general; special expertise in clinical pharmacology

Pulmonary Advisory Committee

In November 2001, we formed a pulmonary advisory committee to assist and advise us on matters relating to identification and understanding of potential pulmonary issues encountered in our development programs. The committee currently includes the following:

Name	Affiliation	Area of Expertise
Jedd Shellito, M.D.	Professor of Microbiology, Immunology and Parasitology, Louisiana State University	Pulmonary Host Defense/Immunology
Talmadge King, M.D.	Chief of Medical Services at San Francisco General Hospital; Professor and Vice Chairman Department of Medicine, University of California, San Francisco	Pulmonary Medicine
Warren Gold, M.D.	Professor of Medicine, University of California, San Francisco	Pulmonary Function Testing
Michael Matthay, M.D.	Professor of Medicine and Anesthesiology, University of California, San Francisco	Pulmonology Medicine & Critical Care
Paul Blanc, M.D.	Professor of Medicine, University of California, San Francisco Chief, Division of Occupational and Environmental	Occupational/Environmental Medicine Medicine, University of California, San Francisco
Rubin Tuder, M.D.	Director Cardiopulmonary Pathology, Johns Hopkins University	Pulmonary Pathology

Item 11. Executive Compensation

COMPENSATION OF DIRECTORS

Each non-employee director of the Company receives an annual retainer of $15,000. In the fiscal year ended December 31, 2001, the total compensation paid to non-employee directors for service as directors was $60,000. The members of the Board of Directors are also eligible for reimbursement for their expenses incurred in connection with attendance at Board of Directors meetings in accordance with Company policy.

Upon their election, each member of the Company's Board of Directors who is not an employee of the Company is automatically granted, under the 1994 Non-Employee Directors' Stock Option Plan (the "Non-Employee Directors' Plan") as amended, without further action by the Company, the Board of Directors or the stockholders of the Company, an option to purchase 30,000 shares of Common Stock of the Company for each three-year term to which he or she is elected. The non-employee directors who began with a one or a two-year term when the Company first instituted the staggered Board of Directors were granted 10,000 and 20,000 shares of Common Stock, respectively. Vesting is monthly over the period of the term being served. Only non-employee directors of the Company are eligible to receive options under the Non-Employee Directors' Plan. Options granted under the Non-Employee Directors' Plan are intended by the Company not to qualify as incentive stock options under the Internal Revenue Code of 1986, as amended. The exercise price of options granted under the Non-Employee Directors' Plan is 100% of the fair market value of the Common Stock subject to the option on the date of the option grant. Option grants under the Non-Employee Directors' Plan are non-discretionary. The term of options granted under

the Non-Employee Directors' Plan is ten years. In the event of a merger of the Company with or into another corporation or a consolidation in which the Company is the surviving corporation, with the outstanding shares of the Company's Common Stock immediately preceding the merger being converted by virtue of the merger into other property, or any other capital reorganization in which 50% of the shares of the Company entitled to vote are exchanged, the vesting of each option will accelerate in full and the option will terminate if not exercised prior to the consummation of the transaction. Non-employee directors are also eligible for discretionary grants of options under the Company's 2000 Equity Incentive Plan.

Options to purchase an aggregate of 480,200 shares of Common Stock have been granted to current non-employee directors of the Company under the Non-Employee Directors' Plan and the 2000 Equity Incentive Plan as of January 31, 2002, of which 150,600 have been exercised. Options to purchase an aggregate of 3,857,292 shares of Common Stock have been granted to directors who are employees of the Company as of January 31, 2002, of which 1,468,245 have been exercised as of January 31, 2002. On November 15, 2000, Mr. Gabrielson, a former director, exercised options to purchase 3,333 shares of Common Stock of the Company pursuant to a grant he received on June 6, 2000. On April 1, 1999, Mr. Lerner entered into a consulting agreement with the Company. Pursuant to this agreement, Mr. Lerner may perform consulting services relating to product marketing and general business issues of at least four half days per year as well as telephone discussions as needed in consideration for his standard consulting fee. In 2000 and 2001, Mr. Lerner received no consulting fees for services performed for the Company.

COMPENSATION OF EXECUTIVE OFFICERS

The following table shows for the fiscal years ended December 31, 2001, 2000 and 1999, respectively, compensation awarded or paid to, or earned by, Inhale's Chief Executive Officer and its other executive officers at December 31, 2001 (the "Named Executive Officers"(1)).

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Annual Compensation Salary ($)	Annual Compensation Bonus ($)	Other Annual Compensation ($)	Securities Underlying Options (#)	All Other Compensation ($)(2)
Ajit S. Gill	2001	$ 422,100	$ 201,135	$ —	370,000	$ 6,066
Chief Executive Officer,	2000	387,788	746,546(3)	—	350,000	6,066
President and Director	1999	248,013	113,249	—	100,000	6,452
Robert B. Chess(4)	2001	254,138	121,270	—	222,000	5,520
Executive Chairman of the	2000	251,250	668,945(3)	—	326,666	5,520
Board of Directors	1999	248,013	113,249	—	100,000	6,005
John S. Patton	2001	222,833	90,125	—	14,000	6,906
Founder, Chief Scientific	2000	209,271	92,369	—	19,600	1,659
Officer and Director	1999	190,774	76,518	—	28,000	6,117
Brigid A. Makes(5)	2001	219,313	68,911	24,000(6)	49,800	5,730
Vice President, Finance & Administration,	2000	205,750	70,636	950(6)	19,600	5,730
Chief Financial Officer and Assistant	1999	87,739	30,000	11,707(6)	140,000	175
Secretary						
Douglas H. Altschuler(7)	2001	61,894	25,000	—	100,000	158
Vice President, General	2000	—	—	—	—	—
Counsel and Secretary	1999	—	—	—	—	—
Stephen L. Hurst	2001	129,050	54,234	—	7,000	4,498
Vice President, Human	2000	171,863	96,044	—	79,600	3,427
Resources	1999	179,316	57,605	—	21,602	1,186

(1) The Named Executive Officers include all the Executive Officers of the Company.

(2) Amounts include perquisites consisting of one or more of the following: (i) life insurance premiums paid by Inhale; (ii) reimbursement for computer equipment used for company business; (iii) entertainment gifts associated with company business; and (iv) Inhale's matching payments under its 401(k) plan.

(3) Includes a stock bonus of 20,000 fully vested shares of Common Stock granted to each of Messrs. Gill and Chess pursuant to the 2000 Equity Incentive Plan on April 19, 2000, each grant with a fair market value of $550,000 on the date of grant.

(4) Mr. Chess resigned as Co-Chief Executive Officer of the Company on April 19, 2000. For the fiscal year ended December 31, 2000, Mr. Chess received compensation for his services as Co-Chief Executive Officer of the Company in the amount of $67,645, reflecting payment for his services as Co-Chief Executive Officer through April 19, 2000. He continues to serve as Executive Chairman of the Board of Directors of the Company and received a base salary of $183,605 in 2000.

(5) Ms. Makes became an executive officer of Inhale on June 28, 1999. Her annualized base salary in 1999 was $200,250.

(6) Includes payments made to Ms. Makes in 2001, 2000 and 1999 for the reimbursement of expenses in connection with Ms. Makes' relocation.

(7) Mr. Altschuler became an executive officer of Inhale on November 19, 2001. His annualized base salary in 2001 was $307,500.

STOCK OPTION GRANTS AND EXERCISES

Inhale grants options to its executive officers under the 2000 Equity Incentive Plan. As of January 31, 2002, options to purchase a total of 9,777,050 shares had been granted under the 2000 Equity Incentive Plan and options to purchase 1,427,350 shares remained available for grant thereunder.

The following tables show for the fiscal year ended December 31, 2001 certain information regarding options granted to, exercised by, and held at year-end by the Named Executive Officers:

OPTION GRANTS IN LAST FISCAL YEAR

Name	Securities Underlying Options Granted(1)	Percentage of Total Options Granted to Employees in Fiscal Year(2)	Exercise or Base Price ($/Share)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(3)	
					5%	10%
Ajit S. Gill	370,000(4)	6.93%	$ 27.8750	2/21/11	$ 6,486,262	$ 16,437,461
Robert B. Chess	222,000(5)	4.16%	$ 27.8750	2/21/11	$ 3,891,757	$ 9,862,477
John S. Patton	14,000(6)	0.26%	$ 27.8750	2/21/11	$ 245,426	$ 621,958
Brigid A. Makes	49,800(7)	0.93%	$ 27.8750	2/21/11	$ 873,016	$ 2,212,393
Douglas H. Altschuler	100,000(8)	1.87%	$ 12.4000	9/18/11	$ 779,829	$ 1,976,241
Stephen L. Hurst	7,000(9)	0.13%	$ 27.8750	2/21/11	$ 122,713	$ 310,979

(1) In January 1995, the Board of Directors amended the provisions of existing option grant forms to provide that upon a change in control, the vesting of all outstanding options held by executive officers would be accelerated by two years. This acceleration also applies to all subsequent grants made to executive officers. Options also accelerate and vest in full upon a change in control, asset sale, merger, consolidation or reverse merger, as described in Inhale's 2000 Equity Incentive Plan, in the event the acquiring Company does not assume the options or does not substitute similar options. The options will also accelerate and vest in full upon a securities acquisition, as described in Inhale's 2000 Equity Incentive Plan. The Board of Directors may re-price the options under the terms of the 2000 Equity Incentive Plan.

(2) Based on an aggregate of 5,335,451 options granted to employees in 2001, including the Named Executive Officers.

(3) The potential realizable value is based on the term of the option at the time of grant (ten years). Assumed stock price appreciation of 5% and 10% is used pursuant to rules promulgated by the SEC. The potential realizable value is calculated by assuming that the market price on the date of grant appreciates at the indicated rate for the entire term of the option and that the option is exercised at the exercise price and sold on the last day of its term at the appreciated price.

(4) Options for 70,000 shares vest monthly over one year commencing in May 2005. Options for 300,000 shares vest monthly over five years commencing in February 2001.

(5) Options for 42,000 shares vest monthly over one year commencing in November 2005. Options for 180,000 shares vest monthly over five years commencing in February 2001.

(6) Options for 14,000 shares vest monthly over one year commencing in April 2005.

(7) Options for 9,800 shares vest monthly over one year commencing in June 2005. Options for 40,000 shares vest monthly over five years commencing in February 2001.

(8) Options for 70,000 shares vest 1/5th on September 18, 2002 and monthly over four years thereafter. Options for 30,000 shares vest 1/5th on September 18, 2002 and monthly over four years thereafter.

(9) Options for 7,000 shares vest monthly over one year commencing in March 2005.

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND DECEMBER 31, 2001 OPTION VALUES

Name	Shares Acquired on Exercise(#)	Value Realized($)(1)	Securities Underlying Unexercised Options at December 31, 2001		Value of Unexercised In-The-Money Options At December 31, 2001(2)	
			Exercisable(#)	Unexercisable(#)	Exercisable($)	Unexercisable($)
Ajit S. Gill	—	$ —	560,570	622,030	$ 3,712,275	$ 532,331
Robert B. Chess	—	$ —	411,901	488,346	$ 2,363,662	$ 691,623
John S. Patton	116,956	$ 1,525,632	168,798	137,402	$ 1,601,350	$ 483,893
Brigid A. Makes	5,000	$ 89,000	71,665	132,735	$ 295,745	$ 318,505
Douglas H. Altschuler	—	$ —	—	100,000	$ —	$ 615,000
Stephen L. Hurst	28,199	$ 542,508	41,182	118,523	$ 226,251	$ 257,358

(1) Based on the fair market value of Inhale's Common Stock on the exercise date, minus the exercise price, multiplied by the number of shares exercised.

(2) Based on the fair market value of Inhale's Common Stock as of December 31, 2001 ($18.55 per share), minus the exercise price, multiplied by the number of shares underlying the options.

REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS ON EXECUTIVE COMPENSATION

The Board of Directors has delegated to the Compensation Committee the authority to establish and administer the Company's compensation programs. The Compensation Committee is comprised of two non-employee Directors: Messrs. Lerner and Glavin. The Compensation Committee is responsible for: (i) determining the most effective total executive compensation strategy, based upon the business needs of the Company and consistent with stockholders' interests; (ii) administering the Company's executive compensation plans, programs and policies; (iii) monitoring corporate performance and its relationship to compensation of executive officers; and (iv) making appropriate recommendations concerning matters of executive compensation.

