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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 September 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 54,913,247 as of October 31, 2001.

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Item 1. Financial Statements

INHALE THERAPEUTIC SYSTEMS, INC.

Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2001 (unaudited)	December 31, 2000 *
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,000	$ 136,012
Short-term investments	323,382	348,829
Accounts receivable	5,321	7,234
Other current assets	10,749	968
Total current assets	369,452	493,043
Property and equipment, net	138,837	110,457
Marketable equity securities	964	9,140
Goodwill and other intangibles	162,631	4,969
Deposits and other assets	13,799	11,931
	$ 685,683	$ 629,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 36,161	$ 24,313
Capital lease obligation—current	977	977
Deferred revenue	7,774	4,913
Total current liabilities	44,912	30,203
Capital lease obligation	29,611	15,269
Convertible subordinated notes and debentures	299,149	299,149
Accrued rent	2,131	2,010
Other long-term liabilities	7,297	5,026
Stockholders' equity:		
Common stock	5	5
Capital in excess of par value	710,941	465,593
Deferred compensation	(1,109)	(1,827)
Accumulated other comprehensive gain/(loss)	(1,629)	5,981
Accumulated deficit	(405,625)	(191,869)
Total stockholders' equity	302,583	277,883
	$ 685,683	$ 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 Inhale'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 accounting principles generally accepted in the United States for complete financial statements.

INHALE THERAPEUTIC SYSTEMS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Contract research revenue	$ 17,236	$ 14,061	$ 48,132	$ 38,483
Product sales	5,169	—	5,169	—
Total revenue	22,405	14,061	53,301	38,483
Operating costs and expenses:				
Cost of goods sold	1,979	—	1,979	—
Research and development	34,212	26,739	98,542	74,232
General and administrative	5,762	3,066	14,200	9,696
Purchased in-process research and development	—	—	146,260	2,292
Amortization of goodwill and intangible assets	8,943	194	16,478	565
Total operating costs and expenses	50,896	29,999	277,459	86,785
Loss from operations	(28,491)	(15,938)	(224,158)	(48,302)
Other income/(expense),net	(263)	752	(603)	752
Debt conversion premium,net	—	—	—	(15,157)
Interest income/(expense), net	1,833	1,971	11,005	4,913
Net loss	$ (26,921)	$ (13,215)	$ (213,756)	$ (57,794)
Basic and diluted net loss per share	$ (0.49)	$ (0.31)	$ (4.07)	$ (1.42)
Shares used in computing basic and diluted net loss per share	54,845	42,266	52,513	40,742

See accompanying notes.

INHALE THERAPEUTIC SYSTEMS, INC.

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

	Nine Months Ended September 30,	
	2001	2000
Cash flows from operating activities:		
Cash used in operations	$ (43,016)	$ (32,656)
Cash flows from investing activities:		
Purchases of short-term investments	(413,201)	(193,312)
Sales of short-term investments	88,446	8,712
Maturities of short-term investments	350,768	101,567
Purchases of property and equipment	(26,559)	(43,035)
Other investing activities	—	(193)
Acquisition of Shearwater, net of cash acquired	(67,246)	—
Acquisition of Bradford, net of cash acquired	(14,825)	—

Net cash used in investing activities	(82,617)	(126,261)
Cash flows from financing activities:		
Proceeds from capital lease financing	15,119	—
Payments of equipment financing obligations	(593)	(28)
Payments of debt conversion incentives	—	(17,182)
Issuance of convertible debt, net of issuance costs	—	222,439
Issuance of common stock, net of issuance costs	5,095	13,353
Net cash provided by financing activities	19,621	218,582
Net (decrease)/increase in cash and cash equivalents	(106,012)	59,665
Cash and cash equivalents at beginning of period	136,012	33,430
Cash and cash equivalents at end of period	$ 30,000	$ 93,095
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
September 30, 2001
(unaudited)

