

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 1997

or,

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

COMMISSION FILE NUMBER: 0-23556

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

CALIFORNIA

94-3134940

-----  
(State of other jurisdiction of (IRS Employer Identification No.)  
incorporation or organization)

1060 EAST MEADOW CIRCLE  
PALO ALTO, CALIFORNIA 94303  
(Address of principal executive offices)

415-846-2600  
(Registrant's telephone number, including area code)

Not applicable

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(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes             No

APPLICABLE ONLY TO CORPORATE ISSUERS

The number of outstanding shares of the registrant's Common Stock, no par value, was 13,642,004 as of May 1, 1997.

INHALE THERAPEUTIC SYSTEMS  
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Item 1.

INHALE THERAPEUTIC SYSTEMS

Condensed Balance Sheets  
(in thousands)

	March 31, 1997	December 31, 1996
	----- (unaudited)	----- (Note)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 36,662	\$ 18,568
Short-term investments	31,123	17,741
Other current assets	887	1,239
	-----	-----
Total current assets	68,672	37,548
Property and equipment, net	4,210	3,770
Deposits and other assets	135	174
	-----	-----
	\$ 73,017	\$ 41,492
	-----	-----
	-----	-----
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 2,987	\$ 3,042
Accrued compensation	1,037	479
Deferred revenue - current portion	5,191	2,723
	-----	-----
Total current liabilities	9,215	6,244
Equipment financing obligations	175	187
Shareholders' equity:		
Common stock, no par value: 30,000 shares authorized, 13,642 shares and 11,835 shares issued and outstanding at March 31, 1997 and December 31, 1996, respectively.	93,415	62,840
Deferred compensation	(47)	(88)
Accumulated deficit	(29,741)	(27,691)
	-----	-----
Total shareholders' equity	63,627	35,061
	-----	-----
	\$ 73,017	\$ 41,492
	-----	-----
	-----	-----

Note: The balance sheet at December 31, 1996 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

SEE ACCOMPANYING NOTES.

INHALE THERAPEUTIC SYSTEMS

Condensed Statements of Operations  
(in thousands, except per share information)  
(unaudited)

	THREE MONTHS ENDED MARCH 31,	
	1997	1996
Contract research revenue	\$ 3,177	\$ 1,482
Operating costs and expenses:		
Research and development	4,569	2,916
General and administrative	1,382	702
	-----	-----
Total operating costs and expenses	5,951	3,618
	-----	-----
Loss from operations	(2,774)	(2,136)
Interest income, net	730	235
	-----	-----
Net loss	\$ (2,044)	\$ (1,901)
	-----	-----
	-----	-----
Net loss per share	\$ (0.16)	\$ (0.19)
	-----	-----
	-----	-----
Shares used in computing net loss per share	12,878	10,151
	-----	-----
	-----	-----

SEE ACCOMPANYING NOTES.

INHALE THERAPEUTIC SYSTEMS

Condensed Statements of Cash Flows  
Increase/(Decrease) in Cash and Cash Equivalents  
(in thousands)  
(unaudited)

	THREE MONTHS ENDED MARCH 31,	
	1997	1996
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash provided by (used in) operations	\$ 1,868	\$ (3,039)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of available for sale securities, net of sales and maturities	(13,388)	1,462
Purchases of property and equipment, net	(898)	(344)
Net cash provided by (used in) investing activities	(14,286)	1,118
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Payments of equipment financing obligations	(63)	(62)
Issuance of common stock, net of issuance costs	30,575	11
Net cash provided by financing activities	30,512	12,083
Net increase (decrease) in cash and cash equivalents	18,094	(1,972)
Cash and cash equivalents at beginning of period	18,568	3,834
Cash and cash equivalents at end of period	\$ 36,662	\$ 1,862

SEE ACCOMPANYING NOTES.

## INHALE THERAPEUTIC SYSTEMS

### NOTES TO CONDENSED FINANCIAL STATEMENTS

March 31, 1997

(unaudited)

#### 1. BASIS OF PRESENTATION

The accompanying unaudited condensed financial statements of Inhale Therapeutic Systems ("Inhale" or the "Company") have been prepared in accordance with generally accepted accounting principles for interim financial information and the instructions for Form 10-Q and Article 10 of Regulation S-X. The balance sheet as of March 31, 1997 and the related statements of operations and cash flows for the three month periods ended March 31, 1997 and 1996, are unaudited but include all adjustments (consisting of normal recurring adjustments) which the Company considers necessary for a fair presentation of the financial position at such dates and the operating results and cash flows for those periods. Although the Company believes that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information normally included in financial statements and related footnotes prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the "Commission"). The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 1996 filed with the Commission.