Compensation Philosophy

The primary goals of the compensation program are to align compensation with the attainment of key business objectives and to enable the Company to attract, retain and reward capable executives who can contribute to the continued success of the Company. Equity participation and a strong alignment to stockholders' interests are key elements of the Company's compensation philosophy. Four key goals form the basis for compensation decisions for all employees of the Company:

1. To attract and retain the most highly qualified management and employee team;

2. To emphasize sustained performance by aligning rewards with stockholder interests, especially through the use of equity participation programs;

3. To pay competitively compared to similar drug delivery and biopharmaceutical companies and to provide appropriate reward opportunities for achieving high levels of performance compared to similar organizations in the marketplace; and

4. To motivate executives and employees to achieve the Company's annual and long-term business goals and encourage behavior toward the fulfillment of those objectives.

To meet these goals, the Compensation Committee has adopted a mix among the compensation elements of salary, stock options and bonuses.

Base Salary

The Compensation Committee recognizes the importance of maintaining compensation practices and levels of compensation competitive with drug delivery and biopharmaceutical companies in comparable stages of development. Base salary represents the fixed component of the executive compensation program. The Company's philosophy regarding base salaries is conservative, maintaining salaries approximately at the competitive industry median. Base salary levels are established on an annual review of marketplace competitiveness with similar pharmaceutical and drug delivery companies and on the basis of individual performance. Periodic increases in base salary are the result of individual contributions evaluated against established performance objectives, relative success toward achieving the Company's annual and long-term business goals, length of service with the Company and an annual salary survey of comparable companies in Inhale's industry. Base salaries for executives were increased for fiscal 2001 to a level consistent with the industry median. In 2001, the Company continued the variable compensation program implemented in 1996 for all employees, including all executive officers, which provides that a portion of total compensation is variable based on certain qualitative and quantitative criteria for both the Company and each employee.

Stock Options

The option plans offered by the Company have been established to provide all executive officers of the Company with an opportunity to share, along with the stockholders of the Company, in the long-term performance of the Company. The Compensation Committee strongly believes that a goal of the compensation program should be to provide key employees who have significant responsibility for the management, growth and future success of the Company with an opportunity to increase their ownership of the Company and potentially gain financially from Company stock price increases. The interests of stockholders, executives and employees should thereby be closely aligned. Executives and employees are eligible to receive stock options generally not more often than once a year, giving them the right to purchase shares of Common Stock of the Company in the future at a price equal to fair market value at the date of grant. All grants must be exercised according to the provisions of the Company's stock option plans. All outstanding options expire ten years from the date of grant.

As the base salaries for executive officers of the Company are in the mid-range for comparable companies, the Company has used stock options as a primary incentive to attract and retain its executive officers. Option amounts are based on salary grade within the Company and overall Company and individual performance. After considering the criteria relating to awarding stock options, the Compensation Committee determined that all executive officers, including the Chief Executive Officer, would receive option grants in fiscal 2001. The options granted to executive officers in fiscal 2001 include options which vest monthly over five years commencing upon the date of grant, as well as providing "evergreen" options, which typically vest over a twelve month period commencing four years after the date of grant.

Section 162(m) of the Code limits the Company to a deduction for federal income tax purposes of no more than $1.0 million of compensation paid to certain Named Executive Officers in a taxable year. Compensation above $1.0 million may be deducted if it is "performance-based compensation" within the meaning of the Code. The Compensation Committee believes that at the present time it is unlikely that the compensation paid to any Named Executive Officer in a taxable year, which is subject to the deduction limit, will exceed $1.0 million. However, the Compensation Committee has determined that stock awards granted under the Equity Incentive Plan with an exercise price at least equal to the fair market value of the Company's Common Stock on the date of grant shall be treated as "performance-based compensation."

Bonuses

Bonus awards are another component of the compensation program. Bonuses, if any, are linked to the achievement of specified corporate goals, which is determined at the discretion of the Board of Directors upon the recommendation of the Compensation Committee. Corporate performance goals on which 2001 bonuses were based were: our acquisitions of Shearwater Corporation and Bradford Particle Design and the integration of these wholly-owned subsidiaries and acquired technologies into the Company's business operations; the successful attainment of anticipated milestones generating payments under current partnered projects; progress in further establishing the necessary infrastructure to support commercialization at anticipated levels; signing of new collaborative partners and converting existing collaborative partners with feasibility agreements to long-term development agreements; advancing our delivery system technology by improving the performance and efficiency of the inhalation device, powder processing and powder filling; and advancing the commercial readiness of our manufacturing facilities. In January 2002, the Compensation Committee reviewed the Company's 2001 corporate performance goals and determined that these goals had been substantially achieved. Based on such achievement, the Compensation Committee awarded bonuses for 2001 for all executive officers.

CEO Compensation

The Compensation Committee determines compensation for the Chief Executive Officer by analyzing the same factors and criteria upon which other executive officers' compensation is based. In its January 2002 meeting, the Compensation Committee awarded Mr. Gill a bonus of approximately 50% of base salary based on their determination that the corporate performance goals established for the Company in 2001 had been substantially achieved. In May 2001, the Compensation Committee agreed to recommend to the Board that Mr. Gill receive an increase in salary and stock option grants for these same reasons. Under the Company's executive compensation program, the total compensation mix for senior executives emphasizes longer-term rewards in the form of stock options. In 2001, Mr. Gill received option grants to purchase 370,000 shares of the Company's Common Stock at the fair market value of the Common Stock on the date of grant, of which 70,000 were evergreen grants.

Summary

The Compensation Committee believes that the compensation of executives by the Company is appropriate and competitive with the compensation programs provided by other drug delivery and biopharmaceutical companies with which the Company competes for executives and employees. The Compensation Committee believes its compensation strategy, principles and practices result in a compensation program tied to stockholder returns and linked to the achievement of annual and longer-term financial and operational results of the Company on behalf of the Company's stockholders.

COMPENSATION COMMITTEE

Irwin Lerner
James B. Glavin

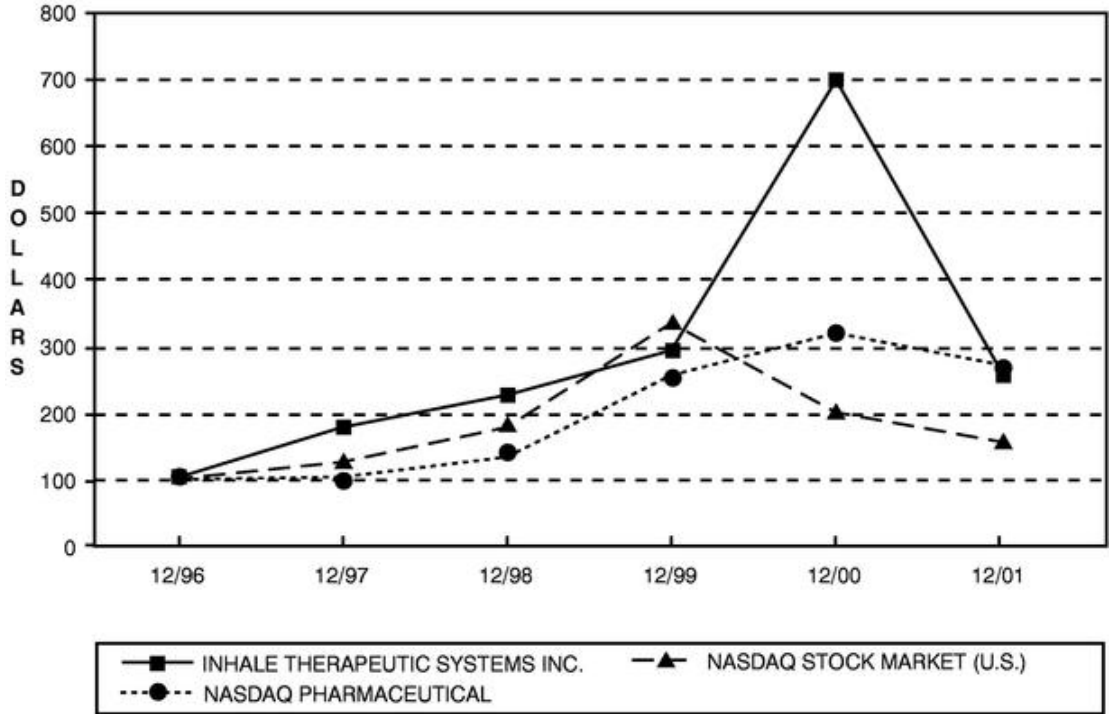
Compensation Committee Interlocks and Insider Participation

None of the members of the Company's Compensation Committee of the Board of Directors is currently, or has been, at any time since our formation, an officer or employee of the Company. On April 1, 1999, Mr. Lerner entered into a consulting agreement with the Company. Pursuant to the agreement, Mr. Lerner may perform consulting services relating to product marketing and general business issues of at least four half days per year as well as telephone discussions as needed in consideration for his standard consulting fee. In 2000 and 2001, Mr. Lerner received no consulting fees for services performed for the Company.

Comparison of Stockholder Return(1)

Set forth below is a line graph comparing the annual percentage change in the cumulative total return on the Company's Common Stock with the RDG Total Return Index for the Nasdaq Stock Market (U.S. Companies) and the RDG Total Return Index for the Nasdaq Pharmaceutical Stocks(2) for the period commencing on December 31, 1996, and ending on December 31, 2001. All values assume reinvestment of the full amount of all dividends.

Comparison of Cumulative Total Return from December 31, 1996, and Ending on December 31, 2001(3)



(1) The material in this report is not "soliciting material" and is not deemed filed with the SEC, and is not to be incorporated by reference into any filing of the company under the Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language contained in any such filing.

(2) The RDG Total Return Index for the Nasdaq Stock Market and for the Nasdaq Pharmaceutical Stocks are calculated by the Research Data Group, Inc. ("RDG").

(3) Assumes that $100.00 was invested on December 31, 1996, in Inhale's Common Stock at the Company's closing sales price of $7.563 per share, as adjusted for the stock split of August 22, 2000, and at the closing sales price for each index on that date and that all dividends were reinvested. No cash dividends have been declared on Inhale's Common Stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the ownership of our Common Stock as of January 31, 2002 by: (i) each director; (ii) each of the Named Executive Officers (as defined below under

"Compensation of Executive Officers); (iii) all executive officers and directors of Inhale as a group; and (iv) all those known by us to be beneficial owners of more than 5% of our Common Stock.

	Beneficial Owner(1)	
Beneficial Ownership(1)	**Number of Shares**	**Percent of Total(2)**
Franklin Resources, Inc.(3) One Franklin Parkway San Mateo, CA 94403	6,628,204	12.0%
OppenheimerFunds, Inc.(4) 498 Seventh Avenue New York, NY 10018	6,000,000	10.9%
Delaware Management Holdings, Inc.(5) 2005 Market Street Philadelphia, PA 19103	4,445,319	8.0%
Massachusetts Financial Services Company(6) 500 Boylston Street Boston, MA 02116	3,229,950	5.9%
Robert B. Chess(7)	791,676	1.4%
Ajit S. Gill(8)	702,640	1.3%
John S. Patton(9)	695,697	1.3%
Brigid A. Makes(10)	86,024	*
Melvin Perelman(11)	75,000	*
James B. Glavin(11)	69,600	*
Stephen L. Hurst(12)	65,719	*

Irwin Lerner(11)	40,000	*
Roy A. Whitfield(11)	31,666	*
Christopher A. Kuebler(11)	2,083	*
Douglas Altschuler	0	*
All directors and executive officers as a group (11 persons)(13)	2,560,105	4.64%

* Less than 1%

(1) This table is based upon information supplied by executive officers, directors and principal stockholders and Schedules 13D and 13G filed with the Securities and Exchange Commission. Unless otherwise indicated in the footnotes to this table and subject to the community property laws where applicable, we believe that each of the stockholders named in the table has sole voting and investment power with respect to the shares shown as beneficially owned.

(2) Applicable percentages are based on 55,128,683 shares of Common Stock outstanding as of January 31, 2002, adjusted as required by rules promulgated by the SEC.

(3) Based solely on a Schedule 13G/A filed with the SEC on February 14, 2002 and on information obtained from Franklin Resources Inc. Franklin Resources, Inc. is the parent holding company of two registered investment advisors: Franklin Advisors, Inc. and Franklin Private Client Group, Inc. Franklin Advisors has shared voting and dispositive power over 6,621,544 of the shares. Franklin Private Client Group, Inc. has shared voting and dispositive power over 6,660 of the shares. Charles B. Johnson and Rupert H. Johnson, Jr. each own in excess of 10% of the outstanding Common Stock of Franklin Private Client Group, Inc. and are the principal shareholders of Franklin Resources, Franklin Advisors and Franklin Private Client Group, Inc. Franklin Resources, Franklin Advisors, Private Client Group, Inc. and their principal shareholders disclaim any beneficial interest in the shares.

