

REGISTRATION NO. 333-68897

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

AMENDMENT NO. 1  
TO  
FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

INHALE THERAPEUTIC SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

94-3134940  
(I.R.S. Employer  
Identification Number)

150 INDUSTRIAL ROAD  
SAN CARLOS, CALIFORNIA 94070  
(650) 631-3100  
(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

ROBERT B. CHESS AND AJIT S. GILL  
CO-CHIEF EXECUTIVE OFFICERS  
INHALE THERAPEUTIC SYSTEMS, INC.  
150 INDUSTRIAL ROAD  
SAN CARLOS, CALIFORNIA 94070  
(650) 631-3100

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

COPIES TO:

MARK P. TANOURY, ESQ.  
COOLEY GODWARD LLP  
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BUILDING 3, SUITE 230  
MENLO PARK, CALIFORNIA 94025  
(650) 843-5000

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC:

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. /X/

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 EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED(1)	PROPOSED MAXIMUM OFFERING PRICE PER SHARE(2)	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE(2)	AMOUNT OF REGISTRATION FEE
Common Stock.....	1,200,000	\$31.69	\$38,028,000	\$10,572(3)

- (1) Pursuant to Rule 416 of the Securities Act, this Registration Statement also covers such indeterminable additional shares as may become issuable as a result of any future stock splits, stock dividends or similar transaction.
- (2) Estimated in accordance with Rule 457(c) solely for the purpose of computing the amount of the registration fee based on the average of the high and low prices of the Company's Common Stock as reported on the Nasdaq National Market on December 8, 1998.
- (3) Previously paid.

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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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SUBJECT TO COMPLETION

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

PROSPECTUS DATED JANUARY , 1999

INHALE THERAPEUTIC SYSTEMS, INC.

1,200,000 SHARES  
COMMON STOCK

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The selling stockholders, Capital Research and Management Company on behalf of SMALLCAP World Fund, Inc. and on behalf of American Variable Insurance Services--Growth Fund, may sell up to 1,200,000 shares of common stock of Inhale Therapeutic Systems, Inc. We will not receive any proceeds from the sale of shares by Capital Research.

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Our common stock is listed on the Nasdaq National Market under the symbol INHL.

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We will not be paying any underwriting commissions or discounts in the offering of these shares.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK.  
SEE "RISK FACTORS" BEGINNING ON PAGE 3.

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NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

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## ABOUT INHALE

THE FOLLOWING IS A SHORT SUMMARY OF OUR BUSINESS. YOU SHOULD CAREFULLY READ THE "RISK FACTORS" SECTION OF THIS PROSPECTUS AND OUR ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 1997 FOR MORE INFORMATION ON OUR BUSINESS AND THE RISKS INVOLVED IN INVESTING IN OUR STOCK. IN ADDITION TO THE HISTORICAL INFORMATION CONTAINED IN THIS PROSPECTUS, THIS PROSPECTUS CONTAINS FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT AND SECTION 21E OF THE EXCHANGE ACT THAT INVOLVE RISKS AND UNCERTAINTIES. OUR ACTUAL RESULTS COULD DIFFER MATERIALLY FROM OUR EXPECTATIONS. FACTORS THAT COULD CAUSE OR CONTRIBUTE TO SUCH DIFFERENCES ARE DISCUSSED IN "RISK FACTORS" BEGINNING AT PAGE 3 OF THIS PROSPECTUS AND IN "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" AND "BUSINESS" IN OUR ANNUAL REPORT.

We are developing a system to deliver drugs to the bloodstream through the lungs by inhaling a powdered version of the drug. Our system is applicable to a wide range of peptides, proteins and other molecules. These are currently delivered mostly by needle injection or shots. As an alternative to shots, delivery through the lungs potentially could expand the market for drug therapies by increasing patient acceptance and improving compliance. This could decrease medical complications and the associated costs of disease management. Deep lung or pulmonary delivery also may enable new therapeutic uses of certain drugs. We are focusing development efforts on applying our delivery system primarily to drugs to treat lung and other diseases that either work and are approved for delivery by injection or are in late stage human testing. In addition, we are applying our delivery technology to selected other applications where our approach may have significant advantages. Several of our projects are in human testing. Insulin is currently starting Phase III clinical trials. 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 shots as a means of delivering large molecule drugs. To date, oral, transdermal and nasal routes of delivery are commercially unattractive alternatives for the natural delivery of most large molecule drugs because they have low natural bioavailability. Bioavailability is the amount of drug absorbed from the delivery site into the bloodstream.

