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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 June 30, 2001

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 /x/ No / /

Applicable Only to Corporate Issuers

The number of outstanding shares of the registrant's Common Stock, $0.0001 par value, was 54,861,649 as of July 31, 2001.

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Item 1. Financials Statements

INHALE THERAPEUTIC SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2001 (unaudited)	December 31, 2000 *
ASSETS		
Current assets:		
Cash and cash equivalents	$ 223,142	$ 136,012
Short-term investments	162,525	348,829
Accounts receivable	10,390	7,234
Other current assets	5,627	968
Total current assets	401,684	493,043
Property and equipment, net	133,341	110,457
Marketable equity securities	2,384	9,140
Goodwill and other intangibles assets	171,006	4,969
Deposits and other assets	14,280	11,931
	$ 722,695	$ 629,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 38,724	$ 24,313
Capital lease obligation — current	977	977
Deferred revenue	19,045	4,913
Total current liabilities	58,746	30,203
Capital lease obligation	26,335	15,269
Convertible subordinated notes and debentures	299,149	299,149
Accrued rent	2,131	2,010
Other long-term liabilities	7,502	5,026
Stockholders' equity:		
Common stock	5	5
Capital in excess of par value	710,480	465,593
Deferred compensation	(1,272)	(1,827)
Accumulated other comprehensive gain/(loss)	(1,677)	5,981
Accumulated deficit	(378,704)	(191,869)
Total stockholders' equity	328,832	277,883
	$ 722,695	$ 629,540

See accompanying notes.

(*)

The consolidated balance Sheet at December 31, 2000 has been derived from the audited financial statements at that date which are included in the Company's Form 10-K, as amended, for the year ended December 31, 2000 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.

INHALE THERAPEUTIC SYSTEMS, INC.
Condensed Consolidated Statements of Operations
(in thousands, except per share information)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2001	2000	2001	2000
Contract research revenue	$ 16,799	$ 13,789	$ 30,896	$ 24,422
Operating costs and expenses:				
Research and development	34,059	25,809	64,330	47,493
General and administrative	4,420	3,095	8,438	6,630
Purchased in-process research and development	83,600	2,292	146,260	2,292
Amortization of goodwill and intangible assets	4,456	186	7,535	371
Total operating costs and expenses	126,535	31,382	226,563	56,786
Loss from operations	(109,736)	(17,593)	(195,667)	(32,364)
Other income	(262)	—	(340)	—
Debt conversion premium, net	—	—	—	(15,157)
Interest income (expense), net	4,204	1,846	9,172	2,942
Net loss	$ (105,794)	$ (15,747)	$ (186,835)	$ (44,579)
Basic and diluted net loss per share	$ (2.05)	$ (0.38)	$ (3.64)	$ (1.20)
Shares used in computing basic and diluted net loss per share	51,607	41,920	51,330	37,194

See accompanying notes.

INHALE THERAPEUTIC SYSTEMS, INC.
Condensed Consolidated Statements of Cash Flows
Increase/(Decrease) in Cash and Cash Equivalents
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2001	2000
Cash flows from operating activities:		
Cash used in operations	$ (12,042)	$ (13,312)
Cash flows from investing activities:		
Purchases of short-term investments	(167,820)	(190,962)
Sales of short-term investments	89,989	7,462
Maturities of short-term investments	263,233	67,771
Purchases of property and equipment	(18,286)	(30,940)
Other investing activities	—	(316)
Acquisition of Shearwater, net of cash acquired	(68,779)	—
Acquisition of Bradford, net of cash acquired	(14,825)	—
Net cash provided by (used in) investing activities	83,512	(146,985)
Cash flows from financing activities:		
Proceeds from capital lease financing	11,424	—

Payments of equipment financing obligations	(378)	(27)
Payments of debt conversion incentives	—	(16,957)
Issuance of convertible debt, net of issuance costs	—	222,439
Issuance of common stock, net of issuance costs	4,614	10,187
Net cash provided by financing activities	15,660	215,642
Net increase (decrease) in cash and cash equivalents	$ 87,130	$ 55,345
Cash and cash equivalents at beginning of period	136,012	33,430
Cash and cash equivalents at end of period	$ 223,142	$ 88,775
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES:		
Common stock issued upon conversion of convertible subordinated debentures, net	$ —	$ 97,220

See accompanying notes.

INHALE THERAPEUTIC SYSTEMS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2001
(unaudited)

1. 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, we have been engaged in the development of advanced drug delivery and formulation solutions for the biopharmaceutical industry. The scope of our technology has recently expanded with two acquisitions made during the first half of 2001. In January, 2001 we acquired Bradford Particle Design, plc ("Bradford"), a United Kingdom company, which provided additional pulmonary capabilities as well as other routes of drug delivery including oral and injectable. In June, 2001 we acquired Shearwater Corporation ("Shearwater"), which is a leader in advanced PEGylation technology for enhancing delivery performance of most major drug classes, including macromolecules such as peptides and proteins, small molecules, and other drugs. In addition to Bradford and Shearwater, which was merged with and into a wholly-owned subsidiary of Inhale that remained as the surviving corporation in the acquisition, we are the parent company of two wholly-owned international subsidiaries: Inhale Therapeutic Systems Deutschland GmbH, incorporated in the Federal Republic of Germany ("Inhale Germany"); and Inhale Therapeutic Systems UK Limited, incorporated in the United Kingdom ("Inhale UK"). Our consolidated financial statements also include the financial statements of a special purpose entity lessor.

Our Board of Directors approved a two-for-one split which was effected as a 100% common stock dividend on August 22, 2000 for stockholders of record as of August 1, 2000. All share and per share amounts in these consolidated financial statements have been retroactively restated to reflect the split.

We expect to incur substantial and potentially increasing losses over at least the next few years as research and development and manufacturing scale-up efforts continue, and as we expand our facilities for manufacturing operations. We plan to continue to finance ourselves primarily through issuances of equity or debt securities, research and development contract revenue, and in the longer term, revenue from product sales and royalties.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The accompanying unaudited condensed consolidated 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 consolidated balance sheet as of June 30, 2001, the condensed consolidated statements of operations for the three and six-month periods ended June 30, 2001 and 2000, and the condensed consolidated statements of cash flows for the six-month periods ended June 30, 2001 and 2000 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 accompanying

financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2000, 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.

Certain prior year amounts have been reclassified to conform to the 2001 presentation.

2. Principles of Consolidation

Our consolidated financial statements include the accounts of Inhale Therapeutic Systems, Inc., Inhale Germany, Inhale UK, the financial statements of a special purpose entity created to finance and manage construction of our new lab and office facility and the accounts of Bradford and Shearwater (See Note 7 "Acquisition of Shearwater Corporation"), our recently acquired subsidiaries.

3. Comprehensive Loss

Comprehensive loss is comprised of net unrealized income (loss) related to our investment in Alliance Pharmaceutical Corp., and net income (loss) on available-for-sale securities (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2001	2000	2001	2000
Net loss	$ (105,794)	$ (15,747)	$ (186,835)	$ (44,579)
Other comprehensive income/(loss)	(2,600)	1,607	(7,708)	(6,626)
Comprehensive loss	$ (108,394)	$ (14,140)	$ (194,543)	$ (51,205)

4. Revenue Recognition

Contract revenue from collaborative research agreements is recorded when earned based on the performance requirements of the contract. Revenue from non-refundable upfront license fees and certain guaranteed payments, where we continue involvement through collaborative development are deferred and recognized as revenue over the period of continued involvement. Revenue from grants and feasibility arrangements are recognized as the related costs are incurred. Our research revenue is derived primarily from clients in the pharmaceutical industry.