(4) Based solely on a Schedule 13G/A filed with the SEC on February 8, 2002 and on information obtained from OppenheimerFunds Inc., a registered investment adviser. OppenheimerFunds Inc. is the parent holding company of Oppenheimer Global Growth & Income Fund, an investment company registered under section 8 of the Investment Company Act of 1940. OppenheimerFunds Inc. has sole voting and dispositive power over none of the shares and shared dispositive power over 6,000,000 of the shares. Oppenheimer Global Growth & Income Fund has sole voting power over 6,000,000 of the shares and shared dispositive power over 6,000,000 of the shares. OppenheimerFunds Inc., Oppenheimer Global Growth & Income Fund and their principal shareholders disclaim any beneficial interest in the shares.

(5) Based solely on information obtained from Delaware Management Holdings, Inc. Delaware Management Holdings, Inc. has sole voting power over 4,425,732 of the shares and has sole dispositive power over 4,433,019 of the shares and shared dispositive power over 12,300 of the shares. Delaware Management Holdings, Inc. expressly disclaims beneficial ownership of such shares.

(6) Based solely on a Schedule 13G filed with the SEC on February 12, 2002 and on information obtained from Massachusetts Financial Services Company, a registered investment advisor. Massachusetts Financial Services Company has sole voting power over 2,757,530 of the shares and has sole dispositive power over 3,229,950 of the shares. Massachusetts Financial Services Company expressly disclaims beneficial ownership of such shares.

(7) Includes 458,435 shares issuable upon exercise of options exercisable within 60 days of January 31, 2002. Also includes 1,821 shares issued pursuant to Inhale's 401(k) Retirement Plan.

(8) Includes 26,100 shares held by Ajit S. Gill & Ann C. Gill, Trustees, under an agreement dated October 14, 1998 FBO Ajit S. Gill & Ann C. Gill ("Gill Trust"). Mr. Gill and his wife, Ann C. Gill, are sole trustees. Mr. Gill and his wife, each acting alone, have the power to vote and dispose of such shares. Also includes 612,954 shares issuable upon exercise of options exercisable within 60 days of January 31, 2002. Also includes 1,630 shares issued pursuant to Inhale's 401(k) Retirement Plan.

(9) Includes 510,954 shares held by John S. Patton & Jamie S. Patton, Trustees, under the July 2, 1997 Patton Revocable Trust ("Patton Trust"). Dr. Patton and his wife, Jamie S. Patton, are sole trustees. Dr. Patton and his wife, each acting alone, have the power to vote and dispose of such shares. Includes 6,342 shares held by three children of Dr. Patton as to which shares Dr. Patton disclaims beneficial ownership. Also includes 177,898 shares issuable upon exercise of options exercisable within 60 days of January 31, 2002. Also includes 503 shares issued pursuant to Inhale's 401(k) Retirement Plan.

(10) Includes 80,665 shares issuable upon exercise of options exercisable within 60 days of January 31, 2002. Also includes 359 shares issued pursuant to Inhale's 401(k) Retirement Plan.

(11) All shares issuable upon exercise of options exercisable within 60 days of January 31, 2002.

(12) Includes 52,902 shares issuable upon exercise of options exercisable within 60 days of January 31, 2002. Also includes 317 shares issued pursuant to Inhale's 401(k) Retirement Plan.

(13) Includes 510,954 shares held by the Patton Trust and an aggregate of 6,342 shares held by Dr. Patton's children, as described in footnote 9. Includes 26,100 shares held by the Gill Trust, as described in footnote 8. Also includes an aggregate of 1,601,203 shares issuable upon exercise of outstanding options exercisable within 60 days of January 31, 2002 (see footnotes 7 through 12). Also includes an aggregate of 4,630 shares issued pursuant to Inhale's 401(k) Retirement Plan (see footnotes 7, 8, 9, 10 and 12).

Item 13. Certain Relationships and Related Transactions

The Company's bylaws provide that the Company will indemnify its Directors and may indemnify its officers, employees and other agents to the fullest extent permitted by Delaware law. The Company is also empowered under its Bylaws to enter into indemnification contracts with its Directors and officers and to purchase insurance on behalf of any person whom it is required or permitted to indemnify.

In addition, the Company's Amended and Restated Certificate of Incorporation, as amended, provides that the liability of the Directors for monetary damages shall be eliminated to the fullest extent permissible under Delaware law. Pursuant to Delaware law, the Company's directors shall not be liable for monetary damages for breach of the directors' fiduciary duty of care to the Company and its stockholders. However, this provision does not eliminate the duty of care, and in appropriate circumstances, equitable remedies such as injunctive or other forms of nonmonetary relief will remain available under Delaware law. In addition, each director will continue to be subject to liability for (i) breach of the Directors duty of loyalty to the corporation or its stockholders, (ii) acts or omissions, (iii) violating Section 174 of the Delaware General Corporation Law, or (iv) any transaction from which the director derived an improper personal benefit. The provision also does not affect a director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

On April 1, 1999, Mr. Lerner entered into a consulting agreement with the Company. Pursuant to the agreement, Mr. Lerner may perform consulting services relating to product marketing and general business issues of at least four half days per year as well as telephone discussions as needed in consideration for his standard consulting fee. In 2000 and 2001, Mr. Lerner received no consulting fees for services performed for the Company.

PART IV

Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K

(a)(1) Consolidated Financial Statements.

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

(2) Consolidated Financial Statement Schedules.

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

(3) Exhibits.

The following exhibits are filed herewith or incorporated by reference:

Exhibit Number		Exhibit Index
2.1	(1)	Agreement and Plan of Merger by and between Inhale Therapeutic Systems, a California corporation, and Inhale Therapeutic Systems (Delaware), Inc., a Delaware corporation.
2.2	(15)	Recommended Offer, dated December 21, 2000, by Cazenove & Co. on behalf of Inhale Therapeutic Systems, Inc. for Bradford Particle Design plc.
2.3	(20)	Agreement and Plan of Merger and Reorganization, dated May 22, 2001, by and among Inhale Therapeutic Systems, Inc., Shearwater Corporation, Square Acquisition Corp., J. Milton Harris and Puffinus, L.P.
2.4	(20)	Amendment to Agreement and Plan of Merger and Reorganization, dated June 21, 2001, by and among Inhale Therapeutic Systems, Inc., Shearwater Corporation, Square Acquisition Corp., J. Milton Harris and Puffinus, L.P.
3.1	(1)	Certificate of Incorporation of Inhale Therapeutic Systems, Inc.
3.2	(1)	Bylaws of Inhale Therapeutic Systems, Inc.
3.3	(13)	Certificate of Amendment of the Amended Certificate of Incorporation of Inhale Therapeutic Systems, Inc.
3.4	(19)	Certificate of Designation of Series A Junior Participating Preferred Stock of Inhale Therapeutic Systems, Inc.
3.5	(24)	Certificate of Designation of Series B Convertible Preferred Stock of Inhale Therapeutic Systems, Inc.
4.1		Reference is made to Exhibits 3.1, 3.2, 3.3., 3.4 and 3.5.
4.2	(2)	Restated Investor Rights Agreement, dated April 29, 1993, as amended October 29, 1993, by and among Inhale Therapeutic Systems, Inc. and certain other persons named therein.
4.3	(3)	Stock Purchase Agreement, dated January 18, 1995, by and between Inhale Therapeutic Systems, Inc. and Pfizer Inc.

4.4	(8)	Form of Purchase Agreement, dated January 28, 1997, by and among Inhale Therapeutic Systems, Inc. and the individual Purchasers.
4.5	(9)	Stock Purchase Agreement, dated December 8, 1998, by and between Inhale Therapeutic Systems, Inc. and Capital Research and Management Company.

4.6	(11)	Purchase Agreement, dated October 6, 1999, by and among Inhale Therapeutic Systems, Inc., Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc.
4.7	(11)	Resale Registration Rights Agreement, dated October 13, 1999, by and among Inhale Therapeutic Systems, Inc., Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc.
4.8	(11)	Indenture, dated October 13, 1999, by and between Inhale Therapeutic Systems, Inc., as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
4.9	(11)	Form of Inhale Registration Rights Agreement, dated January 25, 2000, by and between Inhale Therapeutic Systems, Inc. and Selling Shareholder.
4.10	(12)	Purchase Agreement, dated February 2, 2000, by and among Inhale Therapeutic Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.11	(12)	Resale Registration Rights Agreement, dated February 8, 2000, by and among Inhale Therapeutic Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.12	(12)	Indenture, dated February 8, 2000, by and between Inhale Therapeutic Systems, Inc., as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
4.13	(13)	Specimen common stock certificate.
4.14	(14)	Specimen warrants to purchase shares of common stock.
4.15	(16)	Purchase Agreement, dated October 11, 2000, by and among Inhale Therapeutic Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.16	(16)	Resale Registration Rights Agreement, dated October 17, 2000, by and among Inhale Therapeutic Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities, Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.17	(16)	Indenture, dated October 17, 2000, by and between Inhale Therapeutic Systems, Inc., as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
4.18	(19)	Rights Agreement, dated as of June 1, 2001, by and between Inhale Therapeutic Systems, Inc. and Mellon Investor Services LLC.
4.19	(19)	Form of Right Certificate.
4.20	(24)	Stock Purchase Agreement, dated January 7, 2002, by and between Inhale Therapeutic Systems, Inc. and Enzon, Inc.
10.1	(6)	Inhale Therapeutic Systems, Inc.'s 1994 Non-Employee Directors' Stock Option Plan, as amended.
10.2	(2)	Inhale Therapeutic Systems, Inc.'s 1994 Employee Stock Purchase Plan, as amended.
10.3	(2)	Standard Industrial Lease, dated September 17, 1992, as amended September 18, 1992, by and between Inhale Therapeutic Systems, Inc. and W.F. Batton & Co., Inc.

10.4	(2)	Addendum IV to Lease dated September 17, 1992, dated April 1, 1994, by and among Inhale Therapeutic Systems, Inc., W.F. Batton and Marie A. Batton.
10.5	(5)	Amendment Agreement Number One to Lease dated September 17, 1992, dated October 20, 1995, by and between Inhale Therapeutic Systems, Inc. and W.F. Batton & Co., Inc.

10.6	(5)	Amendment Agreement Number Two to Lease dated September 17, 1992, dated November 15, 1995, by and among Inhale Therapeutic Systems, Inc., W.F. Batton and Marie A. Batton, Trustees of the W.F. Batton and Marie A. Batton Trust UTA dated January 12, 1998 ("Batton Trust").
10.7	(10)	Amendment Agreement Number Three to Lease dated September 17, 1992, dated February 14, 1996, by and between Inhale Therapeutic Systems, Inc. and Batton Trust.
10.8	(10)	Amendment Agreement Number Four to Lease dated September 17, 1992, dated September 15, 1996, by and between Inhale Therapeutic Systems, Inc. and Batton Trust.
10.9	(2)	Sublicense Agreement, dated September 13, 1991, by and between Inhale Therapeutic Systems, Inc. and John S. Patton.
10.10	(4)	Stock Purchase Agreement, dated March 1, 1996, by and between Inhale Therapeutic Systems, Inc. and Baxter World Trade Corporation.
10.11	(7)	Sublease and Lease Agreement, dated October 2, 1996, by and between Inhale Therapeutic Systems, Inc. and T.M.T. Associates L.L.C. ("Landlord").
10.12	(10)	First Amendment to Sublease and Lease Agreement dated October 2, 1996, dated October 30, 1996, by and between Inhale Therapeutic Systems, Inc. and Landlord.
10.13	(10)	Letter Agreement amending Sublease and Lease Agreement dated October 2, 1996, dated April 9, 1997, by and between Inhale Therapeutic Systems, Inc. and Landlord.
10.14	(10)	Third Amendment to Sublease and Lease Agreement dated October 2, 1996, dated April 16, 1997, by and between Inhale Therapeutic Systems, Inc. and Landlord.
10.15	(10)	Fourth Amendment to Sublease and Lease Agreement dated October 2, 1996, dated November 5, 1997, by and between Inhale Therapeutic Systems, Inc. and Landlord.
10.16	(12)	Sublease, dated November 3, 1999, by and between Webvan Group, Inc., as sublessor, and Inhale Therapeutic Systems, Inc., as sublessee.
10.17	(14)	Inhale Therapeutic Systems, Inc.'s 2000 Equity Incentive Plan, as amended.
10.18	(14)	Inhale Therapeutic Systems, Inc.'s Stock Option Agreement issued in accordance with Inhale Therapeutic Systems, Inc.'s 2000 Equity Incentive Plan, as amended.
10.19	(14)	Agreement for the Contribution of 201 Industrial Road Project, made and entered into as of September 14, 2000, by and among Inhale Therapeutic Systems, Inc., Inhale 201 Industrial Road, L.P., a California limited partnership and Bernardo Property Advisors, Inc., a California corporation.
10.20	(14)	Agreement of Limited Partnership of Inhale 201 Industrial Road., L.P., a California limited partnership, made and entered into September 14, 2000, by and among SCIMED PROP III, Inc., a California corporation, as general partner, 201 Industrial Partnership, a California general partnership, as limited partner and Inhale Therapeutic Systems, Inc., as limited partner.

