#### INHALE THERAPEUTIC SYSTEMS

1,800,000 SHARES

COMMON STOCK

This Prospectus relates to the public offering, which is not being underwritten, of 1,800,000 shares of Common Stock, no par value (the "Shares"), of Inhale Therapeutic Systems ("Inhale" or the "Company"). All of these Shares are held and may be offered by certain shareholders of the Company (the "Selling Shareholders") who acquired such Shares pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act") provided by Section 4(2) thereof. The Shares are being registered by the Company pursuant to the terms of certain Stock Purchase Agreements dated January 28, 1997 by and between the Company and the individual Selling Shareholders (the "Purchase Agreements"). See "Selling Shareholders" and "Plan of Distribution."

The sale of the Shares may be effected by the Selling Shareholders from time to time in transactions on the Nasdaq National Market, in privately negotiated transactions or in a combination of such methods of sale, at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing prices or at negotiated prices. The Selling Shareholders may effect such transactions by selling the Shares to or through broker-dealers, and such broker-dealers may receive compensation in the form of discounts, concessions or commissions from the Selling Shareholders and/or the purchasers of the Shares for whom such broker-dealers may act as agents or to whom they may sell as principals or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). See "Plan of Distribution."

None of the proceeds from the sale of the Shares by the Selling Shareholders will be received by the Company. The Company has agreed, among other things, to bear certain expenses (other than fees and expenses of counsel and underwriting discounts and commission and brokerage commissions and fees) in connection with the registration and sale of the Shares being offered by the Selling Shareholders. See "Selling Shareholders."

The Common Stock of the Company is quoted on the Nasdaq National Market under the symbol "INHL." The last reported sales price of the Company's Common Stock on the Nasdaq National Market on February 6, 1997 was \$18.75 per share.

The Selling Shareholders and any agents, broker-dealers or underwriters that participate in the distribution of the Shares may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission received by them and any profit on the resale of the Common Stock purchased by them may be deemed to be underwriting discounts or commissions under the Act. The Company will not receive any proceeds from the sale of shares by the Selling Shareholders. The Company has agreed to indemnify the Selling Shareholders and certain other persons against certain liabilities, including liabilities under the Act. See "Selling Shareholders" and "Plan of Distribution."

THIS OFFERING INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 5 OF THIS PROSPECTUS.

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.

NO PERSON IS AUTHORIZED IN CONNECTION WITH ANY OFFERING MADE HEREBY TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATION NOT CONTAINED OR INCORPORATED BY REFERENCE IN THIS PROSPECTUS, AND ANY INFORMATION OR REPRESENTATION NOT CONTAINED OR INCORPORATED HEREIN MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL, OR A SOLICITATION OF AN OFFER TO BUY, BY ANY PERSON IN ANY JURISDICTION IN WHICH IT IS UNLAWFUL FOR SUCH PERSON TO MAKE SUCH OFFER OR SOLICITATION. NEITHER THE DELIVERY OF THIS PROSPECTUS AT ANY TIME NOR ANY SALE MADE HEREUNDER SHALL, UNDER ANY CIRCUMSTANCES, IMPLY THAT THE INFORMATION HEREIN IS CORRECT AS OF ANY DATE SUBSEQUENT TO THE DATE HEREOF.

#### AVAILABLE INFORMATION

The Company is subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in accordance therewith, files annual and quarterly reports, proxy statements and other information with the Securities and Exchange Commission (the "Commission"). Such reports, proxy statements and other information may be inspected and copied at the Commission's Public Reference Section, 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549, as well as at the Commission's Regional Offices at 7 World Trade Center, 13th Floor, New York, New York 10048; and 500 West Madison Street, Suite 1400, Chicago, Illinois 60661-2511. Copies of such material can be obtained at prescribed rates from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549. The Common Stock of the Company is quoted on the Nasdaq National Market. Reports 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.

### ADDITIONAL INFORMATION

A registration statement on Form S-3 with respect to the Shares offered hereby (the "Registration Statement") has been filed with the Commission under the Act. This Prospectus does not contain all of the information contained in such Registration Statement and the exhibits and schedules thereto, certain portions of which have been omitted pursuant to the rules and regulations of the Commission. For further information with respect to the Company and the Shares offered hereby, reference is made to the Registration Statement and the exhibits and schedules thereto. Statements contained in this Prospectus regarding the contents of any contract or any other documents are not necessarily complete and, in each instance, reference is hereby made to the copy of such contract or document filed as an exhibit to the Registration Statement. The Registration Statement, including exhibits thereto, may be inspected without charge at the Commission's principal office in Washington, D.C., 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 payment of the prescribed fees.

# INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The following documents, filed or to be filed with the Commission under the Exchange Act are hereby incorporated by reference into this Prospectus:

- (i) The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1995, including all material incorporated by reference therein; and
- (ii) The Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996, including all material incorporated by reference therein; and
- (iii) The Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996, including all material incorporated by reference therein; and

- (iv) The Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996, including all material incorporated by reference therein;
- (v) The Company's Current Report on Form 8-K, dated February 6, 1997; and
- (vi) The description of the Common Stock contained in the Company's Registration Statement on Form 8-A as filed on May 2, 1994.

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 Inhale Therapeutic Systems, Attention: Investor Relations, 1060 East Meadow Circle, Palo Alto, California 94303, telephone (415) 354-0700.

THE FOLLOWING IS QUALIFIED IN ITS ENTIRETY BY THE MORE DETAILED INFORMATION INCLUDING "RISK FACTORS" APPEARING ELSEWHERE IN THIS PROSPECTUS AND THE FINANCIAL STATEMENTS AND NOTES THERETO CONTAINED IN THE COMPANY'S ANNUAL REPORT (FORM 10-K) FOR THE YEAR ENDED DECEMBER 31, 1995, INCORPORATED BY REFERENCE HEREIN (THE "ANNUAL REPORT"). EXCEPT FOR THE HISTORICAL INFORMATION CONTAINED HEREIN, THE DISCUSSION IN THIS PROSPECTUS CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. THE COMPANY'S ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE DISCUSSED HEREIN. FACTORS THAT COULD CAUSE OR CONTRIBUTE TO SUCH DIFFERENCES INCLUDE, BUT ARE NOT LIMITED TO, THOSE DISCUSSED IN "RISK FACTORS" BEGINNING AT PAGE 5 OF THIS PROSPECTUS AND THOSE DISCUSSED IN "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" AND "BUSINESS" CONTAINED IN THE ANNUAL REPORT, AS WELL THOSE DISCUSSED ELSEWHERE IN THE PROSPECTUS, THE ANNUAL REPORT, AND ANY OTHER DOCUMENT INCORPORATED HEREIN PRIOR TO THE TERMINATION OF THE OFFERING.

Inhale is developing a pulmonary drug delivery system applicable to a wide range of peptides, proteins and other molecules currently delivered by injection or by other routes including existing inhalation systems. As an alternative to invasive delivery techniques, a pulmonary delivery system potentially could expand the market for pharmaceutical drug therapies by increasing patient acceptance and improving compliance, which in turn could decrease medical complications and the associated costs of disease management. Pulmonary delivery also may enable new therapeutic uses of certain drugs. Inhale is focusing development efforts on applying its pulmonary delivery system primarily to drugs for systemic and local lung diseases that either have proven efficacy and are approved for delivery by injection or are in late stage human clinical trials. In addition, the Company is applying its delivery technology to selected other applications where its approach may have significant advantages. Several Inhale projects are in clinical trials, including insulin (currently in a Phase IIb clinical trial) and numerous other projects are in various stages of research, feasibility, formulation and preclinical development.

Medical science, health care providers and consumers have been searching for alternatives to injection as a means of delivering drugs. To date, oral, transdermal, and nasal routes of delivery have been shown to have low natural bioavailability (the amount of drug absorbed from the delivery site into the bloodstream) due to the large size of macromolecules, making these routes commercially unattractive alternatives for the natural delivery of most macromolecule drugs.

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

Inhale's strategy is to work with collaborative partners to develop and commercialize drugs for systemic and local lung indications using its pulmonary delivery system. Inhale is engaged in early stage feasibility, research or development collaborations with Pfizer Inc. ("Pfizer"), Baxter Healthcare Corporation (a subsidiary of Baxter International) ("Baxter"), Centeon (a company of Armour and Behring), Eli Lilly and Company ("Lilly"), Immunex Corporation, Genzyme Corporation as well as other major international pharmaceutical and biotechnology companies. In addition to its collaborations, Inhale has initiated projects with several drugs (calcitonin, heparin, Interferon-Alpha, Interferon-Beta and follicle stimulating hormone). The Company anticipates that any product that might be developed would be commercialized through a collaborative partner and believes its partnering strategy will enable it to reduce its cash requirements while developing a large and diversified potential product portfolio.