Contract research revenue from one partner represented 73% of Inhale's revenue in the six-month period ended June 30, 2001 and 67% of Inhale's revenue in the comparable period in 2000. Costs of contract research revenue approximate such revenue and are included in operating costs and expenses.

5. Net Loss Per Share

Basic and diluted net loss per share is computed in accordance with Statement of Financial Accounting Standards No. 128, "Earnings Per Share". 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.

6. Inventories

Inventories are included in the other current assets on the balance sheet and consist primarily of raw materials, work-in-process and finished goods and are stated at the lower of cost (first-in, first-out method) or market and consist of the following:

	June 30, 2001 *(in thousands)*	December 31, 2000 *(in thousands)*
Raw Materials	$ 1,707	$ 177
Work-in-Process	1,092	—
Finished Goods	925	—
	$ 3,724	$ 177

7. Acquisition of Shearwater Corporation

In June 2001, we completed the acquisition of Shearwater and paid a total consideration of $192.2 million in cash and stock (including assumption of outstanding options to acquire Shearwater Common Stock) for a 100% interest in Shearwater. In connection with the acquisition, we recorded goodwill and other intangible assets of approximately $90.9 million and recorded a $83.6 million in-process research and development ("IPR&D") charge. At the date of the acquisition, we concluded that the IPR&D technology had no alternative future use and did not qualify for capitalization.

The cost to acquire Shearwater has been allocated to the assets acquired and liabilities assumed according to their respective fair values, with the excess purchase price being allocated to goodwill. The allocation of the aggregate purchase price is based on a formal valuation analysis completed by an independent valuation specialist. A formal valuation analysis for purposes of allocating the fair value of purchased assets and liabilities has been completed, pending receipt of final report.

The estimated purchase cost of Shearwater is as follows (in thousands):

Cash and cash equivalents	$ 72,500
Value of securities issued	88,896
Assumption of Shearwater's common stock options	25,344
Estimated transaction costs and expenses	5,417
	$ 192,157

The purchase price allocation as of June 29, 2001 is as follows (in thousands):

	AMOUNT	USEFUL LIFE	ANNUAL AMORTZATION

			OF INTANGIBLES
		(IN YEARS)	
Net tangible assets of Shearwater	$ 17,615	—	$ —
Intangible assets acquired:			
Developed product technology	2,900	5	580
Core technology	8,100	5	1,620
In-process research and development	83,600	—	—
Assembled workforce	2,020	3	674
Supplier and customer relationships	2,900	5	580
Goodwill	75,022	5	15,004
Total purchase price allocation	$ 192,157		$ 18,458

Developed product technology is based on proprietary know-how that is technologically feasible. Inhale expects to amortize the value assigned to developed product technology on a straight-line basis over an average estimated life of five years.

Core technology is based on developed technology or components of developed technologies that have a value as a basis of platform upon which future development can be profitably exploited. Inhale will amortize the value assigned to core technology on a straight-line basis over an average estimated life of five years.

In-process research and development represents that portion of the purchase price of an acquisition related to the research and development activities which: (i) have not demonstrated their technological feasibility, and (ii) have no alternative future uses. Accordingly, Inhale will recognize an expense of $83.6 million upon consummation of the transaction.

Assembled workforce is comprised of all the skilled employees and includes the estimated cost to replace existing employees, including recruiting and training costs and loss of productivity costs. Inhale will amortize the value assigned to the assembled workforce on a straight-line basis on an average estimated useful life of three years.

Supplier and customer relationship is based on historical costs incurred and is comprised of management's estimation of resources that have been devoted to development of the relationships with key customers. Inhale expects to the value assigned to customer relationships on a straight-line basis over an average estimated life of five years.

Goodwill, which represents the excess of the purchased price of an investment in an acquired business over the fair value of the underlying net identifiable asset, will be amortized on a straight-line basis. Effective January 1, 2002, goodwill will be subject to a non-amortization, impairment assessment, and goodwill will not be amortized after that date.

The unaudited pro forma results of operations is presented for illustrative purposes only and is not necessarily indicative of the operating results or financial positions that would have occurred if the transaction had been consummated at the dates indicated, nor is it necessarily indicative of future operating results or financial position of the combined companies and should not be construed as representative of these amounts for any future dates or periods.

The following unaudited pro forma results of operations of the Company for the six-month periods ended June 30, 2001 and 2000, respectively, assumes the acquisition of Shearwater has been accounted for using the purchase method of accounting as of January 1, 2001 and 2000, respectively, and assumes the purchase price has been allocated to the assets purchased and the liabilities assumed based on fair values at the date of acquisition.

Shearwater's results of operations included in these pro forma financial statements are derived from its unaudited financial statements for the six-month periods ended June 30, 2001 and 2000 respectively. Shearwater financial statements included in the pro forma information as of all dates and for all periods presented have been adjusted, where appropriate, to present Shearwater's financial position and results of operations in accordance with generally accepted accounting principles in the United States. The unaudited pro forma net loss and loss per share amounts do not include a charge for purchased in-process research and development of $83.6 million due to its non-recurring nature. The pro forma results also reflect amortization of goodwill and other intangible assets. Effective January 1, 2002, goodwill will be subject to a non-amortization, impairment assessment, consistent with the new business combination accounting rules. The June 30th, 2001 results include an in-process research and development charge resulting from the Bradford Particle business combination of

approximately $62.7 million. Such previously reported amounts have not been adjusted in this pro forma presentation in order to assess the continuing impact of the Shearwater Business Combination.

(in thousands, except loss per share)	Six Months Ended June 30, 2001 Pro Forma	Six Months Ended June 30, 2000 Pro Forma
	(unaudited)	(unaudited)
Total revenue	$ 37,124	$ 32,695
Net loss	$ (113,719)	$ (52,944)
Net loss per share	$ (2.08)	$ (1.15)

8. Goodwill and Other Intangible Assets

Goodwill and other intangible assets are included in the balance sheet and consist of the following:

	June 30, 2001 (in thousands)	December 31, 2000 (in thousands)
Goodwill	$ 152,321	$ 2,238
Accumulated amortization	(7,021)	(813)
Net goodwill	145,300	1,878
Assembled workforce	2,860	—
Core technology	8,100	—
Customer relations	2,240	—
Development product technology	2,900	—
Intellectual property	8,034	3,544
Supplier and customer relations	2,900	—
Net other intangibles assets	27,034	3,544
Accumulated amortization of other intangible assets	(1,328)	(453)
Net other intangibles assets	25,706	3,091
Net goodwill and other intangibles assets	$ 171,006	$ 4,969

9. New Accounting Pronouncement

On June 29, 2001, the Financial Accounting Standards Board ("FASB"), approved the final standards resulting from its deliberations on business combinations project and issued two statements in July 2001, Statement of Financial Accounting Standards ("SFAS") No. 141, on Business Combinations and SFAS 142, on Goodwill and Other Intangible Assets. SFAS 141 will be effective for any business combinations initiated after June 30, 2001 and also includes the criteria for the recognition of intangible assets separately from goodwill. SFAS 142 will be effective for fiscal years beginning after December 15, 2001 and will require that goodwill not be amortized, but rather be subject to an impairment test at least annually. Separately identified and recognized intangible assets resulting from business combinations completed before July 1, 2001 that do not meet the new criteria for separate recognition of intangible assets will be subsumed into goodwill upon adoption. In addition, the useful lives of recognized intangibles assets acquired in transactions completed before July 1, 2001 will be reassessed and the remaining amortization periods adjusted accordingly. The Company is in the process of evaluating the financial statement impact of these new standards.

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 six-months ended June 30, 2001 and 2000 should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2000. The following discussion contains forward-looking statements that involve risk and uncertainties. Our 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 our Annual Report on Form 10-K, as amended, for the year ended December 31, 2000.

Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date hereof. We undertake 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 our inception in July 1990, we have been engaged in the development of advanced drug delivery and formulation solutions for the biopharmaceutical industry. We have been unprofitable since inception and expect to incur substantial and potentially increasing operating losses over at least the next few years primarily due to increasing research and development expenditures and expansion of late stage clinical and early stage commercial manufacturing facilities. To date, except for sales from two products using our advanced PEGylation technology, we have not sold any commercial products and do not anticipate receiving material revenue from product sales or royalties in the near future. For the period from inception through June 30, 2001, we incurred a cumulative net loss of approximately $378.7 million. The sources of our working capital have been equity and debt financings, financings of equipment acquisitions and tenant improvements, interest earned on investments of cash, and revenues from short-term research and feasibility agreements and development contracts.

We have generally been compensated for research and development expenses during initial feasibility work performed under collaborative arrangements. Partners that enter into collaborative agreements will typically pay for research and development expenses and make additional payments to us as we achieve certain key milestones. We expect to receive royalties from our partners based on their revenues received from product sales. We also expect to receive additional revenue from manufacturing and, with respect to products using our inhaleables technology, the supply of devices. In certain cases, we may enter into collaborative agreements under which our partners would manufacture or package powders or supply inhalation devices, thereby potentially limiting one or more sources of revenue for us. To achieve and sustain profitable operations, we, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products using our drug delivery and formulation technologies. There can be no assurance that we can generate sufficient product or contract research revenue to become profitable or to sustain profitability.

In January 2001, we issued 3,752,456 shares of our common stock to the holders of all of the existing issued ordinary share capital of Bradford. We issued these shares in consideration for the acquisition of the outstanding share capital of Bradford in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, pursuant to Regulation D and Regulation S promulgated under the Act. For each share of Bradford's common stock, we issued 1.8354 new shares of our common stock and paid approximately $9.80 cash, for an aggregate cash payment of

approximately $20.4 million. In addition, we assumed all outstanding options to acquire Bradford common shares which converted into options to acquire 82,283 shares of our common stock.

In June 2001, we entered into an agreement to acquire Shearwater in which cash was paid in the amount of approximately $56.4 million and 3,112,603 shares of common stock were to be issued to the holders of all the outstanding common stock of Shearwater in consideration for the acquisition of Shearwater through its merger with and into a wholly owned subsidiary of Inhale. We issued these shares in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, pursuant to Regulation D promulgated under the Act. For each share of Shearwater common stock, we issued approximately 3.09 new shares of our common stock and paid Shearwater stockholders cash in the amount of $55.94 per share. In addition, we assumed all of the outstanding options to acquire Shearwater common stock which was converted into options to acquire approximately 887,343 shares of our common stock and the holders thereof were also paid in cash in an aggregate amount of $16.1 million at closing. Each outstanding option to purchase Shearwater common stock was converted into the right to receive approximately 3.09 shares of our common stock upon exercise and option holders were paid cash in the amount of $55.94 per share of Shearwater common stock issuable upon exercise of such options. No fractional shares of our common stock were issued in connection with the acquisition. In lieu thereof, any holder of Shearwater common stock was paid cash based on the value of such fractional share.

Results of Operations

Revenue for the three-months ended June 30, 2001 was $16.8 million compared to $13.8 million for the three-months ended June 30, 2000, an increase of 22%. Revenue for the six-months ended June 30, 2001 was $30.9 million compared to $24.4 million for the six-months ended June 30, 2000, an increase of 27%. The increase in revenue for both the three and six month periods was primarily due to the expansion of our existing collaborative agreement with Pfizer, Inc. and includes activities associated with the manufacture of Phase III clinical supplies. Revenue for the three and six months of 2001 and 2000 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 our 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 $34.1 million for the three-months ended June 30, 2001 from $25.8 million for the three-months ended June 30, 2000, an increase of 32%. Research and development expenses increased to $64.3 million for the six-months ended June 30, 2001 from $47.5 million for the six-months ended June 30, 2000, an increase of 35%. The increase for the three and six-month periods was due to increased spending related to the scale-up of technologies for current partnered projects using our inhaleables technology, the continuing development of our global manufacturing capabilities in order to support Phase III inhaleable insulin clinical trials and commercial production, and increased investment in internally funded R&D projects for future products. We expect research, development and process development spending to increase over the next few years as we continue to expand our development efforts under collaborative agreements using our expanded technology portfolio and to scale up our commercial manufacturing facility.

General and administrative expenses were $4.4 million for the three-months ended June 30, 2001 from $3.1 million for the three-months ended June 30, 2000, an increase of 43%. General and administrative expenses increased to $8.4 million for the six months ended June 30, 2001 from $6.6 million for the six months ended June 30, 2000, an increase of 27%. The increase in such expenses in 2001 was due primarily to costs associated with supporting our increased manufacturing and development efforts, including administrative staffing, business development and marketing.

Interest income was $7.3 million during the three months ended June 30, 2001, compared to $5.0 million during the three months ended June 30, 2000, an increase of 47%. Interest income was $15.0 million during the six months ended June 30, 2001, compared to $8.6 million of interest income earned during the six months ended June 30, 2000, an increase of 75%. The higher interest income in 2001 is attributed to a higher cash and investment balances in 2001 than what was available in 2000.

Interest expense was $3.1 million during the three months ended June 30, 2001, compared to $3.1 million during the three months ended June 30, 2000. Interest expense during the six months ended June 30, 2001, was $5.8 million, compared to $5.6 million during a comparable period in of 2000. In addition, in the first quarter of 2000, we paid approximately $15.2 million of a conversion premium to holders of our convertible subordinated debentures issued in October 1999, to convert $98.7 million aggregate principal amount of outstanding convertible subordinated debentures into approximately 6.2 million shares of Inhale's common stock.

Acquired In-process Research and Development

In June 2001, we completed the acquisition of Shearwater in exchange for approximately 4.0 million shares or options to acquire shares of our common stock and cash of $72.5 million. Of the total purchase consideration of $192.2 million, $108.6 million was allocated to the assets acquired based on their fair value on the date of acquisition, including $90.1 million in goodwill and other intangible assets. Approximately $83.6 million of the purchase price was allocated to IPR&D, which was determined to have no alternative future use and was charged as an expense during the three months ended June 30, 2001.

In January 2001, we acquired all of the outstanding share capital of Bradford in exchange for approximately 3.75 million in newly issued shares of our common stock and approximately $20.4 million in cash. Of the total purchase consideration of $152.1 million, $89.4 million was allocated to the assets acquired based on their fair value on the date of acquisition, including $85.8 million in goodwill and other intangible assets. Approximately $62.7 million of the purchase price was allocated to IPR&D which was determined to have no alternative future use and was charged as an expense in the quarter ended March 31,2001.

During the six months ended June 30, 2001 the above acquisitions have resulted in total charge to IPR&D of approximately $146.3 million.

Liquidity and Capital Resources

We have financed our operations primarily through public and private placements of our debt and equity securities, contract research and milestone payments, financing of equipment acquisitions and interest income earned on its investments of cash. At June 30, 2001, we had cash, cash equivalents and short-term investments of approximately $385.7 million.

Our operations used cash of $12.0 million for the six months ended June 30, 2001, compared to $13.3 million for the six months ended June 30, 2000. The decrease in cash used in operations was due principally to the combination of improved timing of partner payments and increased accrued liability balances at

June 30, 2001 compared to the same period in 2000.

We purchased property and equipment of approximately $18.3 million during the six months ended June 30, 2001, compared to $30.9 million for the corresponding period in 2000. The current year activity includes $10.5 million associated with our capital lease obligation with our build-to-suit lease facility. The decrease in purchased property and equipment reflects completion of the first phase of construction of a new San Carlos lab and office facility, balanced by continued investment in our commercial manufacturing facilities, including device manufacturing at third-party contract manufacturers, and expansion of our San Carlos powder processing facilities. Also, in connection with

our acquisition of Bradford, we paid net cash of $14.8 million, which represents cash paid to Bradford shareholders of $20.4 million, net of Bradford's cash balance of $5.6 million. The remainder of the Bradford acquisition was non-cash in nature. In connection with our acquistion of Shearwater, we paid net cash of $68.6 million, which represents cash paid to Shearwater shareholders of $72.5 million, net of Shearwater's cash obtained at June 30, 2001 of $3.9 million. (See Acquired In-process Research and Development).

Cash flows from financing activities were $15.7 million for the quarter ended June 30, 2001 as compared to $215.7 million for the same period in 2000. The decrease in financing activities compared to the same period in 2000 was primarily due to the issuance of $230 million aggregate principal amount of 5% convertible subordinated notes in February 2000.

We expect our cash requirements to continue to grow 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. Our planned facilities expansion includes the completion of our commercial manufacturing facility and the scale-up of device manufacturing with our third-party contract manufacturers.

Given our current cash requirements, we believe that we will have sufficient cash to meet our operating expense requirements for at least the next 32 months. However, we plan to continue to invest heavily in our growth and the need for cash will be dependent upon the timing of these investments. Our capital needs will depend on many factors, including continued scientific progress in our 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 our powder processing and packaging technologies, the timing and cost of our 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 our long-term needs, we intend 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.

RISK FACTORS

In addition to the other information contained in this prospectus, investors should carefully consider the following risk factors in evaluating an investment in our stock. This prospectus includes "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact are "forward-looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below and for the reasons described elsewhere in this prospectus. All forward-looking statements and reasons why results may differ included in this prospectus are made as of the date hereof and we assume no obligation to update any such forward-looking statement or reason why actual results might differ.

We do not know if our drug delivery and formulation technologies are commercially feasible.

We are in an early stage of development. There is a risk that our drug delivery and formulation technologies will not be commercially feasible. Even if our drug delivery and formulation technologies are commercially feasible, they may not be commercially accepted across a range of large and small molecule drugs. We have tested 12 drug formulations using our inhaleables technology in humans, but many of our potential formulations have not been tested in clinical trials. The advanced PEGylation technology platform we recently acquired through our acquisition of Shearwater is currently being used in the development of 15 drugs. While our PEGylation technology has been incorporated in two products that have already been approved for use by the FDA and in three products that our partners have submitted for approval to the FDA through a NDA, many of the drug formulations with which we are incorporating this technology are in the early stages of feasibility testing or human clinical trials. Our supercritical fluids technology recently acquired through our acquisition of Bradford Particle Design is also primarily in an early stage of feasibility. This technology represents a new method of particle manufacturing and is still in research and development, with only one formulation having entered human clinical testing.

Many of the underlying drug compounds contained in our drug formulations have been tested in humans by other companies using alternative delivery routes or technologies. Our potential products require extensive research, development and pre-clinical and clinical testing. Our potential products also may involve lengthy regulatory reviews 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, accomplish the objectives that we and our collaborative partners are seeking through the use of our technologies, meet regulatory standards or continue to meet such standards if already approved. 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. 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 drug delivery and formulation technologies are efficient.

We may not be able to achieve the total system efficiency needed to be competitive with alternative routes of delivery or formulation technologies. 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 when the drug is delivered by injection. Relative bioavailability is the initial screen for whether deep lung delivery using our inhaleables technology of any systemic drug is commercially feasible. We would not consider a drug to be a good candidate for development and commercialization using our inhaleables technology if our drug loss is excessive at any one stage or cumulatively in the manufacturing and delivery process. Our ability to efficiently attach PEG polymer chains to a drug molecule is the initial screen as to whether drug formulations using our advanced PEGylation technology are commercially feasible. We would not consider a drug formulation using our advanced PEGylation technology if we could not efficiently attach a PEG polymer chain to such drug without destroying or impairing the drug's activity. For our supercritical fluids technology, solubility characteristics of a drug in a solvent and the solvent in carbon dioxide provide the initial screen for whether drug formulations using this technology are commercially feasible. We would not consider a drug to be a good candidate for this technology if its solubility characteristics were such that the application of our formulation technology results in very low efficiency in manufacturing of drug powders.

We do not know if our drug formulations are stable.

We may not be able to identify and produce powdered or other formulations of drugs that retain the physical and chemical properties needed to work with our delivery device for deep lung delivery using our inhaleables technology or through other methods of delivery of drugs using our other formulation technologies. 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 formulation and the type and amount of ingredients that are used in the formulation. Problems with powdered drug stability in particular would negatively impact our ability to develop and market products using our drug delivery and formulation technologies or obtain regulatory approval of such products.

We do not know if our drug delivery and formulation technologies are safe.

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

We do not know if our drug delivery and formulation technologies provide 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 or into the lung over time both for a single patient and across patient groups. Reproducible dosing of drugs using our inhaleables technology requires the development of:

- an inhalation or other device that consistently delivers predictable amounts of dry powder to the deep lung;
- accurate unit dose packaging of dry powder; and

- moisture resistant packaging.

Development of appropriate delivery devices, accuracy in measurement of doses, and appropriate packaging may also effect our ability to provide reproducible dosing of drugs using our other delivery and formulation technologies. We may not be able to develop reproducible dosing of any potential product. The failure to do so means that we would not consider such a product as a good candidate for development and commercialization.

We depend on partners for regulatory approvals and commercialization of our products.

Because we are in the business of developing technology for delivering drugs to the lungs, producing improved drug formulations for other routes of delivery and licensing these technologies 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 we sign a collaborative development agreement or license agreement to develop a product with a drug company, the drug company agrees to do some or all of the things described above.

Reliance on collaborative relationships poses a number of risks, including:

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we will not be able to control whether our corporate partners will devote sufficient resources to our programs or products;

- disputes may arise in the future with respect to the ownership of rights to technology developed with corporate partners;
- disagreements with corporate partners could lead to delays in or termination of the research, development or commercialization of product candidates, or result in litigation or arbitration;
- contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform;
- corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue alternative technologies or products either on their own or in collaboration with our competitors;
- corporate partners with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products of their own development; and
- there are risks related to the ability of our distributors and corporate partners to pay us.

Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of products could be delayed.

Inability to establish future successful collaborative relationships may impair our financial results.

We intend to seek future collaborative relationships with corporate partners to fund some of our research and development expenses and to develop and commercialize potential products. Further, we anticipate that our revenues from collaborative agreements will continue to be affected by existing

agreements, as well as by the timing of drug development programs of our corporate partners. We may not be able to negotiate acceptable collaborative arrangements in the future, and any arrangements we do negotiate may not be successful. If we fail to establish additional collaborative relationships, we will be required to undertake research, development, marketing and manufacturing of our proposed products at our own expense or discontinue or reduce these activities.

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 unapproved products on a timely basis, or at all. Our unapproved products must undergo rigorous animal and human testing and an extensive review process mandated by the FDA or equivalent foreign authorities. This process generally takes a number of years and requires the expenditure of substantial resources and the time required for completing such testing and obtaining such approvals is uncertain. The FDA and other U.S. and foreign regulatory agencies also have substantial discretion to terminate clinical trials, require additional testing, delay or withhold registration and marketing approval and mandate product withdrawals. Two products using our advanced PEGylation technology are currently approved for use in the U.S. for specific uses. In addition, our partners have submitted for approval to the FDA three NDAs using our technologies and we plan to manufacture and market other potential products. Even though regulatory approval has been obtained for two products, these products and our manufacturing processes are subject to continued review by the FDA and other regulatory authorities. 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 we, as the manufacturer in certain instances, 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.

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

We do not know if our technologies can be integrated successfully to bring products to market.

We may not be able to integrate all of the relevant technologies to provide complete drug delivery and formulation systems. In particular, our integrated approach to systems development for drugs using our inhaleables technology relies upon several different but related technologies:

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

Our other drug delivery and formulation technologies may present similar challenges relating to the integration of drug formulation, processing, packaging and delivery device technologies. At the same time we may:

- 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 delivery and formulation technologies.

We may not be able to manufacture our products in commercial quantities.

Inhaleables Technology

Powder Processing. We have no experience manufacturing powder processing products for commercial purposes. With respect to drugs using our inhaleables technology, we have only performed powder processing on the 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 some late stage clinical testing and commercialization of our products and could negatively impact our revenues and results of operations.

To date, we have relied primarily 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 preclude 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 utilized for drugs using our inhaleables technology 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 deep lung delivery products and would negatively impact our revenues and results of operations.

Inhalation Device. We face many technical challenges in further developing our inhalation devices to work with a broad range of drugs, to produce such a device in sufficient quantities and to adapt the device to different powder formulations. 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 devices. There is a risk that we will not be able to establish or maintain arrangements with our potential contract manufacturers or effectively scale-up production of our drug delivery devices through contract manufacturers. Our failure to do so would negatively impact our revenues and results of operations. Because our manufacturing processes and those of our contract manufactures are very complex and subject to lengthy governmental approval processes, alternative qualified production sources or capacity may not be available on a timely basis or at all. Disruptions or delays in our manufacturing processes or those of our contract manufacturers for existing or new products could result in increased costs, loss of revenues or market share, or damage to our reputation.

Other Drug Delivery and Formulation Technologies

Our advanced PEGylation and supercritical fluids technologies were recently acquired through our acquisitions of Shearwater and Bradford Particle Design, respectively. Except for our approved products

or products pending approval using our advanced PEGylation technology, all of the drug formulations with which we are incorporating these technologies are in the early stages of feasibility testing or human clinical trials. Because our existing facilities are not large enough for most commercial scale manufacturing, we may not be able to scale-up to large clinical trials or commercial manufacturing for products incorporating either of these technologies 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.

We depend on sole or exclusive suppliers for our inhalation device, bulk drugs and PEG polymer chains.

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

We obtain the bulk drugs we use to manufacture the drugs using our drug delivery and formulation technologies from sole or exclusive 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 Aventis to manufacture biosynthetic recombinant insulin. Under the terms of their agreement, Pfizer and Aventis agreed to construct a jointly owned manufacturing plant in Frankfurt, Germany. Until its completion, Pfizer will provide us with insulin from Aventis's existing plant.

We have also entered into an exclusive agreement with one supplier for a significant portion of the PEG polymer chains we use in our products that incorporate PEGylation technology. NOF Corporation is our predominate supplier of high-quality, high molecular weight, low-diol methoxy, pharmaceutical grade

PEGylation materials pursuant to an exclusive supply agreement with NOF that provides for the supply of these materials. If our sole or exclusive source suppliers fail to provide either bulk drugs or PEGylation materials in sufficient quantities when required, our revenues and results of operations will be negatively impacted.

We do not know if the market will accept products using our drug delivery and formulation technologies.

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 or drug formulation 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 of products demonstrated in 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 product using our drug delivery and formulation technologies. 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 may not pay for them.

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 or third-party payor decision to not provide adequate coverage and reimbursements for our products would limit market acceptance of such products.

Our competitors may develop and sell better drug delivery and formulation technologies.

We are aware of other companies engaged in developing and commercializing pulmonary drug delivery and formulation systems, as well as drug delivery and formulation technology similar to the supercritical fluids technology and the advanced PEGylation technology we are developing through our acquisitions of Bradford Particle Design and Shearwater, respectively. 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.

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 inhalation device, powder processing technology, powder formulations and deep lung route of delivery for certain molecules as well as for our other drug delivery and formulation technologies, and we plan to file additional patent applications. We currently have 165 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 many 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 using our technologies 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, and our drug formulation technologies are subject to issued and pending U.S. and foreign patents that may be owned by competitors. We know that there are issued patents and pending patent applications relating to the formulation and delivery of delivery of large and small molecule drugs, including several for which we are developing deep lung or other delivery formulations using our various technologies. This situation is highly complex, and the ability of any one company, including us, to commercialize a particular drug is unpredictable.

At this time, we are involved in an outstanding lawsuit with Enzon, Inc. whereby Enzon has alleged infringement of its patents related to branched polymer conjugates. In a complaint originally filed in December 1998 and amended in December 2000, Enzon filed suit against Shearwater asserting infringement of certain Enzon patents by certain Shearwater PEG-2 reagents and certain other advanced PEGylation products. Whether or not this litigation is determined in our favor, this action could adversely affect the value of our technology portfolio and have a material impact on our existing collaborative development agreements. If

we are unsuccessful in defending this or other actions, we also may be subject to indemnification obligations with respect to certain of our collaborative partners. If we were to lose key intellectual property right protections, our business, financial condition and results of operations would be materially adversely affected.

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 and other forms of 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 business is subject to the risks of earthquakes and other catastrophic events.

Our corporate headquarters, including most of our research and development operations, are located in the Silicon Valley area of Northern California, a region known for seismic activity. A significant natural disaster such as an earthquake could have a material adverse impact on our business, operating results, and financial condition.

The recent energy crisis in California could disrupt our business and the businesses of our suppliers, contract manufacturers and collaborative partners, and could increase our expenses.

In recent months, the western United States (and California in particular) has experienced repeated episodes of diminished electrical power supply, and we anticipate that this situation could continue to worsen in the near future. As a result of these episodes, certain of our operations or facilities may continue to be subject to "rolling blackouts" or other unscheduled interruptions of electrical power. The prospect of such unscheduled interruptions may continue for the foreseeable future, and we are unable to predict their occurrence or duration. Certain of our suppliers, contract manufacturers and collaborative partners are also located in this area and their operations may also be materially and adversely affected by such interruptions, which in turn could have a material adverse effect on our business or results of operations.

Investors should be aware of industry-wide risks.

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

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

If we fail to manage our growth effectively, our business may suffer.

Our ability to commercialize our products, achieve our expansion objectives, manage our growth effectively and satisfy our commitments under our collaboration agreements depends on a variety of factors. Key factors include our ability to develop products internally, enter into strategic partnerships with collaborators, attract and retain skilled employees and effectively expand our internal organization to accommodate anticipated growth including integration of any potential businesses that we may acquire. If we are unable to manage growth effectively, there could be a material adverse effect on our business, financial condition and results of operations.

Integration of personnel and operations relating to our acquisitions of Bradford Particle Design and Shearwater may disrupt our business and management.

Our acquisition of Bradford Particle Design and Shearwater may present unique risks related to our business. We may not be able to successfully assimilate the additional personnel, operations, acquired technology and products into our business. In particular, we need to assimilate and retain key management, research and engineering personnel. Key personnel from acquired companies such as Bradford Particle Design and Shearwater often decide to pursue other opportunities. In addition, there may be complications if we attempt to integrate any of the technology acquired from these companies with our other technologies, and it is uncertain whether we may accomplish this easily or at all. These integration difficulties could disrupt our ongoing business, distract management and employees or increase expenses. Acquisitions are inherently risky, and we may also face unexpected costs, which may adversely affect operating results in any quarter. Additionally, because Bradford Particle Design is a UK company, we will face additional risks related to cross-border acquisitions and international operations, including foreign legal and regulatory restrictions and potential economic instability. Due diligence conducted in connection with either acquisition may not uncover all the potential problems or liabilities we may have assumed in these transactions. Any of these risks could have a significant impact on our ability to continue our research and development efforts on a competitive and timely basis.

We cannot predict the impact of recent actions and comments by the Securities and Exchange Commission regarding valuation methodologies related to business combinations.

The Securities and Exchange Commission has been reviewing registrants' valuation methodologies of in-process research and development related to business combinations. The valuations we placed on Bradford Particle Design and Shearwater included certain assumptions about the technology, development and future operations of these businesses. These assumptions also determined in large part how these acquisitions were reflected in our financial statements. While we believe that we are in compliance with all of the existing rules and related guidance applicable to our business operations, if the SEC does not agree with our valuation methodologies, or if the assumptions taken at the time of the valuation are not achieved, we may be required to restate our financial statements. In addition, the SEC may change these rules or issue new guidance applicable to our business in the future. There can be no assurance that the SEC will not seek to

reduce the amount of in-process research and development previously expensed by us or require us to make an adjustment related to our valuation assumptions. This would result in the restatement of our previously filed financial statements and could have a material adverse effect on our operating results and financial condition for periods subsequent to the acquisitions.

If we acquire additional companies, products or technologies, we may face risks similar to those faced in our other acquisitions.

We may continue to acquire or make investments in complementary companies, products or technologies. We may not realize the anticipated benefits of any other acquisition or investment. If we acquire another company, we will likely face some or all of the same risks, uncertainties, earnings and

disruptions as discussed above with respect to the Bradford Particle Design and Shearwater acquisitions. In addition, our earnings may suffer because of acquisition-related costs.

We expect to continue to lose money for the next few years.

We have never been profitable and, through June 30, 2001, we have an accumulated deficit of approximately $379 million. We expect to continue to incur substantial and potentially increasing losses over at least the next few years as we expand our research and development efforts, testing activities and manufacturing operations, and as we further expand our late stage clinical and early commercial production facility. All of our potential products are in the early stages of development except for our insulin collaboration using our inhaleables technology and our two approved products and three products pending approval using our PEGylation technology. Except for our approved PEGylation technology products, 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 and other drug delivery systems. 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 will enable us to maintain currently planned operations through at least the next 32 months. However, this expectation is based on our current operating plan, which may change as a result of certain factors, and may result in additional funding requirements 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 material credit facility or other material 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, our substantial leverage 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.

We expect our stock price to remain volatile.

Our stock price is volatile. In the last twelve-month period ending July 31, 2001, based on closing prices on the Nasdaq National Market, our stock price ranged from $15.06 to $56.375. We expect it to remain volatile. A variety of factors may have a significant effect on the market price of our common stock, including:

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

We may incur material litigation costs.

Litigation to which we are currently or have been subjected relates to, among other things, our patent and intellectual property rights, licensing arrangements with other persons, product liability and financing activities. In particular, we are involved in litigation with Enzon that if we are unsuccessful may have a material adverse effect on the value of our advanced PEGylation technology and trigger indemnification obligations with respect to certain of our collaborative partners. We cannot predict with certainty the eventual outcome of this or any other pending litigation, and we might have to incur substantial expense in defending this or future lawsuits or indemnifying third parties with respect to the results of such litigation.

Our indebtedness may result in future liquidity problems.

As of June 30, 2001, we had approximately $335 million in long-term obligations, which represents an increase of approximately $14 million from the fiscal year-ended December 31, 2000. This increased indebtedness has and will continue to impact us by:

- 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.

Currently, we are not generating sufficient cash flow to satisfy the annual debt service payments on our outstanding subordinated convertible debentures and subordinated convertible notes. This may require us to use a portion of the proceeds from the sales of these securities to pay interest or borrow additional funds or sell additional equity to meet our debt service obligations. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result, which would negatively impact our future prospects. As of June 30, 2001, we had cash and short-term investments valued at approximately $386 million.

Anti-takeover provisions in our charter documents and under Delaware law may make it more difficult to acquire us, even though an acquisition may be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. Among other things, these provisions:

- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt; and
- limit who may call a special meeting of stockholders.

On June 1, 2001, our board of directors adopted a preferred share purchase rights plan, commonly known as a "poison pill." The provisions described above, our preferred share purchase rights plan and provisions of the Delaware General Corporation Law relating to business combinations with interested

stockholders may discourage, delay or prevent a third party from acquiring us, even if our stockholders might receive a premium for their shares in the acquisition over then current market prices.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk is principally limited to our cash equivalents and investments that have maturities of less than one year. We maintain a non-trading investment portfolio of investment grade, liquid debt securities that limits the amount of credit exposure to any one issue, issuer or type of instrument. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and are therefore subject to interest rate risk. We currently do not hedge interest rate exposure.

We are subject to market rate risks due to fluctuations in interest rates and equity markets. All of our long-term debt is in the form of fixed-rate notes with original maturities ranging over four years. Accordingly, fluctuations in interest rates can lead to fluctuations in the fair value of such instruments. We have not entered into financial derviatives to reduce its exposure to interest rate risks.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

(a) As a result of our acquisition of Shearwater, we are involved in an outstanding lawsuit with Enzon, Inc. whereby Enzon has alleged infringement of its patents related to branched polymer and their conjugates. In a complaint originally filed in December 1998 and amended in December 2000, Enzon sued Shearwater asserting infringement of certain Enzon patents by certain Shearwater PEG-2 reagents and certain other advanced PEGylation products. This suit is currently pending in the United States District Court for the Northern District of Alabama Northeastern Division. Enzon is seeking damages and injunctive relief.

(b)

On June 20, 2001, we announced the English High Court of Justice ruled that Inhale's European patent covering room-temperature stable glassy materials will no longer be valid in the United Kingdom. The revocation has no effect outside the United Kingdom and does not limit in any way our ability to use glass stabilization.

Item 2. Changes in Securities

(a)

On June 1, 2001, the Board of Directors approved the adoption of a Stockholder Rights Plan under which all stockholders of records as of June 22, 2001 received rights to purchase shares of a new series of Preferred Stock. The Preferred Stock has designations and powers, preferences and rights, and the qualifications, limitations and restrictions which are set forth in a certificate of designation which was filed with the Secretary of State of the State of Delaware. The adoption of the Rights Plan was intended as a means to guard against abusive takeover tactics and was not in response to any particular proposal. The rights were distributed as a non-taxable dividend and will expire in ten years from the record date. The rights will be exercisable only if a person or group acquires 20 percent or more of our common stock or announces a tender offer for 20 percent or more of our common stock . If a person acquires 20 percent or more of our common stock, all rightsholders except the buyer will be entitled to acquire our common stock at a discount. The rights will trade with our common stock, unless and until they are separated upon the occurrence of certain future events. The Board of Directors may terminate the Rights Plan at any time or redeem the rights prior to the time a person acquires more than 20 percent of our common stock. Additional details regarding the Rights Plan are sent forth in our Current Report on Form 8-K filed June 4, 2001, including the exhibits thereto.

(b)

Effective June 29, 2001, we consummated our acquisition of privately-held Shearwater Corporation. The aggregate consideration paid was established in the Agreement at $72.5 million in cash and 4,000,000 shares or options to acquire shares of Inhale common stock in exchange for all of the outstanding capital stock of Shearwater (including shares issuable pursuant to outstanding options). Pursuant to the Merger, each then-outstanding share of common stock of Shearwater was converted into the right to receive approximately 3.09 shares of common stock of Inhale and $55.94 in cash and each then-outstanding option to purchase Shearwater common stock was converted into the right to receive approximately 3.09 shares of Inhale common stock upon exercise. Holders of Shearwater options were also paid a cash payment of $55.94 per share of Shearwater common stock issuable upon exercise of such options. Approximately 3,112,603 shares of Inhale common stock were issued and $56,416,074 in cash was paid to the six former shareholders of Shearwater in the Merger. In addition, we assumed all 287,536 outstanding options to purchase Shearwater common stock which were converted into options to purchase an aggregate of approximately 887,343 shares of Inhale common stock and paid approximately $16,083,926 in cash to 83 Shearwater

optionholders. No fractional shares of Inhale common stock were issued in connection with the Merger. In lieu thereof, any holder of Shearwater common stock who would otherwise have been entitled to receive fractional shares of Inhale common stock was paid an amount based on the value of such fractional shares multiplied by $30.67 (rounded to the nearest whole cent). The shares of Inhale common stock issued as consideration in the Merger were issued in a private placement exempt from the registration requirements of the Securities Act of 1933 (the "Act") pursuant to an exemption under Section 4(2) of the Act. We agreed to file a registration statement on Form S-3 to register the resale of such securities not later than 45 days following the effective date of the Merger, which filing was made on August 10, 2001. Merrill Lynch, Pierce, Fenner & Smith Incorporated served as financial advisor to us in connection with the acquisition of Shearwater and will receive $2,050,000 in payment of certain fees.

Item 3. Defaults upon Senior Securities—None

Item 4. Submission of Matters to a Vote of Security Holders

A.

The annual meeting of the stockholders was held on June 1, 2001.

B.

The following matters were voted upon at the annual meeting:

1.

To elect the following directors to hold office until the 2004 Annual Meeting of Stockholders:

Nominee	In Favor	Withheld
John S. Patton, Ph.D.	40,475,008	166,282
Irwin Lerner	40,461,474	179,816

2.

To ratify the selection of Ernst & Young LLP as independent auditors for the Company for its fiscal year ending December 31, 2001.

For	Against	Abstain	Broker Non-Vote
40,573,580	51,571	16,139	0

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 Index

Exhibit Number		Exhibit Index
2.1	(1)	Agreement and Plan of Merger between Inhale Therapeutic Systems, a California corporation, and Inhale Therapeutic Systems (Delaware), Inc., a Delaware corporation.
2.2	(16)	Recommended Offer, dated December 21, 2000 by Cazenove & Co. on behalf of Inhale Therapeutic Systems, Inc. for Bradford Particle Design plc.
2.3	(21)	Agreement and Plan of Merger and Reogranization among Inhale Therapeutic Systems, Inc., Shearwater Corporation, Square Acquisition Corp., J. Milton Harris and Puffinus, L.P.

2.4	(21)	Amendment to Agreement and Plan of Merger and Reogranization among Inhale Therapeutic Systems, Inc., Shearwater Corporation, Square Acquisition Corp., J. Milton Harris and Puffinus, L.P.
3.1	(1)	Certificate of Incorporation of Inhale.
3.2	(1)	Bylaws of Inhale.
3.3	(14)	Certificate of Amendment of the Amended Certificate of Incorporation.
4.1		Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	(2)	Restated Investor Rights Agreement among Inhale and certain other persons named therein, dated April 29, 1993, as amended October 29, 1993.
4.3	(3)	Stock Purchase Agreement between Inhale and Pfizer Inc., dated January 18, 1995.
4.4	(9)	Form of Purchase Agreement between Inhale and the individual Purchasers, dated January 28, 1997.
4.5	(10)	Stock Purchase Agreement between Inhale and Capital Research and Management Company, dated December 8, 1998.
4.6	(12)	Purchase Agreement among Inhale and Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc. dated October 6, 1999.
4.7	(12)	Registration Rights Agreement among Inhale and Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc., dated October 13, 1999.
4.8	(12)	Indenture between Inhale as Issuer and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated October 13, 1999.
4.9	(12)	Form of Inhale Registration Rights Agreement, between Inhale and Selling Shareholder, dated January 25, 2000.
4.10	(13)	Purchase Agreement among Inhale and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated February 2, 2000.
4.11	(13)	Resale Registration Rights Agreement among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated February 8, 2000.
4.12	(13)	Indenture between Registrant as Issuer and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated February 8, 2000.
4.13	(14)	Specimen common stock certificate.
4.14	(15)	Specimen warrants to purchase shares of common stock.
4.15	(17)	Purchase Agreement among Inhale and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated October 11, 2000.
4.16	(17)	Resale Registration Rights Agreement among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities, Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated October 17, 2000.
4.17	(17)	Indenture between Registrant, as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated October 17, 2000.
4.18	(20)	Certificate of Designation of Series A Junior Participating Preferred Stock.
4.19	(20)	Rights Agreement dated as of June 1, 2001 among Inhale Therapeutic Systems, Inc. and Mellon Investor Services LLC.
4.20	(20)	Form of Right Certificate.
10.1	(4)	Registrant's 1994 Equity Incentive Plan, as amended.
10.2	(7)	Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended.
10.3	(2)	Registrant's 1994 Employee Stock Purchase Plan, as amended.
10.4	(2)	Standard Industrial Lease between Inhale and W.F. Batton & Co., Inc., dated September 17, 1992, as amended September 18, 1992.
10.5	(2)	Addendum IV dated April 1, 1994 to Lease dated September 17, 1992, between Inhale and W.F. Batton and Marie A. Batton, dated September 17, 1992.
10.6	(6)	Amendment Agreement Number One, dated October 20, 1995, to Lease dated September 17, 1992, between Inhale and W.F. Batton & Co., Inc.

10.7	(6)	Amendment Agreement Number Two, dated November 15, 1995, to Lease, 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)	Sublicense Agreement between Inhale and John S. Patton, dated September 13, 1991.
10.11	(5)	Stock Purchase Agreement between Inhale and Baxter World Trade Corporation, dated March 1, 1996.
10.12	(8)	Sublease and Lease Agreement, dated October 2, 1996, between Inhale 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 Inhale 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.
10.17	(13)	Sublease by and between Webvan Group, Inc., as sublessor and Registrant, as sublessee, dated November 3, 1999.
10.18	(15)	Registrant's 2000 Equity Incentive Plan
10.19	(15)	Registrant's Stock Option Agreement issued in accordance with Inhale's 2000 Equity Incentive Plan.
10.20	(15)	Agreement for the Contribution of 201 Industrial Road Project made and entered into as of September 14, 2000 by and among Inhale, Inhale 201 Industrial Road, L.P., a California limited partnership and Bernardo Property Advisors, Inc., a California corporation.
10.21	(15)	Agreement of Limited Partnership of Inhale 201 Industrial Road., L.P., a California limited partnership made and entered into September 14, 2000, by and among SCIMED PROP III, Inc., a California corporation, as general partner, 201 Industrial Partnership, a California general partnership, as limited partner, and Inhale, as limited partner.
10.22	(15)	Build-To-Suit Lease made and entered into as of September 14, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
10.23	(15)	Amendment to Lease dated October 3, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
10.24	(15)	Parking Lease Agreement entered into as of September 14, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
10.25	(18)	Registrant's 2000 Non-Officer Equity Incentive Plan
10.26	(18)	Registrant's Stock Option Agreement issued in accordance with Inhale's 2000 Non-Officer Equity Incentive Plan.
10.27+	(19)	Manufacturing and Supply Agreement among Inhale,Tech Group North America, Bespak Europe, LTD.
99.1	(22)	The Bradford Particle Design plc Approved Employee Share Option Scheme.
99.2	(22)	Form of The Bradford Particle Design plc Approved Employee Share Option Scheme Option Certificate.
99.3	(22)	The Bradford Particle Design plc Unapproved Employee Share Option Scheme.
99.4	(22)	Form of the Bradford Particle Design plc Unapproved Employee Share Option Scheme Option Certificate.

99.5	(22)	Form of Agreement Granting an Enterprise Management Incentives.
99.6	(22)	Agreement Granting Options between Mr. Joseph F. Bohan and Bradford Particle Design plc dated November 5, 1999.
99.7	(22)	Agreement Granting Options between Mr. Joseph F. Bohan and Bradford Particle Design plc dated October 27, 2000.
99.8	(23)	Shearwater Corporation 1996 Nonqualified Stock Option Plan.
99.9	(23)	Amendment to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation, effective May 22, 1998.
99.10	(23)	Second Amendment to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation, effective February 26, 2000.
99.11	(23)	Third Amendment to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation, effective October 5, 2000.
99.12	(23)	Fourth Amendment to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation, effective June 22, 2001.
99.13	(23)	Form of Shearwater Corporation Nonqualified Stock Option Agreement.
99.14	(23)	Form of June 2001 Amendment to Shearwater Corporation Nonqualified Stock Option Agreements.

+ Confidential treatment requested with respect to specific portions that are omitted and filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.

(2) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-1 (No. 33-75942), as amended.

(3) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-1 (No. 33-89502), as amended.

(4) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-8 (No. 33-59735).

(5) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.

(6) Incorporated by reference to the indicated exhibit in Inhale's Annual Report on Form 10-K for the quarter ended December 31, 1995.

(7) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.

(8) 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.

(12) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-3 (No. 333-94161), as amended.

(13) Incorporated by reference to the indicated exhibit in Inhale's Annual Report on Form 10-K for the year ended December 31, 1999.

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(14) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.

(15) Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000.

(16) Incorporated by reference to the indicated exhibit in Inhale's Current Report on Form 8-K, filed on January 11, 2001.

(17) Incorporated by reference to Inhale's Registration Statement on Form S-3 (No. 333-53678), filed on January 12, 2001.

(18) Incorporated by reference to Inhale's Registration Statement on Form S-8 (No. 333-54078), filed on January 19, 2001.

(19) Incorporated by reference to Inhale's Annual Report on Form 10-K, as amended, filed on March 1, 2001.

(20) Incorporated by reference to Inhale's Current Report on Form 8-K, filed on June 4, 2001.

(21) Incorporated by reference to Inhale's Current Report on Form 8-K, filed on July 10, 2001.

(22) Incorporated by referece to Inhale's Registration Statement on Form S-8 (No. 333-55032), filed on February 6, 2001.

(23) Incorporated by referece to Inhale's Registration Statement on Form S-8 (No. 333-67342), filed on August 10, 2001.

(b) Reports on Form 8-K.

On May 23, 2001, we filed a Current Report on Form 8-K announcing an agreement to acquire Shearwater Corporation.

On June 4, 2001, we filed a Current Report on Form 8-K announcing the adoption of a Share Repurchase Rights Plan.

On June 20, 2001, we filed a Current Report on Form 8-K and an amended Current Report on Form 8-K/A announcing a ruling by the English High Court of Justice with respect to the validity of certain European patents in the U.K.

On July 10, 2001, we filed a Current Report on Form 8-K announcing the completion of our acquisition of Shearwater Corporation through the merger of Shearwater with and into a wholly-owned subsidiary of Inhale. On August 10, 2001, we filed an amended Current Report on Form 8-

K/A to provide financial information required with respect to the acquisition of Shearwater.

SIGNATURES

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: August 14, 2001

BY: /s/ AJIT S. GILL

Ajit S. Gill
Chief Executive Officer and Director
(Duly Authorized Officer)

BY: /s/ BRIGID A. MAKES

Brigid A. Makes
Vice President, Finance and Administration,
Chief Financial Officer and Assistant Secretary

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