10.21	(14)	Build-To-Suit Lease, made and entered into as of September 14, 2000, by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale Therapeutic Systems, Inc., as Tenant.
10.22	(14)	Amendment to Lease, dated October 3, 2000, by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale Therapeutic Systems, Inc., as Tenant.
10.23	(14)	Parking Lease Agreement, entered into as of September 14, 2000, by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale Therapeutic Systems, Inc., as Tenant.
10.24	(23)	Inhale Therapeutic Systems, Inc.'s 2000 Non-Officer Equity Incentive Plan.
10.25	(17)	Inhale Therapeutic Systems, Inc.'s Stock Option Agreement issued in accordance with Inhale Therapeutic Systems, Inc.'s 2000 Non-Officer Equity Incentive Plan.
10.26+	(18)	Manufacturing and Supply Agreement by and among Inhale Therapeutic Systems, Inc., Tech Group North America and Bespak Europe, LTD.
10.27	(21)	The Bradford Particle Design plc Approved Employee Share Option Scheme.
10.28	(21)	Form of The Bradford Particle Design plc Approved Employee Share Option Scheme Option Certificate.

10.29	(21)	The Bradford Particle Design plc Unapproved Employee Share Option Scheme.
10.30	(21)	Form of The Bradford Particle Design plc Unapproved Employee Share Option Scheme Option Certificate.
10.31	(21)	Form of Agreement Granting an Enterprise Management Incentives Option.
10.32	(21)	Agreement Granting Options, dated November 5, 1999, by and between Mr. Joseph F. Bohan and Bradford Particle Design plc.
10.33	(21)	Agreement Granting Options, dated October 27, 2000, by and between Mr. Joseph F. Bohan and Bradford Particle Design plc.
10.34	(22)	Shearwater Corporation 1996 Nonqualified Stock Option Plan.
10.35	(22)	Amendment, effective May 22, 1998, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
10.36	(22)	Second Amendment, effective February 26, 2000, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
10.37	(22)	Third Amendment, effective October 5, 2000, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
10.38	(22)	Fourth Amendment, effective June 22, 2001, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
10.39	(22)	Form of Shearwater Corporation Nonqualified Stock Option Agreement.
10.40	(22)	Form of June 2001 Amendment to Shearwater Corporation Nonqualified Stock Option Agreement.
10.41	(25)	Inhale Therapeutic Systems, Inc. 401(k) Retirement Plan.

10.42	(25)	Non-Standardized Adoption Agreement No. 001 for use with Inhale Therapeutic Systems, Inc. 401(k) Retirement Plan.
23.1	(26)	Consent of Ernst & Young LLP, independent auditors.
24.1	(26)	Power of Attorney. Reference is made to signature page.

+ Confidential treatment with respect to specific portions are omitted and filed separately with the SEC.

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

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

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

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

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

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

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

(8) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-3 (No. 333-20787).

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

(10) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999.

(11)

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

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

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

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

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

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

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

(18) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Annual Report on Form 10-K, as amended, for the year ended December 31, 2000.

(19) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Current Report on Form 8-K, filed on June 4, 2001.

(20) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Current Report on Form 8-K, filed on July 10, 2001.

(21) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-55032), filed on February 6, 2001.

(22) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-67342), filed on August 10, 2001.

(23) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-71936), filed on October 19, 2001.

(24) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Current Report on Form 8-K, filed on January 8, 2002.

(25) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-76638), filed on January 11, 2002.

(26) Filed herewith.

(b) Reports on Form 8-K for the three month period ending December 31, 2001:

Current Report on Form 8-K/A, filed October 4, 2001, providing certain additional financial information in connection with the acquisition of Shearwater Corporation.

Current Report on Form 8-K/A, filed October 4, 2001, providing certain additional financial information relating to in-process research and development costs in connection the acquisition of Bradford Particle Design plc.

Current Report on Form 8-K, filed October 25, 2001, announcing Inhale Therapeutic Systems, Inc.'s financial results for the third quarter and nine months ended September 30, 2001 and providing additional information with respect to the status of certain of its collaborative arrangements.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Carlos, County of San Mateo, State of California on April 1, 2002.

By: /s/ AJIT S. GILL

Ajit S. Gill
Chief Executive Officer,
President and Director

/s/ BRIGID A. MAKES

Brigid A. Makes
Vice President, Finance and Administration,
Chief Financial Officer and Assistant Secretary

POWER OF ATTORNEY

KNOW ALL PERSON BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Ajit S. Gill and Brigid A. Makes and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratify and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities and Exchange Act of 1934, as amended, this report has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ AJIT S. GILL Ajit S. Gill	Chief Executive Officer, President and Director (Principal Executive Officer)	April 1, 2002
/s/ ROBERT B. CHESS Robert B. Chess	Executive Chairman of the Board	April 1, 2002
/s/ BRIGID A. MAKES Brigid A. Makes	Chief Financial Officer, Vice President, Finance and Administration (Principal Financial and Accounting Officer) and Assistant Secretary	April 1, 2002
/s/ JOHN S. PATTON John S. Patton	Director, Founder and Chief Scientific Officer	April 1, 2002
/s/ JAMES B. GLAVIN James B. Glavin	Director	April 1, 2002
/s/ MELVIN PERELMAN Melvin Perelman	Director	April 1, 2002
/s/ IRWIN LERNER Irwin Lerner	Director	April 1, 2002
/s/ ROY A. WHITFIELD Roy A. Whitfield	Director	April 1, 2002
/s/ CHRISTOPHER A. KUEBLER Christopher A. Kuebler	Director	April 1, 2002

INHALE THERAPEUTIC SYSTEMS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

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

We have audited the accompanying consolidated balance sheets of Inhale Therapeutic Systems, Inc. as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inhale Therapeutic Systems, Inc. at December 31, 2001 and 2000, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
January 18, 2002

INHALE THERAPEUTIC SYSTEMS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands)

	December 31,	
	2001	2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,814	$ 136,012
Short-term investments	313,542	348,829
Accounts receivable	4,487	583
Other current assets	11,998	7,619
Total current assets	360,841	493,043
Property and equipment, net	142,352	110,457
Marketable equity securities	721	9,140
Goodwill and other intangible assets	153,833	4,969
Deposits and other assets	9,494	11,931
	$ 667,241	$ 629,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,685	$ 6,501
Accrued research and development	10,776	5,486
Accrued general and administrative	7,075	1,713
Accrued compensation	5,977	5,264
Accrued acquisition costs	2,046	—
Other accrued liabilities	3,172	439
Interest payable	4,588	4,910
Capital lease obligation—current	807	977
Deferred revenue	17,073	4,913
Total current liabilities	59,199	30,203
Capital lease obligation—noncurrent	31,909	15,269
Accrued rent	1,921	2,010
Convertible subordinated notes and debentures	299,149	299,149
Other long-term liabilities	4,750	5,026
Commitments and Contingencies		

Stockholders' equity:		
Preferred stock, 10,000 shares authorized, no shares issued or outstanding at December 31, 2001 and 2000	—	—
Common stock, $0.0001 par value; 300,000 authorized; 55,094 shares and 47,374 shares issued and outstanding at December 31, 2001 and 2000, respectively	5	5
Capital in excess of par value	712,039	465,593
Deferred compensation	(923)	(1,827)
Accumulated other comprehensive gain	1,069	5,981
Accumulated deficit	(441,877)	(191,869)
Total stockholders' equity	270,313	277,883
	$ 667,241	$ 629,540

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share information)

	Years ended December 31,		
	2001	2000	1999
Contract research revenue	$ 68,899	$ 51,629	$ 41,358
Product sales	8,569	—	—
Total revenue	77,468	51,629	41,358
Operating costs and expenses:			
Cost of goods sold	4,169	—	—
Research and development	139,651	100,779	64,035
General and administrative	18,861	13,932	7,869
Purchased in-process research and development	146,260	2,292	9,890
Amortization of goodwill & other intangible assets	25,490	765	48
Total operating costs and expenses	334,431	117,768	81,842
Loss from operations	(256,963)	(66,139)	(40,484)
Other income/(expense), net	(4,195)	995	—
Debt conversion premium, net	—	(40,687)	—
Interest income	24,581	20,566	4,111
Interest expense	(13,431)	(12,138)	(2,075)
Net loss	$ (250,008)	$ (97,403)	$ (38,448)
Basic and diluted net loss per share	$ (4.71)	$ (2.32)	$ (1.13)
Shares used in computing basic and diluted net loss per share	53,136	41,998	34,016

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Shares		Capital In Excess of Par Value	Deferred Compensation	Accumulated Other Comprehensive Income/ (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value					
Balance at December 31, 1998	33,848	$ 3	$ 172,846	$ (931)	$ (19)	$ (56,018)	$ 115,881
Common stock issued in connection with technology acquisition	360	—	5,000	—	—	—	5,000
Common stock issued upon exercise of stock options	244	—	1,545	—	—	—	1,545

Compensation in connection with stock options granted to consultants	—	—	798	—	—	—	798
Deferred compensation	—	—	964	(964)	—	—	—
Amortization of deferred compensation	—	—	—	365	—	—	365
Other comprehensive income	—	—	—	—	1,488	—	1,488
Net loss	—	—	—	—	—	(38,448)	(38,448)
Comprehensive loss	—	—	—	—	—	—	(36,960)
Balance at December 31, 1999	34,452	3	181,153	(1,530)	1,469	(94,466)	86,629
Common stock issued upon exercise of stock options	2,177	2	17,320	—	—	—	17,322
Common stock granted to employees	57	—	1,900	—	—	—	1,900
Compensation in connection with stock options granted to consultants	—	—	3,196	—	—	—	3,196
Conversion of convertible subordinated debt into common shares, net of of related issuance costs	10,688	—	260,862	—	—	—	260,862
Deferred compensation	—	—	1,162	(1,162)	—	—	—
Amortization of deferred compensation	—	—	—	865	—	—	865
Other comprehensive income	—	—	—	—	4,512	—	4,512
Net loss	—	—	—	—	—	(97,403)	(97,403)
Comprehensive loss	—	—	—	—	—	—	(92,891)
Balance at December 31, 2000	47,374	5	465,593	(1,827)	5,981	(191,869)	277,883
Common stock issued upon exercise of stock options	855	—	6,048	—	—	—	6,048
Compensation in connection with stock options granted to consultants	—	—	605	—	—	—	605
Shares issued associated with acquisition of Bradford Particle Design Ltd.	3,752	—	125,576	—	—	—	125,576
Shares issued associated with acquisition of Shearwater Corporation	3,113	—	114,240	—	—	—	114,240
Deferred compensation	—	—	(23)	23	—	—	—
Amortization of deferred compensation	—	—	—	881	—	—	881
Other comprehensive loss	—	—	—	—	(4,912)	—	(4,912)
Net loss	—	—	—	—	—	(250,008)	(250,008)
Comprehensive loss	—	—	—	—	—	—	(254,920)
Balance at December 31, 2001	55,094	$ 5	$ 712,039	$ (923)	$ 1,069	$ (441,877)	$ 270,313

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
Increase/(Decrease) in Cash and Cash Equivalents
(In thousands)

	Years ended December 31,		
	2001	2000	1999
Cash flows used in operating activities:			
Net loss	$ (250,008)	$ (97,403)	$ (38,448)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	12,648	7,240	6,649
Amortization of goodwill and other intangible assets	25,490	765	48
Amortization of debt issuance costs	1,366	1,254	131
Amortization of deferred compensation	881	865	365
Gain/(loss) on sale of assets	—	(159)	61
Issuance of common stock for services	604	5,096	798
Debt conversion premium, net	—	40,687	—
Acquired in-process research and development	146,260	2,292	9,890
Loss on impairment of marketable equity securities	3,948	—	—
Changes in assets and liabilities:			
Increase in accounts receivable, other current assets, and other assets	(4,238)	(964)	(8,004)
Increase in accounts payable and other accrued liablities	2,261	4,483	12,724
Increase in deferred revenue	10,014	102	452
Net cash used in operating activities	(50,774)	(35,742)	(15,334)
Cash flows from investing activities:			
Purchases of short-term investments	(491,725)	(462,278)	(122,481)
Sales of short-term investments	157,514	13,643	28,658
Maturities of short-term investments	373,546	206,261	47,174
Purchases of property and equipment	(34,321)	(53,850)	(20,502)
Acquistion of technology	—	(2,292)	(15,288)