The Company was incorporated in California in July 1990. The Company's executive offices are located at 1060 East Meadow Circle, Palo Alto, California 94303, and its telephone number is (415) 354-0700.

### RISK FACTORS

THE FOLLOWING ARE SIGNIFICANT RISK FACTORS THAT SHOULD BE CONSIDERED CAREFULLY IN EVALUATING THE COMMON STOCK OF INHALE. INVESTMENT IN THE COMMON STOCK OF INHALE INVOLVES A HIGH DEGREE OF RISK.

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 other drugs. Only four of the Company's pulmonary delivery formulations, insulin, Interleukin-1 Receptor, salmon calcitonin and a peptide for the treatment of osteoporosis have been subject to any human clinical testing. Although many of the underlying drug compounds with which the Company is working have been tested in humans by others using alternative delivery routes, Inhale's potential products will require extensive research, development, preclinical and clinical testing, and may involve lengthy regulatory review. There can be no assurance that any of the Company's potential products will prove safe and effective in clinical trials, meet applicable regulatory standards, be capable of being produced in commercial quantities at acceptable cost or be successfully marketed. Moreover, even if the Company's products prove to be safe and effective and are approved for marketing by the United States Food and Drug Administration ("FDA") and other regulatory authorities, there can be no assurance that health care providers, payors or patients will accept the Company's products. Any failure of the Company to achieve technical feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or, together with partners, successfully market products, would have a material adverse effect on the Company. See "Risk Factors -- No Assurance of Successful Development or Commercialization of Drugs for Pulmonary Delivery," "-- Government Regulation; Uncertainty of Obtaining Regulatory Approval" and "-- Uncertainty Related to Health Care Reform and Third-Party Reimbursement."

NO ASSURANCE OF SUCCESSFUL DEVELOPMENT OR COMMERCIALIZATION OF DRUGS FOR PULMONARY DELIVERY. The commercial viability of Inhale's pulmonary drug delivery system for any drugs will depend upon the Company achieving sufficient system efficiency (measured by the percentage of bulk drug entering the manufacturing process that eventually is absorbed into the bloodstream relative to injection for systemic indications, or the amount of drug delivered to the lung tissue for local lung indications), formulation stability, safety and dosage reproducibility.

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

Formulation stability (the physical and chemical stability of the formulated drug over time and under various storage conditions) and safety will vary with each drug and the type and amount of excipients that are used in the formulation. Reproducibility (the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups) will require, among other things, the development of an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung.

The Company's integrated approach to systems development relies upon several different but related technologies, and its business strategy depends upon collaborations with corporate partners. Development of powder formulations, processing and packaging technology and the delivery device, establishing collaborations with partners, laboratory and clinical testing, and manufacturing scale-up must proceed contemporaneously so as not to delay any aspect of systems development. Any delay in one component of product or business development could cause consequential delays in the Company's ability to develop, obtain approval of or market therapeutic

products using its system. Further refinement of the Company's device prototype, further scale-up of the powder processing system and automated packaging system will need to be accomplished before initiation of later stage clinical trials.

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

HISTORY OF OPERATING LOSSES; UNCERTAINTY OF FUTURE PROFITABILITY. The Company has not been profitable since inception and, through September 30, 1996, had incurred a cumulative deficit of approximately \$24.4 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.

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

The Company's existing partners have the rights to pursue parallel development of other drug delivery systems which may compete with the Company's pulmonary drug delivery system and to terminate their agreements with the Company at any time without significant penalty. The Company anticipates that any future partners would have similar rights. Although the Company intends generally to formulate and manufacture powders for partners and to supply inhalation devices for such powders, certain partners may choose to formulate or manufacture their own powders, or to develop or supply their own device, thereby limiting one or more potential sources of revenue for Inhale. In addition, the Company anticipates that it may be precluded from entering into arrangements with companies whose products compete with products sold by its partners. The Company also will have limited or no control over the resources that any partner may devote to the Company's products, over partners' development efforts, including the design and conduct of clinical trials, and over the pricing of any such

products. The pharmaceutical and biotechnology industries are consolidating, and acquisitions by, or of, the Company's existing or potential collaborative partners may affect the initiation or continuation of any such collaborations. There can be no assurances that any of the Company's present or future collaborative partners will perform their obligations as expected, will devote sufficient resources to the development, clinical testing or marketing of the Company's potential products or will not terminate their agreements with the Company prematurely. Any parallel development by a partner of alternate drug delivery systems, development by a partner rather than by Inhale of components of the delivery system, preclusion from entering into competitive arrangements, failure to obtain timely regulatory approvals, premature termination of an agreement, or failure by a partner to devote sufficient resources to the development and commercialization of the Company's products would have a material adverse effect on the Company. See "Risk Factors -- Dependence Upon Proprietary Technology; Uncertainty of Obtaining Licenses or Developing Technology."