We approach deep lung drug delivery with the objective of maximizing overall system efficiency while addressing commercial requirements for consistency, stable drug formulations, safety and convenience. We are designing our delivery system to integrate

- customized formulations;
- proprietary fine dry powder processing;
- packaging technology; and
- our proprietary device for inhaling drug powders into the deep lung

for efficient, consistent lung delivery of large molecule powders. To achieve this goal, we are combining an understanding of lung biology, aerosol science, chemical engineering, mechanical engineering, and protein science in our system development efforts. We intend to take bulk drugs supplied by collaborative pharmaceutical and biotechnology partners and formulate and process these drugs into fine powders. The powders would then be packaged into individual dosing units. These dosing units are known as blisters. We have designed the blisters to load into our device, which patients then activate to inhale the aerosolized drugs.

Our strategy is to work with collaborative partners to develop and commercialize drugs using our pulmonary delivery system. We are engaged in early stage feasibility, research or development collaborations with Pfizer, Baxter, Centeon, Lilly, Immunex and Genzyme as well as other major international pharmaceutical and biotechnology companies. In addition to our collaborations, we have initiated projects with several large molecule drugs. We anticipate that a collaborative partner would commercialize any product that we might develop. We believe our partnering strategy will enable us to reduce our cash requirements while developing a large and diversified potential product portfolio.

## RECENT DEVELOPMENTS

During the past 12 months, we advanced our insulin program with Pfizer, entered into an additional collaborative agreement with Lilly, restructured our agreement with Baxter, expanded our management team, and received additional patents covering our deep lung delivery technology. While we have made advancements in our collaborations, none of our products has yet been approved for sale, commercialized or sold. See "Risk Factors."

- Last November Pfizer announced agreements with Hoechst Marion Roussel to manufacture insulin and co-develop and co-promote inhaled insulin.
- Last November Pfizer also announced the beginning of Phase III clinical trials to test the delivery of insulin through the lungs using our system.
- In October 1998 we amended our agreement with Baxter to facilitate signing a new corporate partner to fund further development and commercialization of the undisclosed compound that has been Baxter's focus since April 1998. Baxter will continue to provide development funding for this compound in preparation for Phase II trials while the two companies are seeking the new partner.
- Last September Pfizer released preliminary results from a Phase IIb trial showing that individuals with type 2 diabetes can markedly improve the control of blood sugar without insulin injections by combining our pulmonary insulin with oral glucose lowering agents.
- In September we also adopted a co-Chief Executive Officer (CEO) structure. The two co-CEOs of Inhale are Ajit Gill and Robert Chess. In addition, to help manage our growth, we created the positions of Vice President of Human Resources and General Counsel. Our new Vice President of Human Resources is Don Campodonico and our General Counsel is Stephen Hurst.
- Last June Pfizer released data from the Phase IIb inhaled insulin trials indicating that inhaled insulin is as effective at controlling diabetes as injected insulin.
- Last April we successfully completed an initial Phase II human clinical trial for one drug and a Phase I human clinical trial for a second drug as part of our collaboration with Baxter.
- In April we also agreed with Baxter to focus our efforts on the one compound that Baxter and we believe has the largest commercial potential. Two additional compounds remain in the collaboration and we may develop them further in the future.
- In April we signed an agreement with Initiatech Inc. under which we licensed technology, intellectual property, and patents for protecting biologically active compounds in the dry state.
- In January 1998 we entered into a collaborative agreement with Lilly to develop deep lung delivery for an unspecified protein product. This is our second collaborative agreement with Lilly.
- The United States Patent and Trademark Office granted us six new patents in 1998.

## RISK FACTORS

ANY OF THE FOLLOWING RISKS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS, OPERATING RESULTS AND FINANCIAL CONDITION AND COULD RESULT IN A COMPLETE LOSS OF YOUR INVESTMENT.

