

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

INHALE THERAPEUTIC SYSTEMS

(Exact name of registrant as specified in its charter)

CALIFORNIA	2834	94-3134940
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1525 INDUSTRIAL WAY  
BELMONT, CA 94002  
(650) 631-3100

(Address, including zip code, and telephone number, including area code, of  
registrant's principal executive offices)

ROBERT B. CHESS  
PRESIDENT AND CHIEF EXECUTIVE OFFICER  
INHALE THERAPEUTIC SYSTEMS  
1525 INDUSTRIAL WAY  
BELMONT, CA 94002  
(650) 631-3100

(Name, address, including zip code, and telephone number, including area code,  
of agent for service)

COPIES TO:

MARK P. TANOURY, ESQ. VINCENT P. PANGRAZIO, ESQ. JOHN M. GESCHKE, ESQ. COOLEY GODWARD LLP 3000 SAND HILL ROAD BUILDING 3, SUITE 230 MENLO PARK, CALIFORNIA 94025-7116 (650) 843-5000	VICTOR A. HEBERT, ESQ. RICHARD FRIEDMAN, ESQ. HELLER EHRMAN WHITE & MCAULIFFE 525 UNIVERSITY AVENUE PALO ALTO, CALIFORNIA 94301 (650) 324-7000
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APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC:  
As soon as practicable after the Registration Statement becomes effective.

If the only securities being registered on this Form are being offered  
pursuant to dividend or interest reinvestment plans, please check the following  
box. / /

If any of the securities being registered on this Form are to be offered on  
a delayed or continuous basis pursuant to Rule 415 under the Securities Act of  
1933, other than securities offered only in connection with dividend or interest  
reinvestment plans, check the following box. / /

If this form is filed to register additional securities for an offering  
pursuant to Rule 462(b) under the Securities Act, please check the following box  
and list the Securities Act registration statement number of the earlier  
effective registration statement for the same offering. / /

If this form is a post-effective amendment filed pursuant to Rule 462(c)  
under the Securities Act, check the following box and list the Securities Act  
registration statement number of the earlier effective registration statement  
for the same offering. / /

If delivery of the Prospectus is expected to be made pursuant to Rule 434,  
please check the following box. / /

CALCULATION OF REGISTRATION FEE

TITLE OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED(1)	PROPOSED MAXIMUM OFFERING PRICE PER SHARE(2)	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE(2)
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Common Stock no par value.....	1,725,000	\$30.8125	\$53,151,562.50
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TITLE OF SECURITIES TO BE REGISTERED	AMOUNT OF REGISTRATION FEE
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Common Stock no par value.....	\$16,107
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(1) Includes 225,000 shares of Common Stock issuable upon exercise of the Underwriters' over-allotment option.

(2) Estimated solely for the purpose of calculating the amount of the registration fee under Rule 457(c) of the Securities Act of 1933 based on the average of the high and low sales prices of the Common Stock on the Nasdaq National Market on October 1, 1997.

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THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT THAT SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

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INFORMATION CONTAINED HEREIN IS SUBJECT TO COMPLETION OR AMENDMENT. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE SECURITIES MAY NOT BE SOLD NOR MAY OFFERS TO BUY BE ACCEPTED PRIOR TO THE TIME THE REGISTRATION STATEMENT BECOMES EFFECTIVE. THIS PROSPECTUS SHALL NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY NOR SHALL THERE BE ANY SALE OF THESE SECURITIES IN ANY STATE IN WHICH SUCH OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL PRIOR TO REGISTRATION OR QUALIFICATION UNDER THE SECURITIES LAWS OF ANY SUCH STATE.

1,500,000 Shares

[LOGO]

COMMON STOCK

All of the 1,500,000 shares of Common Stock being offered hereby are being sold by Inhale Therapeutic Systems ("Inhale" or the "Company"). The Company's Common Stock is quoted on the Nasdaq National Market under the symbol INHL. On October 1, 1997, the last reported sale price of the Company's Common Stock was \$30.38 per share. See "Price Range of Common Stock."

THE SHARES OF COMMON STOCK OFFERED HEREBY INVOLVE A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 5.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

	Price to Public	Underwriting Discounts and Commissions (1)	Proceeds to Company (2)
Per Share.....			
Total (3).....			

- (1) The Company has agreed to indemnify the Underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended. See "Underwriting."
- (2) Before deducting expenses payable by the Company estimated at \$500,000. See "Underwriting."
- (3) The Company has granted to the Underwriters a 30-day option to purchase up to 225,000 additional shares of Common Stock on the terms and conditions as set forth above solely to cover over-allotments, if any. If such option is exercised in full, the total Price to Public, Underwriting Discounts and Commissions and Proceeds to Company will be \$ , \$ and \$ , respectively. See "Underwriting."

The shares of Common Stock offered by this Prospectus are offered by the Underwriters subject to prior sale, to withdrawal, cancellation or modification of the offer without notice, to delivery to and acceptance by the Underwriters and to certain further conditions. It is expected that delivery of the certificates representing the shares of Common Stock will be made at the offices of Lehman Brothers Inc., New York, New York on or about , 1997.

LEHMAN BROTHERS

BANCAMERICA ROBERTSON STEPHENS

VECTOR SECURITIES INTERNATIONAL, INC.

VOLPE BROWN WHELAN & COMPANY

, 1997

INHALE HAS DEVELOPED FOUR INNOVATIVE TECHNOLOGIES  
TO ENABLE NON-INVASIVE DELIVERY OF MACROMOLECULES

FORMULATION

Inhale has developed proprietary formulation techniques and methods to produce stable, fillable and dispersible dry powder drug formulations.

[PICTURE DEPICTING  
LABORATORY TECHNICIAN  
AT WORK]

DRY POWDER PROCESSING

To reach the deep lung without damaging the molecule, Inhale has developed proprietary technology to process drug particles into a fine powder of less than five microns.

[PICTURE DEPICTING A  
DRY POWDER  
FORMULATION]

DRY POWDER PACKAGING

Inhale achieves long-term stability of its powder by using individual dose packaging to provide a strong moisture barrier. Unit packaging also enables very precise dosing and the ability to deliver blister-packed doses of different strengths, important for certain drugs, such as insulin.

[PICTURE DEPICTING INHALE'S BLISTER PACKAGING]

[PICTURE DEPICTING HUMAN SUBJECT USING INHALE'S  
PROPRIETARY DELIVERY DEVICE]

THE DELIVERY DEVICE  
Using the Inhale system, a patient takes a slow, deep inhalation of a standing cloud of medicine rather than receiving an injection. Accurate and reliable dosing has been demonstrated with Inhale's device in human studies with several different macromolecules.

CERTAIN PERSONS PARTICIPATING IN THIS OFFERING MAY ENGAGE IN TRANSACTIONS THAT STABILIZE, MAINTAIN OR OTHERWISE AFFECT THE PRICE OF THE COMMON STOCK. SUCH TRANSACTIONS MAY INCLUDE THE PURCHASE OF SHARES OF COMMON STOCK PRIOR TO THE PRICING OF THE OFFERING FOR THE PURPOSE OF MAINTAINING THE PRICE OF THE COMMON STOCK, THE PURCHASE OF SHARES OF COMMON STOCK FOLLOWING THE PRICING OF THE OFFERING TO COVER A SYNDICATE SHORT POSITION IN THE COMMON STOCK OR FOR THE PURPOSE OF MAINTAINING THE PRICE OF THE COMMON STOCK, AND THE IMPOSITION OF PENALTY BIDS. FOR A DESCRIPTION OF THESE ACTIVITIES, SEE "UNDERWRITING."

IN CONNECTION WITH THIS OFFERING, CERTAIN UNDERWRITERS AND SELLING GROUP MEMBERS (IF ANY) MAY ENGAGE IN PASSIVE MARKET MAKING TRANSACTIONS IN THE COMMON STOCK ON THE NASDAQ NATIONAL MARKET IN ACCORDANCE WITH RULE 103 UNDER REGULATION M UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, (THE "EXCHANGE ACT"). SEE "UNDERWRITING."

## PROSPECTUS SUMMARY

THE FOLLOWING IS QUALIFIED IN ITS ENTIRETY BY THE MORE DETAILED INFORMATION APPEARING ELSEWHERE IN THIS PROSPECTUS, INCLUDING RISK FACTORS, AND THE OTHER INFORMATION INCORPORATED BY REFERENCE HEREIN. UNLESS OTHERWISE INDICATED, THE INFORMATION IN THIS PROSPECTUS ASSUMES THAT THE UNDERWRITERS' OVER-ALLOTMENT OPTION WILL NOT BE EXERCISED.

### THE COMPANY

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

Currently there are approximately 30 macromolecule drugs marketed in the United States and about 120 others in human clinical trials. Sales of genetically engineered protein drugs were estimated at \$7.6 billion worldwide in 1995. Most of these drugs are currently delivered by injection. Injections are undesirable for numerous reasons including patient discomfort, inconvenience and risk of infection. Poor patient acceptance of and compliance with injectable therapies can lead to increased incidence of medical complications and higher disease management costs. Alternatives to injection such as oral, transdermal and nasal delivery have to date been shown to be commercially unattractive due to low natural bioavailability (the amount of drug absorbed from the delivery site into the bloodstream). As an alternative to the invasiveness of injection, Inhale believes a pulmonary delivery system could expand the market for macromolecule drug therapies and may enable new therapeutic uses of certain macromolecule drugs.

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

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

THE OFFERING

Common Stock offered.....	1,500,000 shares
Common Stock to be outstanding after the offering.....	15,268,880 shares (1)
Use of proceeds.....	To develop and acquire additional clinical and commercial production capacity, fund research and development efforts and for general corporate purposes. See "Use of Proceeds."
Nasdaq National Market Symbol.....	INHL

SUMMARY FINANCIAL INFORMATION  
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	YEARS ENDED DECEMBER 31,					NINE MONTHS ENDED SEPTEMBER 30,	
	1992	1993	1994	1995	1996	1996	1997
	(UNAUDITED)						
STATEMENT OF OPERATIONS DATA:							
Contract research revenue.....	\$ 98	\$ 708	\$ 1,651	\$ 3,445	\$ 6,890	\$ 4,722	\$11,459
Operating costs and expenses:							
Research and development.....	1,259	2,765	4,934	9,041	14,376	10,129	16,640
General and administrative.....	580	856	2,465	3,232	4,004	2,341	4,244
Total operating costs and expenses.....	1,839	3,621	7,399	12,273	18,380	12,470	20,884
Loss from operations.....	(1,741)	(2,913)	(5,748)	(8,828)	(11,490)	(7,748)	(9,425)
Net interest income.....	60	52	469	1,166	1,581	1,109	2,432
Net loss.....	\$(1,681)	\$(2,861)	\$(5,279)	\$(7,662)	\$(9,909)	\$(6,639)	\$(6,993)
Net loss per share(2).....	\$ (0.61)	\$ (1.03)	\$ (0.86)	\$ (0.78)	\$ (0.88)	\$ (0.60)	\$ (0.52)
Shares used in net loss per share calculation(1).....	2,777	2,787	6,103	9,837	11,207	11,025	13,417

SEPTEMBER 30, 1997	
ACTUAL	AS ADJUSTED(3)
(UNAUDITED)	

BALANCE SHEET DATA:	
Cash, cash equivalents and short-term investments.....	\$ 57,659      \$99,992
Working capital.....	49,743      92,076
Total assets.....	74,848      117,181
Accumulated deficit.....	(34,684)      (34,684)
Total shareholders' equity.....	59,845      102,178

(1) Based on 13,768,880 shares outstanding at September 30, 1997. Assumes no exercise of the Underwriters' over-allotment option. Excludes, as of September 30, 1997, a total of 2,157,029 shares of Common Stock issuable upon exercise of outstanding stock options and 52,727 shares of Common Stock issuable upon exercise of outstanding warrants.

(2) For an explanation of the determination of the number of shares used in computing net loss per share, see note 1 to financial statements.

(3) Adjusted to reflect receipt of estimated net proceeds from the sale of 1,500,000 shares of Common Stock offered by the Company hereby at an assumed offering price of \$30.38 per share. See "Use of Proceeds" and "Capitalization."

## RISK FACTORS

IN ADDITION TO THE OTHER INFORMATION IN THIS PROSPECTUS AND IN THE DOCUMENTS INCORPORATED BY REFERENCE HEREIN, THE FOLLOWING RISK FACTORS SHOULD BE CAREFULLY CONSIDERED IN EVALUATING THE COMPANY AND ITS BUSINESS BEFORE PURCHASING THE COMMON STOCK OFFERED BY THIS PROSPECTUS. THE SECTIONS ENTITLED "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" AND "BUSINESS" IN THIS PROSPECTUS CONTAIN FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND SECTION 21E OF THE EXCHANGE ACT. ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE PROJECTED IN THE FORWARD-LOOKING STATEMENTS AS A RESULT OF THE RISK FACTORS SET FORTH BELOW AND ELSEWHERE IN THIS PROSPECTUS.

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

**UNCERTAINTIES RELATED TO TECHNOLOGY AND PRODUCT DEVELOPMENT.** The success of Inhale's pulmonary drug delivery system for any drugs will depend upon the Company achieving sufficient system efficiency (measured by the percentage of bulk drug entering the manufacturing process that eventually is absorbed into the bloodstream relative to injection for systemic indications, or the amount of drug delivered to the lung tissue for local lung indications), formulation stability, safety and dosage reproducibility.

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

Formulation stability (the physical and chemical stability of the formulated drug over time and under various storage conditions) and safety will vary with each drug and the type and amount of excipients that are used in the formulation. Reproducible dosing (the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups) requires the development of an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung, accurate unit dose packaging of dry powder formulations and moisture resistant packaging. There can be no assurance that the Company will be able to develop successfully such an inhalation device or overcome such other obstacles to reproducible dosing.

The Company's integrated approach to systems development relies upon several different but related technologies. Development of powder formulations, processing and packaging technology and the delivery device, establishing collaborations with partners, laboratory and clinical testing, and manufacturing scale-up must proceed contemporaneously so as not to delay any aspect of systems development. Any delay in



one component of product or business development could cause consequential delays in the Company's ability to develop, obtain approval of or market therapeutic products using its system. Further refinement of the Company's device prototype, further scale-up of the powder processing system and automated packaging system will need to be accomplished before initiation of late stage clinical trials.

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

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

HISTORY OF OPERATING LOSSES; UNCERTAINTY OF FUTURE PROFITABILITY. The Company has not been profitable since inception and, through September 30, 1997, has incurred a cumulative deficit of approximately \$34.7 million. The Company expects to continue to incur substantial and increasing losses over at least the next several years as the Company's research and development efforts, preclinical and clinical testing activities and manufacturing scale-up efforts expand and as the Company plans and builds its late stage clinical and early commercial production facility. All of the Company's potential products are in research or in the early stages of development, and no revenues have been generated from approved product sales. The Company's revenues to date have consisted primarily of payments under short-term research and feasibility agreements and development contracts. To achieve and sustain profitable operations, the Company, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products utilizing its pulmonary drug delivery system. There can be no assurance that the Company can generate sufficient product or contract research revenue to become profitable or to sustain profitability. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

DEPENDENCE UPON COLLABORATIVE PARTNERS. The Company currently does not possess the resources necessary to develop, obtain regulatory approvals, or commercialize any of its potential therapeutic products. The Company's ability to apply its pulmonary delivery system to a broad range of drugs will depend upon its ability to establish and maintain collaborative arrangements since many of the drugs currently approved for sale or in clinical testing are covered by third-party patents. The Company has entered into collaborative arrangements with certain of its partners to fund clinical trials, assist in obtaining regulatory approvals, supply drugs for formulation and market and distribute products. While Inhale has also entered into agreements with partners to test the feasibility of its pulmonary delivery system with certain of their proprietary molecules, there can be no assurance that the Company will be able to enter into additional collaborations or that its feasibility agreements will lead to collaborations. There also can be no assurance that the Company will be able to maintain any such collaborative arrangements or feasibility agreements or that any such collaborative arrangements or feasibility agreements will be successful. The failure of the Company to enter into or maintain such collaborative arrangements and feasibility agreements would have a material adverse effect on the Company. Moreover, the inability of the Company to enter into a collaborative arrangement with the owner of any patented drug may preclude the Company from working with such drug.