Results for any interim period are not necessarily indicative of results for any other interim period or for the entire year.

#### 2. REVENUE RECOGNITION

Contract revenue from collaborative research agreements is recorded when earned and as the related costs are incurred. Payments received which are related to future performance are deferred and recognized as revenue when earned over future performance periods. In accordance with contract terms, up-front and milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements, and accordingly, are generally recognized based on actual efforts expended over the terms of the agreements. The Company's research revenue is derived primarily from partners in the pharmaceutical and biotechnology industries. All of the Company's research and development agreements are generally cancelable by the partner without significant penalty to the partner. Contract research revenue from two partners represented 75% of the Company's revenue in the three month period ended March 31, 1997. Contract revenue from two partners accounted for 85% of the Company's revenue in the comparable period in 1996. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

#### 3. NET LOSS PER SHARE

Net loss per share is computed using the weighted average number of shares of Common Stock outstanding. Common equivalent shares from stock options and warrants are excluded from the computation as their effect is antidilutive.

In February 1997, the Financial Accounting Standard Board issued Statement No. 128, EARNINGS PER SHARE, which is required to be adopted on December 31, 1997. At that time, the Company will be required to change the method currently used to compute earnings per share and to restate all prior periods. Under the new requirements for calculating basic, formerly primary, earnings per share, the dilutive effect of stock options will be excluded. The statement is expected to have no impact on the Company's primary or fully diluted earnings per share for the first quarter ended March 31, 1997 and March 31, 1996.

#### 4. EQUITY

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

Item 2.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations for the three months ended March 31, 1997 and 1996 should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations included in the Company's Annual Report on Form 10-K for the year ended December 31, 1996. The following discussion contains forward-looking statements that involve risk and uncertainties. The Company's actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to, those discussed herein as well as those discussed under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 1996.

Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date hereof. The Company undertakes no obligation to publicly release the results of any revision to these forward-looking statements which may be made to reflect events or circumstances occurring after the date hereof or to reflect the occurrence of unanticipated events.

OVERVIEW

Since its inception in July 1990, Inhale has been engaged in the development of a pulmonary system for the delivery of macromolecules and other drugs for systemic and local lung applications. The Company has been unprofitable since inception and expects to incur significant and increasing additional operating losses over the next several years primarily due to increasing research and development expenditures and expansion of late stage clinical and early stage commercial manufacturing facilities. To date, Inhale has not sold any products and does not anticipate receiving revenue from product sales or royalties in the near future. For the period from inception through March 31, 1997, the Company incurred a cumulative net loss of approximately \$29.7 million. Inhale's sources of working capital have been equity financing, financing of equipment acquisitions, interest earned on investments of cash, and revenues from short-term research and feasibility agreements and development contracts.

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

RESULTS OF OPERATIONS

Revenue in the first quarter of 1997 was \$3,177,000, as compared to \$1,482,000 in the first quarter of 1996, an increase of 114%. The increase in revenue was primarily due to the signing of additional corporate partners in 1997. In January 1997 the Company entered into a development agreement with Eli Lilly and Company ("Lilly") to develop pulmonary-delivery for a selected osteoporosis product. Under the terms of the agreement, Inhale will receive up to an estimated \$20 million in initial fees, funding for research and milestone payments. In return, Lilly will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties on any marketed products. In addition, in January 1997 the Company entered into an agreement with Centeon L.L.C. to develop a

pulmonary formulation of alpha-1 proteainase inhibitor. Under this agreement the Company will receive up to an estimated \$15 million in funding for research and milestone payments and royalties on future product sales. In return, Centeon will receive commercialization rights worldwide outside of Japan. Revenue for the first quarter of 1997 and 1996 was comprised of reimbursed research and development expenses and the amortization of the pro-rata portion of the up-front signing and milestone payments based on actual efforts expended. Costs of contract research revenue approximate such revenue and are included in research and development expense.

Research and development expenses increased to approximately \$4,569,000 in the first quarter of 1997 from \$2,916,000 in the first quarter of 1996, an increase of 57%. The increase is primarily attributed to continued expansion of research activities resulting from an increase in the number of projects, additional hiring of scientific personnel, and increased costs of laboratory supplies and consulting services. The Company expects research, development and process development spending to increase significantly over the next few years as the Company continues to expand its research and development and prepares for its initial commercial manufacturing.