Acquisition of Shearwater, net of cash acquired	(67,246)	—	—
Acquisition of Bradford, net of cash acquired	(14,805)	—	—
Other investing activities, net	—	(1,232)	—
Net cash used in investing activities	(77,037)	(299,748)	(82,439)
Cash flows from financing activities:			
Proceeds from loan and capital lease financing	17,653	16,246	—
Payments of loan and capital lease obligations	(1,089)	(50)	(64)
Payments of debt conversion incentives	—	(40,687)	—
Issuance of convertible subordinated debentures and notes, net	—	445,241	104,806
Issuance of common stock, net of issuance costs	6,049	17,322	1,545
Net cash provided by financing activities	22,613	438,072	106,287
Net (decrease)/ increase in cash and cash equivalents	(105,198)	102,582	8,514
Cash and cash equivalents at beginning of period	136,012	33,430	24,916
Cash and cash equivalents at end of period	$ 30,814	$ 136,012	$ 33,430

See accompanying notes

INHALE THERAPEUTIC SYSTEMS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2001

Note 1—Organization and Summary of Significant Accounting Policies

Organization and Basis of Presentation

We are working to become the world's leading drug delivery company by providing a portfolio of technologies and expertise that will enable our pharmaceutical partners to improve drug performance throughout the drug development process. We are focused on two main opportunities: improved delivery of drug compounds and improved performance of drug powders and other formulations. To fulfill these needs, we are developing several technologies. The first enables inhalation for delivery of a range of drugs, including peptides, proteins and small molecules for treatment of systemic and respiratory diseases. The second technology, advanced PEGylation, is designed to enhance the efficacy and performance of most major drug classes, including macromolecules such as peptides and proteins and smaller sized molecular compounds, and other drugs. A third technology uses a proprietary processing method known as supercritical fluids processing to develop drug formulations for multiple types of drug delivery.

In an effort to capitalize on what we believe is a growing market need for performance-enabling drug delivery technologies, we expanded our technology offerings by acquiring Shearwater Corporation and Bradford Particle Design Ltd. in 2001. These acquisitions have added two additional technologies, advanced PEGylation and Solution Enhanced Dispersion by Supercritical Fluids ("SEDS™") to our portfolio.

We are also the parent company of Inhale Therapeutic Systems Deutschland GmbH, incorporated in the Federal Republic of Germany ("Inhale Germany") and Inhale Therapeutic Systems UK Limited, incorporated in the United Kingdom ("Inhale UK"). Our consolidated financial statements also include the financial statements of a real estate partnership lessor.

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

We expect to continue to incur substantial and potentially increasing losses over at least the next few years as we expand our research and development efforts and testing activities, scale up manufacturing operations and further expand our late stage clinical and early commercial production facility. We plan to continue to finance ourselves primarily through issuances of equity or debt securities, research and development contract revenue, and in the longer term, revenue from product sales and royalties.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Certain prior year amounts have been reclassified to conform to the 2001 presentation.

Principles of Consolidation

Our consolidated financial statements include the accounts of the parent company, Inhale Germany, Inhale UK, the financial statements of a real estate partnership created to finance and manage construction of our new lab and office facility, and the accounts of Bradford Particle Design and Shearwater, acquired during the 2001 fiscal year.

Significant Concentrations

Cash equivalents and investments are financial instruments that potentially subject us to concentrations of risk to the extent of amounts recorded in the consolidated balance sheet. We limit our concentration of risk by diversifying our investments among a variety of industries and issuers. Our professional portfolio managers adhere to this investment policy as approved by our Board of Directors.

We have not experienced significant credit losses from our accounts receivable or collaborative research agreements, and none are currently expected. We perform a regular review of our customer activity and associated credit risks and do not require collateral from our customers.

In addition, we are dependent on our partners, vendors and contract manufacturers to provide raw materials, drugs and devices of appropriate quality and reliability and to meet applicable regulatory requirements. Consequently, in the event that supplies are delayed or interrupted for any reason, our ability to develop our products could be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

We are dependent on Pfizer and Aventis as the source of a significant proportion of our revenue. In the event that these collaborations are terminated, our ability to develop and supply our products could be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

Should the collaboration be discontinued prior to the launch of inhaleable Insulin we will need to find alternative funding sources to replace the collaborative revenue and will need to reassess the realizability of certain costs capitalized in connection with the commercial scale-up. Additionally, we may have contingent payments to our contract manufacturers to reimburse them for their capital outlay to the extent that they cannot re-deploy their assets.

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board issued Statements of Financial Accounting Standards No. 141, *Business Combinations*, and No. 142, *Goodwill and Other Intangible Assets*. Statement 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. Statement 141 also includes guidance on the initial recognition and measurement of goodwill and other intangible assets arising from business combinations completed after June 30, 2001. Statement 142 prohibits the amortization of goodwill and intangible assets with indefinite useful lives. Statement 142 requires that these assets be reviewed for impairment at least annually. Intangible assets with finite lives will continue to be amortized over their estimated useful lives.

We will adopt Statement 142 beginning in the first quarter of 2002. Application of the nonamortization provisions of Statement 142 is expected to result in a reduction in net loss of $22.5 million ($0.42 per share based upon shares used in computing basic and diluted net loss per share in 2001) in 2002. We will reclassify an assembled workforce intangible asset with an unamortized balance of $2.3 million to goodwill on January 1, 2002 and will test goodwill for impairment using the two-step process prescribed in Statement 142. The first step is a screen for potential impairment, while the second step measures the amount of the impairment, if any. We expect to perform the first of the required impairment tests of goodwill and indefinite lived intangible assets as of January 1, 2002 in the first quarter of 2002. We do not expect that these initial tests will have a significant impact on our earnings and financial position.

In August 2001, the FASB issued SFAS 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS 144 supercedes SFAS 121, Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of, and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business. SFAS 144 establishes a single accounting model for assets to be disposed of by sale whether previously held and used or newly acquired. SFAS 144 retains the provisions of APB No. 30 for presentation of discontinued operations in the income statement, but broadens the presentation to include a component of an entity. SFAS 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. We do not expect the adoption of SFAS 144 to have a significant impact on our results of operations or financial position.

Cash, Cash Equivalents and Investments

We consider all highly liquid investments with a maturity from date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include demand deposits held in banks, interest bearing money market funds and repurchase agreements. All other investments are classified as short-term investments. Short-term investments consist of federal and municipal government securities, corporate bonds and 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.

At December 31, 2001, all 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 as accumulated other comprehensive gain. 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.

Inventories

Inventories consist primarily of finished goods, work in process and raw materials and are stated at the lower of cost (first in first out method) or market. Inventories amounted to approximately $3.2 million at December 31, 2001 ($200,000 at December 31, 2000) and are included in other current assets.

Property and Equipment

Property and equipment are stated at cost. Major improvements are capitalized, while maintenance and repairs are expensed when incurred. Laboratory and other equipment are depreciated using the straight-line method over estimated useful lives of three to seven years. Vehicles are depreciated using the straight-line method over estimated useful life of five years. Leasehold improvements and buildings, which are subject to the terms of a build-to-suit lease, are depreciated using the straight-line method over the shorter of the estimated useful life or the remaining term of the lease.

Goodwill and Other Intangible Assets

Goodwill, which represents the excess of the purchased price of an investment in an acquired business over the fair value of the underlying net identifiable assets, was amortized on a straight-line basis through

December 31, 2001. Effective January 1, 2002, goodwill will no longer be amortized, but will be subject to an impairment assessment at least annually, consistent with the new business combination accounting rules.

Assembled workforce is comprised of all skilled employees and includes the estimated cost to replace existing employees, including recruiting and training costs and loss of productivity costs. We are amortizing the value assigned to the assembled workforce on a straight-line basis on an average estimated useful life of three years through December 31, 2001. Effective January 1, 2002, consistent with the new business combination accounting rules, assembled workforce will be reclassified as goodwill and will be subject to an impairment assessment at least annually.

Core technology is based on developed technology or components of developed technologies that have a value as a basis of the platform upon which future development can be profitably exploited. We are amortizing the value assigned to core technology on a straight-line basis over an average estimated life of five years.

Developed product technology is based on proprietary know-how that is technologically feasible. We are amortizing the value assigned to developed product technology on a straight-line basis over an average estimated life of five years.

Intellectual property is recognized for the intrinsic value of the Company or its subsidiaries' name and products in the marketplace. We are amortizing the value assigned on a straight-line basis over an average estimated life of five years.

Supplier and customer relations is based on historical costs incurred and is comprised of management's estimation of resources that have been devoted to the development of relationships with key customers. We are amortizing the value assigned to customer relationships on a straight-line basis over an average estimated life of five years.

We periodically evaluate whether changes have occurred that would require revision of the remaining estimated useful lives of these assets or otherwise render the assets unrecoverable. If such an event occurred, we would determine whether the goodwill or intangibles are impaired. To date, no such impairment losses have been recorded.

Comprehensive Gain/Loss

Comprehensive loss is comprised of net loss and other comprehensive gain/loss for the years ended December 31, 2001 and 2000. For the year ended December 31, 2001, other comprehensive gain included unrealized gains/losses on available-for-sale securities and translation adjustments. For the year ended

December 31, 2000, other comprehensive loss included unrealized gains related our investment in Alliance and unrealized gains/losses on available-for-sale securities (in thousands):

	December 31,	
	2001	2000
Net loss	$ (250,008)	$ (97,403)
Change in net unrealized gains/(losses) on available-for-sale securities	(8,702)	4,512
Net unrealized loss reclassified into earnings	3,948	—
Translation adjustment	(158)	—
Comprehensive loss	$ (254,920)	$ (92,891)

Stock-Based Compensation

As permitted by the provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," we continue to follow Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees" and related interpretations in accounting for our employee stock option plans. Under APB 25, if the exercise price of our employee stock options equals or exceeds the fair market value of the underlying stock on the date of grant as determined by the closing price of our common stock as quoted on the Nasdaq Stock Market, no compensation expense is recognized. See Note 10 for pro forma disclosures required by SFAS 123.

Stock compensation expense for options granted to nonemployees has been determined in accordance with SFAS 123 and Emerging Issues Task Force No. 96-18 as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to nonemployees is remeasured as the underlying options vest.

Revenue Recognition

Contract revenue from collaborative research agreements is recorded when earned based on the performance requirements of the contract. Revenue from non-refundable upfront license fees and certain guaranteed payments where we continue involvement through collaborative development are deferred and

recognized as revenue over the period of continued involvement. Payments received from milestone achievements are deferred and recorded as revenue over the next period of continued development. Revenue from grants and feasibility arrangements are recognized as the related costs are incurred. Our research revenue is derived primarily from clients in the pharmaceutical industry and consists of reimbursement of development costs, reimbursement of certain expenses, payment of clinical supplies and amortization of milestones. Contract research revenue from three partners represented 66%, 10% and 5% of our revenue in 2001. Three partners accounted for 69%, 13% and 9% of our revenue in 2000 and 71%, 10% and 9% of our revenue in 1999. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

Product sales relate to sales of PEGylated derivatives. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured. Allowances, if any, are established for estimated product returns and discounts.

Research and Development

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

Net Loss Per Share

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

	Years Ended December 31,		
	2001	2000	1999
Warrants	56	56	40
Options	14,672	10,064	9,106
Convertible debentures and notes	6,644	6,644	6,776
	21,372	16,764	15,922

Accounting for Income Taxes

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

Note 2—Cash and Available-For-Sale Securities

The following is a summary of operating cash and available-for-sale securities as of December 31, 2001 (in thousands):

	Cost	Net Unrealized Gains (Loss)	Fair Value
Obligations of U.S. government agencies	$ 138,394	$ 622	$ 139,016
U.S. corporate commercial paper	170,880	618	171,498
Repurchase agreements, secured by U.S. Government securities	5,315	—	5,315
Cash and other debt securities	28,540	(13)	28,527
Equity securities	721	—	721
	$ 343,850	$ 1,227	$ 345,077
Amounts included in cash and cash equivalents	$ 30,814	$ —	$ 30,814
Amounts included in short-term investments	312,315	1,227	313,542
Amounts included in marketable equity securities	721	—	721
	$ 343,850	$ 1,227	$ 345,077

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

	Cost	Net Unrealized Gains	Fair Value
Obligations of U.S. government agencies	$ 299,604	$ 1,013	$ 300,617
U.S. corporate commercial paper	147,482	496	147,978
Repurchase agreements, secured by U.S. Government securities	11,261	—	11,261
Cash and other debt securities	24,984	1	24,985
Equity securities	4,669	4,471	9,140
	$ 488,000	$ 5,981	$ 493,981
Amounts included in cash and cash equivalents	$ 135,873	$ 139	$ 136,012
Amounts included in short-term investments	347,458	1,371	348,829
Amounts included in marketable equity securities	4,669	4,471	9,140
	$ 488,000	$ 5,981	$ 493,981

We determine the estimated fair value amounts by using available market information. The gross realized losses and gains on the sale of available-for-sale debt securities during the years ended December 31, 2001 and 2000 were not material. At December 31, 2001 and 2000, the average portfolio duration was approximately nine months and six months, respectively, and the contractual maturity of any single investment did not exceed twenty-four months at December 31, 2001 (eighteen months at December 31, 2000). The gross unrealized gains on available for sale securities at December 31, 2001 amounted to approximately $3.0 million.