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

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

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

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

WE DO NOT KNOW IF OUR DEEP LUNG SYSTEM IS SAFE. We may not be able to prove potential products to be safe. Our products require lengthy laboratory, animal and human testing. For most of our products we are in the early stage of human testing. If we find that any product is not safe, we will not be able to commercialize the product. The safety of our deep lung formulations will vary with each drug and the ingredients used in its formulation.

WE DO NOT KNOW IF OUR DEEP LUNG SYSTEM PROVIDES CONSISTENT DOSES OF MEDICINE. We may not be able to provide reproducible dosages of stable formulations sufficient to achieve clinical success. Reproducible dosing is the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups. Reproducible dosing requires the development of:

- an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung;



- accurate unit dose packaging of dry powder formulations; and
- moisture resistant packaging.

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

WE DO NOT KNOW IF OUR TECHNOLOGIES CAN BE INTEGRATED IN TIME TO BRING PRODUCT TO MARKET. We may not be able to integrate all of the relevant technologies to provide an integrated deep lung delivery system. Our integrated approach to systems development relies upon several different but related technologies:

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

At the same time we must:

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

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

OUR DEEP LUNG DELIVERY SYSTEM MAY NOT BE COMMERCIALY ACCEPTED. We may not be able to achieve commercial viability of our deep lung delivery system. In order to sell any potential product, we must make it commercially acceptable to the market. This means that we must:

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

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

WE EXPECT TO CONTINUE TO LOSE MONEY FOR THE NEXT SEVERAL YEARS. We have never been profitable and, through September 30, 1998, have incurred a cumulative deficit of approximately \$49.7 million. We expect to continue to incur substantial and increasing losses over at least the next several years as we expand our research and development efforts, testing activities and manufacturing operations, and as we complete our late stage clinical and early commercial production facility. All of our potential products are in research or in the early stages of development except for our insulin collaboration. We have generated no revenues from approved product sales. Our revenues to date have consisted primarily of payments under short-term research and feasibility agreements and development contracts. To achieve and sustain profitable operations, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products using our deep lung drug delivery system. There is a risk that we will not generate sufficient product or contract research revenue to become profitable or to sustain profitability.

WE DEPEND ON PARTNERS FOR REGULATORY APPROVALS AND COMMERCIALIZATION OF OUR PRODUCTS. Since Inhale is in the business of developing technology for delivering drugs to the lungs and licensing this



technology to companies that make and sell drugs, we do not have the people and other resources to do the following things:

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

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

WE DO NOT KNOW IF WE WILL BE ABLE TO PRODUCE OUR PRODUCTS IN COMMERCIAL QUANTITIES. We must scale-up our current powder processing and filling facilities and comply with the good manufacturing practice standards prescribed by the United States Food and Drug Administration and other standards prescribed by other regulatory agencies to achieve drug production levels that are adequate to support late stage human clinical testing and early commercial sales.

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

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

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

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

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

WE DO NOT KNOW IF THE MARKET WILL ACCEPT INHALE'S DEEP LUNG DELIVERY SYSTEM. The commercial success of our potential products depends upon market acceptance by health care providers, third-party payors, like health insurance companies and Medicare, and patients. Our products under development use a new method of drug delivery and there is a risk that our potential products will not be accepted by the market. Market acceptance will depend on many factors, including

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

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

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

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

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

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

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

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

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

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

OUR COMPETITORS MAY DEVELOP AND SELL BETTER DRUG DELIVERY SYSTEMS. We are aware of other companies engaged in developing and commercializing pulmonary drug delivery systems and enhanced injectable drug delivery systems. Many of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do and represent significant competition for us. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' financial, marketing and other resources. Accordingly, our competitors may succeed in developing competing technologies, obtaining United States Food and Drug Administration approval for products or gain market acceptance before us. We cannot assure that developments by others will not make our products or technologies uncompetitive or obsolete.

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

- fluctuations in our operating results;
- announcements of technological innovations or new therapeutic products;
- announcement or termination of collaborative relationships by Inhale or our competitors;
- governmental regulation;

- clinical trial results;
- developments in patent or other proprietary rights;
- public concern as to the safety of drug formulations developed by Inhale or others; and
- general market conditions.