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

The Company has no experience manufacturing products for large scale clinical testing or commercial purposes. To date, the Company has performed powder processing 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."

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

The Company expects that its existing capital resources, contract research revenues from collaborations and the net proceeds of this offering and interest thereon, will enable the Company to maintain its current and planned operations at least through 1998. Thereafter, the Company may need to raise substantial additional capital to fund its operations. The Company intends to seek such additional funding through collaborative or partnering arrangements, the extension of existing arrangements, or through public or private equity or debt financings. There can be no assurance that additional financing will be available on acceptable terms or at all. If additional funds are raised by issuing equity securities, further dilution to shareholders may result. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its research or development programs or obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop or commercialize.

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

The patent positions of pharmaceutical, biotechnology and drug delivery companies, including Inhale, are uncertain and involve complex legal and factual issues. Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued. As a consequence, the Company does not know whether any of its patent applications will result in the issuance of patents or, if any patents issue, whether they will provide significant proprietary protection or will be circumvented or invalidated. Since patent applications in the United States are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, the Company cannot be certain that it was the first inventor of inventions covered by its pending patent applications or that it was the first to file patent applications for such inventions. Moreover, the Company may have to participate in interference proceedings declared by the PTO to determine priority of invention, which could result in substantial cost to the Company, even if the eventual outcome is favorable to the Company. There can be no assurance that the Company's patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject the Company to significant

liabilities to third parties, require disputed rights to be licensed from or to third parties or require the Company to cease using the technology in dispute.

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

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

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

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

The PTO has recently adopted changes to the United States patent law which change the term of issued patents, subject to certain transition periods, to 20 years from the date of filing rather than 17 years from date

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

DEPENDENCE UPON AND NEED TO ATTRACT KEY PERSONNEL. The Company is highly dependent upon the principal members of its scientific and management staff. The Company does not have employment contracts with its key employees, nor does the Company have key man insurance policies on them. The Company also relies on consultants and advisors to assist the Company in formulating research and development strategy. To pursue its product development and commercialization plans, the Company will be required to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation and manufacturing. Expansion in product development and manufacturing also is expected to require the addition of management personnel and the development of additional expertise by existing management personnel. Retaining and attracting qualified personnel, consultants and advisors will be critical to the Company's success. The Company faces competition for qualified individuals from numerous pharmaceutical, biotechnology and drug delivery companies, universities and other research institutions. There can be no assurance that the Company will be able to retain its current key employees or attract and retain qualified additional personnel and management when needed 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 experiences obtaining such regulatory approval, does not have the expertise or other resources to do so and intends to rely on its partners to fund clinical testing and to obtain product approvals. See "Risk Factors -- Dependence Upon Partners."

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

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

In both domestic and foreign markets, sales of the Company's potential products, if any, will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. There can be no assurance that the Company's proposed products will be considered cost effective or that adequate third-party reimbursement will be available to enable Inhale to maintain price levels sufficient to realize an appropriate return on its investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before the Company's proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services.

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

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

PRODUCT LIABILITY; AVAILABILITY OF INSURANCE. The design, development and manufacture of the Company's products involve an inherent risk of product liability claims and associated adverse publicity. Although the Company currently maintains general liability insurance, there can be no assurance that the coverage limits of the

Company's insurance policies will be adequate. The Company obtained clinical trial product liability insurance of \$3.0 million for certain clinical trials and intends to obtain insurance for future clinical trials of insulin and other products under development. However, there can be no assurance that the Company will be able to obtain or maintain insurance for any future clinical trials. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. A successful claim brought against the Company in excess of the Company's insurance coverage would have a material adverse effect upon the Company and its financial condition.

HAZARDOUS MATERIALS. The Company's research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. Although the Company believes that its safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could 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 technology companies have historically been highly volatile and the market from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in the Company's operating results, announcements of technological innovations or new therapeutic products or the announcement or termination of collaborative relationships by the Company or its competitors, governmental regulation, clinical trial results, developments in patent or other proprietary rights, public concern as to the safety of drug formulations developed by the Company or others and general market conditions may have a significant effect on the market price of the Common Stock. The Company securities are subject to a high degree of risk and volatility.