General and administrative expenses increased to \$1,382,000 in the first quarter of 1997 from \$702,000 in the first quarter of 1996, an increase of 97%. The increase was due primarily to support of the Company's increased research efforts including administrative staffing, business development activities and marketing activities. General and administrative expenses are expected to continue to increase to support increased levels of research, development and manufacturing activities.

Net interest income increased to \$730,000 in the first quarter of 1997 compared to \$235,000 in the first quarter of 1996, an increase of 211%. Interest income was earned on larger cash and investment balances held by the Company in the quarter ended March 31, 1997, compared to the same period in 1996. The higher cash and investment balances are a result of the Company receiving milestone and research funding payments from collaborative partners as well as the completion of a private placement of the Company's Common Stock in February 1997 which raised net proceeds of \$30.4 million.

#### LIQUIDITY AND CAPITAL RESOURCES

The Company has financed its operations primarily through private placements and public offerings of its equity securities, contract research and milestone revenues, interest income earned on its investments of cash and financing of equipment acquisitions. On February 7, 1997 the Company completed a private placement of its Common Stock, selling 1.8 million newly issued shares for net proceeds of \$30.4 million. At March 31, 1997, the Company had cash, cash equivalents and short-term investments of approximately \$67.8 million.

The Company's operations generated cash of \$1.9 million in the three months ended March 31, 1997, as compared to the Company's operations using \$3.0 million for the three months ended March 31, 1996. The increase in cash flow from operations is due primarily to the increase in advance payments received under the Company's collaborative agreements for work to be performed in future periods. Cash generated from operations differed from the Company's net operating losses in these periods due principally to depreciation expenses, decreases in accounts receivable and increases in accounts payable and accrued liabilities.

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

The Company believes that its cash, cash equivalents and short-term investments as of March 31, 1997 of approximately \$67.8 million, together with interest income and possible additional equipment financing, will be sufficient to meet its operating expense and capital expenditure requirements at least

through 1998. However, the Company's capital needs will depend on many factors, including continued scientific progress in its research and development arrangements, progress with pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of developing and the rate of scale-up of the Company's powder processing and packaging technologies, the timing and cost of its late-stage clinical and early commercial production facility, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technologies and the status of competitive products. To satisfy its long-term needs, the Company intends to seek additional funding, as necessary, from corporate partners and from the sale of securities. There can be no assurance that additional funds, if and when required, will be available to the Company on favorable terms, if at all.

#### RISK FACTORS

**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.

**HISTORY OF OPERATING LOSSES; UNCERTAINTY OF FUTURE PROFITABILITY.** The Company has not been profitable since inception and, through March 31, 1997, had incurred a cumulative deficit of approximately \$29.7 million. The Company expects to continue to incur substantial and increasing losses over at least the next several years as the Company's research and development efforts, preclinical and clinical testing activities and manufacturing scale-up efforts expand and as the Company plans and builds its late stage clinical and early commercial production facility. All of the Company's potential products are in research or in the early stages of development, and no revenues have been generated from approved product sales. The Company's revenues to date have consisted primarily of payments under short-term research and feasibility agreements and development contracts. To achieve and sustain profitable operations, the Company, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products utilizing its pulmonary drug delivery system. There can be no assurance that the Company can generate sufficient product or contract research revenue to become profitable or to sustain profitability.

**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 drug.

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.

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 of issuance. Beginning in June 1995, the patent term became 20 years from the earliest effective filing date of the underlying patent application. Such change may reduce the effective term of protection for patents that are pending for more than three years in the PTO. In addition, as of January 1996, all inventors who work outside of the United

States are able to establish a date of invention on the same basis as those working in the United States. Such change could adversely affect the ability of the Company to prevail in a priority of invention dispute with a third party located or doing work outside of the United States. While the Company cannot predict the effect that such changes will have on its business, such changes could have a material adverse effect on the Company's ability to protect its proprietary information and sustain the commercial viability of its products. Furthermore, the possibility of extensive delays in such process, could effectively further reduce the term during which a marketed product could be protected by patents.

**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.

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.

**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. The Company is also aware of other companies currently engaged in the development and commercialization of pulmonary drug delivery systems and enhanced injectable drug delivery systems. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than the Company and represent significant competition for the Company. Acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance competitors' financial, marketing and other resources.



Accordingly, the Company's competitors may succeed in developing competing technologies, obtaining FDA approval for products 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.