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

INVESTORS SHOULD BE AWARE OF INDUSTRY-WIDE RISKS. In addition to the risks associated specifically with Inhale described above, investors should also be aware of general risks associated with drug development and the pharmaceutical industry. These include but are not limited to:

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

## WHERE YOU CAN FIND MORE INFORMATION

Our principal executive offices are located at 150 Industrial Road, San Carlos, CA 94070. Our telephone number is (650) 631-3100. We maintain an Internet home page at [www.inhale.com](http://www.inhale.com). The contents of our web page are not a part of this prospectus.

We have filed with the SEC a registration statement on Form S-3 to register the common stock offered by this prospectus. However, this prospectus does not contain all of the information contained in the registration statement and the exhibits and schedules to the registration statement. We strongly encourage you to carefully read the registration statement and the exhibits and schedules to the registration statement. We also file annual, quarterly and special reports, proxy statements and other information with the SEC.

You may inspect and copy such material at the public reference facilities maintained by the SEC at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549, as well as at the SEC's regional offices at 500 West Madison Street, Suite 1400, Chicago, Illinois 60661 and 7 World Trade Center, Suite 1300, New York, New York 10048. You may also obtain copies of such material from the SEC at prescribed rates by wiring to the Public Reference Section of the SEC, 450 Fifth Street, N.W., Washington, D.C. 20549.

Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public from the SEC's Website at [www.sec.gov](http://www.sec.gov).

The SEC allows us to "incorporate by reference" the information contained in documents that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference which we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934;

1. Our Annual Report on Form 10-K for the fiscal year ended December 31, 1997, filed on March 23, 1998 and an amendment thereto filed April 30, 1998, including all material incorporated by reference therein;
2. Our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 1998, filed on May 14, 1998, including all material incorporated by reference therein;
3. Our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1998, filed on August 13, 1998, including all material incorporated by reference therein;
4. Our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1998, filed on November 12, 1998, including all material incorporated by reference therein;
5. Our Current Report on Form 8-K, filed on April 7, 1998, including all material incorporated by reference therein; and
6. The description of the common stock contained in our Registration Statement on Form 8-A as filed on May 2, 1994.

You may request a copy of these filings, at no cost to you, by writing or telephoning us at:

Inhale Therapeutic Systems, Inc.  
Attention: Investor Relations  
150 Industrial Road  
San Carlos, CA 94070  
Telephone: (650) 631-3100

Our common stock is quoted on the Nasdaq National Market under the symbol "INHL". The last reported sales price of the common stock on the Nasdaq National Market ("Nasdaq") on January 27, 1999 was \$33.375 per share. You may inspect reports and other information concerning us at the offices of the National Association of Securities Dealers, Inc., 1735 K Street, N.W., Washington, D.C. 20006.

You should rely only on the information incorporated by reference or provided in this prospectus. We have authorized no one to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document.

#### USE OF PROCEEDS

We will not receive any proceeds from the sale of Common Stock by the selling stockholders in the offering.

#### DIVIDEND POLICY

We have never paid cash dividends. We currently intend to retain any earnings for use in our business and do not anticipate paying any cash dividends in the foreseeable future.



SELLING STOCKHOLDERS

All of the shares of our common stock offered pursuant to this prospectus are held by Capital Research and Management Company, on behalf of the funds listed in the table below. The shares are being registered to permit public secondary trading of the shares, and Capital Research may offer the shares for resale from time to time. Capital Research may sell the shares offered through this Prospectus from time to time at prevailing prices in the over-the-counter market or in privately-negotiated transactions. We agreed to prepare and file such amendments and supplements to the Registration Statement as may be necessary to keep the Registration Statement effective until such shares are no longer, by reason of Rule 144(k) under the Securities Act or any rule of similar effect, required to be registered for the sale thereof by Capital Research.

The following table sets forth the number of shares of common stock owned beneficially by the funds as of the date of this Prospectus and the number of shares that may be offered pursuant to this Prospectus. This information is based upon information provided to us by Capital Research. Applicable percentage of ownership is based on 16,914,620 shares of common stock outstanding on December 10, 1998. There are currently no agreements, arrangements or understandings with respect to the sale of any of the shares.

