

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 September 30, 1998

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, INC.
(Exact name of registrant as specified in its charter)

DELAWARE

94-3134940

(State of other jurisdiction of
incorporation or organization)

(IRS Employer Identification No.)

150 INDUSTRIAL ROAD
SAN CARLOS, CALIFORNIA 94070
(Address of principal executive offices)

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

Not applicable

(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, \$0.0001 par value, was 15,690,495 as of October 26, 1998.

INHALE THERAPEUTIC SYSTEMS, INC.
INDEX

PART I: FINANCIAL INFORMATION

	PAGE
Item 1. Condensed Financial Statements - unaudited	3
Condensed Balance Sheets - September 30, 1998 and December 31, 1997	3
Condensed Statements of Operations for the three and nine month periods ended September 30, 1998 and 1997	4
Condensed Statements of Cash Flows for the nine month period ended September 30, 1998 and 1997	5
Notes to Condensed Financial Statements.	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	7

PART II: OTHER INFORMATION

Item 1. Legal Proceedings.17
Item 2. Changes in Securities.17
Item 3. Defaults Upon Senior Securities.17
Item 4. Submission of Matters to a Vote of Security Holders.17
Item 5. Other Information.17
Item 6. Exhibits and Reports on Form 8-K17
Signatures20

Item 1.

INHALE THERAPEUTIC SYSTEMS, INC.

Condensed Balance Sheets
(in thousands)

	September 30, 1998	December 31, 1997
	----- (unaudited)	----- (Note)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,312	\$ 14,948
Short-term investments	44,552	85,225
Other current assets	1,673	752
	-----	-----
Total current assets	64,537	100,925
Property and equipment, net	37,918	18,694
Deposits and other assets	144	143
	-----	-----
	\$ 102,599	\$ 119,762
	-----	-----
	-----	-----
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 5,308	\$ 10,428
Deferred revenue	5,060	6,686
	-----	-----
Total current liabilities	10,368	17,114
Equipment financing obligations	4,957	5,102
Accrued rent	849	453
Stockholders' equity:		
Common stock	1,569	1,377
Capital in excess of par value	135,452	133,896
Deferred compensation	(864)	(538)
Accumulated deficit	(49,732)	(37,642)
	-----	-----
Total stockholders' equity	86,425	97,093
	-----	-----
	\$ 102,599	\$ 119,762
	-----	-----
	-----	-----

Note: The balance sheet at December 31, 1997 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, INC.

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	1998	1997	1998	1997
Contract research revenue	\$ 4,883	\$ 4,309	\$ 15,427	\$11,459
Operating costs and expenses:				
Research and development	8,941	6,427	24,803	16,640
General and administrative	1,819	1,345	5,769	4,244
	-----	-----	-----	-----
Total operating costs and expenses	10,760	7,772	30,572	20,884
	-----	-----	-----	-----
Loss from operations	(5,877)	(3,463)	(15,145)	(9,425)
Interest income, net	835	812	3,104	2,432
	-----	-----	-----	-----
Net loss	\$(5,042)	\$(2,651)	\$(12,041)	\$(6,993)
	-----	-----	-----	-----
Basic and diluted net loss per share	\$ (0.32)	\$ (0.19)	\$ (0.77)	\$ (0.52)
	-----	-----	-----	-----
Shares used in computing basic and diluted net loss per share	15,681	13,726	15,630	13,417
	-----	-----	-----	-----

SEE ACCOMPANYING NOTES.

INHALE THERAPEUTIC SYSTEMS, INC.

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	1998	1997
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (12,041)	\$ (6,993)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,321	1,611
Amortization of deferred compensation	127	88
Increase in other current assets, deposits and other assets	(921)	(5,421)
Increase (decrease) in accounts payable and accrued liabilities	(4,703)	2,915
Increase (decrease) in deferred revenue	(1,626)	5,785
	-----	-----
Net cash used in operations	(16,843)	(2,015)
	-----	-----
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of available for sale securities	(120,184)	(53,354)
Sales and maturities of available for sale securities	160,808	23,063
Purchases of property and equipment	(21,546)	(8,196)
	-----	-----
Net cash provided by (used in) investing activities	19,078	(38,487)
	-----	-----
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of equipment financing obligations	(165)	(128)
Issuance of common stock, net of issuance costs	1,294	31,689
	-----	-----
Net cash provided by financing activities	1,129	31,561
	-----	-----
Net increase (decrease) in cash and cash equivalents	3,364	(8,941)
Cash and cash equivalents at beginning of period	14,948	18,568
	-----	-----
Cash and cash equivalents at end of period	\$ 18,312	\$ 9,627
	-----	-----

SEE ACCOMPANYING NOTES.