1. Organization and Basis of Presentation

Inhale Therapeutic Systems, Inc. ("Inhale") was incorporated in the State of California in July 1990 and reincorporated in the State of Delaware in July 1998. We develop advance approaches for drug delivery and drug formulation for the biopharmaceutical industry. We are focused on two main opportunities: improved delivery of drug compound and improved performance of drug powders and other formulations. To fulfill these needs, we are developing several technologies. The first enables inhalation for delivery of a range of drugs, including peptides, a protein derivative, proteins and small molecules, for treatment of systemic and respiratory diseases. A second technology uses a proprietary processing method known as supercritical fluids processing to develop drug formulations for multiple types of drug delivery. The third technology, advanced PEGylation, is designed to enhance the efficacy and performance of most major drug classes, including large sized molecular compounds, macromolecules, such as peptides and proteins, small sized molecular compounds, and other drugs. We currently have or are developing 20 therapeutic drugs and one compound used as a diagnostic agent incorporating our technologies that are either approved for use, in the process of being reviewed for approval by the appropriate regulatory agency, or in clinical trials. We are the parent company of Bradford Particle Design, plc ("Bradford") and Shearwater Corporation ("Shearwater"), each of which were acquired in 2001 as well as two additional 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 September 30, 2001, the condensed consolidated statements of operations for the three and nine-month periods ended September 30, 2001 and 2000, and the condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2001 and 2000 have been prepared by us without audit, but include all adjustments (consisting only of normal recurring adjustments) which we consider necessary for a fair presentation of the financial position at such dates and the operating results and cash flows for those periods. Although we believe that the disclosures in these financial statements are adequate to make the information presented not

misleading, certain information normally included in financial statements and related footnotes prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission ("the Commission"). The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in 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 Bradford Particle Design, plc and Shearwater Corporation"), our recently acquired subsidiaries.

3. Comprehensive Loss

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
Net loss	$ (26,921)	$ (13,215)	$ (213,756)	$ (57,794)
Other comprehensive income/(loss)	48	(3,677)	(7,610)	(10,303)
Comprehensive loss	$ (26,873)	$ (16,892)	$ (221,366)	$ (68,097)

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 65% of our revenue in the nine-month period ended September 30, 2001 and 68% of our revenue in the comparable period in 2000. Costs of contract research revenue approximate such revenue and are included in operating costs and expenses.

Revenue from product sales is earned when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collectibility is reasonably assured. Allowances, if any, are established for estimated product returns and discounts.

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 (in thousands):

	September 30, 2001	December 31, 2000
Raw materials	$ 969	$ 177
Work-in-process	997	—
Finished goods	1,308	—
	$ 3,274	$ 177

7. Acquisition of Bradford Particle Design, plc and Shearwater Corporation

In January 2001, we acquired all of the outstanding share capital of Bradford in exchange for approximately 3.75 million newly issued shares of our common stock and approximately $20.4 million in cash. The acquisition was accounted for under the purchase method of accounting. 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 and estimated acquisitions costs of $4.0 million. Approximately $62.7 million of the purchase price was allocated to in-process research and development ("IPR&D") which was charged to expense in the quarter ended March 31, 2001. 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 results of operations for Bradford for the period from January 31, 2001 through September 30, 2001 are included in our unaudited condensed consolidated income statement for the three and nine-months ended September 30, 2001.

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 an $83.6 million 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 results of operations for Shearwater for the period from July 1, 2001 through September 30, 2001 are included in our unaudited condensed consolidated income statement for the three and nine-months ended September 30, 2001.

IPR&D 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. During the nine-months ended September 30, 2001, we recognized total charges to purchase to IPR&D of approximately $146.3 million upon consummation of both acquisitions.

The amounts of IPR&D were determined based on an analysis using risk-adjusted cash flows expected to be generated by the products that may result from the in-process platform technology for Bradford and from the in-process technology for Shearwater. The analysis included forecasted future cash flows that were expected to result from the progress made on each of the in-process projects prior to the purchase dates. These cash flows were estimated by first forecasting, on a product-by-product basis, net revenues expected from the sales of the first generation of each in-process project and risk

adjusted these revenues to reflect the probability of advancing to the next stage of the FDA approval process. Appropriate operating expenses were deducted from the total forecasted net revenues for Bradford and on a product by product basis from the forecast for Shearwater to establish a forecast of net returns on the completed portion of the in-process technology. Finally, these net returns were discounted to a present value using discount rates that incorporate the weighted average cost of capital relative to the biotech industry and our company as well as product specific risks associated with the purchased in-process research and development products. The product specific risk factors included the products phase of development, type of molecule under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, pre-clinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, an overall discount rate of 47% for Bradford and 22% for Shearwater was used for the purchase valuation, which represents a considerable risk premium to our weighted average cost of capital.

The forecast data in the analysis was based on internal product level forecast information maintained by management in the ordinary course of managing the business. The inputs used by management in analyzing IPR&D was based on assumptions, which management believed to be reasonable but which are inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur.