NAME	SHARES BENEFICIALLY OWNED PRIOR TO THE OFFERING		MAXIMUM NUMBER OF SHARES BEING OFFERED	SHARES BENEFICIALLY OWNED AFTER THE OFFERING	
	NUMBER	PERCENT(1)		NUMBER	PERCENT(1)
Capital Research and Management Company on behalf of SMALLCAP World Fund, Inc.....	1,000,000	5.91%	1,000,000	0	0
Capital Research and Management Company on behalf of American Variable Insurance Series--Growth Fund.....	200,000	1.18%	200,000	0	0
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Total.....	1,200,000	7.09%	1,200,000	0	0
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## PLAN OF DISTRIBUTION

The shares offered hereunder may be sold from time to time by Capital Research and Management Company on behalf of SMALLCAP World Fund, Inc. and on behalf of American Variable Insurance Series--Growth Fund in one or more transactions at fixed prices, at market prices at the time of sale, at varying prices determined at the time of sale or at negotiated prices. Capital Research may offer their shares of common stock in one or more of the following transactions:

- on any national securities exchange or quotation service on which the common stock may be listed or quoted at the time of sale, including the Nasdaq National Stock Market;
- in the over-the-counter market;
- in private transactions;
- by pledge to secure debts and other obligations; or
- a combination of any of the above transactions.

Under the Securities Exchange Act of 1934, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of such distribution. In addition, Capital Research will be subject to applicable provisions of the Securities Exchange Act of 1934, which provisions may limit the timing of purchases and sales of shares of common stock by Capital Research or any other such person.

If Capital Research notifies Inhale of any material arrangement that it has entered into with a broker or dealer for selling shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, Inhale will file a supplemented prospectus, if required, pursuant to Rule 424(c) under the Securities Act of 1933. In that supplemented prospectus, Inhale will disclose:

- the name of each such broker-dealer;
- the number of shares involved;
- the price at which such shares were sold;
- the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable;
- that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented; and
- any other facts material to the transaction.

Capital Research may from time to time offer shares of common stock to or through underwriters, broker/dealers or agents. Capital Research and any underwriters, broker/dealers or agents that participate in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act of 1933. Any profits on the resale of shares of common stock and any compensation received by any underwriter, broker/dealer or agent may be deemed to be underwriting discounts and commissions under the Securities Act of 1933.

Any or all of the sales or other transactions involving the shares described

above, whether effected by Capital Research, 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.

To comply with the securities laws of certain jurisdictions, if applicable, the common stock must be offered or sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain jurisdictions the common stock may not be sold unless it has been registered or qualified for sale or an exemption is available and is complied with.

All costs associated with this offering, other than fees and expenses of counsel for the selling stockholders and underwriting discounts and commissions and brokerage commissions and fees, will be paid by us. We have agreed to indemnify the selling stockholders 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.

#### EXPERTS

Ernst & Young LLP, independent auditors, have audited our financial statements included in our Annual Report on Form 10-K for the three years ended December 31, 1997, as set forth in their report, which is incorporated in this prospectus by reference. Our financial statements are incorporated by reference in reliance on their report, given on their authority as experts in accounting and auditing.

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WE HAVE AUTHORIZED NO ONE TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS THAT ARE NOT CONTAINED IN THIS PROSPECTUS. YOU SHOULD RELY ONLY ON THE INFORMATION INCORPORATED BY REFERENCE OR PROVIDED IN THIS PROSPECTUS. YOU MUST NOT RELY ON ANY UNAUTHORIZED INFORMATION.

THIS PROSPECTUS DOES NOT OFFER TO SELL OR BUY ANY SHARES IN ANY JURISDICTION WHERE IT IS UNLAWFUL. YOU SHOULD NOT ASSUME THAT THE INFORMATION IN THIS PROSPECTUS IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE ON THE FRONT OF THE DOCUMENT.

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1,200,000 SHARES

COMMON STOCK

INHALE THERAPEUTIC  
SYSTEMS, INC.

-----  
PROSPECTUS  
-----

JANUARY , 1999  
-----  
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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 payable by Inhale Therapeutic Systems, Inc., hereinafter referred to as the "Registrant" or the "Company" in connection with the sale of the Shares being registered. All the amounts shown are estimates except for the registration fee. None of these expenses will be paid by the selling stockholders.