INHALE THERAPEUTIC SYSTEMS, I NC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
September 30, 1998
(unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION

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

On June 23, 1998, the Company held its Annual Shareholders Meeting at which the Shareholders approved the Company's reincorporation in Delaware. The Company completed its reincorporation in Delaware on July 1, 1998.

The accompanying unaudited condensed financial statements of Inhale 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 September 30, 1998 and the related statements of operations and cash flows for the nine month periods ended September 30, 1998 and 1997, are unaudited but include all adjustments for the three and nine months ended September 30, 1998 and 1997 (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, 1997 as 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. COMPREHENSIVE INCOME

Comprehensive income is equal to net income for the three and nine month periods ended September 30, 1998 and 1997.

3. 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 three partners represented 91% of the Company's revenue in the nine month period ended September 30, 1998. Contract revenue from two partners accounted for 70% of the Company's revenue in the comparable period in 1997. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

4. NET LOSS PER SHARE

Basic and diluted net loss per common share is computed in conformance with Statement of Financial Accounting Standards No. 128, "Earnings Per Share", which the Company adopted in 1997. Accordingly, the weighted average number of common shares outstanding are used while common stock equivalent shares for stock options and warrants are not included in the per share calculations as the effect of their inclusion would be antidilutive.

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 and nine months ended September 30, 1998 and 1997 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, 1997. 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 under the heading "Risk Factors" as well as those discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 1997.

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 commercial products and does not anticipate receiving revenue from product sales or royalties in the near future. For the period from inception through September 30, 1998, the Company incurred a cumulative net loss of approximately \$49.7 million. The sources of working capital have been equity financings, financings of equipment acquisitions, interest earned on investments of cash, and payments received under research 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 third quarter of 1998 was \$4.9 million compared to \$4.3 million in the third quarter of

1997, an increase of 13%. Revenues for the nine months ended September 30, 1998 were \$15.4 million as compared to \$11.5 million for the nine months ended September 30, 1997, an increase of 35%. The increase in revenue for both the three and nine months periods was primarily due to the expansion of the Company's existing collaborative agreements. Revenue for the first, second and third quarters of 1998 and 1997 was comprised of reimbursed research and development expenses as well as the amortization of the pro-rata portion of up-front signing and milestone payments received from the Company's collaborative partners. Recognition of up-front signing and milestone payments is based on actual efforts expended. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

Research and development expenses increased to approximately \$8.9 million in the third quarter of 1998 from \$6.4 million in the corresponding period of 1997, an increase of 39%. Research and development expenses for the nine months ended September 30, 1998 were \$24.8 million compared to \$16.6 million for the nine months ended September 30, 1997, an increase of 49%. The increase for both the three and nine month periods was due primarily to continued expansion of research activities resulting from an increase in the number of projects, additional hiring of scientific and development personnel, costs associated with validation process development for the Company's commercial manufacturing facility and increased costs of laboratory supplies, tooling and other product development expenses. The Company expects research, development and process development spending to increase significantly over the next few years as the Company expands its development efforts under collaborative agreements and scales up its late stage clinical and early stage commercial manufacturing facility.

General and administrative expenses increased to \$1.8 million in the third quarter of 1998 from \$1.3 million in the third quarter of 1997, an increase of 35%. For the nine month period ended September 30, 1998, general and administrative expenses were \$5.8 million compared to \$4.2 million in the comparable period of 1997, an increase of 36%. The increase for the three and nine month periods was due primarily to costs associated with supporting the Company's increased research efforts including administrative staffing, business development and marketing activities, and the purchase of additional computer equipment and supplies. General and administrative expenses are expected to continue to increase over the next few years to support increasing levels of research, development and manufacturing activities.

Net interest income increased to \$840,000 in the third quarter of 1998 compared to \$810,000 in the third quarter of 1997, an increase of 3%. Net interest income increased to \$3.1 million in the nine month period ended September 30, 1998 compared to \$2.4 million for the nine months ended September 30, 1997. Interest income was earned on larger cash and investment balances held by the Company in the nine month period ended September 30, 1998, compared to the same period in 1997. The higher cash and investment balances are the result of the Company receiving milestone and research funding payments from collaborative partners as well as the completion of a public offering of the Company's Common Stock in November 1997 which raised net proceeds of approximately \$40.0 million.

LIQUIDITY AND CAPITAL RESOURCES

The Company has financed its operations primarily through public and private placements of its equity securities, contract research and milestone payments, financing of equipment acquisitions and interest income earned on its investments of cash. At September 30, 1998, the Company had cash, cash equivalents and short-term investments of approximately \$62.9 million.

The Company's operations used cash of \$16.8 million in the nine months ended September 30, 1998, as compared to \$2.0 million used in the nine months ended September 30, 1997. The increase in net cash used in operations is principally due to the continued expansion of research activities resulting from an increase in the number of projects and providing the related general and administrative support for these increased research efforts, including increased business development and marketing expenses.

The Company purchased property and equipment of approximately \$21.5 million during the nine months ended September 30, 1998, compared to \$8.2 million for the corresponding period in 1997. The increase is primarily due to the build-out of the Company's manufacturing facility and corporate headquarters in San Carlos, California. This facility will support the Company's commercial manufacturing requirements.

The Company expects its cash requirements to continue to increase at an accelerated rate due to expected increases in costs associated with further research and development of its technologies, resulting in larger numbers 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, investments in technologies, inhalation device prototype construction and facilities expansion, including the completion of its late stage clinical and commercial manufacturing facility.

The Company believes that its cash, cash equivalents and short-term investments as of September 30, 1998, together with interest income and possible additional equipment financing, will be sufficient to meet its operating expense and capital expenditure requirements at least through 1999. However, the Company's capital needs will depend on many factors, including continued scientific progress in its research and development arrangements, progress with pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of 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.

YEAR 2000 COMPLIANCE

The Company is aware of the issues associated with the programming code in existing computer systems as the millennium (Year 2000) approaches. The Year 2000 ("Y2K") problem is pervasive and complex as virtually every computer operation may be affected in some way by the rollover of the two digit year value to "00". The issue is whether systems will properly recognize date sensitive information when the year changes to 2000. If the Company's software and firmware with date-sensitive functions are not Y2K compliant, they may recognize a date with "00" as the year 1900 rather than the year 2000. This could result in a system failure or miscalculations causing disruptions of operations, including, among other things, interruptions in manufacturing operations, a temporary inability to process transactions, or engage in similar normal business activities.

The Company is utilizing both internal and external resources to conduct a comprehensive review of its systems to identify those systems that could be affected by the Y2K problem and is developing an implementation plan to resolve the issue by the end of 1999. The scope of the Y2K effort includes information technology ("IT") such as software and hardware, non-IT systems or embedded technology such as microcontrollers contained in various manufacturing and lab equipment, environmental and safety systems, facilities and utilities, and the Y2K readiness of key third parties such as suppliers and financial institutions. A multi-step Y2K readiness plan has been developed for its internal systems which includes development of corporate awareness, inventory and assessment of internal systems, project planning, project implementation (which includes remediation, upgrading and replacement), and validation testing.

The Company has initiated formal communication with significant vendors and suppliers to determine the extent to which the Company's operations are vulnerable to those third parties' failure to remediate their own Y2K issues. Suppliers of hardware, software or other products that might contain embedded processors were requested to provide information regarding Y2K compliance status of their products. The Company will continue to seek information from non-responsive suppliers and plans to contact replacement vendors and suppliers through the second quarter of 1999 and then develop and implement contingency plans. In addition, in order to protect against the acquisition of additional non-compliant products, the Company now requires suppliers to warrant that products sold or licensed to the Company are Y2K compliant. In the event that any of the Company's significant suppliers do not successfully and timely achieve Y2K compliance, the Company's business or operations could be adversely affected. There can be no assurance that the systems of other companies on which the Company's systems rely will be converted on a timely basis and would not have an adverse effect on the Company's operations.

The Company has not yet fully developed a comprehensive contingency plan to address situations that may result if the Company is unable to achieve Y2K readiness of its critical operations. Development of contingency plans is in

progress and will develop in detail and expand during the remainder of 1998 and the first half of 1999. There can be no assurance that the Company will be able to develop a contingency plan that will adequately

address issues that may arise in the year 2000. The failure of the Company to develop and implement, if necessary, an appropriate contingency plan could have a material impact on the operations of the Company. Finally, the Company is also vulnerable to external forces that might generally affect industry and commerce, such as utility and transportation company Y2K compliance failures and related service interruptions.

The Company anticipates completing the mission critical, high impact Y2K issues by the first half of 1999, which is prior to any anticipated impact on its operating systems and expects the Y2K project to continue beyond the year 2000 with respect to the upgrading, replacement and testing of non-critical systems. These dates are contingent upon the timeliness and accuracy of software and hardware upgrades from vendors, adequacy and quality of resources available to work on completion of the project and any other unforeseen factors. The total expense of the Y2K project is currently estimated at approximately \$1 million, which is not material to the Company's business operations or financial condition. The expenses of the Y2K project are being funded through operating cash flows.

The costs of the project and the date on which the Company believes it will complete the Y2K modifications are based on management's best estimates, which were derived utilizing numerous assumptions of future events, including the continued availability of certain resources, third-party modification plans and other factors. There can be no assurance that these estimates will be achieved and actual results could differ materially from those anticipated.

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 small molecule drugs. Only six of the Company's fourteen pulmonary delivery formulations, insulin, interleukin-1 receptor, salmon calcitonin, an osteoporosis drug and two small molecules 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, pre-clinical and clinical testing, and may involve lengthy regulatory review. There can be no assurance that any of the Company's potential products will prove to be safe and effective in clinical trials, meet applicable regulatory standards, be capable of being produced in commercial quantities at acceptable cost or be marketed successfully. Any failure of the Company to achieve technical feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or, together with partners, successfully market products, would have a material adverse effect on the Company.

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

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

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

The Company's integrated approach to systems development relies upon several different but related technologies. Development of powder formulations, processing and packaging technology and the delivery device, establishing collaborations with partners, laboratory and clinical testing, and manufacturing scale-up must proceed contemporaneously so as not to delay any aspect of systems development. Any delay in one component of product or business development could cause consequential delays in the Company's ability to develop, obtain approval of or market therapeutic products using its system. Further refinement of the Company's device prototype, further scale-up of the powder processing system and automated packaging system will need to be accomplished before initiation of late stage clinical trials.

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

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

HISTORY OF OPERATING LOSSES; UNCERTAINTY OF FUTURE PROFITABILITY. The Company has not been profitable since inception and, through September 30, 1998, has incurred a cumulative deficit of approximately \$49.7 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 COLLABORATIVE PARTNERS. The Company currently does not possess the resources necessary to develop, obtain regulatory approvals, or commercialize any of its potential therapeutic products. The Company's ability to apply its pulmonary delivery system to a broad range of drugs will

depend upon its ability to establish and maintain collaborative arrangements since many of the drugs currently approved for sale or in clinical testing are covered by third-party patents. The Company has entered into collaborative arrangements with certain of its partners to fund clinical trials, assist in obtaining regulatory approvals, supply drugs for formulation and market and distribute products. While Inhale has also entered into agreements with partners to test the feasibility of its pulmonary delivery system with certain of their proprietary molecules, there can be no assurance that the Company will be able to enter into additional

collaborations or that its feasibility agreements will lead to collaborations. There also can be no assurance that the Company will be able to maintain any such collaborative arrangements or feasibility agreements or that any such collaborative arrangements or feasibility agreements will be successful. The failure of the Company to enter into or maintain such collaborative arrangements and feasibility agreements would have a material adverse effect on the Company. Moreover, the inability of the Company to enter into a collaborative arrangement with the owner of any patented drug may preclude the Company from working with such drug, and the inability of any partner to supply drugs for formulation would have a material adverse effect on the Company.

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

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

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

Fine particle powders and small quantity packaging (such as those to be used in the Company's delivery system) require special handling. The Company has designed and qualified small scale automated filling equipment for small quantity packaging of fine powders. The Company faces significant technical

challenges scaling-up an automated filling system that can accurately and economically handle the small dose and particle sizes of its powders in commercial quantities. There can be no assurances that the Company will be able to scale-up its automated filling equipment in a timely manner or at commercially reasonable costs. Any failure or delay in such scale-up would delay product development or bar commercialization of the Company's products and would have a material adverse effect on the Company.

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

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

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

The Company expects that its existing capital resources, contract research revenues from collaborations and the net proceeds from the November 1997 public offering and the interest thereon, will enable the Company to maintain its current and planned operations at least through 1999. Thereafter, the Company may need to raise substantial additional capital to fund its operations. The Company intends to seek such additional funding through collaborative or partnering arrangements, the extension of existing arrangements, or through public or private equity or debt financings. There can be no assurance that additional financing will be available on acceptable terms or at all. If additional funds are raised by issuing equity securities, further dilution to shareholders may result. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its research or development programs or obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates or products that the Company would otherwise seek to develop or commercialize.

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. Currently the Company has been issued twenty-four U.S. and foreign patents

which cover certain aspects of its proprietary technology and the Company has a number of patent applications pending. There can be no assurance that any of the patents applied for by the Company will issue, or that any patents that issue or have issued 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 issued U.S. patents 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. An adverse outcome could subject the Company to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require the Company to cease using the technology in dispute.

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

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

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

The Company's ability to develop and commercialize its technology will

be affected by the Company's or its partners' access to the drugs which are to be formulated. Many drugs, including powder formulations of certain drugs which are presently under development by the Company, are subject to issued and pending United States and foreign patent rights which may be owned by competing entities. There are issued patents and pending patent applications relating to the pulmonary delivery of macromolecule drugs, including several for which the Company is developing pulmonary delivery formulations. The resulting patent situation is highly complex, and the ability of any one company

to commercialize a particular biopharmaceutical drug is highly unpredictable. The Company intends generally to rely on the ability of its partners to provide access to the drugs which are to be formulated for pulmonary delivery. There can be no assurance that the Company's partners will be able to provide access to drug candidates for formulation for pulmonary delivery or that, if such access is provided, the Company or its partners will not be accused of, or determined to be, infringing a third party's rights and will not be prohibited from working with the drug or be found liable for damages that may not be subject to indemnification. Any such restriction on access or liability for damages would have a material adverse effect on the Company.

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

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

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

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

The time required for completing such testing and obtaining such approvals is uncertain. Further refinement of the device prototype, further scale-up of the powder processing system and automated powder filling and packaging system will need to be accomplished before initiation of later

stage clinical trials. Any delay in any of these components of product development may delay testing. In addition, delays or rejections may be encountered based upon changes in FDA policy, including FDA policy relating to GMP compliance, during the period of product development. Similar delays may also be encountered in other countries. If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which the product may be marketed, and the marketed product, its

manufacturer, and its manufacturing facilities remain subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on such product or manufacturer, including withdrawal of the product from the market. There can be no assurance that regulatory approval will be obtained for any products developed by the Company on a timely basis, or at all. The failure to obtain timely regulatory approval of its products, any product marketing limitations or a product withdrawal would have a material adverse effect on the Company.

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

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

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

The Company is in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. The Company is aware of a number of companies currently seeking to develop new products and non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems and colonic absorption systems. Several of these companies may have developed or be developing dry powder devices that could be used for pulmonary delivery. The Company is also aware of other companies currently engaged in the development and commercialization of pulmonary drug delivery systems and enhanced injectable drug delivery systems. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than the Company and represent significant competition for the Company. Acquisitions of

competing drug delivery companies by large pharmaceutical companies could enhance competitors' financial, marketing and other resources. Accordingly, the Company's competitors may succeed in developing competing technologies, obtaining FDA approval for products or gain market acceptance more rapidly than the Company. There can be no assurance that developments by others will not render the Company's products or technologies uncompetitive or obsolete.

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

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

ANTI-TAKEOVER PROVISIONS. Certain provisions of the Company's Certificate of Incorporation and the Delaware General Corporation Law could discourage a third party from attempting to acquire, or make it more difficult for a third party to acquire, control of the Company without approval of the Company's Board of Directors. Such provisions could also limit the price that certain investors might be willing to pay in the future for shares of Common Stock. Certain of the provisions allow the Board of Directors to authorize the issuance of Preferred Stock with rights superior to those of the Common Stock.

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

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

Pursuant to the Company's bylaws, stockholders who wish to bring matters or propose nominees for director at the Company's 1999 Annual Meeting of Stockholders must provide specified information to the Company between March 25, 1999 and April 24, 1999 (unless such matters are included in the Company's proxy statement pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended).

- Item 6. Exhibits and Reports on Form 8-K

The following exhibits are filed herewith or incorporated by reference

EXHIBIT	EXHIBIT TITLE
2.1	Agreement and Plan of Merger Between Inhale Therapeutic Systems, a California Corporation, and Inhale Therapeutic Systems (Delaware), a Delaware Corporation
3.1	Certificate of Incorporation of the Registrant.
3.2	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.
4.6 (1)	Specimen stock certificate.
4.9 (2)	Stock Purchase Agreement between the Registrant and Pfizer Inc., dated January 18, 1995.
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, as amended (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.
10.8 (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.
10.11(2)	Lease dated September 17, 1992, 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.
10.15 (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

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- (1) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-75942), as amended.
 - (2) Incorporated by reference to the indicated exhibit in the Company's Registration Statement (No. 33-89502), as amended.
 - (3) Incorporated by reference to the indicated exhibit in the Company's Annual Report on Form 10-K for the year ended December 31, 1994.
 - (4) Incorporated by reference to the Company's Registration Statement on Form S-8 (No. 333-59735).
 - (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.
- (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, INC.

DATE: November 10, 1998

BY: /S/ Robert B. Chess

Robert B. Chess
Co-Chief Executive Officer and Director
(Duly Authorized Officer)

BY: /S/ Christian O. Henry

Christian O. Henry
Corporate Controller
(Chief Accounting Officer)

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE FINANCIAL STATEMENTS AS FILED ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 1998 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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(12,041)	
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