Bradford and Shearwater's results of operations included in the following pro forma financial information are derived from their unaudited financial statements for the three and nine-months ended September 30, 2001 and 2000, respectively. Bradford's financial statements have been adjusted, where appropriate, to present their financial position and results of operations in accordance with accounting principles generally accepted in the United States. The unaudited pro forma net loss and loss per share amounts do not include the charges for purchased research and development of approximately $146.3 million, due to its non-recurring nature, but includes the amortization of goodwill and other intangible assets.

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 Inhale for the three and nine-month periods ended September 30, 2001 and 2000, respectively, assumes the acquisition of Bradford and 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:

	September 30,		September 30,	
	Three Months Ended 2001 Pro Forma	Three Months Ended 2000 Pro Forma	Nine Months Ended 2001 Pro Forma	Nine Months Ended 2000 Pro Forma
(unaudited, in thousands, except per share information)				
Total revenue	$ 22,405	$ 18,768	$ 59,616	$ 52,179
Net loss	$ (26,921)	$ (21,843)	$ (79,991)	$ (73,824)
Net loss per share	$ (0.49)	$ (0.44)	$ (1.52)	$ (1.55)

9. Goodwill and Other Intangible Assets

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

	September 30, 2001	December 31, 2000
Goodwill	$ 152,320	$ 2,238
Accumulated amortization	(14,598)	(360)
Net goodwill	137,722	1,878
Assembled workforce	2,860	—
Core technology	8,100	—

Customer relations	2,240	—
Developed product technology	2,900	—
Intellectual property	8,602	3,544
Supplier and customer relations	2,900	—
Total other intangible assets	27,602	3,544
Accumulated amortization of other intangible assets	(2,693)	(453)
Net other intangible assets	24,909	3,091
Net goodwill and other intangible assets	$ 162,631	$ 4,969

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 through December 31, 2001. Effective January 1, 2002, goodwill will be subject to a non-amortization, impairment assessment, consistent with the new business combination accounting rules, and goodwill will not be amortized after that date.

Assembled workforce is comprised of all skilled employees and includes the estimated cost to replace existing employees, including recruiting and training costs and loss of productivity costs. We are amortizing the value assigned to the assembled workforce on a straight-line basis on an average estimated useful life of three 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. We are amortizing the value assigned to core technology on a straight-line basis over an average estimated life of five years.

Customer relations 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. We are amortizing the value assigned to customer relationships on a straight-line basis over an average estimated life of five years.

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

Intellectual property is recognized for the intrinsic value of Bradford's name and products in the marketplace. We are amortizing the value assigned on a straight-line basis over an average estimated life of five years.

Supplier and customer relations is based on historical costs incurred and is comprised of management's estimation of resources that have been devoted to the development of relationships with

key customers. We are amortizing the value assigned to customer relationships on a straight-line basis over an average estimated life of five years.

10. Recent Accounting Pronouncement

In July 2001, the Financial Accounting Standards Board ("FASB") issued two statements as a result of its deliberations on the business combinations project: 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. Inhale is in the process of evaluating the financial statement impact of these new standards.

In August, 2001, the FASB issued SFAS 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS 144 supercedes SFAS 121, Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of, and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business. SFAS 144 establishes a single accounting model for assets to be disposed of by sale whether previously held and used or newly acquired. SFAS No. 144 retains the provisions of APB No. 30 for presentation of discontinued operations in the income statement, but broadens the presentation to include a component of an entity. SFAS 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. Inhale is in the process of evaluating the financial statement impact of these new standards.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Condition and Results of Operations for the three and nine-months ended September 30, 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 drug formulations 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 September 30, 2001, we incurred a cumulative net loss of approximately $405.6 million. The sources of our working capital have been equity offerings 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 September 30, 2001 was $22.4 million compared to $14.1 million for the three-months ended September 30, 2000, an increase of 59%. Revenue for the nine-months ended September 30, 2001 was $53.3 million compared to $38.5 million for the nine-months ended September 30, 2000, an increase of 39%. The increase in revenue for both the three and nine-month periods was primarily due to the expansion of our existing collaborative agreements and the inclusion of Shearwater's product sales. Revenue for the three and nine-months ended September 30, 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 and product sales. Recognition of up-front signing and progress payments are amortized over the period of development. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

Cost of goods sold, associated with product sales, for the three and nine-months ended September 30, 2001 was $2.0 million due to the inclusion of Shearwater's financial results for this period.