Registration fee.....	\$ 10,572
Printing and engraving expenses.....	\$ 3,000
Legal fees and expenses.....	\$ 30,000
Accounting fees and expenses.....	\$ 10,000
Miscellaneous.....	\$ 2,000
	-----
Total.....	\$ 55,572
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ITEM 15. INDEMNIFICATION OF OFFICERS AND DIRECTORS.

Under Section 145 of the Delaware General Corporation Law, the Registrant has broad powers to indemnify its directors and officers against liabilities they may incur in such capacities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act").

The Registrant's Certificate of Incorporation provides for the elimination of liability for monetary damages for breach of the directors' fiduciary duty of care to the Registrant and its stockholders. These provisions do not eliminate the directors' duty of care and, in appropriate circumstances, equitable remedies such as an injunctive or other forms of non-monetary relief will remain available under Delaware law. In addition, each director will continue to be subject to liability for breach of the director's duty of loyalty to the Registrant, for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for any transaction from which the director derived an improper personal benefit, and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provision does not affect a director's responsibilities under any other laws, such as the federal securities laws or state or federal environmental laws.

ITEM 16. EXHIBITS

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
-----	-----
4.1(1)	Stock Purchase Agreement between the Registrant and Capital Research and Management Company, dated December 8, 1998.
5.1(1)	Opinion of Cooley Godward LLP.
23.1	Consent of Ernst and Young LLP, Independent Auditors.
23.2(1)	Consent of Cooley Godward LLP. Reference is made to Exhibit 5.1.
24.1(1)	Power of Attorney (included on signature pages).
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(1) Previously filed.

ITEM 17. UNDERTAKINGS.

The undersigned registrant hereby undertakes:

- (1) To file, during any period during which offers or sales are being made, a post-effective amendment to this registration statement;
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or any decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low end or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

PROVIDED, HOWEVER, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

- (2) That, for purposes of determining liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities to be offered therein, and the offering of such securities at that time shall be deemed to be an initial BONA FIDE offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which shall remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to provisions described in Item 15, 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 Securities 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 Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Carlos, County of San Mateo, State of California, on the 28th day of January, 1999.

INHALE THERAPEUTIC SYSTEMS, INC.

By: /s/ ROBERT B. CHESS\*  
-----  
Robert B. Chess  
CO-CHIEF EXECUTIVE OFFICER AND DIRECTOR

By: /s/ AJIT S. GILL  
-----  
Ajit S. Gill  
CO-CHIEF EXECUTIVE OFFICER AND DIRECTOR



Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ ROBERT B. CHESS* ----- Robert B. Chess	Co-Chief Executive Officer and Director (Co-Principal Executive Officer)	January 28, 1999
/s/ AJIT S. GILL ----- Ajit S. Gill	Co-Chief Executive Officer and Director (Co-Principal Executive Officer)	January 28, 1999
/s/ CHRISTIAN O. HENRY* ----- Christian O. Henry	Controller (Principal Financial and Accounting Officer)	January 28, 1999
/s/ TERRY L. OPDENDYK* ----- Terry L. Opdendyk	Chairman of the Board	January 28, 1999
/s/ MARK J. GABRIELSON* ----- Mark J. Gabrielson	Director	January 28, 1999
/s/ JAMES B. GALVIN* ----- James B. Galvin	Director	January 28, 1999
/s/ JOHN S. PATTON* ----- John S. Patton	Vice President and Director	January 28, 1999
/s/ MELVIN PERELMAN* ----- Melvin Perelman	Director	January 28, 1999

/s/ AJIT S. GILL

-----  
Ajit S. Gill  
Attorney-in-fact

\*By:

INDEX TO EXHIBITS

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24.1(1)	Power of Attorney (included on signature pages).

(1) Previously filed.

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form S-3) and related Prospectus of Inhale Therapeutic Systems, Inc. for the registration of 1,200,000 shares of its common stock and to the incorporation by reference therein of our report dated January 22, 1998, with respect to the financial statements of Inhale Therapeutic Systems, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 1997, filed with the Securities and Exchange Commission.

/s/ ERNST & YOUNG LLP

Palo Alto, California  
January 28, 1999