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

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

The Company has no experience manufacturing products for large scale clinical testing or commercial purposes. To date, the Company has performed powder processing on the small scale needed for early stage trials and for testing formulations of certain other potential therapeutic products and scaled-up

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

Fine particle powders and small quantity packaging (such as those to be used in the Company's delivery system) require special handling. The Company has designed and qualified small scale automated filling equipment for small quantity packaging of fine powders. The Company faces significant technical challenges scaling-up an automated filling system that can accurately and economically handle the small dose and particle sizes of its powders in commercial quantities. There can be no assurances that the Company will be able to scale-up its automated filling equipment in a timely manner or at commercially reasonable costs. Any failure or delay in such scale-up would delay product development or bar commercialization of the Company's products and would have a material adverse effect on the Company.

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

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

FUTURE CAPITAL NEEDS; UNCERTAINTY OF ADDITIONAL FUNDING. The Company's operations to date have consumed substantial and increasing amounts of cash. The negative cash flow from operations is expected to continue and to accelerate in the foreseeable future. The development of the Company's technology and proposed products will require a commitment of substantial funds to conduct costly and time-consuming research, preclinical and clinical testing, establish an early commercial production facility and bring any such products to market. The Company's future capital requirements will depend on many factors, including continued progress in the research and development of the Company's technology and drug

delivery system, the ability of the Company to establish and maintain collaborative arrangements with others and the terms thereof, payments received from partners under research and development agreements, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of development and the rate of scale-up of the Company's powder processing and packaging technologies, the timing and costs of its late stage clinical and early commercial production facility, the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technology and the status of competitive products. See "Risk Factors-- Dependence Upon Collaborative Partners."

The Company expects that its existing capital resources, contract research revenues from collaborations and the net proceeds of this offering and interest thereon, will enable the Company to maintain its current and planned operations at least through 1999. Thereafter, the Company may need to raise substantial additional capital to fund its operations. The Company intends to seek such additional funding through collaborative or partnering arrangements, the extension of existing arrangements, or through public or private equity or debt financings. There can be no assurance that additional financing will be available on acceptable terms or at all. If additional funds are raised by issuing equity securities, further dilution to shareholders may result. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its research or development programs or obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop or commercialize. See "Management's Discussion and Analysis of Financial Condition and Results of Operations;" and "Use of Proceeds."

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

The patent positions of pharmaceutical, biotechnology and drug delivery companies, including Inhale, are uncertain and involve complex legal and factual issues. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued. As a consequence, the Company does not know whether any of its patent applications will result in the issuance of patents or, if any patents issue, whether they will provide significant proprietary protection or will be circumvented or invalidated. Since patent applications in the United States are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, the Company cannot be certain that it was the first inventor of inventions covered by its pending patent applications or that it was the first to file patent applications for such inventions. Moreover, the Company may have to participate in interference proceedings declared by the United States Patent and Trademark Office ("PTO") to determine priority of invention, which could result in substantial cost to the Company, even if the eventual outcome is favorable to the Company. An adverse outcome could subject the Company to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require the Company to cease using the technology in dispute.

The Company is aware of numerous pending and issued U.S. and foreign patent rights and other proprietary rights owned by third parties that relate to aerosol devices and delivery, pharmaceutical formulations, dry powder processing technology and the pulmonary route of delivery for certain macromolecules. The Company cannot predict with any certainty which, if any, patents and patent applications will be considered relevant to the Company's technology by authorities in the various

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

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

Third parties from time to time have asserted and may assert that the Company is employing technology that they believe is based on issued patents, trade secrets or know-how of others. In addition, future patents may issue to third parties which the Company's technology may infringe. The Company could incur substantial costs in defending itself and its partners against any such claims. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief which could effectively block the Company's ability to further develop or commercialize some or all of its products in the United States and abroad, and could result in the award of substantial damages. In the event of a claim of infringement, the Company and its partners may be required to obtain one or more licenses from third parties. There can be no assurances that the Company or its partners will be able to obtain such licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any such license could have a material adverse effect on the Company.

The Company's ability to develop and commercialize its technology will be affected by the Company's or its partners' access to the drugs which are to be formulated. Many drugs, including powder formulations of certain drugs which are presently under development by the Company, are subject to issued and pending United States and foreign patent rights which may be owned by competing entities. There are issued patents and pending patent applications relating to the pulmonary delivery of macromolecule drugs, including several for which the Company is developing pulmonary delivery formulations. Specifically, patents have been granted in the United States and Europe directed to aerosol formulations for the treatment of the lung containing alpha-1 antitrypsin (U.S.) and serine protease inhibitors, including alpha-1 antitrypsin (Europe). The Company's development partner for alpha-1 antitrypsin, Centeon, is negotiating with multiple partners to secure rights under these patents. The failure by Centeon to secure rights under these patents could result in the termination of this program by Centeon. The resulting patent situation is highly complex, and the ability of any one company to commercialize a particular biopharmaceutical drug is highly unpredictable. The Company intends generally to rely on the ability of its partners to provide access to the drugs which are to be formulated for pulmonary delivery. There can be no

assurance that the Company's partners will be able to provide access to drug candidates for formulation for pulmonary delivery or that, if such access is provided, the Company or its partners will not be accused of, or determined to be, infringing a third party's rights and will not be prohibited from working with the drug or be found liable for damages that may not be subject to indemnification. Any such restriction on access or liability for damages would have a material adverse effect on the Company.

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

In 1995 the PTO adopted changes to the United States patent law that changed the term of issued patents, subject to certain transition periods, to 20 years from the date of filing rather than 17 years from date of issuance. Beginning in June 1995, the patent term became 20 years from the earliest effective filing date of the underlying patent application. Such change may reduce the effective term of protection for patents that are pending for more than three years in the PTO. In addition, as of January 1996, all inventors who work outside of the United States are able to establish a date of invention on the same basis as those working in the United States. Such change could adversely affect the ability of the Company to prevail in a priority of invention dispute with a third party located or doing work outside of the United States. While the Company cannot predict the effect that such changes will have on its business, such changes could have a material adverse effect on the Company's ability to protect its proprietary information and sustain the commercial viability of its products. Furthermore, the possibility of extensive delays in such process, could effectively further reduce the term during which a marketed product could be protected by patents. See "Risk Factors--Dependence Upon Collaborative Partners," "--Government Regulation; Uncertainty of Obtaining Regulatory Approval;" and "Business--Patents and Proprietary Rights."

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

**GOVERNMENT REGULATION; UNCERTAINTY OF OBTAINING REGULATORY APPROVAL.** The production and marketing of the Company's products and its ongoing research and development activities are subject to regulation by numerous governmental authorities in the United States and other countries. Prior to marketing a new dosage form of any drug, including one developed for use with the Company's pulmonary drug delivery system, whether or not such drug was already approved for marketing in another dosage form, the product must undergo rigorous preclinical and clinical testing and an extensive review process mandated by the FDA and equivalent foreign authorities. These processes generally take a number of years and require the expenditure of substantial resources. None of the Company's proposed products has been submitted to the FDA for marketing approval. The Company has no experience obtaining such regulatory approval, does

not have the expertise or other resources to do so and intends to rely on its partners to fund clinical testing and to obtain product approvals. See "Risk Factors--Dependence Upon Collaborative Partners."

The time required for completing such testing and obtaining such approvals is uncertain. Further refinement of the device prototype, further scale-up of the powder processing system and automated powder filling and packaging system will need to be accomplished before initiation of later stage clinical trials. Any delay in any of these components of product development may delay testing. In addition, delays or rejections may be encountered based upon changes in FDA policy, including FDA policy relating to GMP compliance, during the period of product development. Similar delays may also be encountered in other countries. If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which the product may be marketed, and the marketed product, its manufacturer, and its manufacturing facilities remain subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer, including withdrawal of the product from the market. There can be no assurance that regulatory approval will be obtained for any products developed by the Company on a timely basis, or at all. The failure to obtain timely regulatory approval of its products, any product marketing limitations or a product withdrawal would have a material adverse effect on the Company. See "Business--Government Regulation."

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

In both domestic and foreign markets, sales of the Company's products under development will depend in part upon the availability of reimbursement from third-party payors, such as government health administration authorities, managed care providers, private health insurers and other organizations. In addition, other third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. There can be no assurance that the Company's proposed products will be considered cost effective or that adequate third-party reimbursement will be available to enable Inhale to maintain price levels sufficient to realize an appropriate return on its investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before the Company's proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products. If adequate coverage and reimbursement levels are not provided by the government and third-party payors for the Company's potential products, the market acceptance of these products would be adversely affected, which would have a material adverse effect on the Company.

**HIGHLY COMPETITIVE INDUSTRY; RISK OF TECHNOLOGICAL OBSOLESCENCE.** The biotechnology and pharmaceutical industries are highly competitive and rapidly evolving and significant developments are expected to continue at a rapid pace. The Company's success depends upon maintaining a competitive position in the development of products and technologies for pulmonary delivery of pharmaceutical drugs. If a competing company were to develop or acquire rights to a better dry powder pulmonary delivery device or fine powder processing technology, a better system for efficiently and reproducibly delivering drugs to the deep lung, a non-invasive drug delivery system which is more attractive for the delivery of drugs than pulmonary

delivery, or an invasive delivery system which overcomes some of the drawbacks of current invasive systems for chronic or subchronic indications (such as a sustained release system), the Company's business could be materially adversely affected.

The Company is in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. The Company is aware of a number of companies currently seeking to develop new products and non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems and colonic absorption systems. Several of these companies may have developed or be developing dry powder devices that could be used for pulmonary delivery. The Company is also aware of other companies currently engaged in the development and commercialization of pulmonary drug delivery systems and enhanced injectable drug delivery systems. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than the Company and represent significant competition for the Company. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance competitors' financial, marketing and other resources. Accordingly, the Company's competitors may succeed in developing competing technologies, obtaining FDA approval for products or gain market acceptance more rapidly than the Company. There can be no assurance that developments by others will not render the Company's products or technologies uncompetitive or obsolete. See "Business--Competition."

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

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

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

**POTENTIAL VOLATILITY OF STOCK PRICE.** The market prices for securities of early stage biotechnology companies have historically been highly volatile and the market from time to time experienced significant



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

SHARES ELIGIBLE FOR FUTURE SALE; REGISTRATION RIGHTS. Future sales of substantial amounts of Common Stock in the public market could have an adverse effect on the price of the Company's Common Stock and may impair the Company's ability to raise additional funds through equity financings. Upon completion of the offering, the Company will have outstanding an aggregate of 15,268,880 shares of Common Stock, assuming no exercise of the Underwriters' over-allotment option and no exercise of outstanding options and based upon the number of shares outstanding as of September 30, 1997. Of these shares, all of the shares sold in this offering and approximately 10,644,140 additional shares already outstanding will be freely tradeable without restriction or further registration under the Securities Act (unless such shares are subject to an agreement not to sell described below). The remaining 3,124,740 shares of Common Stock held by existing shareholders are "restricted securities" as that term is defined in Rule 144 under the Securities Act (the "Restricted Shares"). Restricted Shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 promulgated under the Securities Act. The Company and its executive officers and directors, who own in the aggregate 1,083,544 shares of Common Stock, have agreed, subject to certain limited exceptions, that they will not, without the prior written consent of Lehman Brothers Inc., directly or indirectly, sell, offer, contract to sell, transfer the economic risk of ownership in, make any short sale, pledge or otherwise dispose of any shares of Common Stock or other securities convertible or exchangeable or exercisable for, or any other rights to purchase or acquire shares, of Common Stock owned by them during the 90 day period commencing on the date of this Prospectus. In addition, 725,552 shares of Common Stock issued to Pfizer in January 1995 and 1,335,587 shares of Common Stock issued to Baxter in March 1996 are subject to agreements with the Company restricting the sale, transfer or other disposition of such shares until February 2000 and March 1999, respectively, unless the Company agrees to an earlier release of such restrictions. The Company has filed a registration statement under the Securities Act to register shares of Common Stock reserved for issuance under the Company's equity incentive plans, thus permitting the resale of such shares by non-affiliates and by affiliates, subject to Rule 144 volume limitations applicable thereto, in the public market without restriction under the Securities Act. As of September 30, 1997, there was a total of 2,157,029 shares of Common Stock subject to outstanding options under the Company's equity incentive plans, 694,227 of which were vested and exercisable. The holders of 677,044 shares of Common Stock are entitled to certain demand registration rights with respect to such shares. In addition, Pfizer has the right to include any shares of Common Stock issued pursuant to its Stock Purchase Agreement with the Company, dated January 18, 1995 in the first public offering of the Common Stock effected after January 18, 2000 and Baxter has the right to include any shares of Common Stock issued pursuant to its Stock Purchase Agreement with the Company, dated March 1, 1996 in the first public offering of the Common Stock effected after March 1, 1999.

#### THE COMPANY

Inhale Therapeutic Systems was incorporated in California in July 1990. The Company's executive offices are located at 1525 Industrial Way, Belmont, California, 94002 and its telephone number is (650) 631-3100.

#### USE OF PROCEEDS

The net proceeds to the Company from the sale of the 1,500,000 shares of Common Stock offered hereby are estimated to be \$42,332,500 (\$48,757,375 if the Underwriters' over-allotment option is exercised in full), at an assumed offering price of \$30.38 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

The Company expects to use approximately 75% of the net proceeds of this offering to develop and acquire additional clinical and commercial production technology, capacity, and facilities and to cover expenses associated with additional personnel necessary to permit the Company to manufacture and package dry powder formulations for human clinical trials and commercial production. Approximately 25% of the net proceeds will be used to fund further development of the Company's proprietary device and other research and development activities, the acquisition of other complementary technologies, working capital and general corporate purposes. The amounts and timing of funds required for specific uses by the Company cannot be precisely determined by the Company at this time. See "Management's Discussion and Analysis of Financial Condition and Results of Operations--Liquidity and Capital Resources." The Company expects that its existing capital resources, including contract research revenues and milestone revenues from current collaborations, and possible additional equipment leases, together with the net proceeds of this offering and interest thereon, will enable the Company to maintain its current and planned operations at least through 1999. Pending such uses, the net proceeds of this offering will be invested in short-term, interest-bearing, investment-grade instruments. See "Risk Factors--Future Capital Needs; Uncertainty of Additional Funding."

#### DIVIDEND POLICY

The Company has never declared or paid any cash dividends on its capital stock. The Company currently intends to retain any future earnings to finance the growth and development of its business and therefore does not anticipate paying any cash dividends in the foreseeable future.

CAPITALIZATION

The following table sets forth the capitalization of the Company (i) as of September 30, 1997, and (ii) as adjusted as of September 30, 1997, to give effect to the issuance and sale of the 1,500,000 shares of Common Stock offered hereby at an assumed offering price of \$30.38 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. This table should be read in conjunction with the financial statements and the notes thereto included elsewhere in this Prospectus.