PART II: OTHER INFORMATION

- Item 1. Legal Proceedings - Not Applicable
- Item 2. Changes in Securities - None
- Item 3. Defaults upon Senior Securities - None
- Item 4. Submission of Matters to a Vote of Security Holders - None
- Item 5. Other Information - None

Item 6. Exhibits and Reports on Form 8-K

(#) Exhibits

The following exhibits are filed herewith or incorporated by reference

EXHIBIT	EXHIBIT TITLE
3.1 (3)	Restated Articles of Incorporation of the Registrant.
3.2 (1)	Bylaws of the Registrant.
4.1	Reference is made to Exhibits 3.1 through 3.2.
4.2 (1)	Restated Investor Rights Agreement among the Registrant and certain other persons named therein, dated April 29, 1993, as amended October 29, 1993.
4.5 (1)	Warrant to purchase 18,182 Shares of Series C Preferred Stock between the Registrant and Phoenix Leasing Incorporated, dated October 29, 1993.
4.6 (1)	Specimen stock certificate.
4.9 (2)	Stock Purchase Agreement between the Registrant and Pfizer Inc., dated January 18, 1995.
4.10 (8)	Warrant to purchase 10,000 shares of Common Stock between the Registrant and Thomas J. Peirona, dated November 1, 1996.
4.11 (8)	Warrant to purchase 10,000 shares of Common Stock between the Registrant and Kiet Nguyen, dated November 1, 1996.
4.12 (9)	Form of Stock Purchase Agreement between the Registrant and the Selling Shareholders dated January 28, 1997.
10.1 (4)	Registrant's 1994 Equity Incentive Plan (the "Equity Incentive Plan").
10.2 (1)	Form of Incentive Stock Option under the Equity Incentive Plan.
10.3 (1)	Form of Nonstatutory Stock Option under the Equity Incentive Plan.
10.4 (7)	Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended.
10.5 (1)	Registrant's 1994 Employee Stock Purchase Plan.
10.6 (1)	Standard Industrial Lease between the Registrant and W.F. Batton & Co., Inc., dated September 17, 1992, as amended September 18, 1992.
10.7 (1)	Master Equipment Lease between the Registrant and Phoenix Leasing Incorporated, dated August 15, 1992 and Schedules i to 4 thereto.
10.8 (1)	Senior Loan and Security Agreement between the Registrant and Phoenix Leasing Incorporated, dated September 15, 1993.
10.9 (1)	Sublicense Agreement between the Registrant and John S. Patton, dated September 13, 1991.
10.10(2)	Offer Letter, dated September 16, 1994, from the Registrant to Jack M. Anthony.
10.11(2)	Addendum to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
10.12(6)	Lease dated May 31, 1995, between the Registrant and W.F. Batton & Marie A. Batton.
10.13(6)	Addendum Number One to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
10.14(6)	Addendum to Lease dated May 31, 1995 between the Registrant and W.F. Batton & Marie A. Batton.
10.15(6)	Addendum Number Two to Lease dated September 17, 1992, between the Registrant and W.F. Batton & Marie A. Batton.
10.16(5)	Stock Purchase Agreement between the Registrant and Baxter World Trade Corporation, dated March 1, 1996.
10.17(8)	Sublease and Lease Agreement, dated October 2, 1996 between the Registrant and T.M.T. Associates L.L.C.
27.1	Financial Data Schedule

(1) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-75942), as amended.

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

(b) Reports on Form 8-K.

On February 6, 1997 the Company filed a report on Form 8-K providing an update of the Company's activities.

(c) See Exhibits listed under Item 14(a)(3).

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto.

INHALE THERAPEUTIC SYSTEMS

DATE: May 13, 1997

BY: /S/Robert B. Chess  
 -----  
 Robert B. Chess  
 President, Chief Executive  
 Officer and Director

DATE: May 13, 1997

BY: /S/Judi R. Lum  
 -----  
 Judi R. Lum  
 Chief Financial Officer



THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE FINANCIAL STATEMENTS FOR INHALE THERAPEUTIC SYSTEMS FOR THE THREE MONTH PERIOD ENDED MARCH 31, 1997 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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3-MOS	DEC-31-1997	JAN-01-1997	MAR-31-1997
			36,662
		31,123	
		0	
		0	
		0	
		887	0
		0	
		73,017	
	9,215		0
	0		
		0	
		93,415	
		(29,788)	
73,017			0
		3,177	0
		0	
		5,951	
		0	
		0	
		(2,044)	
	(2,044)		0
		0	
		0	
		0	0
		(2,044)	
		(0.16)	
		(0.16)	