We own common stock of Alliance Pharmaceutical Corp. which we account for as an available-for-sale long-term marketable equity security. There were no restrictions on the sale of our Alliance stock at December 31, 2000 or 2001. In 2001, our equity investment in Alliance was determined to be impaired and a loss on investment of $3.9 million was recorded. All other shares held at December 31, 2001 and 2000 were reported at market value with temporary declines in fair market value recorded in stockholders' equity as other comprehensive loss.

Note 3—Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31, 2001	December 31, 2000
Laboratory and other equipment	$ 45,757	$ 34,553
Building and leasehold improvements	80,633	55,476
Land	7,817	7,422
Vehicles	62	—
Construction in progress and other assets not placed in service	46,049	34,732
Property and equipment at cost	180,318	132,183
Less accumulated amortization and depreciation	(37,966)	(21,726)
Property and equipment, net	$ 142,352	$ 110,457

At December 31, 2001 and 2000, building and leasehold improvements included $28.6 million and $14.9 million, respectively, related to a build-to-suit lease with a real estate partnership. Accumulated depreciation of the building under lease was approximately $1.9 million and $100,000 in the years ended December 31, 2001 and 2000, respectively. In relation to construction in progress, interest amounting to $1.3 million was capitalized during the year ended December 31, 2001 ($0 in the years ended December 31, 2000 and 1999).

We have expensed certain plant design, engineering and validation costs based on our evaluation that it is unclear whether such costs are ultimately recoverable.

Note 4—Collaborative Research and Development Agreements

We perform research and development for others pursuant to feasibility agreements and development and license agreements. Under the feasibility agreements, we are generally reimbursed for the cost of work performed. Under our development and license agreements, we will be reimbursed for development costs and may also be entitled to milestone payments when and if certain development milestones are achieved. All of our research and development agreements are generally cancelable by our partners without significant financial penalty to the partner.

In November 2001, we entered into a collaboration with Chiron Corporation ("Chiron") to develop a next-generation inhaleable formulation of tobramycin for the treatment of *Pseudomonas aeruginosa* in cystic fibrosis patients and to explore the development of other inhaled antibiotics using our Inhance™

inhaleables technology. We did not recognize revenue in 2001 for the tobramycin compound collaboration.

In October 2001, we entered into a collaboration with R.W. Johnson Pharmaceutical Research Institute and the Janssen Research Foundation, subsidiaries of Johnson & Johnson, for the development of multiple small molecule compounds using our inhaleables technology. During 2001, feasibility revenue was recorded in connection with this agreement.

In June 2001, we acquired Shearwater Corporation. Associated with our acquisition, we recognized $300,000 in contract research revenue and $8.6 million in product sales. Of the $8.6 million in product sales, $7.0 million was associated with collaborative agreements with the following partners: Schering-Plough Corporation, Pharmacia Corporation, F. Hoffmann-La Roche, Ltd. and Amgen Inc.

On February 1, 2000, Shearwater entered into a manufacturing agreement with Schering-Plough Corporation in connection with the PEG reagent used in PEG-INTRON™ (PEG-interferon alpha) for use in the treatment of the hepatitis C virus. Under the terms of this agreement, we manufacture the PEG reagent and Schering-Plough holds an exclusive worldwide license to PEG-INTRON, the first and only PEGylated interferon product approved for marketing in the United States and worldwide. In 2001, Schering-Plough accounted for $2.1 million of our product sales.

On November 9, 1998, Shearwater announced that it had entered into a license, manufacturing and supply agreement with F. Hoffmann-La Roche Ltd. whereby we license to Roche the PEG reagent used in Roche's PEGASYS™ product for the treatment of chronic hepatitis C. This agreement provides us with milestone payments, rights to manufacture the PEG reagent and a share of future revenues related to our PEGASYS™ product. On April 5, 1999, Shearwater entered into a subsequent agreement with Roche related to further collaborative work on PEGASYS™, a PEGylated interferon alpha-2a product. PEGASYS™ was filed for approval with the FDA for a hepatitis C indication on May 22, 2000. Under the terms of the collaborative arrangement with Roche, the FDA filing triggered a $1.0 million milestone payment to Shearwater by Roche. In 2001, Roche accounted for $1.2 million of our product sales.

On April 4, 2000, Shearwater entered into a license, manufacturing and supply agreement with Sensus Drug Development Corporation for the PEGylation of Sensus' Somavert™ (pegvisomant for injection), a human growth hormone receptor antagonist. The agreement provides us with milestone payments, rights to manufacture the PEG reagent and a share of future revenues. In March 2001, Sensus was acquired by Pharmacia Corp. In 2001, Pharmacia accounted for $1.3 million of our product sales.

In February 1999, we entered into a collaborative agreement with Biogen Inc. ("Biogen") to develop pulmonary delivery for Biogen's Avonex®, a drug used in the treatment of multiple sclerosis. Under the terms of the agreement, we recognized revenue of $3.5 million, $4.7 million and $2.2 million in 2001, 2000, and 1999, respectively. In January 2002, Biogen announced that it does not plan to further develop inhaleable Avonex®for multiple sclerosis at this time, but is working with us to evaluate other potential indications for the inhaled formulation or other opportunities for collaboration.

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

In January 1997, we entered into a collaborative agreement with Lilly to develop an inhaleable formulation of Fortéo™, a version of parathyroid hormone, PTH 1-34, used in the treatment of osteoporosis. Under the terms of the agreement, we could receive funding of up to $20.0 million of initial

fees, research and development and progress payments. Lilly could receive global commercialization rights for the pulmonary delivery of the products while we receive royalties on any marketed products. We could also manufacture packaged powders for and supply devices to Lilly. Under this agreement, we recognized revenue of $3.8 million in 1998. In late 1998, unexpected observations from a long-term test in rats of the injectible version of parathyroid hormone led Lilly to suspend further clinical development of the injectible and pulmonary versions of Fortéo™pending further analysis. In September 2000, we announced the reinitiation of the Fortéo™ development program with Lilly. In 2001, we recognized revenue of $3.7 million. In October 2001, however, Lilly further informed us that other than on-going stability work, additional activities with respect to the program will be suspended.

In December 1996, we entered into a collaborative agreement with Aventis Behring L.L.C. to develop a pulmonary formulation of alpha-1 proteinase inhibitor to treat patients with alpha-1 antitrypsin deficiency, or genetic emphysema. Under the terms of the collaboration, Aventis Behring will receive commercialization rights worldwide excluding Japan and we could receive royalties on product sales, an up-front signing fee and up to an estimated $15.0 million in research and development funding and milestone payments. Aventis Behring will manufacture the active ingredient for use in our delivery device. We will manufacture and package the dry powder and supply inhalation devices to Aventis Behring for commercialization and marketing. Under this agreement, we recognized revenue of $7.8 million, $6.8 million, and $3.9 million in 2001, 2000 and 1999, respectively.

In March 1996, we entered into a collaboration agreement with Baxter Healthcare Corporation to use our dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In connection with the collaboration, Baxter made a $20.0 million equity investment in our company at a 25% premium to the market price of our stock at the time of the investment. Baxter received worldwide commercialization rights in exchange for up to an estimated $60.0 million in research and development funding and milestone payments for four molecules. In October 1998, we announced that we had reached an agreement with Baxter to amend our collaborative agreement to facilitate signing a new corporate partner to fund further development and commercialization of the undisclosed compound that had been the focus since April 1998. Baxter's obligations under this amendment expired in September 1999. As a result, rights to the compounds reverted to us and are now available for other partnering opportunities. We recognized revenue associated with this program of $4.3 million in 1999.

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

revenue of $51.0 million, $35.7 million and $29.5 million in 2001, 2000 and 1999, respectively. Pfizer is currently in active discussions with the United States Food and Drug Administration regarding the requirements for a New Drug Application, or NDA, with respect to inhaleable insulin. In December 2001, Pfizer announced that it had decided to include an increased level of controlled, long-term safety data in the NDA and that it expected to complete this additional study in 2002.

Costs associated with research and development activities attributable to these agreements have approximated the revenues recognized.

Note 5—Goodwill and Other Intangible Assets

Goodwill and other intangible assets consist of the following (in thousands):

	December 31,	
	2001	2000
Goodwill	$ 153,834	$ 2,238
Accumulated amortization	(22,246)	(360)
Net goodwill	131,588	1,878
Assembled workforce	2,860	—
Core technology	8,100	—
Developed product technology	2,900	—
Intellectual property	7,301	3,544
Supplier and customer relations	5,140	—
Total other intangible assets	26,301	3,544
Accumulated amortization of other intangible assets	(4,056)	(453)
Net other intangible assets	22,245	3,091
Net goodwill and other intangibles	$ 153,833	$ 4,969

ACQUISITIONS OF BRADFORD PARTICLE DESIGN AND SHEARWATER CORPORATION

In June 2001, we completed the acquisition of Shearwater and paid a total consideration of $192.2 million in cash and stock (including assumption of outstanding options to acquire Shearwater common stock) for a 100% interest in Shearwater. The acquisition was accounted for under the purchase method of accounting and the results of Shearwater's operations from the date of acquisition have been included in the consolidated statement of operations. In connection with the acquisition, we recorded goodwill and other intangible assets of approximately $94.6 million and recorded an $83.6 million purchased in-process research and development charge. At the date of the acquisition, we concluded that the IPR&D technology had no alternative future use and did not qualify for capitalization. The cost to acquire Shearwater has been allocated to the assets acquired and liabilities assumed according to their respective fair values, with the excess purchase price being allocated to goodwill.

In January 2001, we acquired all of the outstanding share capital of Bradford Particle Design in exchange for approximately 3.75 million newly issued shares of our common stock and approximately $20.4 million in cash. The acquisition was accounted for under the purchase method of accounting and the results of Bradford Particle Design's operations from the date of acquisition have been included in the consolidated statement of operations. Of the total purchase consideration of $152.1 million, $89.4 million was allocated to the assets acquired based on their fair value on the date of acquisition, including $80.1 million in goodwill and other intangible assets and estimated acquisitions costs of $4.0 million. Approximately $62.7 million of the purchase price was allocated to IPR&D, which was charged to expense. At the date of the acquisition, we concluded that the IPR&D technology had no alternative future use and did not qualify for capitalization. The following table describes information with reference to the goodwill

and other intangible assets resulting from the acquisitions of Shearwater Corporation and Bradford Particle Design (in thousands):

	Acquisitions
In-process research and development	$ 146,260
Intangible assets acquired:	
Developed product technology	2,900
Core technology	8,100
Assembled workforce	2,860
Supplier and customer relations	5,140
Intellectual property	4,130
Total intangible assets acquired	23,130

Goodwill	151,597
Total	$ 320,987

IPR&D represents that portion of the purchase price of an acquisition related to the research and development activities which: (i) have not demonstrated their technological feasibility, and (ii) have no alternative future uses. During the year ended December 31, 2001, we recognized a total purchased IPR&D charge of approximately $146.3 million upon consummation of both acquisitions.

The amounts of IPR&D were determined based on an analysis using risk-adjusted cash flows expected to be generated by the products that may result from the in-process platform technology for Bradford Particle Design and from the in-process technology for Shearwater. The analysis included forecasted future cash flows that were expected to result from the progress made on each of the in-process projects prior to the purchase dates. These cash flows were estimated by first forecasting, on a product-by-product basis, net revenues expected from the sales of the first generation of each in-process project and risk adjusting these revenues to reflect the probability of advancing to the next stage of the FDA approval process. Appropriate operating expenses were deducted from the total forecasted net revenues for Bradford Particle Design and on a product-by-product basis from the forecast for Shearwater to establish a forecast of net returns on the completed portion of the in-process technology. Finally, these net returns were discounted to a present value using discount rates that incorporate the weighted average cost of capital relative to the biotech industry and our company as well as product specific risks associated with the purchased in-process research and development products. The product specific risk factors included the products' phase of development, type of molecule under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, preclinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, an overall discount rate of 47% for Bradford Particle Design and 22% for Shearwater was used for the purchase valuation, which represents a risk premium to our weighted average cost of capital.