12

#### USE OF PROCEEDS

The Company will not receive any proceeds from the sale of Common Stock by the Selling Shareholders in the offering.

### DIVIDEND POLICY

The Company has never paid cash dividends. The Company's Board of Directors currently intends to retain any earnings for use in the Company's business and does not anticipate paying any cash dividends in the foreseeable future.

#### SELLING SHAREHOLDERS

The Shares covered by this Prospectus were acquired from the Company pursuant to the Purchase Agreements for an aggregate purchase price of \$32,400,000 (\$18.00 per share). The offer and sale by the Company of the Common Stock to the Selling Shareholders pursuant to the Purchase Agreements was made pursuant to an exemption from the registration requirements of the Securities Act provided by Section 4(2) thereof. The Purchase Agreements contain representations and warranties as to each Selling Shareholder's status as an "accredited investor" as such term is defined in Rule 501promulgated under the Securities Act. Vector Securities International, Inc., the placement agent, was paid a fee equal to 5.5% of the aggregate purchase price in connection with the sale of the Shares by the Company to the Selling Shareholders pursuant to the Purchase Agreements. In addition, the Company agreed to reimburse such placement agent for its travel and out-of-pocket expenses incurred in connection with the sale of the Shares by the Company to the Selling Shareholders pursuant to the Purchase Agreements up to a maximum of \$100,000.

Pursuant to the Purchase Agreements, each Selling Shareholder has represented that he, she or it acquired the Shares for investment and with no present intention of distributing the Shares. The Company agreed, in such Purchase Agreements, to prepare and file a registration statement as soon as practicable and to bear all expenses other than fees and expenses of counsel for the Selling Shareholders and underwriting discounts and commissions and brokerage commissions and fees. In addition, and in recognition of the fact that the Selling Shareholders, even though purchasing the Shares without a view to distribution, may wish to be legally permitted to sell the Shares when each deems appropriate, the Company filed with the Commission a Registration Statement on Form S-3, of which this Prospectus forms a part, with respect to, among other things, the resale of the Shares from time to time at prevailing prices in the over-the-counter market or in privately-negotiated transactions and has agreed to prepare and file such amendments and supplements to the Registration Statement as may be necessary to keep the Registration Statement effective until all Shares offered hereby have been sold pursuant thereto or until such Shares are no longer, by reason of Rule 144 under the Securities Act or any other rule of similar effect, required to be registered for the sale thereof by the Selling Shareholders.

None of the Selling Shareholders has had a material relationship with the Company within the past three years except as a result of the ownership of the Shares or other securities of the Company.

The following table sets forth the name of the Selling Shareholders, the number of shares of Common Stock owned beneficially by the Selling Shareholders as of Janaury 28, 1997 and the number of shares which may be offered pursuant to this Prospectus. This information is based upon information provided by the Selling Shareholders. There are currently no agreements, arrangements or understandings with respect to the sale of any of the Shares. The Shares are being registered to permit public secondary trading of the Shares, and the Selling Shareholders may offer the Shares for resale from time to time.

NAME 	OWNED E	BENEFICIALLY PRIOR TO THE PFERING	MAXIMUM NUMBER OF SHARES BEING OFFERED	SHARES BENEFICIALLY OWNED AFTER THE OFFERING					
	NUMBER	PERCENT(1)		NUMBER	PERCENT (1)				
Franklin Global Health Care Fund	215,000	1.6%	200,000	15,000	*				
Franklin Small Cap Growth Fund	168,000	1.2	168,000	0					
Franklin Valuemark Annuity - Small Cap Growth Fund	32,000	*	32,000	0					
The Global Health Sciences Fund(2)	108,550	*	108,550	0					
Invesco Strategic Portfolios, Inc Health Sciences(2)	216,450	1.6	216,450	0					
Quantum Partners LDC(3)	750,000	5.5	750,000	0					
T. Rowe Price New Horizons Fund, Inc.(4)	543 <b>,</b> 750	4.0	243,750	300,000	2.2%				
T. Rowe Price Health Sciences Fund, Inc.(4)	81,250	*	81,250	0					
TOTAL	2,115,000		1,800,000	315,000					

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Less than 1%.

<sup>(1)</sup> Applicable percentage of ownership is based on 11,834,792 shares of Common Stock outstanding on January 28, 1997, and assumes the sale and issuance of 1,800,000 shares of Common Stock pursuant to the Purchase Agreements.