	SEPTEMBER 30, 1997	
	ACTUAL	AS ADJUSTED
	(IN THOUSANDS)	
Equipment financing obligations, less current portion.....	\$ 148	\$ 148
Shareholders' equity:		
Preferred stock, no par value; 10,000,000 shares authorized; no shares issued and outstanding.....	--	--
Common stock, no par value; 30,000,000 shares authorized; 13,768,880 shares issued and outstanding, actual; and 15,268,880 shares issued and outstanding, as adjusted(1).....	94,529	136,862
Accumulated deficit.....	(34,684)	(34,684)
Total shareholders' equity.....	59,845	102,178
Total capitalization.....	\$ 59,993	\$ 102,326

(1) Excludes, as of September 30, 1997, 2,157,029 shares of Common Stock issuable upon exercise of outstanding stock options and 52,727 shares of Common Stock issuable upon exercise of outstanding warrants.

PRICE RANGE OF COMMON STOCK

The Company's Common Stock is traded on the Nasdaq National Market under the symbol INHL. The following table sets forth the closing information on the high and low closing bid prices for the Company's Common Stock as reported on the Nasdaq National Market for the periods indicated below.

FISCAL PERIOD	HIGH	LOW
1995		
First Quarter.....	\$ 11.375	\$ 7.250
Second Quarter.....	8.000	7.000
Third Quarter.....	14.750	7.625
Fourth Quarter.....	11.500	7.250
1996		
First Quarter.....	16.750	9.750
Second Quarter.....	21.500	15.00
Third Quarter.....	18.625	12.625
Fourth Quarter.....	17.625	12.875
1997		
First Quarter.....	22.625	15.125
Second Quarter.....	25.000	18.375
Third Quarter.....	33.625	18.750
Fourth Quarter (through October 1, 1997).....	\$ 31.375	\$ 30.250

As of October 1, 1997, there were approximately 117 holders of record of the Company's Common Stock. On October 1, the last sale price reported on the Nasdaq National Market for the Common Stock was \$30.38 per share.

DILUTION

The net tangible book value of the Company at September 30, 1997 was approximately \$59,845,000 or \$4.35 per share of Common Stock. Net tangible book value per share represents the amount of the Company's total tangible assets less its total liabilities, divided by the total number of shares of Common Stock outstanding. After giving effect to the issuance and sale of the 1,500,000 shares of Common Stock offered hereby (at an assumed offering price of \$30.38 per share) and receipt of the net proceeds (after deducting underwriting commissions and discounts and estimated offering expenses payable by the Company) therefrom, the adjusted pro forma net tangible book value of the Company at September 30, 1997 would have been approximately \$102,177,500 or \$6.69 per share, representing an immediate increase in net tangible book value of \$2.34 per share to existing shareholders and an immediate dilution of \$23.69 per share to the persons purchasing shares at the public offering price ("New Investors"). The following table illustrates this per share dilution:

Public offering price per share.....		\$ 30.38
Net tangible book value per share at September 30, 1997.....	\$ 4.35	
Increase per share attributable to purchase by New Investors.....	2.34	
	-----	
Adjusted pro forma net tangible book value per share as of September 30, 1997 after offering(1)(2).....		6.69
		-----
Dilution per share to New Investors(1)(2).....	\$ 23.69	
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- (1) If the Underwriters' over-allotment option is exercised in full, the adjusted pro forma net tangible book value per share will be \$7.01, resulting in immediate dilution to New Investors of \$23.37 per share.
- (2) If all outstanding options and warrants outstanding at September 30, 1997 to purchase an aggregate of 2,209,756 shares of Common Stock at a weighted average exercise price of \$11.98 were exercised in full in addition to the Underwriters' over-allotment option, the adjusted pro forma net tangible book value per share would be \$7.63, resulting in immediate dilution to New Investors of \$22.75 per share.

SELECTED FINANCIAL DATA

The selected financial data set forth below with respect to the Company's statements of operations for each of the five years in the period ended December 31, 1996 are derived from audited financial statements of the Company that have been audited by Ernst & Young LLP, independent auditors, and are qualified by reference to such financial statements and notes related thereto. The balance sheet data at December 31, 1995 and 1996 and the statement of operations data for each of the three years in the period ended December 31, 1996, are derived from audited financial statements included elsewhere in this Prospectus. The balance sheet data at December 31, 1992, 1993 and 1994 and the statement of operations data for each of the two years in the period ended December 31, 1993 are derived from audited financial statements not included in this Prospectus. The balance sheet data at September 30, 1997 and the statement of operations data for the nine months ended September 30, 1996, and 1997 are derived from unaudited financial statements included elsewhere herein. The unaudited financial statements include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for fair presentation of its financial position and results of operations for these periods. Operating results for the nine months ended September 30, 1997 are not necessarily indicative of the results that may be expected for the entire year ending December 31, 1997. This selected financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Financial Statements and Notes thereto incorporated by reference or included elsewhere herein.

	YEARS ENDED DECEMBER 31,					NINE MONTHS ENDED SEPTEMBER 30,	
	1992	1993	1994	1995	1996	1996	1997
(IN THOUSANDS, EXCEPT PER SHARE DATA)							
<b>STATEMENT OF OPERATIONS DATA:</b>							
Contract research revenue.....	\$ 98	\$ 708	\$ 1,651	\$ 3,445	\$ 6,890	\$ 4,722	\$ 11,459
Operating costs and expenses:							
Research and development.....	1,259	2,765	4,934	9,041	14,376	10,129	16,640
General and administrative.....	580	856	2,465	3,232	4,004	2,341	4,244
Total operating costs and expenses.....	1,839	3,621	7,399	12,273	18,380	12,470	20,884
Loss from operations.....	(1,741)	(2,913)	(5,748)	(8,828)	(11,490)	(7,748)	(9,425)
Interest income.....	80	156	592	1,252	1,638	1,156	2,453
Interest expense.....	(20)	(104)	(123)	(86)	(57)	(47)	(21)
Net loss.....	\$ (1,681)	\$ (2,861)	\$ (5,279)	\$ (7,662)	\$ (9,909)	\$ (6,639)	\$ (6,993)
Net loss per share(1).....	\$ (0.61)	\$ (1.03)	\$ (0.86)	\$ (0.78)	\$ (0.88)	\$ (0.60)	\$ (0.52)
Shares used in net loss per share calculation(1).....	2,777	2,787	6,103	9,837	11,207	11,025	13,417

	DECEMBER 31,					SEPTEMBER 30, 1997	
	1992	1993	1994	1995	1996	ACTUAL	AS ADJUSTED(2)
(IN THOUSANDS)							
<b>BALANCE SHEET DATA:</b>							
Cash, cash equivalents and short-term investments.....	\$ 3,712	\$ 5,513	\$ 14,423	\$ 19,927	\$ 36,309	\$ 57,659	\$ 99,992
Working capital.....	3,345	4,954	13,451	17,701	31,304	49,743	92,076
Total assets.....	4,376	7,190	17,249	23,248	41,492	74,848	117,181
Equipment financing obligations, less current portion.....	229	652	460	353	187	148	148
Accumulated deficit.....	(1,968)	(4,829)	(10,108)	(17,770)	(27,691)	(34,684)	(34,684)
Total shareholders' equity.....	3,742	5,891	15,427	20,182	35,061	59,845	102,178

(1) Net loss per share is based upon the weighted average number of common and certain dilutive common equivalent shares outstanding. See note 1 to financial statements.

(2) As adjusted to reflect the sale by the Company of 1,500,000 shares of Common Stock at the assumed offering price of \$30.38 per share and the application of the net proceeds therefrom as described in "Use of Proceeds."

MANAGEMENT'S DISCUSSION AND ANALYSIS  
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THIS PROSPECTUS CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. THE STATEMENTS CONTAINED IN THIS PROSPECTUS THAT ARE NOT HISTORICAL ARE FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT AND SECTION 21E OF THE EXCHANGE ACT, INCLUDING WITHOUT LIMITATION STATEMENTS REGARDING THE COMPANY'S EXPECTATIONS, BELIEFS, INTENTIONS OR STRATEGIES REGARDING THE FUTURE. ALL FORWARD-LOOKING STATEMENTS INCLUDED IN THIS DOCUMENT ARE BASED ON INFORMATION AVAILABLE TO THE COMPANY ON THE DATE HEREOF, AND THE COMPANY ASSUMES NO OBLIGATION TO UPDATE ANY SUCH FORWARD-LOOKING STATEMENTS. THE COMPANY'S ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE ANTICIPATED IN THESE FORWARD-LOOKING STATEMENTS AS A RESULT OF CERTAIN FACTORS, INCLUDING THOSE SET FORTH BELOW, UNDER "RISK FACTORS" AND ELSEWHERE IN THIS PROSPECTUS.

READERS ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON THESE FORWARD-LOOKING STATEMENTS, WHICH REFLECT MANAGEMENT'S ANALYSIS ONLY AS OF THE DATE HEREOF. THE COMPANY UNDERTAKES NO OBLIGATION TO PUBLICLY RELEASE THE RESULTS OF ANY REVISION TO THESE FORWARD-LOOKING STATEMENTS WHICH MAY BE MADE TO REFLECT EVENTS OR CIRCUMSTANCES OCCURRING AFTER THE DATE HEREOF OR TO REFLECT THE OCCURRENCE OF UNANTICIPATED EVENTS.

#### OVERVIEW

Since its inception in July 1990, Inhale has been engaged in the development of a pulmonary system for the delivery of macromolecules and other drugs for systemic and local lung applications. The Company has been unprofitable since inception and expects to incur significant and increasing additional operating losses over the next several years primarily due to increasing research and development expenditures and expansion of late stage clinical and early stage commercial manufacturing facilities. To date, Inhale has not sold any products and does not anticipate receiving revenue from product sales or royalties in the near future. For the period from inception through September 30, 1997, the Company incurred a cumulative net loss of approximately \$34.7 million. The sources of working capital have been equity financing, financing of equipment acquisitions, interest earned on investments of cash, and revenues from short-term research and feasibility agreements and development contracts.

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

#### RESULTS OF OPERATIONS

##### NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997

Revenues for the nine months ended September 30, 1996 were \$4.7 million as compared to \$11.5 million for the nine months ended September 30, 1997. The 143% increase in revenue for the nine month period ended September 30, 1997 as compared to September 30, 1996 was primarily due to the signing of additional corporate partners in 1997 as well as the expansion of the Company's existing collaborative agreements. In January 1997 the Company entered into a development agreement with Lilly to develop a pulmonary delivery product for an osteoporosis drug. Under the terms of the agreement, Inhale will

receive up to an estimated \$20 million in initial fees, funding for research and milestone payments. In return, Lilly will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. In addition, in January 1997 the Company announced an agreement with Centeon L.L.C. to develop a pulmonary formulation of alpha-1 proteinase inhibitor. Under this agreement, the Company will receive up to an estimated \$15 million in funding for research and milestone payments and royalties on future product sales. In return, Centeon will receive commercialization rights worldwide outside of Japan. Revenue for the nine month periods ended September 30, 1996 and 1997 was comprised of reimbursed research and development expenses and the amortization of the pro-rata portion of the up-front signing and milestone payments based on actual efforts expended. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

Research and development expenses for the nine months ended September 30, 1996 were \$10.1 million compared with \$16.6 million for the nine months ended September 30, 1997. The 64% increase for the nine month period ended September 30, 1997 compared with the nine month period ended September 30, 1996 is primarily attributed to continued expansion of research activities resulting from an increase in the number of projects, additional hiring of scientific personnel, costs associated with the development of the Company's commercial manufacturing facility and increased costs of laboratory supplies and consulting services. The Company expects research, development and process development spending to increase significantly over the next few years as the Company continues to expand research and development and prepares for initial commercial manufacturing.

For the nine month period ended September 30, 1996 general and administrative expenses were \$2.3 million compared with \$4.2 million in the comparable period of 1997. The 81% increase for the nine month period ended September 30, 1997 compared with the nine month period ended September 30, 1996 was due primarily to support of the Company's increased research efforts including administrative staffing, business development activities and marketing activities. General and administrative expenses are expected to continue to increase to support increased levels of research, development and manufacturing activities.

Net interest income was \$1.1 million for the nine months ended September 30, 1996 compared with \$2.4 million for the nine months ended September 30, 1997. The 119% increase in net interest income for the nine month period ended September 30, 1997 when compared with 1996 was due to the Company maintaining larger cash and investment balances. The higher cash and investment balances resulted from receipt by the Company of milestone and research funding payments from collaborative partners and \$30.4 million of net proceeds received from a private placement of the Company's Common Stock in February 1997.

#### YEARS ENDED DECEMBER 31, 1994, 1995 AND 1996

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

Contract revenues are expected to fluctuate from year to year, and future contract revenues cannot be predicted accurately. The level of contract revenues depends in part upon future success in obtaining new collaborative agreements, timely completion of feasibility studies, the continuation of existing collaborations and achievement of milestones under current and future agreements. Nevertheless, the Company expects higher contract revenues in 1997 as it continues its activities under collaborative development agreements.



Research and development expenses were \$4.9, \$9.0 and \$14.4 million for the years ended December 31, 1994, 1995 and 1996, respectively. These expenses represent proprietary research expenses as well as the costs related to contract research revenue and include salaries and benefits of scientific and development personnel, laboratory supplies, consulting services, facilities, costs of obtaining intellectual property protection for Inhale's technologies and expenses associated with the development of manufacturing processes. The \$4.1 million increase in research and development expenses in 1995 from 1994 and the \$5.3 million increase in 1996 from 1995 were primarily due to the hiring of additional research personnel and increased expenses associated with expanding laboratory and clinical manufacturing facilities. The Company expects research and development and process development spending to increase significantly over the next few years as the Company expands proprietary development efforts under collaborative agreements and scales up a manufacturing facility for late stage clinical trials and early commercial manufacturing.

General and administrative expenses were \$2.5, \$3.2 and \$4.0 million for the years ended December 31, 1994, 1995 and 1996, respectively. The \$767,000 increase in general and administrative expenses in 1995 from 1994 and the \$772,000 increase in 1996 from 1995 was due primarily to costs associated with supporting the Company's increased research and development programs and accelerated business development efforts. The Company expects general and administrative spending to increase over the next few years as the Company expands operations.

Net interest income was \$469,000, \$1.2 million and \$1.6 million for the years ended December 31, 1994, 1995 and 1996, respectively. The increase of \$697,000 in net interest income in 1995 from 1994 was due primarily to higher cash balances as a result of the \$7.2 million net proceeds received from the Company's follow-on public offering of Common Stock in March 1995. In addition, in February 1995 Pfizer made a \$5.0 million equity investment in Inhale at a 25% premium-to-market price in conjunction with the January 1995 agreement between the Company and Pfizer. The \$415,000 increase in net interest income in 1996 from 1995 was due primarily to interest earned on higher average cash balances as a result of Baxter making a \$20.0 million equity investment in Inhale at a 25% premium-to-market price in conjunction with the March 1996 development agreement between the Company and Baxter. In addition, in October 1996 Pfizer made an additional \$5.0 million investment in Inhale pursuant to the January 1995 agreement between the Company and Pfizer to develop insulin products using Inhale's non-invasive pulmonary drug delivery system.

At December 31, 1996, the Company had federal net operating loss carryforwards of approximately \$23.0 million. These carryforwards will expire beginning in the year 2006. Utilization of net operating loss carryforwards may be subject to substantial annual limitation due to the ownership change limitation provided for by the Internal Revenue Code of 1986. The annual limitation may result in the expiration of net operating loss carryforwards before utilization.