The forecast data in the analysis was based on internal product level forecast information maintained by management in the ordinary course of managing the business. The inputs used by management in analyzing IPR&D was based on assumptions, which management believed to be reasonable but which are inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur.

Bradford Particle Design and Shearwater's results of operations included in the following pro forma financial information are derived from their unaudited financial statements for the years ended December 31, 2001 and 2000, respectively. Bradford Particle Design's financial statements have been adjusted, where appropriate, to present their financial position and results of operations in accordance with accounting principles generally accepted in the United States. The unaudited pro forma net loss and loss per share amounts do not include the charges for purchased research and development of approximately $146.3 million, due to its non-recurring nature, but includes the amortization of goodwill and other intangible assets.

The unaudited pro forma results of operations is presented for illustrative purposes only and is not necessarily indicative of the operating results or financial positions that would have occurred if the transactions had been consummated at the dates indicated, nor is it necessarily indicative of future operating results or financial position of the combined companies and should not be construed as representative of these amounts for any future dates or periods.

The following unaudited pro forma results of operations of Inhale for the years ended December 31, 2001 and 2000, respectively, assumes the acquisition of Bradford Particle Design and Shearwater has been accounted for using the purchase method of accounting as of January 1, 2001 and 2000, respectively, and assumes the purchase price has been allocated to the assets purchased and the liabilities assumed based on fair values at the date of acquisition:

(Unaudited, in thousands, except per share information)	Year Ended December 31, 2001 Pro Forma	Year Ended December 31, 2000 Pro Forma
Total revenue	$ 83,783	$ 69,904
Net loss	(116,589)	(133,537)
Net loss per share	$ (2.12)	$ (2.73)

PulmoSphere® Technology

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

investment in Alliance and the assets acquired in connection with the PulmoSphere® acquisition were recorded at their fair market value as follows (in thousands):

Property and equipment, net	$ 200
Purchased in-process research and development charged to operations in 1999	9,890
Intellectual property, net	3,171
Assembled workforce	96

Goodwill	2,030
Total cash purchase consideration	15,387
Common stock of Alliance	5,000
Total purchase consideration	$ 20,387

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

Other Purchased Technology

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

Note 6—Other Assets

Other assets consist of the following (in thousands) at:

	December 31,	
	2001	2000
Debt issuance costs, net	$ 7,213	$ 8,579
Deposits and other assets	2,281	3,352
Total other assets	$ 9,494	$ 11,931

Debt issuance costs are associated with our outstanding series of convertible subordinated debentures and notes (See Note 7) and are amortized over the term of the related debt.

Note 7—Convertible Subordinated Debentures & Notes

In October 2000, we received approximately $222.8 million in net proceeds from the issuance of $230.0 million aggregate principal amount of convertible subordinated notes to certain qualified institutional buyers pursuant to an exemption under the Securities Act of 1933, as amended. Interest on the notes accrues at a rate of 3.5% per year, subject to adjustment in certain circumstances. The notes will mature in October 2007 and are convertible into shares of our common stock at a conversion price of

$50.46 per share, subject to adjustment under certain circumstances. The notes are redeemable in part or in total at any time before October 17, 2003 at $1,000 per $1,000 principal amount plus a provisional redemption exchange premium, payable in cash or shares of common stock, of $105.00 per $1,000 principal amount, plus accrued and unpaid interest, if any, to the redemption date, if the closing price of our common stock has exceeded 150% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days. The notes are also redeemable in part or in total at any time after October 17, 2003 at certain redemption prices dependent upon the date of redemption if the closing price of our common stock has exceeded 120% of the conversion price then in effect for at least 20 trading days within a period of 30 consecutive trading days. Interest is payable semi-annually on April 17 and October 17. The notes are unsecured obligations, which rank junior in right of payment to all of our existing and future senior debt.

In October 2000, we also entered into privately negotiated agreements with certain holders of our outstanding 5.0% convertible subordinated notes due February 2007 and sold in February 2000 providing for the conversion of our notes into common stock in exchange for a cash payment. To date, we have secured agreements that provide for the conversion of $168.6 million aggregate principal amount of these outstanding 5.0% convertible subordinated notes into approximately 4.4 million shares of common stock for cash payments of approximately $25.5 million. Approximately $61.4 million of these 5.0% convertible subordinated notes remain outstanding at December 31, 2001.

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

Also in February 2000, we entered into privately negotiated agreements with certain holders of our outstanding 6.75% convertible subordinated debentures sold in October and November 1999, providing for the conversion of approximately $100.7 million aggregate principal amount of the outstanding debentures into approximately 6.3 million shares of common stock for net payments of approximately $15.2 million. Approximately $7.8 million of these 6.75% convertible subordinated debentures remain on the books at December 31, 2001. These debentures will mature in October 2006 and are convertible into shares of our common stock at a conversion price of $16.01 per share, subject to adjustment in certain circumstances. The debentures are redeemable in part or in total at our

option on or after October 13, 2002. Interest is payable semi-annually on April 13 and October 13. The debentures are unsecured subordinated obligations, which rank junior in right of payment to all of our existing and future senior debt.

Costs relating to the issuances of these notes and debentures are recorded as long-term assets and are amortized over the term of the debt. As of December 31, 2001 and 2000, we had approximately $299.1 million in outstanding convertible subordinated notes and debentures with a fair market value of

approximately $204.5 million and $338 million, respectively. The fair market was obtained through quoted market prices.

Note 8—Commitments, Long-term Debt and Tenant Improvement Loan

Facilities Lease & Financing

We lease our office and laboratory facilities under several arrangements expiring through the year 2016. Rent expense was approximately $2.5 million, $3.1 million and $2.5 million for the years ended December 31, 2001, 2000 and 1999, respectively.

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

Future non-cancelable commitments under operating leases and the tenant improvement loan at December 31, 2001 are as follows (in thousands):

	Operating Leases	Tenant Improvement Loan
Years ending December 31,		
2002	$ 2,343	$ 503
2003	2,214	503
2004	2,100	503
2005	2,148	503
2006	2,200	503
2007 and thereafter	11,824	4,964
Total minimum payments required	$ 22,829	$ 7,479
Less amount representing interest		(2,630)
Present value of future payments		4,849
Less current portion		(45)
Non-current portion		$ 4,804

Build-to-Suit Lease

In October 2000, we entered into a build-to-suit lease transaction with a real estate partnership to finance and manage construction of our San Carlos research and office facility. We contributed land and existing construction in progress to the real estate partnership and lease the research and office facility for a period of 16 years through 2016. In addition, all costs related to the construction paid by us prior to the October transaction were reimbursed to us. Due to our continuing involvement in the real estate partnership and other provisions of the agreement, the real estate partnership is consolidated in our financial statements as a capital lease obligation.

The total committed future minimum lease payments under the terms of this lease agreement are as follows (in thousands):

Years ending December 31,	
2002	$ 5,518
2003	5,628
2004	5,741
2005	5,855
2006	5,973
2007 and thereafter	64,858
Total minimum payments required	93,573
Less amount representing interest	(46,852)
Present value of future payments	$ 46,721

We have recorded a total of $32.7 million and $16.2 million relating to this build-to-suit lease as of December 31, 2001 and 2000, respectively, which represents the present value of future minimum payments for the construction completed net of payments on the lease.

Note 9—Contingencies

In August 2000, we entered into supply agreements with two contract manufacturers to provide for the manufacturing of our inhalation device. Under the terms of the agreements, we may be obligated to reimburse both parties for the actual unamortized and unrecovered portion of any equipment procured or facilities established and the interest accrued for their capital overlay in the event that inhaleable insulin does not gain FDA approval to the extent that the contract manufacturers cannot re-deploy the assets. At the present time, it is not possible to estimate the loss that will occur should inhaleable insulin not be approved.

Note 10—Stockholders' Equity

Preferred Stock

The Company has authorized 10,000,000 shares of Preferred Stock, each share having a par value of $0.0001. Three million one hundred thousand (3,100,000) shares of Preferred Stock are designated Series A Junior Participating Preferred Stock (the "Series A Preferred Stock") and forty thousand (40,000) shares of Preferred Stock are designated as Series B Convertible Preferred Stock (the "Series B Preferred Stock").

Series A Preferred Stock

On June 1, 2001 the Board of Directors of the Company approved the adoption of a Share Purchase Rights Plan (the "Plan"). Terms of the Plan provide for a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of the Company's Common Stock (the "Common Shares"). The Rights have certain anti-takeover effects and will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by the Company's Board of Directors. The dividend distribution was payable on June 22, 2001 (the "Record Date") to the stockholders of record on that date. Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Preferred Stock at a price of $225.00 per one one-hundredth of a share of Series A

Preferred Stock (the "Purchase Price"), subject to adjustment. Each one one-hundredth of a share of Series A Preferred Stock has designations and powers, preferences and rights, and the qualifications, limitations and restrictions which make its value approximately equal to the value of a Common Share.

The Rights are not exercisable until the Distribution Date (as defined in the Certificate of Designation for the Series A Preferred Stock). The Rights will expire on June 1, 2011, unless the Rights are earlier redeemed or exchanged by the Company. Each share of Series A Preferred Stock will be entitled to a minimum preferential quarterly dividend payment of $1.00 but will be entitled to an aggregate dividend of 100 times the dividend declared per Common Share. In the event of liquidation, the holders of the Series A Preferred Stock would be entitled to a minimum preferential liquidation payment of $100 per share, but would be entitled to receive an aggregate payment equal to 100 times the payment made per Common Share. Each share of Series A Preferred Stock will have 100 votes, voting together with the Common Shares. Finally, in the event of any merger, consolidation or other transaction in which Common Shares are exchanged, each share of Series A Preferred Stock will be entitled to receive 100 times the amount of consideration received per Common Share. Because of the nature of the Series A Preferred Stock dividend and liquidation rights, the value of one one-hundredth of a share of Series A Preferred Stock should approximate the value of one Common Share. The Series A Preferred Stock ranks junior to the Series B Preferred Stock and would rank junior to any other series of the Company's preferred stock. Until a Right is exercised, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

Series B Preferred Stock

In connection with a strategic alliance with Enzon, Inc., we entered into a Preferred Stock Purchase Agreement pursuant to which we sold to Enzon and Enzon purchased from us forty thousand (40,000) shares of non-voting Series B Preferred Stock at a purchase price of one thousand dollars ($1,000) per share for an aggregate purchase price of forty million dollars ($40,000,000). A Certificate of Designation filed with the Secretary of State of Delaware sets forth the rights, privileges and preferences of the Series B Preferred Stock. Pursuant to the Certificate of Designation, the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is convertible, in whole or in part, into that number of shares of the Company's Common Stock (the "Conversion Shares") equal to the quotient of $1,000 per share divided by the Conversion Price. The "Conversion Price" shall initially be equal to $22.79 per share or 125% of the Closing Price and at no time can the Preferred Stock convert into shares of Common Stock at a discount to the Closing Price. The "Closing Price" equals $18.23 per share and was based upon the average of the Company's closing bid prices as listed on the Nasdaq National Market for the twenty (20) trading days preceding the date of the closing of the transaction.

The Series B Preferred Stock is convertible at the option of the holder after the first anniversary of the original issuance of the Series B Preferred Stock (the "Original Issue Date") or, if earlier, upon a Change in Control (as defined in the Certificate of Designation). Except with respect to an automatic conversion as described below, the Conversion Price shall be equal to 125% of the Closing Price until the third anniversary of the Original Issue Date. Upon the third anniversary of the Original Issue Date, the Conversion Price shall be adjusted to be equal to either (i) the Closing Price, in the event that the average of the closing bid prices of Inhale's Common Stock as quoted on the Nasdaq National Market for the twenty (20) trading days preceding the third anniversary of the original issuance (the "Future Price") is less than or equal to the Closing Price; (ii) the Future Price (as defined above) if the Future Price is greater than the Closing Price but less than 125% of the Closing Price; or (iii) 125% of the Closing Price if the Future Price is equal to or greater than 125% of the Closing Price.