<sup>(2)</sup> The above named entities are affiliated with the Invesco Trust Company, which serves as investment advisor to these entities.

<sup>(3)</sup> The address for Quantum Partners LDC is: c/o Soros Fund Management LLC, 888 Seventh Avenue, 33rd Floor, New York, New York 10106, Attention: Michael C. Neus, Esq.

<sup>(4)</sup> The address for the above named entities is: 100 East Pratt Street, Baltimore, Maryland 21202. Certain entities affiliated with this Selling Shareholder beneficially own additional securities of the Company. Such shares are not included in the information set forth above.

#### PLAN OF DISTRIBUTION

The Shares offered hereunder may be sold from time to time by the Selling Shareholders, or by pledgees, donees, transferees or other successors in interest. Such sales may be made on the Nasdaq National Market or in the over-the-counter market or otherwise, at prices and on terms then prevailing or related to the then-current market price, or in negotiated transactions. The Shares may be sold to or through one or more broker-dealers, acting as agent or principal, in underwritten offerings, block trades, agency placements, exchange distributions, brokerage transactions or otherwise, or in any combination of transactions.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the Shares may not simultaneously engage in market making activities with respect to the Company's Common Stock for a period of two business days prior to the commencement of such distribution. In addition and without limiting the foregoing, the Selling Shareholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Rules 10b-6 and 10b-7, which provisions may limit the timing of purchases and sales of shares of Common Stock by the Selling Shareholders.

At the time a particular offer of Shares is made, to the extent required, a supplemental prospectus will be distributed which will set forth the number of shares being offered and the terms of the offering including the name or names of any underwriters, dealers or agents, the purchase price paid by any underwriter for the Shares purchased from the Selling Shareholders and any discounts, concessions or commissions allowed or reallowed or paid to dealers.

In connection with any transaction involving the Shares, broker-dealers or others may receive from the Selling Shareholders, and/or the purchasers of the Shares for whom such broker-dealers act as agents or to whom they may sell as principals or both, compensation in the form of discounts, concessions or commissions in amounts to be negotiated at the time (which compensation as to a particular broker-dealer might be in excess of customary commissions). Broker-dealers and any other persons participating in a distribution of the Shares may be deemed to be "underwriters" within the meaning of the Act in connection with such distribution, and any such discounts, concessions or commissions may be deemed to be underwriting discounts or commissions under the Act.

Any or all of the sales or other transactions involving the Shares described above, whether effected by the Selling Shareholders, any broker-dealer or others, may be made pursuant to this Prospectus. In addition, any Shares that qualify for sale pursuant to Rule 144 under the Act may be sold under Rule 144 rather than pursuant to this Prospectus.

In order to comply with the securities laws of certain states, if applicable, the Shares may be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the Shares may not be sold unless the Shares have been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

All costs associated with this offering, other than fees and expenses of counsel for the Selling Shareholders and underwriting discounts and commissions and brokerage commissions and fees, will be paid by the Company. The Company has agreed to indemnify the Selling Shareholders against certain liabilities in connection with any offering of the Shares pursuant to this Prospectus, including liabilities arising under the Act.

### LEGAL MATTERS

The validity of the 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.

## EXPERTS

The financial statements Inhale Therapeutic Systems appearing in Inhale Therapeutic Systems' Annual Report (Form 10-K) for the year ended December 31, 1995, 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 and schedules are incorporated herein by reference in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

No dealer, salesman or other person has been authorized to give any information or to make any representations other than those contained in this Prospectus and, if given or made, such other information and representations must not be relied upon as having been authorized by the Company. This Prospectus does not constitute an offer or solicitation by anyone in any state in which such offer or solicitation is not authorized, or in which the person making such offer or solicitation is not qualified to do so, or to any person to whom it is unlawful to make such offer or solicitation. The delivery of this Prospectus at any time does not imply that the information herein is correct as of any time subsequent to the date hereof.

### TABLE OF CONTENTS

																		Ε	Page
Available Information . Additional Information . Incorporation of Certain																			
Documents by Reference The Company Risk Factors Use of Proceeds Dividend Policy Selling Shareholders Plan of Distribution . Legal Matters Experts	· · · · · · · · · · · · · · · · · · ·											 	.4 .5 13 13 13 15						
1,800,000 Shares  Common Stock																			
INHALE THERAPEUTIC SYSTEMS																			
Prospectus																			

February 7, 1997