#### LIQUIDITY AND CAPITAL RESOURCES

The Company has financed its operations primarily through private placements and public offerings of its equity securities, contract research and milestone revenues, interest income earned on its investments of cash and financing of equipment acquisitions. In its initial public offering completed May 1994, the Company raised net proceeds of approximately \$14.4 million and raised additional net proceeds of \$7.2 million in its public offering completed in March 1995. On February 7, 1997 the Company completed a private placement of its Common Stock, selling 1.8 million newly issued shares for net proceeds of \$30.4 million. At September 30, 1997, the Company had cash, cash equivalents and short-term investments of approximately \$57.7 million.

The Company's operations used cash of \$6.7 million in the nine months ended September 30, 1996 and \$2.0 million for the nine months ended September 30, 1997. The decrease in cash used by operations from the nine months ended September 30, 1996 to the nine months ended September 30, 1997 is due

primarily to the increase in advance payments received under the Company's collaborative agreements for work to be performed in future periods. Cash used in operations differed from the Company's net operating losses in these periods due principally to depreciation expenses, decreases in accounts receivable and increases in other current assets, notes receivable, accounts payable, deferred revenue and accrued liabilities. The Company's operations used cash of \$4.0, \$5.3 and \$5.8 million in the years ended December 31, 1994, 1995 and 1996, respectively. These amounts differed from the Company's net operating losses in these periods due principally to depreciation expenses and increases in accounts payable, accrued liabilities and deferred revenue. Additionally, in 1994, non-cash amortization of deferred compensation expense of approximately \$348,000 contributed to the difference between the net operating losses and cash used by operations.

In the nine months ended September 30, 1996 the Company purchased property and equipment of \$1.6 million compared with \$8.2 million for the same period in 1997. The Company purchased property and equipment of \$1.4, \$1.3 and \$2.2 million during the years ended December 31, 1994, 1995 and 1996, respectively. The increase for the nine months ended September 30, 1997 is primarily due to the expansion of the Company's new facility in Belmont, California. The increase in 1996 was primarily due to the purchase of equipment as a result of the expansion of research and development activity.

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

The Company believes that its cash, cash equivalents and short-term investments as of September 30, 1997 together with the net proceeds from this offering, use of the \$10.0 million credit facility obtained from Silicon Valley Bank in May 1997, interest income and possible additional equipment financing, will be sufficient to meet its operating expense and capital expenditure requirements at least through 1999. However, the Company's capital needs will depend on many factors, including continued scientific progress in its research and development arrangements, progress with pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of scaling-up the Company's powder processing and packaging technologies, the timing and cost of its late-stage clinical and early commercial production facility, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technologies and the status of competitive products. To satisfy its long-term needs, the Company intends to seek additional funding, as necessary, from corporate partners and from the sale of securities. There can be no assurance that additional funds, if and when required, will be available to the Company on favorable terms, if at all.

#### RECENT ACCOUNTING PRONOUNCEMENT

In February 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 128 "Earnings Per Share" ("SFAS 128") which requires disclosure of basic earnings per share and diluted earnings per share and is effective for periods ending subsequent to December 15, 1997. The pro forma effect of adoption of SFAS 128 would have no effect on the financial statements.

## OPPORTUNITY FOR PULMONARY DRUG DELIVERY

## MACROMOLECULES

Innovations in biotechnology and recombinant techniques have led to a large increase in the number of macromolecule drugs over the last several years. These drugs, which are identical or similar to the body's natural molecules, are enabling new therapies for many previously untreated or poorly treated diseases. Approximately 30 macromolecule drugs are approved for marketing in the United States and approximately 120 additional macromolecule drugs are in human clinical trials, many for chronic and subchronic diseases. Sales of genetically engineered protein drugs were estimated at \$7.6 billion worldwide in 1995. Worldwide sales of insulin, for example, were estimated at \$2.5 billion in 1995.

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

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

Oral delivery is a common method of delivery for many small molecule drugs. However, drug delivery scientists generally believe that oral delivery provides extremely low delivery system efficiency for most macromolecules. In addition, the Company believes that dosage reproducibility for oral delivery of macromolecules may be very poor because of their low oral bioavailability. While several companies are working on oral delivery for macromolecule drugs, no commercially viable system is currently being marketed.

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

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

Pulmonary drug delivery systems, such as MDIs, existing dry powder inhalers and nebulizers, are used primarily to deliver drugs to the airways of the lung for local lung applications. Approximately 30 drugs are approved for marketing by the FDA for delivery into the lung, but none of these delivery devices was designed to optimize drug delivery to the deep lung for absorption into the bloodstream. Current MDIs, dry powder inhalers and nebulizers typically deliver only a fraction of the drug to the deep lung, with most of the drug being lost in the delivery device or in the mouth and throat. Consequently, the Company

believes that the total efficiency of such systems generally is not high enough to be commercially feasible for systemic delivery of most macromolecule drugs.

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

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

Inhale also believes that opportunities for an integrated pulmonary delivery system exist in the delivery of macromolecules for local lung diseases due to the limitations of current pulmonary devices. Biotechnology and pharmaceutical companies are developing new macromolecule drugs for pulmonary diseases such as asthma, cystic fibrosis, emphysema, lung cancer, pneumonia and bronchitis. Pulmonary delivery is the preferred route for treating most lung diseases, since much smaller amounts of certain drugs generally are needed than for systemic administration and the drug can be applied directly to the site of action, thereby potentially reducing systemic side effects.

#### OTHER MOLECULES

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

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

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

## STRATEGY

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

- DEVELOP A BROADLY APPLICABLE PULMONARY DELIVERY SYSTEM. Inhale is developing its non-invasive pulmonary drug delivery system to be applicable to a wide range of peptides, proteins and other molecules currently delivered by injection or poorly delivered by inhalation or other routes. Inhale intends to develop an effective non-invasive delivery alternative that can: (i) expand market penetration for existing therapeutics currently delivered by injection, infusion or other routes; (ii) commercialize new indications by using pulmonary delivery as a new route of administration; and (iii) extend existing patents or seek new patents to gain important competitive advantages for Inhale and its partners.
- BUILD COMPETITIVE ADVANTAGE THROUGH AN INTEGRATED SYSTEMS APPROACH. The Company is developing a commercially viable pulmonary delivery system through an integrated systems solution. Inhale combines its expertise in aerosol engineering, chemical engineering, mechanical engineering, aerosol science, protein formulations, fine powder processing and powder filling, and pulmonary physiology and biology to build a proprietary, fully-integrated system for pulmonary delivery of therapeutic drugs. The Company believes that building expertise in technology across several disciplines provides it with a significant competitive advantage.
- PARTNER WITH PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES. Inhale's strategy is to market its proposed products through collaborative partners. The Company is seeking to work with partners that have significant clinical development and marketing resources, and currently has collaborations with several large pharmaceutical and biotechnology companies. For patented drug products, Inhale intends to partner with owners or licensees from the outset of the project. For drugs that are off-patent or licensed-in, Inhale may perform initial feasibility screening work, formulations development and early stage human clinical trials before entering into a partner relationship for further development. The Company believes this partnering strategy enables it to reduce its cash requirements while developing a large and diversified potential product portfolio.
- FOCUS ON APPROVED DRUGS. To date, Inhale has focused primarily on drugs that either have proven efficacy and are approved for marketing or are in late stage clinical trials. The Company believes that working primarily with drugs with demonstrated efficacy reduces the technical risk of its projects. In the future, Inhale anticipates working on drugs at earlier stages of development.
- EXPAND MANUFACTURING CAPABILITY. Inhale intends to formulate, manufacture and package dry powders for most of its drugs and to subcontract the manufacture of its device. The Company believes that this strategy will provide manufacturing economies of scale across a range of therapeutic products and expand capacity for additional partnerships and commercial scale production.

## INHALE'S PULMONARY DELIVERY SYSTEM

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

- SYSTEM EFFICIENCY/COST: The system must attain a certain minimum efficiency in delivering a drug to the bloodstream as compared with injection. Bioavailability (the percentage of drug absorbed into the bloodstream from the lungs relative to that absorbed from injection) is the most important element of system efficiency, since it cannot be increased without enhancing the natural permeability of the delivery site. Total system efficiency is critical because of the high cost of macromolecule

drugs. Total system efficiency is determined by the amount of drug loss during manufacture, in the delivery device, in reaching the site of absorption, and during absorption from that site into the bloodstream. Inhale believes that for most systemic macromolecule drugs, a non-invasive delivery system must show total delivery system efficiency of at least 5% to 25% compared to injection for the system to be commercially viable.

- **REPRODUCIBILITY:** The system must deliver a consistent and predictable amount of drug to the lung and into the bloodstream.
- **FORMULATION STABILITY:** Formulations used in the system must remain physically and chemically stable over time and under a range of storage conditions.
- **SAFETY:** The system should not introduce local toxicity problems during chronic or subchronic use by a wide patient population.
- **CONVENIENCE:** The system must be convenient to the patient in terms of comfort, ease of operation, transportability and required dosage time.

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

Inhale has chosen to base its pulmonary delivery system on dry powders for several reasons. Many proteins are more stable in dry powders than in liquids. In addition, dry powder aerosols can carry approximately five times more drug in a single breath than MDI systems and, for many drugs, at least 25 times more than currently marketed liquid or nebulizer systems. The Company believes that a dry powder system for drugs requiring higher doses, such as insulin, alpha-1 antitrypsin and heparin, could decrease dosing time as compared with nebulizers.

Inhale takes bulk drugs supplied by partners and formulates and processes them into fine powders that are then packaged into individual blisters. The blisters are designed to be loaded into Inhale's device, which patients activate to inhale the aerosolized drugs. Once inhaled, the aerosol particles are deposited in the deep lung, dissolved in the alveolar fluid and absorbed into the bloodstream. Although Inhale is in the advanced stages of developing its system technologies, there can be no assurance that the Company's products will ever be successfully commercialized.

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

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

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

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

- **EFFECTIVELY DISPERSE FINE PARTICLES INTO AN AEROSOL CLOUD.** Fine powders have different dispersion requirements than large powders. Most current dry powder inhalers use larger powders and are not efficient in dispersing powders with diameters of one to five microns. Inhale has developed and is refining its dispersion system for its prototype device specifically for fine powders. Inhale's device has been designed to efficiently remove powders from the packaging, effectively break-up the powder particles and create an aerosol cloud while maintaining the integrity of the macromolecule drug.
- **EFFICIENTLY AND REPRODUCIBLY DELIVER THE AEROSOL CLOUD TO THE DEEP LUNG.** Inhale has developed a proprietary aerosol cloud handling system in its device that facilitates deep lung powder deposition and reproducible patient dosing. Its design is intended to enable the aerosolized particles to be transported from the device to the deep lung during a patient's breath, reducing losses in the throat and upper airways. In addition, the aerosol cloud handling system, in combination with the dispersion mechanism and materials used in the device, is designed to decrease powder loss in the device itself.
- **ELIMINATE THE USE OF PROPELLANTS TO AVOID ASSOCIATED ENVIRONMENTAL CONCERNS AND FORMULATION DIFFICULTIES.** Unlike MDIs, the Inhale device does not use propellants. The oily surfactants required to stabilize propellant formulations can cause aggregation of macromolecules. Current chlorofluorocarbon propellants, which are used in most commercial MDI systems, are being phased out in many countries due to environmental concerns.

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

The success of Inhale's pulmonary drug delivery system for any drug will depend upon the Company achieving sufficient formulation stability, safety dosage reproducibility and system efficiency (measured by

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



THERAPEUTIC PRODUCTS UNDER DEVELOPMENT

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

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

STATUS:

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

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

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

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

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

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

\*\* NOT CURRENTLY PARTNERED.

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

## INHALE'S PULMONARY DRUG DELIVERY PROGRAMS IN PROGRESS

Inhale has 14 programs in development, five of which are in human clinical trials and nine of which are sponsored by collaborative partners. In general, the Company's partnership arrangements provide for funding for development, payments upon the achievement of certain milestones and royalty and manufacturing revenues upon the commencement of commercial sales. The arrangements are cancellable by the partner at any time without significant penalty.

**PFIZER PROGRAM.** Insulin is a protein hormone naturally secreted by the pancreas to induce the removal of glucose from the blood. Diabetes, the inability of the body to regulate properly blood glucose levels, is caused by insufficient production of insulin by the pancreas or insufficient use of the insulin that is secreted. Over time, high blood glucose levels can lead to failure of the microvascular system which may lead to blindness, loss of circulation, kidney failure, heart disease or stroke. Insulin currently is marketed only in injectable form. Worldwide sales of insulin were estimated at \$2.1 billion in 1996. Insulin is supplied by various manufacturers, including Eli Lilly and Novo-Nordisk A/S.

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

Regular insulin is generally administered 30 minutes before mealtimes and generally is given only twice a day. A ten-year study by the National Institutes of Health ("NIH"), however, demonstrated that the side effects of diabetes could be significantly reduced by dosing more frequently. The NIH study recommended dosing regular insulin three to four times per day, a regimen which would more closely mirror the action of naturally produced insulin in non-diabetics. However, many patients are reluctant to increase their number of doses because they find injections unpleasant and inconvenient.

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

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

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

**BAXTER PROGRAM.** In March 1996, Inhale entered into a collaboration agreement with Baxter to use Inhale's dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In connection with the collaboration, Baxter made a \$20 million equity investment in Inhale at a 25% premium to the market price of Inhale stock at the time of the investment. Baxter will receive worldwide commercialization rights in exchange for up to an estimated \$60 million in research and

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

In September 1997, Inhale announced that the first compound from its collaboration with Baxter has entered Phase II clinical testing using Inhale's pulmonary delivery system.

**ELI LILLY PROGRAM.** In January 1997, Inhale entered into a collaborative agreement with Lilly to develop pulmonary delivery for a selected osteoporosis product. Osteoporosis is estimated to affect approximately 25 million Americans, mostly women. If not prevented or left untreated, osteoporosis can progress painlessly until a bone breaks. As many as 35,000 people die each year as a result of hip fractures--usually because of complications that result from surgery or from being confined to bed. Associated medical costs of the estimated 1.5 million bone fractures caused annually by osteoporosis are estimated to be about \$10 billion per year in the United States.

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

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

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

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

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

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

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

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

Alpha-1 antitrypsin is approved in the United States and several European countries for augmentation treatment of alpha-1 antitrypsin deficiency. Current treatment is given by systemic intravenous infusion on a weekly basis. This "replacement therapy" consists of a concentrated form of alpha-1 antitrypsin derived from human plasma.

In January 1997, Inhale and Centeon entered into a collaboration to develop a pulmonary formulation of alpha-1 proteinase inhibitor to treat patients with alpha-1 antitrypsin deficiency. Under the terms of the collaboration, Centeon will receive commercialization rights worldwide excluding Japan and Inhale will receive royalties on product sales, an up-front signing fee and up to an estimated \$15 million in research and development funding and milestone payments. Centeon will manufacture the active ingredient for use in Inhale's delivery device. Inhale will manufacture and package the dry powder and supply inhalation devices to Centeon for commercialization and marketing.

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

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

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

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

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

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

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

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

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

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

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

#### MANUFACTURING

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

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

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

products and would have a material adverse effect on the Company. See "Risk Factors--Limited Manufacturing Experience; Risk of Scale-Up."

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

Inhale plans to subcontract the manufacture of its pulmonary delivery devices before commercial production of its first product. The Company has identified contract manufacturers that it believes have the technical capabilities and production capacity to manufacture its devices, and which can meet the requirements of GMP. There can be no assurance that Inhale will be able to obtain and maintain satisfactory contract manufacturing on commercially acceptable terms, if at all. The Company's dependence upon third parties for the manufacture of its potential inhalation device may adversely affect the Company's cost of goods and its ability to develop and commercialize products on a timely and competitive basis.

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

The Company also faces technical challenges in further developing its inhalation device to achieve the efficiency necessary to deliver a broad range of drugs, to produce such a device in quantities sufficient for later stage clinical trials and early commercialization, and to adapt the device as may be required for different powder formulations. There can be no assurance that Inhale will successfully achieve such efficiencies, will be able to produce such quantities or will be able to adapt the device as required. The failure of the Company to overcome any such challenges would have a material adverse effect on the Company. To date, the Company has used small machine shops for production of its prototype inhalation devices. For late stage clinical trials and initial commercial production, the Company intends to use one or more contract manufacturers to produce its device. There can be no assurance that Inhale will be able to enter into or maintain satisfactory contract manufacturing arrangements. The failure of the Company to enter into and maintain such arrangements would have a material adverse effect on the Company. See "Risk Factors--Limited Manufacturing Experience; Risk of Scale-Up."

#### GOVERNMENT REGULATION

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

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

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

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

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

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

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

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

The Company's research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. Although the Company believes that its safety procedures



for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could exceed the resources of the Company. The Company may incur substantial costs to comply with environmental regulations. See "Risk Factors--Hazardous Materials".

Many of the drugs with which the Company is working are already approved for marketing by the FDA. The Company believes that when working with approved drugs, the approval process for delivery by pulmonary delivery may require less time and fewer tests than for new chemical entities. However, the Company expects that its formulations often will use excipients not currently approved for pulmonary use. Use of these excipients will require additional toxicological testing that may increase the costs of, or lengthen the time in, gaining regulatory approval. In addition, regulatory procedures applicable to the Company's products may change as regulators gain experience in the area of macromolecules, and any such changes may delay or increase the cost of regulatory approval.

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

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

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

Prior to marketing a new dosage form of any drug, including one developed for use with the Company's pulmonary drug delivery system, whether or not such drug was already approved for marketing in another dosage form, the product must undergo rigorous pre-clinical and clinical testing and an extensive review process mandated by the FDA and equivalent foreign authorities. These processes generally take a number of years and require the expenditure of substantial resources. None of the Company's proposed products has been submitted to the FDA for marketing approval. The Company has no experience obtaining such regulatory approval, does not have the expertise or other resources to do so and intends to rely on its partners to fund clinical testing and to obtain product approvals.

The time required for completing such testing and obtaining such approvals is uncertain. Further refinement of the device prototype, further scale up of the powder processing system and development of a prototype automated powder filling and packaging system will need to be accomplished before initiation of later stage clinical trials. Any delay in any of these components of product development may delay testing. In addition, delays or rejections may be encountered based upon changes in FDA policy, including the FDA's policy relating to GMP compliance, during the period of product development. Similar delays may also be encountered in other countries. If regulatory approval of a product is granted, such approval may

entail limitations on the indicated uses for which the product may be marketed, and the marketed product, its manufacturer, and its manufacturing facilities remain subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer, including withdrawal of the product from the market. There can be no assurance that regulatory approval will be obtained for any products developed by the Company on a timely basis, or at all. The failure to obtain timely regulatory approval of its products, any product marketing limitations or a product withdrawal would have a material adverse effect on the Company. See "Risk Factors--Government Regulation; Uncertainty of Obtaining Regulatory Approval."

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

In both domestic and foreign markets, sales of the Company's products under development will depend in part upon the availability of reimbursement from third-party payors, such as government health administration authorities, managed care providers, private health insurers and other organizations. In addition, other third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. There can be no assurance that the Company's proposed products will be considered cost effective or that adequate third-party reimbursement will be available to enable Inhale to maintain price levels sufficient to realize an appropriate return on its investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before the Company's proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products. If adequate coverage and reimbursement levels are not provided by the government and third-party payors for the Company's potential products, the market acceptance of these products would be adversely affected, which would have a material adverse effect on the Company. See "Risk Factors-- Uncertainty Related to the Health Care Industry and Third-Party Reimbursement."

#### PATENTS AND PROPRIETARY RIGHTS

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

Inhale expects that its integrated system for the development of pulmonary delivery technology for macromolecule drugs will yield innovations in dry powder formulations, powder processing, powder packaging and device design. It is the Company's strategy to build proprietary positions in each of its technological areas. The Company's success will depend in part upon its ability to protect its proprietary technology from infringement, misappropriation, duplication and discovery. Inhale has filed patent applications covering certain aspects of its device and powder processing technology and powder formulations and pulmonary route of delivery for certain molecules, and plans to file additional patent applications. There can be no assurance that any of the patents applied for by the Company will issue, or that any

patents that issue will be valid and enforceable. Even if such patents are enforceable, the Company anticipates that any attempt to enforce its patents could be time consuming and costly.

The patent positions of pharmaceutical, biotechnology and drug delivery companies, including Inhale, are uncertain and involve complex legal and factual issues. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued. As a consequence, the Company does not know whether any of its patent applications will be circumvented or invalidated. Since patent applications in the United States are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, the Company cannot be certain that it was the first inventor of inventions covered by its issued patents or pending patent applications or that it was the first to file patent applications for such inventions. Moreover, the Company may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial cost to the Company, even if the eventual outcome is favorable to the Company. An adverse outcome could subject the Company to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require the Company to cease using the technology in dispute.

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

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

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

able to obtain such licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any such required license could have a material adverse effect on the Company.

The Company's ability to develop and commercialize its technology will be affected by the Company's or its partners' access to the drugs which are to be formulated. Many biopharmaceutical drugs, including some of those which are presently under development by the Company, are subject to issued and pending United States and foreign patent rights which may be owned by competing entities. There are issued patents and pending patent applications relating to the pulmonary delivery of macromolecule drugs, including several for which the Company is developing pulmonary delivery formulations. Specifically, patents have been granted in the United States and Europe directed to aerosol formulations for the treatment of the lung containing alpha-1 antitrypsin (U.S.) and serine protease inhibitors including alpha-1 antitrypsin (Europe). The Company's development partner for alpha-1 antitrypsin, Centeon, is negotiating with multiple partners to secure rights under these patents. The failure by Centeon to secure rights under these patents could result in the termination of this program by Centeon. The resulting patent situation is highly complex, and the ability of any one company to commercialize a particular biopharmaceutical drug is highly unpredictable. The Company intends generally to rely on the ability of its partners to provide access to the drugs which are to be formulated for pulmonary delivery. There can be no assurance, however, that the Company's partners will be able to provide access to drug candidates for formulation for pulmonary delivery or that, if such access is provided, the Company or its partners will not be accused of, or determined to be, infringing a third party's rights and will not be prohibited from working with the drug or be found liable for damages that may not be subject to indemnification. Any such restriction on access or liability for damages would have a material adverse effect on the Company.

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

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

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

## COMPETITION

The Company believes that products developed using Inhale's technology will compete on the basis of system efficiency, dosage reproducibility, safety, patient convenience and cost. There is intense competition to develop a solution to the non-invasive delivery of drugs from several drug delivery and pharmaceutical companies, many of which are much larger and have far greater resources than Inhale. These include companies working on developing systems for other non-invasive routes of delivery, such as oral, transdermal, bucal, nasal, and needle-less injections, as well as companies working on pulmonary delivery systems. In addition, several companies are working on sustained release injectable systems. While these latter systems involve injections, the lower number of injections could be competitive with Inhale's pulmonary delivery technology in certain applications. The Company believes its technology and integrated pulmonary delivery systems approach provides it with important competitive advantages in the delivery of drugs compared with currently known alternatives. However, new drugs or further developments in alternative drug delivery methods may provide greater therapeutic benefits for a specific drug or indication, or may offer comparable performance at lower cost than the Company's proprietary pulmonary delivery system.

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

The Company's success depends upon maintaining a competitive advantage in the development of products and technologies for pulmonary delivery of pharmaceutical drugs. If a competing company were to develop or acquire rights to a better dry powder pulmonary delivery device or fine powder processing technology, a better system for efficiently and reproducibly delivering macromolecule drugs to the deep lung, a non-invasive drug delivery system which is more attractive for delivering drugs to the deep lung, a non-invasive drug delivery system which is more attractive for the delivery of drugs than pulmonary delivery, or an invasive delivery system which overcomes some of the drawbacks of current invasive systems for chronic or subchronic indications (such as sustained release system), the Company's business could be materially adversely affected.

The Company is in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. The Company is aware of a number of companies currently seeking to develop new products and non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems, bucal and colonic absorption systems. Several of these companies may have developed or be developing dry powder devices that could be used for pulmonary delivery of macromolecules. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than the Company and represent significant competition for the Company. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance competitors' financial, marketing and other resources. Accordingly, the Company's competitors may succeed in developing competing technologies, obtaining FDA approval for products or gain market acceptance more rapidly than the Company. There can be no assurance that developments by others will not render the Company's products or technologies noncompetitive or obsolete. See "Risk Factors--Highly Competitive Industry; Risk of Technological Obsolescence."

## EMPLOYEES

As of September 22, 1997, Inhale had 129 employees, 109 engaged in research and development activities and 20 in general administration and business development. Sixty-eight of the employees hold advanced degrees, of which 28 are Ph.D.s. The Company employs scientists and engineers with expertise in the areas of pulmonary biology, aerosol science, mechanical engineering, protein chemistry and chemical engineering. None of the Company's employees are covered by a collective bargaining agreement and the Company has experienced no work stoppages. Inhale believes that it maintains good relations with its employees.

## RESEARCH AND DEVELOPMENT

Research and development expenditures totaled \$4.9, \$9.0 and \$14.4 million, for the years ended December 31, 1994, 1995 and 1996, respectively. Research and development expenditures funded by partners were approximately \$1.7, \$3.4 and \$6.9 million for the years ended December 31, 1994, 1995 and 1996, respectively.

## PROPERTIES

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

In late 1996, the Company entered into a 15-year lease agreement for a facility totaling approximately 121,000 square feet in Belmont, California. The Company intends to consolidate its operations into this facility over the next twelve months and intends to use the facility as its initial commercial manufacturing site. As of September 23, 1997, approximately one-third of Inhale's employees had moved into this new facility. The lease provides Inhale with an option to lease approximately 100,000 additional square feet in the same facility.

MANAGEMENT

The following table sets forth the names, ages and positions of the executive officers and directors of the Company as of September 30, 1997:

NAME	AGE	POSITION
Robert B. Chess	40	President, Chief Executive Officer and Director
Ajit S. Gill	49	Chief Operating Officer
John S. Patton, Ph.D.	51	Vice President, Research and Director
Robert M. Platz	45	Vice President, Technology
Stephen L. Hurst	42	Vice President, Intellectual Property and Licensing
Judi R. Lum	37	Vice President, Finance and Administration and Chief Financial Officer
Terry L. Opendyck	49	Chairman of the Board of Directors
Mark J. Gabrielson	41	Director
James B. Glavin	62	Director
Melvin Perelman, Ph.D.	66	Director

ROBERT B. CHESS has served as President of the Company since December 1991 and as Chief Executive Officer since May 1992. Mr. Chess was also elected a Director of the Company in May 1992. From September 1990 until October 1991, he was an Associate Deputy Director in the White House Office of Policy Development. In March 1987, Mr. Chess co-founded Penederm Incorporated ("Penederm"), a topical dermatological drug delivery company, and served as its President until February 1989. 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 Harvard Business School.

AJIT S. GILL, Chief Operating Officer, has also served as the Company's Chief Financial Officer from January 1993 until October 1996. 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.

JOHN S. PATTON, PH.D., a co-founder of Inhale, has been Vice President, Research since December 1991 and a Director of the Company since July 1990. He served as President of the Company from its incorporation in July 1990 to December 1991. From 1985 to 1990, Dr. Patton was a Project Team Leader with Genentech, Inc., a biotechnology company, where he headed their non-invasive drug delivery activities. Dr. Patton was on the faculty of the Marine Science and Microbiology Departments at the University of Georgia from 1979 through 1985, where he was granted tenure in 1984. Dr. Patton received a BS in Zoology and Biochemistry from Pennsylvania State University, an MS from the University of Rhode Island, a Ph.D. in Biology from the University of California, San Diego and received post doctorate fellowships in biomedicine from Harvard Medical School and the University of Lund, Sweden.

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

received a BS in biology and an MS in Chemical Engineering from the University of California, Los Angeles.

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

JUDI R. LUM has served as Vice President, Finance and Administration and Chief Financial Officer since October 1996. From July 1995 until joining the Company, she served as Vice President of Finance and Administration for an ophthalmics start-up and previously was Director of Corporate Development for GenPharm International from November 1993 to February 1995. From February 1989 to October 1993, Ms. Lum worked at Raychem Corporation where she held various positions including Director of Finance for the Industrial Sector. She received her BA in Economics from Stanford University in 1981 and an MBA degree from the Stanford University Graduate School of Business in 1986.

TERRY L. OPDENDYK has been the Chairman of the Board of Directors of the Company since August 1991. He served as acting Chief Executive Officer of the Company between August 1991 and May 1992. Mr. Opdendyk has been the Managing General Partner of ONSET Ventures III, a California Limited Partnership, since 1997; a general partner of the general partner of ONSET, a California Limited Partnership, a venture capital limited partnership, since 1984; a general partner of the general partner of ONSET Enterprise Associates, L.P. ("OEA"), a venture capital limited partnership, since 1989; a general partner of the general partner of ONSET Enterprise Associates II, L.P., a venture capital partnership, since 1994; a special limited partner of the general partner of New Enterprise Associates V, Limited Partnership, a venture capital limited partnership, since 1990; and a special limited partner of the general partner of New Enterprise Associates VI, Limited Partnership and New Enterprise Associates VII, Limited, both of which are venture capital limited partnerships, since 1993 and 1996, respectively. From 1980 to 1984, he served as president of VisiCorp, a computer software company. Prior to 1980, Mr. Opdendyk held management positions with Intel Corp., a semiconductor manufacturer, a Hewlett-Packard Co., a computer and peripherals manufacturer. Mr. Opdendyk is a director of several private companies.

MARK J. GABRIELSON has been a director of the Company since May 1992. Since January 1991 he has been a general partner of Prince Ventures, L.P., a venture capital management firm that serves as the general partner of Prince Venture Partners III, L.P. ("Prince"). In addition, Mr. Gabrielson is the President of Pharmaply, Inc., Chairman of Strategic Medical Information, Inc. and Chairman and Chief Executive Officer of Ontyx, Inc. Prior to joining Prince, Mr. Gabrielson served in a variety of marketing and business positions with SmithKline Beecham plc since July 1975. Mr. Gabrielson is a director of Penederm.

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

MELVIN PERELMAN, PH.D. has been a director of the Company since January 1996. Dr. Perelman spent 36 years at Lilly and, most recently as Executive Vice-President and President of Lilly Research Laboratories, a position which he held from 1986 until his retirement in 1993. Dr. Perelman served as President of



Lilly International from 1976 until 1986. Dr. Perelman is a member of the Board of Directors of Cinergy, Inc. and of The Immune Response Corporation.

In addition to the executive officers, the following non-executive officers are considered key employees: Terry Boardman, Vice President, Process Development and Manufacturing; Michael Glembourtt, Vice President, Program Management; Christopher Searcy, Vice President, New Business Opportunities; Adrian Smith, Vice President, Device Development and Manufacturing and Lynn Van Campen, Vice President, Pharmaceutical Development.

SCIENTIFIC ADVISORS

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

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

PRINCIPAL SHAREHOLDERS

The following table sets forth certain information with respect to the beneficial ownership of the Company's outstanding Common Stock as of August 31, 1997, and after the sale of Common Stock offered hereby (assuming no exercise of the Underwriters' over-allotment option) by: (i) each person (or group of affiliated persons) who is known by the Company to own beneficially more than 5% of the Common Stock; (ii) each of the Company's directors; (iii) the Company's Chief Executive Officer and each of the four other most highly compensated executive officers of the Company at December 31, 1996; and (iv) all directors and executive officers of the Company as a group.

NAME	NUMBER OF SHARES(1)	PERCENTAGE BENEFICIALLY OWNED(1)(2)	
		BEFORE OFFERING	AFTER OFFERING
Baxter World Trade Corporation One Baxter Parkway Deerfield, Illinois 60015 (3).....	1,335,987	9.7 %	8.7 %
Franklin Advisers, Inc. 777 Mariners Island Blvd. San Mateo, California 94404 (3).....	988,000	7.2 %	6.5 %
Quantum Partners LDC c/o Soros Fund Management LLC 888 Seventh Avenue, 33rd Floor New York, New York 10106 (3).....	750,000	5.4 %	4.9 %
Pfizer Inc. 235 East 42nd Street New York, New York 10017 (3).....	725,552	5.3 %	4.8 %
Mark J. Gabrielson c/o Prince Venture Partners One Gorham Island Westport, Connecticut 06880 (4).....	701,044	5.1 %	4.6 %
John S. Patton (5).....	423,031	3.1 %	2.8 %
Robert B. Chess (6).....	350,369	2.5 %	2.3 %
Robert M. Platz (7).....	283,010	2.0 %	1.8 %
Ajit S. Gill (8).....	151,531	1.1 %	1.0 %
Terry L. Opdendyk (9).....	132,992	1.0 %	*
James B. Glavin (10).....	51,000	*	*
Stephen L. Hurst (11).....	30,739	*	*
Melvin Perelman (12).....	12,000	*	*
All directors and executive officers as a group (10 persons) (13).....	2,143,090	15.1 %	13.7 %

\* Represents beneficial ownership of less than 1%.

(1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Beneficial ownership for purposes of this table also includes the total number of options to purchase Common Stock exercisable within 60 days after August 31, 1997 held by such persons. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.

(2) Percentage of beneficial ownership is based on 13,768,880 shares of Common Stock outstanding as of September 30, 1997 and 15,268,880 outstanding after completion of this offering.

(3) Information as to shares beneficially owned based solely on information contained in Form 13-D as filed with the Securities and Exchange Commission on or before February 14, 1997 or Form 13-F as filed with the Securities and Exchange Commission on June 30, 1997.

- (4) Includes 677,044 shares held by Prince Venture Partners III ("Prince"). Mr. Gabrielson is a general partner of the general partner of Prince and disclaims beneficial ownership of such shares except to the extent of his pro rata interest therein. Also includes 24,000 shares issuable to Mr. Gabrielson upon the exercise of outstanding options.
- (5) Includes 56,031 shares issuable to Dr. Patton upon the exercise of outstanding options.
- (6) Includes 61,614 shares issuable to Mr. Chess upon the exercise of outstanding options.
- (7) Includes 50,005 shares issuable to Mr. Platz upon the exercise of outstanding options.
- (8) Includes 100,156 shares issuable to Mr. Gill upon the exercise of outstanding options.
- (9) Includes 14,400 shares issuable to ONSET Enterprise Associates, L.P. ("OEA") upon the exercise of outstanding options. Mr. Opdendyk is a general partner of the general partner of OEA and disclaims beneficial ownership of such shares except to the extent of his pro rata interest therein. Also includes 9,600 shares issuable to Mr. Opdendyk upon the exercise of outstanding options.
- (10) Includes 45,000 shares issuable to Mr. Glavin upon the exercise of outstanding options.
- (11) Includes 2,321 shares issuable to Mr. Hurst upon the exercise of outstanding options.
- (12) All shares issuable to Dr. Perelman upon the exercise of outstanding options.
- (13) Includes 382,502 shares issuable upon the exercise of outstanding options.

UNDERWRITING

Under the terms and subject to the conditions contained in the Underwriting Agreement, the form of which is filed as an Exhibit 1.1 to the Registration Statement, of which this Prospectus forms a part, the underwriters named below (the "Underwriters") have severally agreed to purchase from the Company, and the Company has agreed to sell to each Underwriter, the aggregate number of shares of Common Stock set forth opposite the name of each such Underwriter below:

UNDERWRITERS	NUMBER OF SHARES
Lehman Brothers Inc. ....	
BancAmerica Robertson Stephens.....	
Vector Securities International, Inc. ....	
Volpe Brown Whelan & Company, LLC.....	
Total.....	1,500,000

The Company has been advised by the Underwriters that they propose to offer the Common Stock to the public at the offering price set forth on the cover page hereof, and to certain dealers at such public offering price less a selling concession not in excess of \$            per share. The Underwriters may allow, and such dealers may reallocate, a concession of not more than \$            per share to certain other Underwriters or to certain other brokers or dealers. After this offering to the public, the offering price and other selling terms may be changed by the Underwriters.

The Underwriting Agreement provides that the obligations of the several Underwriters to pay for and accept delivery of the shares of Common Stock offered hereby are subject to approval of certain legal matters by counsel and to certain other conditions, including the condition that no stop order suspending the effectiveness of the Registration Statement is in effect and no proceedings for such purpose are pending or threatened by the Securities and Exchange Commission (the "Commission") and that there has been no material adverse change or any development involving a prospective material adverse change in the condition of the Company from that set forth in the Registration Statement otherwise than as set forth or contemplated in this Prospectus, and that certain certificates, opinions and letters have been received from the Company and its counsel and independent auditors. The Underwriters are obligated to take and pay for all of the above shares of Common Stock if any such shares are taken.

The Company and the Underwriters have agreed in the Underwriting Agreement to indemnify each other against certain liabilities, including liabilities under the Securities Act.

The Company has granted to the Underwriters an option to purchase up to an additional 225,000 shares of Common Stock, exercisable solely to cover over-allotments, at the public offering price, less the underwriting discounts and commissions shown on the cover page of this Prospectus. Such option may be exercised at any time until 30 days after the date of the Underwriting Agreement. To the extent that the option is exercised, each Underwriter will be committed to purchase a number of the additional shares of Common Stock proportionate to such Underwriter's initial commitment as indicated in the preceding table.

The Underwriters have informed the Company that they do not intend to confirm sales to accounts over which they exercise discretionary authority.

Until the distribution of the Common Stock is completed, rules of the Commission may limit the ability of the Underwriters and certain selling group members to bid for and purchase shares of Common Stock. As an exception to these rules, the Underwriters are permitted to engage in certain transactions that stabilize the price of the Common Stock. Such transactions may consist of bids or purchases for the purpose of pegging, fixing or maintaining the price of the Common Stock. In addition, if the Underwriters

over-allot (i.e., if they sell more shares of Common Stock than are set forth on the cover page of this Prospectus), and thereby create a short position in the Common Stock in connection with the offering, the Underwriters may reduce that short position by purchasing Common Stock in the open market. The Underwriters may also elect to reduce any short position by exercising all or part of the over-allotment option described herein.

The Underwriters may also impose a penalty bid on selling group members. This means that if the Underwriters purchase shares of Common Stock in the open market to reduce the Underwriters' short position or to stabilize the price of the Common Stock, they may reclaim the amount of the selling concession from the selling group members who sold those shares as part of the offering. In general, purchases of a security for the purpose of stabilization or to reduce a syndicate short position could cause the price of the security to be higher than it might otherwise be in the absence of such purchases. The imposition of a penalty bid might have an effect on the price of a security to the extent that it were to discourage resales of the security by purchasers in the offering. Neither the Company nor any of the Underwriters makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the Common Stock. In addition, the Company may not make any representation that the Underwriters will engage in such transactions or that such transactions, once commenced, will not be discontinued without notice.

The Underwriters and dealers may engage in passive market marking transactions in the Common Stock in accordance with Rule 103 of Regulation M promulgated by the Commission. In general, a passive market maker may not bid for, or purchase, the Common Stock at a price that exceeds the highest independent bid. In addition, the net daily purchases made by any passive market maker generally may not exceed 30% of its average daily trading volume in the Common Stock during a specified two month prior period, or 200 shares, whichever is greater. A passive market maker must indemnify passive market making bids as such on the Nasdaq electronic inter-dealer reporting system. Passive market making may stabilize or maintain the market price of the Common Stock above independent market levels. Underwriters and dealers are not required to engage in passive market and may end passive market making activities at any time.

Shareholders of the Company beneficially owning an aggregate of approximately 1,083,544 shares of Common Stock have agreed not to offer, sell or otherwise dispose of their shares, with certain limited exceptions, upon the expiration of 90 days after the date of this offering without the prior written consent of Lehman Brothers Inc. Except for the Common Stock to be sold in the offering, the Company has agreed not to offer, sell, contract to sell or otherwise issue any Common Stock or other capital stock or any securities convertible into or exchangeable for, or any rights to acquire, Common Stock or other capital stock, with certain limited exceptions prior to the expiration of 90 days from the date of this Prospectus without the prior written consent of Lehman Brothers Inc.

#### LEGAL MATTERS

The validity of the shares of Common Stock offered hereby will be passed upon for the Company by Cooley Godward LLP, Menlo Park, California ("Cooley Godward"). Mark P. Tanoury, a partner of Cooley Godward, is Secretary of the Company. Certain legal matters will be passed upon for the Underwriters by Heller Ehrman White & McAuliffe, Palo Alto, California.

#### EXPERTS

The financial statements of the Company at December 31, 1995 and 1996 and for each of the three years in the period ended December 31, 1996, appearing in this Prospectus and the Registration Statement have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon appearing elsewhere herein and are included in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

The financial statements of Inhale Therapeutic Systems appearing in the Company's Annual Report (Form 10-K) for the year ended December 31, 1996, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

#### ADDITIONAL INFORMATION

The Company has filed a Registration Statement on Form S-3 under the Securities Act, including amendments thereto, (the "Registration Statement") relating to the Common Stock offered hereby with the Securities and Exchange Commission, Washington, D.C. This Prospectus does not contain all of the information set forth in the Registration Statement and the exhibits and schedules thereto certain portions of which have been omitted pursuant to the rules and regulations of the Commission. Statements contained in this Prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the Registration Statement, each such statement being qualified in all respects by such reference. For further information with respect to the Company and the Common Stock offered hereby, reference is made to such Registration Statement, exhibits and schedules thereto. A copy of the Registration Statement may be inspected by anyone without charge at the Commission's principal office at 450 Fifth Street, N.W., Washington, D.C. 20549, and copies of all or any part thereof may be obtained from the Public Reference Section, Securities and Exchange Commission, Washington, D.C. 20549 upon the payment of certain prescribed fees.

#### AVAILABLE INFORMATION

The Company is subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in accordance therewith, files reports, proxy statements and other information with the Commission. Such reports, proxy statements and other information filed by the Company may be inspected and copied at the Commission's Public Reference Section located at 450 Fifth Street, N.W., Washington, D.C. 20549, and at the Commission's regional offices located at 7 World Trade Center, Suite 1300, New York, New York 10048, and 500 West Madison Street, Chicago, Illinois 60661. Copies of such material also can be obtained from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. The Commission also makes electronic filings publicly available on the Internet. The Commission's Internet address is <http://www.sec.gov>. The Commission's Web site also contains reports, proxy and information statements and other information regarding the Company that has been filed with the Commission. The Common Stock of the Company is quoted on the Nasdaq National Market. Reports, proxy statements and other information concerning the Company may be inspected at the National Association of Securities Dealers, Inc. at 1735 K Street, N.W., Washington, D.C. 20006.

#### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The following documents, filed with the Commission under the Exchange Act (File No. 0-23566), are hereby incorporated by reference into this Prospectus:

- a) The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1996, filed on or about March 26, 1997 including all material incorporated by reference therein;
- b) The Company's Current Report on Form 8-K, filed on or about February 6, 1997;
- c) The Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 1997, filed on or about May 13, 1997, including all material incorporated by reference therein;

d) The Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1997, filed on or about August 12, 1997, including all material incorporated by reference therein; and

e) The Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1997, filed on or about October 3, 1997, including all material incorporated by reference therein; and

f) The description of the Common Stock contained in the Company's Registration Statement on Form 8-A.

The footnote disclosure in note 6 to the financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1996 has been updated with respect to additional items occurring after the filing of the Form 10-K. See note 6 in the financial statements included in this Prospectus and Registration Statement at F-17.

All documents filed by the Company pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this Prospectus and prior to the termination of the offering shall be deemed to be incorporated by reference herein and to be a part hereof from the date of filing of such documents. Any statement contained in this Prospectus or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Prospectus to the extent that a statement contained herein or in any subsequently-filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Prospectus.

The Company will provide without charge to each person, including any beneficial owner, to whom this Prospectus is delivered, upon written or oral request of such person, a copy of any and all of the documents that have been incorporated by reference herein (not including exhibits to such documents unless such exhibits are specifically incorporated by reference herein or into such documents). Such request may be directed to: Investor Relations, Inhale Therapeutic Systems, 1525 Industrial Way, Belmont, California 94002.

INHALE THERAPEUTIC SYSTEMS  
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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Shareholders of  
Inhale Therapeutic Systems

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

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

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

ERNST & YOUNG LLP

Palo Alto, California  
February 10, 1997

INHALE THERAPEUTIC SYSTEMS

BALANCE SHEETS

(IN THOUSANDS)

ASSETS

	DECEMBER 31,		SEPTEMBER 30,
	1995	1996	1997
			(UNAUDITED)
Current assets:			
Cash and cash equivalents.....	\$ 3,834	\$ 18,568	\$ 9,627
Short-term investments.....	16,093	17,741	48,032
Note receivable.....	--	--	5,000
Other current assets.....	487	1,239	1,699
Total current assets.....	20,414	37,548	64,358
Property and equipment, net.....	2,660	3,770	10,355
Deposits and other assets.....	174	174	135
	\$ 23,248	\$ 41,492	\$ 74,848

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:			
Accounts payable.....	\$ 717	\$ 1,130	\$ 1,884
Accrued liabilities.....	899	1,746	3,077
Accrued compensation.....	274	479	1,069
Deferred revenue.....	578	2,723	8,508
Equipment financing obligations--current portion.....	245	166	77
Total current liabilities.....	2,713	6,244	14,615
Equipment financing obligations.....	353	187	148
Accrued rent.....	--	--	240
Commitments			
Shareholders' equity:			
Preferred stock, 10,000 shares authorized, no shares issued or outstanding.....	--	--	--
Common stock, no par value; 30,000 shares authorized; 10,142, 11,835 and 13,769 shares issued and outstanding at December 31, 1995 and 1996, and September 30, 1997, respectively.....	38,202	62,840	94,529
Deferred compensation.....	(250)	(88)	--
Accumulated deficit.....	(17,770)	(27,691)	(34,684)
Total shareholders' equity.....	20,182	35,061	59,845
	\$ 23,248	\$ 41,492	\$ 74,848

See accompanying notes

INHALE THERAPEUTIC SYSTEMS

STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)

	YEARS ENDED DECEMBER 31,			NINE MONTHS ENDED SEPTEMBER 30,	
	1994	1995	1996	1996	1997
	(UNAUDITED)				
Contract research revenue.....	\$ 1,651	\$ 3,445	\$ 6,890	\$ 4,722	\$ 11,459
Operating costs and expenses:					
Research and development.....	4,934	9,041	14,376	10,129	16,640
General and administrative.....	2,465	3,232	4,004	2,341	4,244
Total operating costs and expenses.....	7,399	12,273	18,380	12,470	20,884
Loss from operations.....	(5,748)	(8,828)	(11,490)	(7,748)	(9,425)
Interest income.....	592	1,252	1,638	1,156	2,453
Interest expense.....	(123)	(86)	(57)	(47)	(21)
Net loss.....	\$ (5,279)	\$ (7,662)	\$ (9,909)	\$ (6,639)	\$ (6,993)
Net loss per share.....	\$ (0.86)	\$ (0.78)	\$ (0.88)	\$ (0.60)	\$ (0.52)
Shares used in net loss per share calculation.....	6,103	9,837	11,207	11,025	13,417

See accompanying notes

INHALE THERAPEUTIC SYSTEMS

STATEMENT OF SHAREHOLDERS' EQUITY

(IN THOUSANDS)

	PREFERRED STOCK		COMMON STOCK		DEFERRED COMPENSATION	ACCUMULATED DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT		
Balance at December 31, 1993.....	2,909	\$ 10,697	934	\$ 23	\$ --	\$ (4,829)
Conversion of Series A, B, and C convertible preferred stock to common stock.....	(2,909)	(10,697)	5,236	10,697	--	--
Issuance of common stock in initial public offering, net of issuance costs of \$1,698.....	--	--	2,150	14,427	--	--
Deferred compensation related to the issuance of certain stock options granted to employees.....	--	--	--	760	(760)	--
Amortization of deferred compensation.....	--	--	--	--	348	--
Exercise of stock options for cash by employees and consultants.....	--	--	336	40	--	--
Net loss.....	--	--	--	--	--	(5,279)
Balance at December 31, 1994.....	--	--	8,656	25,947	(412)	(10,108)
Issuance of common stock in connection with a collaborative agreement.....	--	--	453	5,000	--	--
Issuance of common stock in follow-on offering, net of issuance costs of \$757.....	--	--	1,000	7,243	--	--
Amortization of deferred compensation.....	--	--	--	--	162	--
Exercise of stock options for cash by employees and consultants.....	--	--	33	12	--	--
Net loss.....	--	--	--	--	--	(7,662)
Balance at December 31, 1995.....	--	--	10,142	38,202	(250)	(17,770)
Issuance of common stock in connection with collaborative agreements, net of issuance costs of \$806.....	--	--	1,608	24,196	--	--
Amortization of deferred compensation.....	--	--	--	--	162	--
Exercise of stock options for cash by employees and consultants.....	--	--	85	442	--	--
Unrealized loss on securities held as available-for-sale.....	--	--	--	--	--	(12)
Net loss.....	--	--	--	--	--	(9,909)
Balance at December 31, 1996.....	--	--	11,835	62,840	(88)	(27,691)
Issuance of common stock for cash in connection with private placement, net of issuance costs of \$1,940 (unaudited)....	--	--	1,800	30,460	--	--
Issuance of common stock in connection with licensing agreement (unaudited).....	--	--	28	600	--	--
Issuance of common stock upon exercise of stock options for cash (unaudited).....	--	--	106	629	--	--
Amortization of deferred compensation (unaudited).....	--	--	--	--	88	--
Net loss (unaudited).....	--	--	--	--	--	(6,993)
Balance at September 30, 1997 (unaudited)..	--	\$ --	13,769	\$ 94,529	\$ --	\$ (34,684)

TOTAL  
SHAREHOLDERS'  
EQUITY

Balance at December 31, 1993.....	\$ 5,891
Conversion of Series A, B, and C convertible preferred stock to common stock.....	--
Issuance of common stock in initial public offering, net of issuance costs of \$1,698.....	14,427
Deferred compensation related to the issuance of certain stock options granted to employees.....	--
Amortization of deferred compensation.....	348
Exercise of stock options for cash by employees and consultants.....	40
Net loss.....	(5,279)
Balance at December 31, 1994.....	15,427
Issuance of common stock in connection with a collaborative agreement.....	5,000
Issuance of common stock in follow-on offering, net of issuance costs of \$757.....	7,243
Amortization of deferred compensation.....	162
Exercise of stock options for cash by	

employees and consultants.....	12
Net loss.....	(7,662)
	-----
Balance at December 31, 1995.....	20,182
Issuance of common stock in connection with collaborative agreements, net of issuance costs of \$806.....	24,196
Amortization of deferred compensation.....	162
Exercise of stock options for cash by employees and consultants.....	442
Unrealized loss on securities held as available-for-sale.....	(12)
Net loss.....	(9,909)
	-----
Balance at December 31, 1996.....	35,061
Issuance of common stock for cash in connection with private placement, net of issuance costs of \$1,940 (unaudited)....	30,460
Issuance of common stock in connection with licensing agreement (unaudited).....	600
Issuance of common stock upon exercise of stock options for cash (unaudited).....	629
Amortization of deferred compensation (unaudited).....	88
Net loss (unaudited).....	(6,993)
	-----
Balance at September 30, 1997 (unaudited)..	\$ 59,845
	-----
	-----

See accompanying notes

INHALE THERAPEUTIC SYSTEMS

STATEMENTS OF CASH FLOWS

INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS

(IN THOUSANDS)

	YEARS ENDED DECEMBER 31,			NINE MONTHS ENDED SEPTEMBER 30,	
	1994	1995	1996	1996	1997
				(UNAUDITED)	
<b>CASH FLOWS USED IN OPERATING ACTIVITIES</b>					
Net loss.....	\$ (5,279)	\$ (7,662)	\$ (9,909)	\$ (6,639)	\$ (6,993)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization.....	539	955	1,071	780	1,611
Amortization of deferred compensation.....	348	162	162	122	88
Increase in other current assets, deposits and other assets.....	(317)	(110)	(752)	(1,643)	(5,421)
Increase (decrease) in accounts payable and accrued liabilities.....	696	847	1,465	(70)	2,915
Increase in deferred revenue.....	8	483	2,145	780	5,785
Net cash used in operating activities.....	(4,005)	(5,325)	(5,818)	(6,670)	(2,015)
<b>CASH FLOWS USED IN INVESTING ACTIVITIES</b>					
Purchases of short-term investments.....	(22,786)	(49,318)	(58,993)	(39,118)	(281,447)
Sales of short-term investments.....	4,102	7,812	2,020	2,020	1,100
Maturities of short-term investments.....	18,601	29,326	55,313	30,782	250,056
Purchases of property and equipment, net.....	(1,371)	(1,340)	(2,181)	(1,608)	(8,196)
Net cash used in investing activities.....	(1,454)	(13,520)	(3,841)	(7,924)	(38,487)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>					
Payments of equipment loan obligations.....	(27)	(32)	(52)	(35)	(55)
Payments of capital lease obligations.....	(154)	(205)	(193)	(166)	(73)
Issuance of equipment loan obligations.....	--	151	--	--	--
Issuance of common stock, net of issuance costs.....	14,467	12,255	24,638	19,592	31,689
Net cash provided by financing activities.....	14,286	12,169	24,393	19,391	31,561
Net increase (decrease) in cash and cash equivalents....	8,827	(6,676)	14,734	4,797	(8,941)
Cash and cash equivalents at beginning of period.....	1,683	10,510	3,834	3,834	18,568
Cash and cash equivalents at end of period.....	\$ 10,510	\$ 3,834	\$ 18,568	\$ 8,631	\$ 9,627

See accompanying notes

INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997  
AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

NOTE 1--ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

ORGANIZATION AND BASIS OF PRESENTATION

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

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

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

INTERIM FINANCIAL INFORMATION

The financial information at September 30, 1997 and for the nine months ended September 30, 1996 and 1997 has been prepared in accordance with generally accepted accounting principles for interim financial information. Such information is unaudited but includes all adjustments (consisting only of normal recurring adjustments) which the Company considers necessary for a fair presentation of the financial position at such date and the operating results and cash flows for those periods. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for a full fiscal year.

CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

The Company considers all highly liquid investments with a maturity from date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include demand deposits held in banks and interest bearing money market funds. All other liquid investments are classified as short-term investments. Short-term investments consist of federal and municipal government securities, repurchase agreements or corporate commercial paper with A1 or P1 short-term ratings and A or better long-term ratings with remaining maturities at date of purchase of greater than 90 days and less than one year. The Company limits its concentration of risk by diversifying its investments among a variety of industries and issuers. The Company has experienced no losses on its investments.

At September 30, 1997 and December 31, 1996 and 1995, all short-term investments are designated as available-for-sale and are carried at fair value, with material unrealized gains and losses, if any, reported in shareholders' equity. The amortized cost of securities is adjusted for amortization of material premiums and accretion of discounts to maturity. Such amortization, if any, is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if

INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997 AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

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

The following is a summary of available-for-sale securities as of September 30, 1997 (unaudited):

AVAILABLE-FOR-SALE SECURITIES			
COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
(IN THOUSANDS)			
Obligations of U.S. government agencies.....	\$ 19,997	\$ --	\$ 19,997
U.S. corporate commercial paper.....	28,035	--	28,035
Repurchase agreements, secured by U.S. government securities.....	3,860	--	3,860
Corporate repurchase agreements.....	4,490	--	4,490
Other.....	17	--	17
	\$ 56,399	\$ --	\$ 56,399
Amounts included in cash and cash equivalents.....	\$ 8,367	\$ --	\$ 8,367
Amounts included in short-term investments.....	48,032	--	48,032
	\$ 56,399	\$ --	\$ 56,399

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

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



INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997 AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

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

The following is a summary of available-for-sale securities as of December 31, 1995:

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

The gross realized losses and gains on the sale of securities available-for-sale during the years ended December 31, 1996 and 1995, and the nine month periods ended September 30, 1997 and 1996, were not material. As of September 30, 1997, the contractual maturity of any single investment did not exceed one year (nine and six months at December 31, 1996 and 1995, respectively).

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

PROPERTY AND EQUIPMENT

Property and equipment is stated at cost and consists of the following (in thousands):

	SEPTEMBER 30, 1997	DECEMBER 31, 1996      1995	
	(UNAUDITED)		
Laboratory and other equipment.....	\$ 6,384	\$ 3,679	\$ 1,997
Leasehold improvements.....	7,749	2,258	1,759
Leased equipment.....	677	677	677
	<u>14,810</u>	<u>6,614</u>	<u>4,433</u>
Less accumulated depreciation and amortization.....	(4,455)	(2,844)	(1,773)
	<u>\$ 10,355</u>	<u>\$ 3,770</u>	<u>\$ 2,660</u>

INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997  
AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

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

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

REVENUE RECOGNITION

Contract revenue from collaborative research agreements is recorded when earned and as the related costs are incurred. Payments received which are related to future performance are deferred and recognized as revenue when earned over future performance periods. In accordance with contract terms, up front and milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements, and accordingly, are generally deferred when received and recognized as revenue based on actual efforts expended over the remaining terms of the agreements. The Company's research revenue is derived primarily from clients in the pharmaceutical and biotechnology industries. Contract research revenue from two partners represented 77% and 14% of the Company's revenue in 1996. Contract revenue from two partners accounted for 78% and 13% of the Company's revenue in 1995, and two partners accounted for 56% and 18% of the Company's revenue in 1994. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

STOCK-BASED COMPENSATION

In accordance with the provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("FAS 123"), the Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and related interpretations in accounting for its employee stock options plans. Under APB 25, if the exercise price of the Company's employee stock options equals or exceeds the fair value of the underlying stock on the date of grant as determined by the Company's Board of Directors, no compensation expense is recognized.

RESEARCH AND DEVELOPMENT AGREEMENTS

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

INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997  
AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

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

The Company accounts for income taxes under Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" (Statement 109). Under Statement 109, the liability method is used in accounting for income taxes.

NET LOSS PER SHARE

The net loss per common share is computed based upon the weighted average number of common shares outstanding. Common equivalent shares are not included in the per share calculations where the effect of their inclusion would be antidilutive.

In February 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 128 "Earnings Per Share" ("SFAS 128") which requires disclosure of basic earnings per share and diluted earnings per share and is effective for periods ending subsequent to December 15, 1997. The pro forma effect of adoption of SFAS 128 would have no effect on the financial statements.

NOTE 2--COMMITMENTS AND EQUIPMENT FINANCING OBLIGATIONS

The Company leases its office and laboratory facilities under several arrangements expiring through the year 2012. Rent expense was approximately \$416,000, \$217,000 and \$185,000 for the years ended December 31, 1996, 1995 and 1994, respectively.

Included in property and equipment at December 31, 1996 and 1995, are assets with costs of \$677,000 acquired pursuant to capital lease obligations and equipment loans secured by the equipment with interest rates ranging from 14% to 18% per annum. Accumulated amortization of assets acquired pursuant to these equipment financing obligations was approximately \$658,000 and \$541,000 at December 31, 1996 and 1995,

INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997 AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

NOTE 2--COMMITMENTS AND EQUIPMENT FINANCING OBLIGATIONS (CONTINUED) respectively. Future noncancellable commitments under equipment financing obligations and operating leases at December 31, 1996 are as follows:

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

The above operating lease amounts have been reduced by \$435,000 during the nine months ended September 30, 1997.

NOTE 3--SHAREHOLDERS' EQUITY

COMMON STOCK

EMPLOYEE STOCK PURCHASE PLAN

In February 1994, the Company's Board of Directors adopted the Employee Stock Purchase Plan (the "Purchase Plan"). Under the Purchase Plan, 150,000 shares of common stock have been reserved for purchase by the Company's employees pursuant to section 423(b) of the Internal Revenue Code of 1986. As of December 31, 1996 and September 30, 1997, no shares of common stock have been issued under the Purchase Plan.

STOCK OPTION PLANS

EQUITY INCENTIVE PLAN

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

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997  
AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

NOTE 3--SHAREHOLDERS' EQUITY (CONTINUED)

qualified stock options, restricted stock purchase awards, stock bonuses and stock appreciation rights to consultants, employees, officers and employee directors.

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

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

NON-EMPLOYEE DIRECTORS' STOCK OPTION PLAN

In February 1994, the Company's Board of Directors adopted the Non-employee Directors' Stock Option Plan under which options to purchase up to 200,000 shares of the Company's common stock at fair market value may be granted to the Company's non-employee directors. During the year ended December 31, 1996, options to purchase a total of 60,000 shares were granted to non-employee directors of the Company at an exercise price ranging from \$10.13 to \$17.50 per share. As of December 31, 1996, options on 6,000 shares had been exercised and options to purchase 81,000 shares were exercisable.

INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997 AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

NOTE 3--SHAREHOLDERS' EQUITY (CONTINUED)

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

	OPTIONS AVAILABLE FOR GRANT	OPTIONS OUTSTANDING		WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE
		NUMBER OF SHARES	EXERCISE PRICE PER SHARE	
(IN THOUSANDS, EXCEPT PER SHARE INFORMATION)				
Balance at December 31, 1993.....	1,212	484	\$ 0.06-15.25	\$ 0.12
Shares authorized.....	690	--	--	--
Options granted.....	(708)	708	0.22-10.25	5.43
Options exercised.....	--	(336)	0.06-0.56	0.12
Options canceled.....	8	(8)	0.22-10.25	5.39
Balance at December 31, 1994.....	1,202	848	0.06-15.25	4.50
Options granted.....	(428)	428	7.63-12.00	9.34
Options exercised.....	--	(33)	0.06-2.78	0.36
Options canceled.....	10	(10)	0.22-10.00	1.84
Balance at December 31, 1995.....	784	1,233	0.06-15.25	6.32
Shares authorized.....	1,500	--	--	--
Options granted.....	(620)	620	10.13-19.25	14.05
Options exercised.....	--	(85)	0.06-12.00	5.22
Options canceled.....	109	(109)	0.31-15.25	8.33
Balance at December 31, 1996.....	1,773	1,659	0.06-19.25	9.13
Options granted (unaudited).....	(635)	635	16.13-22.75	18.98
Options exercised (unaudited).....	--	(106)	0.06-16.13	5.95
Options canceled (unaudited).....	32	(32)	0.56-19.25	15.56
Balance at September 30, 1997 (unaudited).....	1,170	2,157	\$ 0.06-22.75	\$ 12.10

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

INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997 AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

NOTE 3--SHAREHOLDERS' EQUITY (CONTINUED)

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

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
	NUMBER	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	NUMBER	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE
(IN THOUSANDS, EXCEPT PER SHARE AND YEAR INFORMATION)					
\$ 0.06- 5.56.....	483	\$ 3.21	6.88	244	\$ 1.83
5.75- 9.13.....	435	8.04	7.95	166	7.76
9.88-14.50.....	484	11.66	9.03	86	10.96
15.25-19.25.....	257	17.32	9.55	18	17.80
	-----	-----	---	---	-----
\$ 0.06-19.25.....	1,659	\$ 9.13	8.20	514	\$ 5.83
	-----	-----	---	---	-----
	-----	-----	---	---	-----

Pro forma information regarding net loss and loss per share is required by Statement 123, which also requires that the information be determined as if the Company has accounted for its employee stock options granted subsequent to December 31, 1994 under the fair value method of that Statement. The fair value for these options was estimated at the date of grant using a Black-Sholes option pricing model with the following weighted-average assumptions for 1995 and 1996: risk-free interest rate of 6.4%; a dividend yield of 0.0%; volatility factors of the expected market price of the Company's common stock of 0.62; and a weighted-average expected life of 6 years.

The Black-Sholes options valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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

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

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

INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997 AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

NOTE 3--SHAREHOLDERS' EQUITY (CONTINUED)  
WARRANTS

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

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

RESERVED SHARES

A total of 4,152,727 shares of common stock have been reserved for issuance at December 31, 1996 for the various equity incentive plans and the warrants.

NOTE 4--INCOME TAXES

As of December 31, 1996, the Company had federal net operating loss carryforwards of approximately \$23.0 million. The net operating loss and credit carryforwards will expire at various dates beginning in 2006 through 2011 if not utilized.

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

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

Because of the Company's lack of earnings history, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$3.0 million during the year ended December 31, 1995. The deferred tax assets, all of which are offset by a valuation allowance, have increased through September 30, 1997 due to continuing losses.



INHALE THERAPEUTIC SYSTEMS

NOTES TO FINANCIAL STATEMENTS (CONTINUED)

DECEMBER 31, 1996

(INFORMATION WITH RESPECT TO THE NINE MONTHS ENDED SEPTEMBER 30, 1996 AND 1997 AND AS OF SEPTEMBER 30, 1997 IS UNAUDITED)

NOTE 4--INCOME TAXES (CONTINUED)

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

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

	YEARS ENDED DECEMBER 31,		
	1996	1995	1994
Supplemental disclosure of cash flows information:			
Interest paid.....	\$ 57	\$ 86	\$ 123
Deferred compensation related to the issuance of certain stock options.....	\$ --	\$ --	\$ 760

NOTE 6--SUBSEQUENT EVENTS (UNAUDITED)

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

In April 1997 the Company provided the landlord of its facility in Belmont, California a short term loan of \$5.0 million. The loan bears interest at 8.5%. The Company receives monthly interest payments and the principal is due and payable at the end of the six-month loan term. In addition, the loan is secured by a deed of trust on the facility. The loan is recorded on the balance sheet at September 30, 1997 as a note receivable.

In October 1997 the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission for an underwritten public offering of up to 1,725,000 shares of common stock. The registration statement has not yet become effective and there can be no assurance that the offering will be completed.

[COMPANY LOGO]

THE HEADING "ABSORPTION OF MACROMOLECULE DRUGS IN THE DEEP LUNG" OVER PICTURE OF CLUSTER OF ALVEOLI AND MAGNIFICATION OF THE PROCESS OF TRANSCYTOSIS AND THE FOLLOWING CAPTION: "AEROSOL PARTICLE IN ALVEOLUS DISSOLVES IN SURFACE FLUID ALLOWING MACROMOLECULES TO BE TRANSPORTED NATURALLY THROUGH THE ALVEOLAR EPITHELIAL AND CAPILLARY ENDOTHELIAL CELLS INTO THE BLOOD THROUGH TRANSCYTOSIS."

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NO DEALER, SALES REPRESENTATIVE OR ANY OTHER PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS IN CONNECTION WITH THIS OFFERING OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATIONS MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY OF THE UNDERWRITERS. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OTHER THAN THE SHARES OF COMMON STOCK TO WHICH IT RELATES OR AN OFFER TO, OR A SOLICITATION OF, ANY PERSON IN ANY JURISDICTION IN WHICH SUCH AN OFFER OR SOLICITATION WOULD BE UNLAWFUL. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL, UNDER ANY CIRCUMSTANCES, CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY OR THAT THE INFORMATION CONTAINED HEREIN IS CORRECT AS OF ANY TIME SUBSEQUENT TO THE DATE HEREOF.

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1,500,000 SHARES

[LOGO]

COMMON STOCK

-----  
 PROSPECTUS  
 , 1997

-----  
 LEHMAN BROTHERS

BANCAMERICA ROBERTSON STEPHENS

VECTOR SECURITIES INTERNATIONAL, INC.

VOLPE BROWN WHELAN & COMPANY

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PART II  
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by the Registrant in connection with the sale of the Common Stock being registered. All the amounts shown are estimates except for the registration fee and the NASD filing fee.

Registration fee.....	\$ 16,107
NASD filing fee.....	5,186
Nasdaq listing fee.....	17,500
Blue sky qualification fees and expenses.....	5,000
Printing and engraving expenses.....	150,000
Legal fees and expenses.....	100,000
Accounting fees and expenses.....	50,000
Transfer agent and registrar fees.....	5,000
Miscellaneous.....	151,207
	-----
Total.....	\$ 500,000
	-----
	-----

ITEM 15. INDEMNIFICATION OF OFFICERS AND DIRECTORS.

The Registrant's Bylaws provide that the Registrant shall indemnify its directors and executive officers and may indemnify its officers, employees and other agents to the fullest extent permitted by California law. The Registrant 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. Pursuant to California law, the Registrant's directors shall not be liable for monetary damages for breach of the directors' fiduciary duty of care of the Registrant and its shareholders. However, this provision does not eliminate the duty of care, and in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under California law. In addition, each director will continue to be subject to liability for (i) acts or omissions that involve intentional misconduct or a knowing and culpable violation of law, (ii) acts or omissions that a director believes to be contrary to the best interests of the Company or its shareholders or that involve the absence of good faith on the part of the director, (iii) any transaction from which a director derived an improper personal benefit, (iv) any transaction that constitutes an illegal distribution or dividend under California law, and (vii) any transaction involving an unlawful conflict of interest between the director and the Registrant under California law. 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.

The Underwriting Agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the Underwriters of the Registrant and its officers and directors for certain liabilities arising under the Securities Act or otherwise.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits.

EXHIBIT	EXHIBIT TITLE
-----	
*1.1	Form of Underwriting Agreement
3.1(3)	Restated Articles of Incorporation of the Registrant.
3.2(1)	Bylaws of the Registrant.
4.1	Reference is made to Exhibits 3.1 through 3.2.

## EXHIBIT

## EXHIBIT TITLE

- 
- 4.2(1) Restated Investor Rights Agreement among the Registrant and certain other persons named therein, dated April 29, 1993, as amended October 29, 1993.
- 4.5(1) Warrant to purchase 18,182 Shares of Series C Preferred Stock between the Registrant and Phoenix Leasing Incorporated, dated October 29, 1993.
- 4.6(1) Specimen stock certificate.
- 4.9(2) Stock Purchase Agreement between the Registrant and Pfizer Inc., dated January 18, 1995.
- 4.10(8) Warrant to purchase 10,000 shares of Common Stock between the Registrant and Thomas J. Peirona, dated November 1, 1996.
- 4.11(8) Warrant to purchase 10,000 shares of Common Stock between the Registrant and Kiet Nguyen, dated November 1, 1996.
- 4.12(9) Form of Stock Purchase Agreement between the Registrant and the Selling Shareholders dated January 28, 1997.
- \*5.1 Opinion of Cooley Godward LLP.
- 10.1(4) Registrant's 1994 Equity Incentive Plan (the "Equity Incentive Plan").
- 10.2(1) Form of Incentive Stock Option under the Equity Incentive Plan.
- 10.3(1) Form of Nonstatutory Stock Option under the Equity Incentive Plan.
- 10.4(7) Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended.
- 10.5(1) Registrant's 1994 Employee Stock Purchase Plan.
- 10.6(1) Standard Industrial Lease between the Registrant and W.F. Batton & Co., Inc., dated September 17, 1992, as amended September 18, 1992.
- 10.7(1) Master Equipment Lease between the Registrant and Phoenix Leasing Incorporated, dated August 15, 1992 and Schedules i to 4 thereto.
- 10.8(1) Senior Loan and Security Agreement between the Registrant and Phoenix Leasing Incorporated, dated September 15, 1993.
- 10.9(1) Sublicense Agreement between the Registrant and John S. Patton, dated September 13, 1991.
- 10.10(2) Offer Letter, dated September 16, 1994, from the Registrant to Jack M. Anthony.
- 10.11(2) Addendum to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
- 10.12(6) Lease dated May 31, 1995, between the Registrant and W.F. Batton & Marie A. Batton.
- 10.13(6) Addendum Number One to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
- 10.14(6) Addendum to Lease dated May 31, 1995 between the Registrant and W.F. Batton & Marie A. Batton.
- 10.15(6) Addendum Number Two to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
- 10.16(5) Stock Purchase Agreement between the Registrant and Baxter World Trade Corporation, dated March 1, 1996.
- 10.17(8) Sublease and Lease Agreement, dated October 2, 1996 between the Registrant and T.M.T. Associates L.L.C.

EXHIBIT	EXHIBIT TITLE
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23.1	Consent of Independent Auditors
*23.2	Consent of Cooley Godward LLP (filed with Exhibit 5.1)
27.1	Financial Data Schedule (10)

- (1) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-75942), as amended.
- (2) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-89502), as amended.
- (3) Incorporated by reference to the indicated exhibit in the Company's Annual Report on Form 10-K for the year ended December 31, 1994.
- (4) Incorporated by reference to the Company's Registration Statement on Form S-8 (No. 333-07969).
- (5) Incorporated by reference to the indicated exhibit in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.
- (6) Incorporated by reference to the indicated exhibit in the Company's Annual Report on Form 10-K for the year ended December 31, 1995.
- (7) Incorporated by reference to the indicated exhibit in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.
- (8) Incorporated by reference to the indicated exhibit in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
- (9) Incorporated by reference to the Company's Registration Statement on Form S-3 (No. 333-20787)
- (10) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.

\* To be filed by amendment.

#### ITEM 17. UNDERTAKINGS.

Inssofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the Registrant pursuant to the provisions described in Item 14 or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned Registrant undertakes that: (1) for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus as filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective, and (2) for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has caused this Registration Statement on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Belmont, State of California, on the 3rd day of October, 1997.

## INHALE THERAPEUTIC SYSTEMS

By: /s/ ROBERT B. CHESS

-----  
 Robert B. Chess  
 PRESIDENT, CHIEF EXECUTIVE OFFICER AND  
 DIRECTOR

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints jointly and severally, Robert B. Chess and Judi R. Lum, and each one of them, his or her attorneys-in-fact, each with the power of substitution, for him or her in any way and all capacities, to sign any and all amendments (including post-effective amendments and registration statements filed pursuant to Rule 462) to this Registration Statement and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on the 3rd day of October, 1997.

NAME	TITLE	DATE
/s/ ROBERT B. CHESS ----- Robert B. Chess	President, Chief Executive Officer and Director (PRINCIPAL EXECUTIVE OFFICER)	October 3, 1997
/s/ JUDI R. LUM ----- Judi R. Lum	Vice President, Finance and Administration and Chief Financial Officer (PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER)	October 3, 1997
/s/ JOHN S. PATTON ----- John S. Patton	Vice President and Director	October 3, 1997
/s/ MARK J. GABRIELSON ----- Mark J. Gabrielson	Director	October 3, 1997
/s/ JAMES B. GLAVIN ----- James B. Glavin	Director	October 3, 1997
/s/ MELVIN PERLEMAN ----- Melvin Perleman	Director	October 3, 1997
/s/ TERRY L. OPDENDYK ----- Terry L. Opdendyk	Chairman of the Board	October 3, 1997

## EXHIBIT INDEX

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10.3(1)	Form of Nonstatutory Stock Option under the Equity Incentive Plan.
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10.10(2)	Offer Letter, dated September 16, 1994, from the Registrant to Jack M. Anthony.
10.11(2)	Addendum to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
10.12(6)	Lease dated May 31, 1995, between the Registrant and W.F. Batton & Marie A. Batton.
10.13(6)	Addendum Number One to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
10.14(6)	Addendum to Lease dated May 31, 1995 between the Registrant and W.F. Batton & Marie A. Batton.
10.15(6)	Addendum Number Two to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.



## EXHIBIT

## EXHIBIT TITLE

10.16(5)	Stock Purchase Agreement between the Registrant and Baxter World Trade Corporation, dated March 1, 1996.
10.17(8)	Sublease and Lease Agreement, dated October 2, 1996 between the Registrant and T.M.T. Associates L.L.C.
23.1	Consent of Independent Auditors
*23.2	Consent of Cooley Godward LLP (filed with Exhibit 5.1)
27.1	Financial Data Schedule (10)

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- (1) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-75942), as amended.
  - (2) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-89502), as amended.
  - (3) Incorporated by reference to the indicated exhibit in the Company's Annual Report on Form 10-K for the year ended December 31, 1994.
  - (4) Incorporated by reference to the Company's Registration Statement on Form S-8 (No. 333-07969).
  - (5) Incorporated by reference to the indicated exhibit in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.
  - (6) Incorporated by reference to the indicated exhibit in the Company's Annual Report on Form 10-K for the year ended December 31, 1995.
  - (7) Incorporated by reference to the indicated exhibit in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.
  - (8) Incorporated by reference to the indicated exhibit in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
  - (9) Incorporated by reference to the Company's Registration Statement on Form S-3 (No. 333-20787)
  - (10) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1997.

\* To be filed by amendment.

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the reference to our firm under the captions "Selected Financial Data" and "Experts" and to the use of our report dated February 10, 1997, in the Registration Statement (Form S-3) and related Prospectus of Inhale Therapeutic Systems for the registration of 1,725,000 shares of its common stock.

We also consent to the incorporation by reference therein of our report dated February 10, 1997 with respect to the financial statements of Inhale Therapeutic Systems included in its Annual Report (Form 10-K) for the year ended December 31, 1996, filed with the Securities and Exchange Commission.

ERNST & YOUNG LLP

Palo Alto, California  
October 3, 1997