To the extent not previously converted, the Series B Preferred Stock will automatically convert into shares of Inhale Common Stock, based on the then effective Conversion Price, upon the earliest of (i) the fourth anniversary of the Original Issue Date; (ii) immediately prior to an Asset Transfer or Acquisition (as defined in the Certificate of Designation); or (iii) with the consent of the holders of a majority of the then outstanding Series B Preferred Stock immediately prior to a liquidation, dissolution or winding up of Inhale. In the event of an automatic conversion pursuant to an asset transfer, acquisition or liquidation, the adjustment mechanism described above will be applied immediately prior to the automatic conversion.

Common Stock

Employee Stock Purchase Plan

In February 1994**,** our Board of Directors adopted the Employee Stock Purchase Plan (the "Purchase Plan"). Under the Purchase Plan, 300,000 shares of common stock have been reserved for purchase by our employees pursuant to section 423(b) of the Internal Revenue Code of 1986. As of December 31, 2001, no shares of common stock have been issued under the Purchase Plan.

Stock Option Plans

2000 Equity Incentive Plan

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

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

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

Non-Employee Directors' Stock Option Plan

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

2000 Non-Officer Equity Incentive Plan

Our 1998 Non-Officer Equity Incentive Plan was adopted by the Board of Directors on August 18, 1998 and was amended and restated in its entirety and renamed the "2000 Non-officer Equity Incentive Plan" on June 6, 2000 (the "2000 Plan"). The purpose of the 2000 Plan is to attract and retain qualified personnel, to provide additional incentives to employees and consultants and to promote the success of our business. Pursuant to the 2000 plan, we may grant or issue non-qualified stock options, rights to acquire restricted stock and stock bonuses to employees and consultants who are neither Officers nor Directors of Inhale.

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

A summary of activity under the 2000 Equity Incentive Plan, the Non-Employee Directors' Stock Option Plan and the 2000 Non-Officer Equity Incentive Plan is as follows (in thousands, except for per share information):

		Options Outstanding		
	Options Available For Grant	Number of Shares	Exercise Price Per Share	Weighted-Average Exercise Price Per Share
Balance at December 31, 1998	3,042	6,326	$ 0.01-17.63	$ 9.24
Shares authorized	2,500	—	—	—
Options granted	(3,150)	3,150	0.01-20.94	13.58
Options exercised	—	(248)	0.01-17.06	6.30
Options canceled	122	(122)	5.01-17.06	13.23
Balance at December 31, 1999	2,514	9,106	0.01-20.94	10.76
Shares authorized	5,500	—	—	—
Options granted	(4,283)	4,283	0.01-61.63	33.62
Shares awarded	(57)	—	—	—
Options exercised	—	(2,173)	0.01-42.50	8.40
Options canceled	280	(280)	7.25-60.88	28.07
Balance at December 31, 2000	3,954	10,936	0.01-61.63	19.79
Shares authorized	4,570	—	—	—
Options granted	(5,335)	5,335	0.032-50.50	21.32
Options exercised	—	(855)	0.005-21.22	6.20

Options canceled	744	(744)	0.005-60.50	23.82
Balance at December 31, 2001	3,933	14,672	$ 0.005-61.63	$ 20.96

At December 31, 2001, 2000 and 1999, options were exercisable to purchase 5.6 million, 2.9 million and 3.0 million shares at weighted-average exercise prices of $14.57, $11.27 and $7.46 per share, respectively.

Weighted average fair value of options granted during the years ended December 31, 2001, 2000 and 1999, was $25.62, $34.20 and $14.17, respectively. The following table provides information regarding our stock option plans as of December 31, 2001 (in thousands, except per share information):

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (in years)	Number	Weighted-Average Exercise Price Per Share
$0.01-0.01	179	$ 0.01	7.6	77	$ 0.01
0.01-0.01	7	0.01	8.8	2	0.01
0.03-0.03	759	0.03	9.4	760	0.03
0.11-0.15	16	0.13	1.2	16	0.13
1.39-1.39	34	1.39	2.0	35	1.39
2.78-3.88	160	3.18	2.9	160	3.18
4.56-6.00	443	4.89	3.6	443	4.89
7.00-9.81	842	8.71	5.3	727	8.61
10.94-16.28	4,622	14.18	7.4	1,842	14.00
16.64-24.33	1,940	21.91	8.8	317	21.20
25.00-37.47	4,239	29.50	8.7	833	28.97
37.56-55.19	1,395	44.59	8.5	330	44.45
56.38-61.63	36	58.02	8.5	9	58.61
$0.01-61.63	14,672	$ 20.96	7.9	5,551	$ 14.57

In 2001, the Company granted 7,000 options to consultants with exercise prices below the market price of the stock on the grant date. The weighted-average exercise price and weighted-average fair value of these options as of December 31, 2001 were $17.92 and $9.52, respectively.

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

	2001	2000	1999
Risk-free interest rate	4.8%	6.4%	5.6%
Dividend yield	0.0%	0.0%	0.0%
Volatility factor	0.725	0.688	0.600
Weighted average expected life	5 years	5 years	5 years

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

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

	2001	2000	1999
Pro forma net loss	$ (308,766)	$ (122,989)	$ (48,077)
Pro forma basic and diluted net loss per common share	$ (5.81)	$ (2.93)	$ (1.42)

Warrants

During the year ended December 31, 2000, we issued six warrants to purchase a total of 16,000 shares of common stock. Some of the warrants bear an exercise price of $45.88 per share, expire in 10 years and are fully vested. Other warrants are exercisable under certain circumstances at a price to be determined

and expire six years from the date on which any vested shares become exercisable. Total charges recorded during 2000 as a result of these issuances were approximately $0.1 million. No warrants were issued during the year ended December 31, 2001.

Deferred Compensation

Deferred compensation during the year ended December 31, 2001 was immaterial. Deferred compensation of $1.2 million and $0.96 million had been recorded in the years ended December 31, 2000 and 1999, respectively. These amounts represent the difference between the exercise price and the deemed fair market value of certain of our stock options granted in these periods and are being amortized to expense over the three-year vesting period of the options.

Reserved Shares

At December 31, 2001, we have reserved shares of common stock for issuance as follows (in thousands):

Warrants to purchase common stock	56
Employee purchase plan	300
Convertible subordinated notes and debentures	6,644
Stock options	18,605
Total	25,605

Note 11—Income Taxes

As of December 31, 2001, we had federal and state net operating loss carryforwards of approximately $206.0 million and $13.0 million, respectively. We also had federal and state research and other tax credit carryforwards of approximately $5.0 million and $4.6 million, respectively. The federal and state net operating loss and credit carryforwards will expire at various dates beginning in 2002 through 2021 if not utilized.

Utilization of the federal and state net operating loss and credit carryforwards may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of

1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

There is no provision for income taxes because we have incurred operating losses. Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

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

	December 31,	
	2001	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 70,700	$ 55,000
Research and other credits	8,000	4,900
Capitalized research expenses	9,300	3,400
Deferred revenue	6,100	1,900
Depreciation	4,600	1,000
Other	14,200	1,900
Total deferred tax assets	112,900	68,100
Valuation allowance for deferred tax assets	(112,900)	(68,100)
Net deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Because of our lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $44.8 million and $29.0 million during the years ended December 31, 2001 and 2000, respectively.

Note 12—Statement of Cash Flows Data (in thousands):

	Years Ended December 31,		
	2001	2000	1999

Supplemental disclosure of cash flows information:			
Interest paid	$ 11,643	$ 7,031	$ 470
Supplemental schedule of non-cash investing and financing activities:			
Deferred compensation related to the issuance of stock options	$ (23)	$ 1,162	$ 964
Issuance of common stock in connection with acquisitions	$ 239,816	$ —	$ 5,000
Non-cash disclosure related to acquisition of Bradford Particle Design:			
Tangible assets acquired, net of cash	$ 2,100	$ —	$ —
Acquired in-process research and development	62,660	—	—
Goodwill and other intangible assets acquired	80,108	—	—
Acquisition costs incurred	(4,000)	—	—
Liabilities assumed	(487)	—	—
Common stock and options issued	(125,576)	—	—
Cash paid for acquisition of Bradford Particle Design (net of cash received)	$ 14,805	$ —	$ —
Non-cash disclosure related to acquisition of Shearwater Corporation:			
Tangible assets acquired, net of cash	$ 15,212	$ —	$ —
Acquired in-process research and development	83,600	—	—
Goodwill and other intangible assets acquired	94,619	—	—
Acquisition costs incurred	(5,417)	—	—
Liabilities assumed	(6,528)	—	—
Common stock and options issued	(114,240)	—	—
Cash paid for acquisition of Shearwater Corporation (net of cash received)	$ 67,246	$ —	$ —

Note 13—Subsequent Events

In January 2002, we announced a broad strategic alliance with Enzon, Inc. that included a collaboration to develop three products using our Inhance™ pulmonary delivery platform and SEDS™ supercritical fluids platform; an agreement making us solely responsible for licensing Enzon's PEG patents, which includes over 40 US patents; an option for Enzon to license our PEGylation patents and an agreement to explore the development of non-invasive delivery of single-chain antibody products via the pulmonary route. Further, Enzon made a $40.0 million investment in our convertible preferred stock, and we agreed to the settlement of the patent infringement litigation filed by Enzon against our subsidiary, Shearwater.

In January 2002, we announced a program that offered our employees the opportunity to elect to return certain outstanding stock options in exchange for replacement options. The offer to exchange options was adopted in recognition of the fact that many outstanding employee stock options have exercise prices that exceed the current market price of our stock considerably. The offer was not extended to directors or executive officers of the Company, but was offered to certain Inhale employees for the exchange of certain options to purchase shares of the Company's Common Stock granted prior to July 24,

2001 with exercise prices per share greater than or equal to $25.00 per share currently outstanding under the Company's 2000 Non-Officer Equity Incentive Plan, as amended (the "Eligible Options"), for replacement options (the "Replacement Options") to purchase shares of the Common Stock to be granted under the 2000 Non-Officer Plan. The Company conducted the exchange with respect to the Eligible Options on a one-for-two (1:2) basis. If an employee accepted this offer with respect to any Eligible Option, such employee also was obligated to exchange all options to acquire Common Stock of the Company granted to such employee on or after July 24, 2001 (the "Mandatory Exchange Options"). The Company conducted the exchange with respect to Mandatory Exchange Options on a one-for-one (1:1) basis. On March 18, 2002, the Company filed an Amendment No. 2 to Schedule TO announcing that 90 employees participated in the exchange offer, exchanging 1,217,500 Eligible Options and 78,170 Mandatory Exchange Options to purchase shares of Common Stock of the Company. The Company intends to issue Replacement Options to purchase 686,920 shares of Common Stock on August 26, 2002 at an exercise price equal to the closing price of the Company's Common Stock as reported on the Nasdaq National Market on the last market trading day prior to the date of grant.

Note 14—Subsequent Events (unaudited)

In March 2002, we announced the expansion of our agreement with Alliance Pharmaceutical Corp. regarding the PulmoSphere® particle and particle processing technology, aspects of which we initially acquired from Alliance in November, 1999. The PulmoSphere® technology is a particle formation method designed to enhance the performance of drugs delivered via the lung in propellant-based metered-dose inhalers and dry powder inhalers. As a result of the supplemental agreement, Inhale has paid to Alliance $5.25 million in exchange for rights beyond inhaleable applications and other considerations. Under the terms of the supplemental agreement, Inhale has the right to use the PulmoSphere® technology for alternative methods of delivery in addition to inhaleable applications. Further, Alliance assigned five new patent applications covering methods of producing microparticles to Inhale. Alliance retains the rights to use the technology on products to be instilled directly into the lung, and obtains the rights to commercialize up to four products administered with inhalers, two of which will be royalty-free. Inhale will pay Alliance future milestone or royalty payments on a reduced number of products developed by Inhale or its licensees utilizing the technology.

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EXHIBIT 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-79630, 333-07969, 333-59735, 333-65919, 333-74669, 333-32788, 333-54078, 333-55032, 333-67342, 333-71936, and 333-76638) pertaining to the 1994 Equity Incentive Plan, the 1998 Non-Officer Equity Incentive Plan, the 2000 Non-Officer Equity Incentive Plan and the 401(k) Retirement Plan of Inhale Therapeutic Systems, Inc., the Bradford Particle Design plc Share Option Schemes, and the Shearwater Corporation 1996 Nonqualified Stock Option Plan, as amended, and in the Registration Statements (Form S-3 Nos. 333-32576, 333-36152, 333-53678, 333-54080, and 333-67340) and in the related Prospectuses, respectively, of our report dated January 18, 2002, with respect to the consolidated financial statements of Inhale Therapeutic Systems, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2001.

/s/ Ernst & Young LLP

Palo Alto, California
March 27, 2002

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EXHIBIT 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS