UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934. For the quarterly period ended September 30, 1999 [] TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934. For the transition period from_ 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 (IRS Employer Identification No.) incorporation or organization) 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. [X] Yes [] No

APPLICABLE ONLY TO CORPORATE ISSUERS

The number of outstanding shares of the registrant's Common Stock, \$0.0001 par value, was 17,036,906 as of October 31, 1999.

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INHALE THERAPEUTIC SYSTEMS, INC.

CONDENSED BALANCE SHEETS (IN THOUSANDS)

		SEPTEMBER 30, 1999 (UNAUDITED)	DECEMBER 31, 1998
	ASSETS		
Current asset			
	Cash and cash equivalents	\$19,284	\$24,916
	Short-term investments Accounts receivable	39,077	57,946
	Other current assets	1,167 4,938	1,013 665
	Other current assets	4,930	
	Total current assets	64,466	84,540
Property and	equipment, net	56,810	49,863
Deposits and		93	93
		\$121,369 ==========	\$134,496 ========
Current liabi	Accounts payable and accrued liabilities Deferred revenue	\$11,812 4,216	\$8,397 4,359
	Total current liabilities	16,028	12,756
Equipment fin	ancing obligations	0	9
Tenant improvement loan		4,904	4,931
Accrued rent		1,292	919
Stockholders'	equity:		
ocockiloraci 5	Common stock	2	2
	Capital in excess of par value	174,515	172,847
	Deferred compensation	(1,029)	(931)
	Accumulated other comprehensive loss	(53)	(19)
	Accumulated deficit	(74,290)	(56,018)
	Total stockholders' equity	99,145	115,881
		\$121,369	\$134,496
		===========	=========

SEE ACCOMPANYING NOTES.

(*) The balance sheet at December 31, 1998 has been derived from the audited Financial Statements at that date, which are included in the Company's Form 10-K for the year ended December 31, 1998 as filed with the Securities and Exchange Commission. This balance sheet does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

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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,	
	1999	1998	1999	1998
Contract research revenue	\$ 10,628	\$ 4,883	\$ 28,285	\$ 15,427
Operating costs and expenses: Research and development General and administrative	16,084 2,177	8,941 1,819	43,413 5,374	24,803 5,769
Total operating costs and expenses	18,261	10,760	48,787	30,572
Loss from operations	(7,633)	(5,877)	(20,502)	(15, 145)
Interest income, net	588	835	2,228	3,104
Net loss	\$ (7,045)	\$(5,042)	\$(18,274)	\$(12,041)
Basic and diluted net loss per share	\$ (0.41) ======	\$ (0.32) ======	\$ (1.08) =======	\$ (0.77) ========
Shares used in computing basic and diluted net loss per share	17,000 ======	15,681 =======	16,960 ======	15,630

SEE ACCOMPANYING NOTES.

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INHALE THERAPEUTIC SYSTEMS, INC.

CONDENSED STATEMENTS OF CASH FLOWS INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS (IN THOUSANDS) (UNAUDITED)

	NINE MONTHS ENDED SEPTEMBER 30,	
	1999	1998
CASH FLOWS FROM OPERATING ACTIVITIES: Cash used in operations	(\$15,358)	(\$16,843)
CASH FLOWS FROM INVESTING ACTIVITIES: Sale of short-term investments, net of purchases and maturities Purchases of property and equipment	18,836 (10,398)	40,624 (21,546)
Net cash provided by investing activities	8,438	19,078
CASH FLOWS FROM FINANCING ACTIVITIES: Payments of equipment financing obligations and tenant improvement loan Issuance of common stock, net of issuance costs	(46) 1,334	(165) 1,294
Net cash provided by financing activities	1,288	1,129
Net increase (decrease) in cash and cash equivalents	(5,632)	3,364
Cash and cash equivalents at beginning of period	24,916	14,948
Cash and cash equivalents at end of period	\$19,284 =======	\$18,312 =======

SEE ACCOMPANYING NOTES.

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INHALE THERAPEUTIC SYSTEMS, INC. NOTES TO CONDENSED FINANCIAL STATEMENTS SEPTEMBER 30, 1999 (UNAUDITED)

ORGANIZATION AND BASIS OF PRESENTATION

Inhale Therapeutic Systems, Inc. ("Inhale" or the "Company") was incorporated in the State of California in July 1990 and reincorporated in the State of Delaware in July 1998. Since inception, Inhale has been engaged in the development of a system to deliver drugs to the bloodstream through the lungs by inhaling a powdered version of the drug. The system is applicable to a wide range of peptides, proteins and other molecules.

The accompanying unaudited condensed financial statements of Inhale have been prepared by management 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 condensed balance sheet as of September 30, 1999, the condensed statements of operations for the three and nine month periods ended September 30, 1999 and 1998, and the condensed statements of cash flows for the nine month periods ended September 30, 1999 and 1998 have been prepared by Inhale without audit, but include all adjustments (consisting only of normal recurring adjustments) which Inhale considers necessary for a fair presentation of the financial position at such dates and the operating results and cash flows for those periods. Although Inhale 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 Inhale's Annual Report on Form 10-K for the year ended December 31, 1998 as filed with the Commission.

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

2. COMPREHENSIVE LOSS

Other comprehensive losses (primarily unrealized losses on available for sale securities) amounted to \$34,000 and \$48,000, respectively, for the nine month periods ended September 30, 1999 and 1998.

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 progress payments from collaborative research agreements are considered to be payments to support continued research and development activities under the agreements. In accordance with the Company's revenue recognition policy, these payments are included in deferred revenue and are recognized as the related research and development expenditures are incurred.

Contract research revenue from one partner represented 74% of Inhale's revenue in the nine month period ended September 30, 1999. Contract revenue from three partners accounted for 45%, 24% and 21% of Inhale's total revenue in the corresponding period in 1998. Costs of contract research revenue approximate such revenue and are included in operating costs and expenses.

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NET LOSS PER SHARE

The weighted average number of common shares outstanding are used in the per share calculations while common stock equivalent shares for stock options and warrants are not included as the effect of their inclusion would be antidilutive.

5. SEGMENT INFORMATION

Management has organized Inhale's business in one operating segment which includes activities related to the development of systems for the pulmonary delivery of macromolecule drugs. Inhale's operations are presently located in the United States and Inhale derives all of its revenues from within the United States.

SUBSEQUENT EVENTS

In October 1999 Inhale entered into an agreement with Alliance Pharmaceutical Corp. ("Alliance") to acquire Alliance's PulmoSpheres-Registered Trademark- particle and particle processing technology for use in respiratory drug delivery. In November 1999, this transaction was completed. Under the terms of the agreement, Alliance received \$15 million in cash from Inhale and \$5 million worth of Inhale stock. In exchange, Inhale received the rights to PulmoSpheres-Registered Trademark- technology in the field of respiratory delivery, other related assets and \$5 million of Alliance stock. Alliance will also receive potential future milestone payments based on the achievement of defined events, and royalties on eventual sales of a defined number of products commercialized using the technology. Alliance also retained the right to develop up to two respiratory products yet to be specified which will be designated by Alliance and formulated by Inhale using the PulmoSpheres-Registered Trademark-technology on a royalty-free basis.

In October 1999 Inhale received \$97 million in net proceeds from the issuance of \$100 million aggregate principal amount of convertible subordinated debentures to certain qualified institutional buyers under Rule 144A of the Securities Act of 1933, as amended. In November 1999, Inhale received approximately \$8.2 million in net proceeds from the issuance of approximately \$8.5 million aggregate principal amount of additional convertible subordinated debentures. Interest on the debentures will accrue at a rate of 6.75% per year, subject to adjustment in certain circumstances. The debentures will mature in 2006 and are convertible into shares of Inhale's common stock at a conversion price of \$32.0075 per share, subject to adjustment in certain circumstances.

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, 1999 and 1998 should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations included in Inhale's Annual Report on Form 10-K for the year ended December 31, 1998. The following discussion contains forward-looking statements that involve risk and uncertainties. Inhale'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 Inhale's Annual Report on Form 10-K for the year ended December 31, 1998.

Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date hereof. Inhale 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. Inhale 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, 1999, Inhale incurred a cumulative net loss of approximately \$74.3 million. The sources of working capital have been revenues, including milestone payments, from short-term research and feasibility agreements and development contracts, equity financings, financings of equipment acquisitions and tenant improvements, and interest earned on investments of cash.

Inhale has generally been compensated for research and development expenses during initial feasibility work performed under collaborative arrangements. Partners that enter into collaborative agreements generally pay for some or all research and development expenses and make additional payments to Inhale as Inhale achieves certain key milestones. Inhale expects to receive royalties from its partners based on their revenues received from product sales, and to receive revenue from the manufacturing of powders and the supply of devices. In certain cases, Inhale may enter into collaborative agreements under which Inhale's partners would manufacture or package powders or supply inhalation devices, thereby potentially limiting one or more sources of revenue for Inhale. To achieve and sustain profitable operations, Inhale, 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 Inhale can generate sufficient product or contract research revenue to become profitable or to sustain profitability.

RESULTS OF OPERATIONS

Revenue in the third quarter of 1999 was \$10.6 million compared to \$4.9 million in the third quarter of 1998, an increase of approximately 118%. Revenues for the nine months ended September 30, 1999 were \$28.3 million as compared to \$15.4 million for the nine months ended September 30, 1998, an increase of 83%. The increase in revenue for both the three and nine month periods was primarily due to the expansion of Inhale's existing collaborative agreement with Pfizer, Inc. and includes activities associated with the manufacture of Phase III clinical supplies. Revenue for the first, second and third quarters of 1999 and 1998 was comprised of reimbursed research and development expenses as well as the amortization of the pro-rata portion of up-front signing and progress payments received from Inhale's collaborative partners. Recognition of up-front signing and progress 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 \$16.1 million in the third quarter of 1999 from \$8.9 million in the corresponding period of 1998, an increase of 80%. Research and development expenses for the nine months ended September 30, 1999 were \$43.4 million compared to \$24.8 million for the nine months ended September 30, 1998, an increase of 75%. The increase for the three and nine month periods was due to increased spending $\ensuremath{\mathsf{S}}$ related to the scale-up of technologies and the continuing development of the Company's manufacturing capabilities in order to support Phase III inhaleable insulin clinical trials and commercial production. In addition, the Company hired additional scientific and development personnel to handle an increase in the number of development projects and incurred increased expenses $% \left(1\right) =\left(1\right) \left(1$ associated with device development. The largest components of the 75% increase in research and development expenses for the nine months ended September 30, 1999 compared to the same period in 1998 were the increases of \$7.1 million in salaries and employee benefits expense, a \$4.0 million increase in research and development supplies and services, and a \$5.5 million increase in facilities and administrative expense allocations associated with supporting the research and development efforts. Inhale expects research, development and process development spending to increase over the next few years as Inhale continues to expand its development efforts under collaborative agreements and scales up its commercial manufacturing facility.

General and administrative expenses increased to \$2.2 million in the third quarter of 1999 from \$1.8 million in the third quarter of 1998. The increase for the three month period was due to the increased support required by the scale-up of technologies and the continuing development of the Company's manufacturing capabilities in order to support Phase III inhaleable insulin clinical trials and commercial production. For the nine month period ended September 30, 1999, general and administrative expenses were \$5.4 million compared to \$5.8 million in the comparable period of 1998, a decrease of 7%. The decrease for the nine month period was due principally to a change in the Company's methodology for allocating administrative costs to research and development expenses. In the third quarter of 1998, the Company began allocating information systems costs associated with supporting the Inhale organization including systems infrastructure development, maintenance and

support activities. In 1999 the Company began allocating human resources costs, including administrative staffing expenses, as these costs were also associated with supporting the Inhale organization. For the nine month period ended September 30, 1999, the allocation of information systems costs and human resources costs resulted in a decrease in administrative expenses of \$1.8 million and \$0.9 million, respectively, which was partially offset by a net increase in administrative expenses of \$2.3 million related to increased facilities costs and the allocated share of administrative expenses associated with supporting the Company's increased research efforts, including administrative staffing and business development activities. 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 decreased to \$588,000 in the third quarter of 1999 compared to \$835,000 in the third quarter of 1998, a decrease of 30%. Net interest income decreased to \$2.2 million in the nine month period ended September 30, 1999 compared to \$3.1 million for the nine months ended September 30, 1998. Interest income was earned on lower cash and investment balances held by Inhale in the three and nine month periods ended September 30, 1999, compared to the same periods in 1998. Interest expense is expected to increase as interest accrues on the convertible subordinated debentures issued in October and November, 1999.

LIQUIDITY AND CAPITAL RESOURCES

Inhale 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, 1999, Inhale had cash, cash equivalents and short-term investments of approximately \$58.4 million. In October 1999, Inhale received \$97 million in net proceeds from the sale of convertible subordinated debentures. In November 1999, Inhale received approximately \$8.2 million in net proceeds from the sale of additional convertible subordinated debentures.

Inhale's operations used cash of \$15.4 million in the nine months ended September 30, 1999, as compared to \$16.8 million used in the nine months ended September 30, 1998. The decrease in cash used in operations was due principally to increases in accounts payable and accrued liabilities.

Inhale purchased property and equipment of approximately \$10.4 million during the nine months ended September 30, 1999, compared to \$21.5 million for the corresponding period in 1998. The decrease in purchased property and equipment is due to the fact that 1998 spending included costs related to the build-out of Inhale's headquarters and construction of phase one of its manufacturing plant located in San Carlos, California, which is now largely complete.

Inhale 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, 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 Inhale's late stage clinical and commercial manufacturing facility.

Given its current cash requirements, the Company believes that it will have sufficient cash to meet its operating expense requirements for at least the next 18 months. However, the Company plans to continue to invest heavily in its growth and the need for cash will be dependent upon the timing of these investments. Inhale'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 Inhale'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, Inhale 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 Inhale on favorable terms, if at all.

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Inhale is currently considering expansion opportunities which would involve the sale and leaseback of land adjacent to its current facilities and the development of new facilities on such land. Inhale anticipates that its lease obligations relating to this proposal would be approximately \$60.0 million over the term of the lease, which Inhale expects to extend approximately 15 years.

YEAR 2000 COMPLIANCE

Inhale is aware of the issues associated with the programming code in existing computer systems as the 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 Inhale'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.

Inhale 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 has developed 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.

This plan includes the following elements:

- Awareness raising Inhale's awareness of the Y2K issue.
- 2) Discovery keeping an inventory and monitoring the compliance status of key financial, informational and operations systems subject to Y2K issues.
- 3) Assessment determining both the business impact of noncompliance and the likelihood of noncompliance from each of the entities in the inventory.
- 4) Validation and Remediation the process of validating entities to ascertain compliance and remediate non-compliant entities.

As of September 30, 1999, Inhale had completed the Validation and Remediation phase of mission critical and high impact systems. In addition, Inhale is stockpiling mission critical and high impact supplies in anticipation of January 1, 2000 and has established a contingency task force to manage any situation which may arise during the turn of the century to the passing of February 29, 2000 and beyond if necessary.

Inhale initiated formal communication with significant vendors and suppliers to determine the extent to which Inhale'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. Inhale identified mission critical vendors and suppliers and stockpiling measures are being implemented. In addition, in order to protect against the acquisition of additional non-compliant products, Inhale now requires suppliers to warrant that products sold or licensed to Inhale are Y2K compliant. In the event that any of Inhale's significant suppliers do not successfully achieve Y2K compliance in a timely manner, Inhale's business or operations could be adversely affected. There can be no assurance that the systems of other companies on which Inhale's systems rely will be converted on a timely basis and would not have an adverse effect on Inhale's operations.

As of September 30, 1999, Inhale has substantially developed a comprehensive contingency plan to address situations that may result if Inhale or any of its critical third parties are unable to achieve Y2K readiness of its critical operations. The contingency plan will be implemented should situations occur where Inhale is unable to achieve Y2K readiness in its critical operations. There can be no assurance that Inhale's contingency plan will adequately address all issues that may arise in the year 2000. The failure of Inhale to develop and implement, if necessary, an appropriate contingency plan could have a material impact on the operations of Inhale. Finally, Inhale is also vulnerable to external forces that might generally affect industry and commerce, such as utility and transportation company Y2K

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compliance failures and related service interruptions. If Inhale, its suppliers or collaborative partners fail to remedy any Y2K issues, the most likely worst case scenario would be a delay in Inhale's research programs and efforts to scale-up to manufacturing capacity. Certain chemicals and products could also be spoiled in the event of an extended power outage. If either of these events occur, this in turn could result in the incurrence of material costs or loss of revenue. Presently, Inhale is unable to reasonably estimate the duration and extent of any such interruption, or quantify the effect it may have on it's future revenues and results of operations.

Although Inhale completed its mission critical and high impact system issues in the third quarter of 1999, Inhale 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 \$750,000, of which approximately \$450,000 has been spent through September 30, 1999, which is not material to Inhale'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 Inhale 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

WE DO NOT KNOW IF OUR DEEP LUNG DRUG DELIVERY SYSTEM IS COMMERCIALLY FEASIBLE.

We are in an early stage of development. There is a risk that our deep lung delivery technology will not be commercially feasible. Even if our deep lung delivery technology is commercially feasible, it may not be commercially accepted across a range of large and small molecule drugs. We have tested six deep lung delivery formulations in humans, but many of our potential formulations have not been tested in humans.

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

WE DO NOT KNOW IF OUR DEEP LUNG DELIVERY SYSTEM IS EFFICIENT.

We may not be able to achieve the total system efficiency needed to be competitive with alternative routes of delivery. Total system efficiency is determined by the amount of drug loss during manufacture, in the delivery device, in reaching the site of absorption, and during absorption from that site into the bloodstream. Deep lung bioavailability is the percentage of a drug that is absorbed into the bloodstream when that drug is delivered directly to the lungs as compared to injection. Bioavailability is the initial screen for whether deep lung delivery of any systemic drug is commercially feasible. We would not consider a drug to be a good candidate for development and commercialization if its drug loss is excessive at any one stage or cumulatively in the manufacturing and delivery process or if its deep lung bioavailability is too low.

WE DO NOT KNOW IF OUR DEEP LUNG DRUG FORMULATIONS ARE STABLE.

We may not be able to identify and produce powdered versions of drugs that retain the physical and chemical properties needed to work with our delivery device. Formulation stability is the physical and chemical stability of the drug over time and under various storage, shipping and usage conditions. Formulation stability will vary with each deep lung formulation and the type and amount of ingredients that are used in the formulation. Problems with

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powdered drug stability would negatively impact our ability to develop and market our potential products or obtain regulatory approval.

WE DO NOT KNOW IF OUR DEEP LUNG SYSTEM IS SAFE.

We may not be able to prove potential products to be safe. Our products require lengthy laboratory, animal and human testing. Most of our products are in pre-clinical testing or the early stage of human testing. If we find that any product is not safe, we will not be able to commercialize the product. The safety of our deep lung formulations will vary with each drug and the ingredients used in its formulation.

WE DO NOT KNOW IF OUR DEEP LUNG SYSTEM PROVIDES CONSISTENT DOSES OF MEDICINE.

We may not be able to provide reproducible dosages of stable formulations sufficient to achieve clinical success. Reproducible dosing is the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups. Reproducible dosing requires the development of:

- an inhalation device that consistently delivers predictable amounts of dry powder formulations to the deep lung;
- accurate unit dose packaging of dry powder formulations; and
- moisture resistant packaging.

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

WE DEPEND ON PARTNERS FOR REGULATORY APPROVALS AND COMMERCIALIZATION OF OUR PRODUCTS

Since Inhale is in the business of developing technology for delivering drugs to the lungs and licensing this technology to companies that make and sell drugs, we do not have the people and other resources to do the following things:

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

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

WE MAY NOT OBTAIN REGULATORY APPROVAL FOR OUR PRODUCTS ON A TIMELY BASIS OR AT ALL.

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

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

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

WE DO NOT KNOW IF OUR TECHNOLOGIES CAN BE INTEGRATED IN TIME TO BRING PRODUCT TO MARKET.

We may not be able to integrate all of the relevant technologies to provide a deep lung drug delivery system. Our integrated approach to systems development relies upon several different but related technologies:

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

At the same time we must:

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

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

WE MAY NOT BE ABLE TO MANUFACTURE OUR PRODUCTS IN COMMERCIAL QUANTITIES.

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

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

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

INHALATION DEVICE. We face many technical challenges in further developing our inhalation device to work with a broad range of drugs, to produce such a device in sufficient quantities and to adapt the device to different powder

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formulations. In addition, we are attempting to develop a smaller inhalation device, which presents particular technical challenges. There is a risk that we will not successfully achieve any of these challenges. Our failure to overcome any of these challenges would negatively impact our revenues and results of operations.

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

WE DEPEND ON KEY SUPPLIERS FOR OUR INHALATION DEVICE AND BULK DRUGS.

We plan to subcontract the manufacture of our pulmonary delivery device before commercial production of our first product. We have identified contract manufacturers that we believe have the technical capabilities and production capacity to manufacture our devices and which can meet the requirements of good manufacturing practices. We cannot assure you that we will be able to obtain and maintain satisfactory contract manufacturing on commercially acceptable terms, if at all. Our dependence on third parties for the manufacture of our inhalation device may negatively impact our cost of goods and our ability to develop and commercialize products on a timely and competitive basis.

We obtain the bulk drugs we use to formulate and manufacture the dry powders for our deep lung delivery system from sole sources of supply. For example, with respect to our source of bulk insulin, we have entered into a collaborative agreement with Pfizer which has, in turn, entered into an agreement with Hoechst to manufacture biosynthetic recombinant insulin. Under the terms of their agreement, Pfizer and Hoechst agreed to construct a jointly owned manufacturing plant in Frankfurt, Germany. Until its completion, Pfizer will provide us with insulin from Hoechst's existing plant. If our sole source suppliers fail to provide bulk drugs in sufficient quantities when required, our business would be negatively impacted.

WE DO NOT KNOW IF THE MARKET WILL ACCEPT OUR DEEP LUNG DELIVERY SYSTEM.

The commercial success of our potential products depends upon market acceptance by health care providers, third-party payors like health insurance companies and Medicare, and patients. Our products under development use a new method of drug delivery and there is a risk that our potential products will not be accepted by the market. Market acceptance will depend on many factors, including:

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

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

IF OUR PRODUCTS ARE NOT COST EFFECTIVE, GOVERNMENT AND PRIVATE INSURANCE PLANS WILL NOT PAY FOR OUR PRODUCTS.

In both domestic and foreign markets, sales of our products under development will depend in part upon the availability of reimbursement from third-party payors, such as government health administration authorities, managed care providers, private health insurers and other organizations. In addition, such third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Legislation and regulations affecting the pricing of pharmaceuticals may change before our proposed products are approved for marketing. Adoption of such legislation

and regulations could further limit reimbursement for medical products. A government third party payor decision to not provide adequate coverage and reimbursements for our products would limit market acceptance of such products.

WE EXPECT TO CONTINUE TO LOSE MONEY FOR THE NEXT SEVERAL YEARS.

We have never been profitable and, through September 30, 1999, have incurred a cumulative deficit of approximately \$74.3 million. We expect to continue to incur substantial and increasing losses over at least the next several years as we expand our research and development efforts, testing activities and manufacturing operations, and as we complete our late stage clinical and early commercial production facility. All of our potential products are in research or in the early stages of development except for our insulin collaboration. We have generated no revenues from approved product sales. Our revenues to date have consisted primarily of payments under short-term research and feasibility agreements and development contracts. To achieve and sustain profitable operations, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products using our deep lung drug delivery system. There is a risk that we will not generate sufficient product or contract research revenue to become profitable or to sustain profitability.

WE MAY NEED TO RAISE ADDITIONAL CAPITAL THAT MAY NOT BE AVAILABLE.

We anticipate that our existing capital resources, including the approximate \$105 million net proceeds from the issuance of convertible subordinated debentures in October and November, 1999, will enable us to maintain currently planned operations through at least the next 18 months. However, this expectation is based on our current operating plan, which is expected to change as a result of many factors, and we may need additional funding sooner than anticipated. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in dilution to our stockholders.

We have no credit facility or other committed sources of capital. To the extent operating and capital resources are insufficient to meet future requirements, we will have to raise additional funds to continue the development and commercialization of our technologies. Such funds may not be available on favorable terms, or at all. In particular, the substantial leverage we will continue to experience from the sale of convertible subordinated debentures in October and November, 1999 may limit our ability to obtain additional financing. If adequate funds are not available on reasonable terms, we may be required to curtail operations significantly or to obtain funds by entering into financing, supply or collaboration agreements on unattractive terms. Our inability to raise capital could negatively impact our business.

OUR PATENTS MAY NOT PROTECT OUR PRODUCTS AND OUR PRODUCTS MAY INFRINGE ON THIRD-PARTY PATENT RIGHTS.

We have filed patent applications covering certain aspects of our device, powder processing technology, and powder formulations and deep lung route of delivery for certain molecules, and we plan to file additional patent applications. We currently have 40 issued U.S. and foreign patents that cover certain aspects of our technology and we have a number of patent applications pending. There is a risk that any of the patents applied for will not issue, or that any patents that issue or have issued will not be valid and enforceable. Enforcing our patent rights would be time consuming and costly.

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

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

OUR COMPETITORS MAY DEVELOP AND SELL BETTER DRUG DELIVERY SYSTEMS.

We are aware of other companies engaged in developing and commercializing pulmonary drug delivery systems and enhanced injectable drug delivery systems. Many of these companies have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do and represent significant competition for us. Acquisitions of or collaborations with competing drug delivery companies by large pharmaceutical companies could enhance our competitors' financial, marketing and other resources. Accordingly, our competitors may succeed in developing competing technologies, obtaining regulatory approval for products or gaining market acceptance before us. Developments by others could make our products or technologies uncompetitive or obsolete. Our competitors may introduce products or processes competitive with or superior to ours.

INVESTORS SHOULD BE AWARE OF INDUSTRY-WIDE RISKS.

In addition to the risks associated specifically with Inhale described above, investors should also be aware of general risks associated with drug development and the pharmaceutical industry. These include, but are not limited to:

- changes in and compliance with government regulations;
- handling of hazardous materials;
- hiring and retaining qualified people; and
- insuring against product liability claims.

WE MAY NOT ACHIEVE YEAR 2000 COMPLIANCE.

We are aware of the issues associated with the programming code in existing computer systems as the 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 our 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, or a temporary inability to process transactions or engage in similar normal business activities.

We have substantially developed a comprehensive contingency plan to address situations that may result if we are unable to achieve Y2K readiness of our critical operations. We cannot assure you that our contingency plan will adequately address all issues that may arise in the year 2000.

In addition, we have initiated formal communication with significant vendors and suppliers to determine the extent to which our operations are vulnerable to those third parties' failure to remediate their own Y2K issues. In the event that any of our significant suppliers do not successfully achieve Y2K compliance in a timely manner, our business or operations could be negatively affected. We cannot assure you that the systems of other companies on which our systems rely will be converted on a timely basis and will not have an adverse effect on our operations.

We are 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. Certain chemicals and products could be spoiled in the event of an extended power outage. This, in turn, could result in the incurrence of material costs or loss of revenue. The failure by us or our suppliers to develop and implement successfully appropriate plans could have a negative impact on our operations and financial condition.

WE EXPECT OUR STOCK PRICE TO REMAIN VOLATILE.

Our stock price is volatile. In the last twelve months, based on closing prices on the Nasdaq National Market, our stock price ranged from \$21.50 to \$34.88. We expect it to remain volatile. A variety of factors may have a significant effect on the market price of our common stock, including:

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- fluctuations in our operating results;
- announcements of technological innovations or new therapeutic products;
- announcement or termination of collaborative relationships by Inhale or our competitors;
- governmental regulation;
- clinical trial results or product development delays;
- developments in patent or other proprietary rights;
- public concern as to the safety of drug formulations developed by Inhale or others; and
- general market conditions.

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

OUR INDEBTEDNESS HAS INCREASED SUBSTANTIALLY

As of September 30, 1999, we had approximately \$6.2 million in long-term debt. Upon completion of the sale of approximately \$109 million aggregate principal amount of convertible subordinated debentures in October and November, 1999, our long-term debt increased substantially. This increased indebtedness will impact us by:

- significantly increasing our interest expense and related debt service costs;
- making it more difficult to obtain additional financing; and
- constraining our ability to react quickly in an unfavorable economic climate.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in the reported market risks since December 31, 1998.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings - None

Item 2. CHANGES IN SECURITIES - On October 13, 1999, Inhale completed the sale of \$100 million aggregate principal of 6 3/4% convertible subordinated debentures due 2006 to certain qualified institutional buyers pursuant to an exemption from registration under Section 4(2)of the Securities Act and the rules and regulations promulgated thereunder. The initial purchasers of the debentures were Lehman Brothers, Inc., Deutsche Bank Securities, Inc. and U.S. Bancorp Piper Jaffray. Net of discounts to the initial purchasers of \$3million, Inhale received net proceeds of \$97 million from the sale of the debentures. The debentures mature on October 13, 2006 and are convertible at any time prior to maturity into shares of Inhale Common Stock at a conversion price equal to \$32.0075 per share. On November 10, 1999, Inhale completed the additional sale of approximately \$8.5 million aggregate principal of the convertible subordinated debentures following the exercise of an over-allotment option by the initial purchasers. Net of discounts to the initial purchasers of \$253,500, Inhale received approximately \$8.2 million from the sale of the additional debentures.

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- 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
 - (a) The following exhibits are filed herewith or incorporated by reference:

EXHIBIT EXHIBIT TITLE

- 2.1 (1) Agreement and Plan of Merger between Inhale Therapeutic Systems, a California corporation, and Inhale Therapeutic Systems (Delaware), Inc., a Delaware corporation.
- 3.1 Certificate of Incorporation of Registrant. (1)
- Bylaws of the Registrant. 3.2 (1)
 - Reference is made to Exhibits 3.1 and 3.2.
- Restated Investor Rights Agreement among the Registrant and certain other persons named therein, dated April 29, 1993, as amended October 29, 1993.
- 4.3 (2) Specimen stock certificate.
- 4.4 (3) Stock Purchase Agreement between the Registrant and Pfizer Inc., dated January 18, 1995.
- 4.5 Form of Purchase Agreement between the Registrant and the individual Purchasers, dated January (9) 28. 1997.
- 4.6 (10) Stock Purchase Agreement between the Registrant and Capital Research and Management Company, dated December 8, 1998.
- 10.1 (4)
- Registrant's 1994 Equity Incentive Plan, as amended.
 Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended. 10.2 (7)
- Registrant's 1994 Employee Stock Purchase Plan, as amended. 10.3 (2)
- Standard Industrial Lease between the Registrant and W.F. Batton & Co., Inc., dated September 17, 10.4 (2) 1992, as amended September 18, 1992. Addendum IV dated April 1, 1994 to Lease dated September 17, 1992,
- 10.5 (2)
- between the Registrant and W.F. Batton and Marie A. Batton, dated September 17, 1992. Amendment Agreement Number One, dated October 20, 1995, to Lease
- 10.6 (6) dated September 17, 1992, between the Registrant and W.F. Batton & Co., Inc. Amendment Agreement Number Two, dated November 15, 1995, to Lease,
- 10.7 (6) dated September 17, 1992, between Registrant and W.F. Batton and Marie A. Batton, Trustees of the W.F. Batton and Marie A. Batton Trust UTA dated January 12, 1998 ("Batton Trust").
- 10.8 (11) Amendment Agreement Number Three, dated February 14, 1996, to Lease, dated September 17, 1992, between Registrant and Batton Trust.

 10.9 (11) Amendment Agreement Number Four, dated September 15, 1996, to Lease,
- dated September 17, 1992, between Registrant and Batton Trust. 10.10 (2) Senior Loan and Security Agreement between the Registrant and Phoenix Leasing Incorporated, dated September 15, 1993.
- 10.11 (2) Sublicense Agreement between the Registrant and John S. Patton, dated September 13, 1991.
- 10.11 (5) Stock Purchase Agreement between the Registrant and Baxter World Trade
- Corporation, dated March 1, 1996.

 10.12 (8) Sublease and Lease Agreement, dated October 2, 1996 between the Registrant and T.M.T.

 Associates L.L.C. ("Landlord").

 10.13 (11) First Amendment, dated October 30, 1996, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
- 10.14 (11) Letter Agreement, dated April 9, 1997, amending Sublease and Lease Agreement, dated October 2, 1996, between the Registrant and Landlord.
- 10.15 (11) Third Amendment, dated April 16, 1997, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
- 10.16 (11) Fourth Amendment, dated November 5, 1997, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
- 27.1 Financial Data Schedule

- Incorporated by reference to the indicated exhibit in Inhale's Quarterly (1)
- Report on Form 10-Q for the quarter ended June 30, 1998. Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-1 (No. 33-75942), as amended.
- Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-1 (No. 33-89502), as amended.
- Incorporated by reference to Inhale's Registration Statement on Form S-8 (No. 333-59735).
- Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.
- Incorporated by reference to the indicated exhibit in Inhale's Annual Report on Form 10-K for the year ended December 31, 1995.
- Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.
 - Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
- (9) Incorporated by reference to Inhale's Registration statement on Form S-3 (No. 333-20787).
- (10) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-3 (No. 333-68897), as amended.
- (11) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.
 - (b) The following Current Reports on Form 8-K were filed during the quarter ended September 30, 1999:
 - Current Report on Form 8-K, dated September 29, 1999, reporting the Company's intention to issue \$100 million aggregate principal amount of convertible subordinated debentures, plus an additional amount of debentures if the over-allotment option is exercised in full.
 - (ii) Current Report on Form 8-K, dated October 4, 1999, reporting the Company's entering into a definitive Asset Purchase Agreement with Alliance Pharmaceutical Corp. to acquire Alliance's PulmoSpheres(R) particle and processing technology and other related assets for use in respiratory drug delivery. Page 19 of 20

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 12, 1999

BY: /s/ ROBERT B. CHESS

Robert B. Chess

Chairman and Co-Chief Executive Officer and Director

(Duly Authorized Officer)

BY: /s/ AJIT S. GILL

Ajit S. Gill

President and Co-Chief Executive Officer and Director

(Duly Authorized Officer)

BY: /s/ BRIGID A. MAKES

Brigid A. Makes

Vice President of Finance and Administration and Chief

Financial Officer

(Chief Accounting Officer)

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE QUARTERLY FINANCIAL STATEMENTS OF INHALE THERAPEUTIC SYSTEMS INC., AS FILED ON FORM 10-Q FOR THE PERIOD ENDED SEPTEMBER 30, 1999 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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