Research and development expenses increased to $34.2 million for the three-months ended September 30, 2001 from $26.7 million for the three-months ended September 30, 2000, an increase of 28%. Research and development expenses increased to $98.5 million for the nine-months ended September 30, 2001 from $74.2 million for the nine-months ended September 30, 2000, an increase of 33%. The increase for the three and nine-month periods was due to increased spending related to the development effort for both partner and internally funded programs, the scale-up of technologies and the continuing development of global manufacturing capabilities for both inhalation devices and drug powders in order to support inhaleable insulin clinical trials and commercial operations, as well as the addition of Shearwater and Bradford to our operations through acquisitions during 2001. 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 $5.8 million for the three-months ended September 30, 2001 from $3.1 million for the three-months ended September 30, 2000, an increase of 88%. General

and administrative expenses increased to $14.2 million for the nine-months ended September 30, 2001 from $9.7 million for the nine-months ended September 30, 2000, an increase of 46%. 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 as well as the addition of Shearwater and Bradford to our operations.

Interest income was $5.4 million during the three-months ended September 30, 2001, compared to $5.3 million during the three-months ended September 30, 2000, an increase of 2%. Interest income was $20.4 million during the nine-months ended September 30, 2001, compared to $13.9 million of interest income earned during the nine-months ended September 30, 2000, an increase of 47%. The higher interest income in 2001 is attributed primarily to a higher cash balance in 2001 than what was available in 2000.

Interest expense was $3.5 million during the three-months ended September 30, 2001, compared to $3.4 million during the three-months ended September 30, 2000. Interest expense during the nine-months ended September 30, 2001, was $9.4 million, compared to $9.0 million during a comparable period in 2000. In addition, in the first quarter of 2000, we paid a conversion premium of approximately $15.2 million 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.

Purchased In-process Research and Development ("IPR&D")

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.

In June 2001, we completed the acquisition of Shearwater in exchange for our payment of approximately $56.4 million and 3,112,603 shares of common stock to the holders of all the outstanding common stock of Shearwater. 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 an aggregate amount of $16.1 million in cash at closing. 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 $90.9 million in goodwill and other intangible assets. Approximately $83.6 million of the purchase price was allocated to purchased 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.

During the nine-months ended September 30, 2001 both acquisitions have resulted in an aggregate total charge to IPR&D of approximately $146.3 million.

IPR&D 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.

The amounts of IPR&D were determined based on an analysis using risk-adjusted cash flows expected to be generated by the products that may result from the in-process platform technology for Bradford and from the in-process technology for Shearwater. The analysis included forecasted future cash flows that were expected to result from the progress made on each of the in-process projects prior to the purchase dates. These cash flows were estimated by first forecasting, on a product-by-product

basis, net revenues expected from the sales of the first generation of each in-process project and risk adjusted these revenues to reflect the probability of advancing to the next stage of the FDA approval process. Appropriate operating expenses were deducted from the total forecasted net revenues for Bradford and on a product by product basis from the forecast for Shearwater to establish a forecast of net returns on the completed portion of the in-process technology. Finally, these net returns were discounted to a present value using discount rates that incorporate the weighted average cost of capital relative to the biotech industry and our company as well as product specific risks associated with the purchased in-process research and development products. The product specific risk factors included the products phase of development, type of molecule under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, pre-clinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, an overall discount rate of 47% for Bradford and 22% for Shearwater was used for the purchase valuation, which represents a considerable risk premium to our weighted average cost of capital.

The forecast data in the analysis was based on internal product level forecast information maintained by Inhale's management in the ordinary course of managing the business. The inputs used by management in analyzing in-process research and development was based on assumptions, which management believed to be reasonable but which are inherently uncertain and unpredictable. These assumptions may be incomplete or inaccurate, and no assurance can be given that unanticipated events and circumstances will not occur.

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 investments of cash. At September 30, 2001, we had cash, cash equivalents and short-term investments of approximately $353.0 million.

Our operations used cash of $43.0 million for the nine months ended September 30, 2001, compared to $32.7 million for the nine-months ended September 30, 2000. The increase in cash used in operations was due principally to the funding of internal projects, investment in infrastructure for commercial operations and the acquisition of Shearwater and Bradford as compared to the same period in 2000.

We purchased property and equipment of approximately $26.6 million during the nine-months ended September 30, 2001, compared to $43.0 million for the corresponding period in 2000. The current year activity includes $14.8 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, offset 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 acquisition of Shearwater, we paid net cash of $67.2 million which represents cash paid to Shearwater shareholders of $72.5 million, net of Shearwater's cash obtained at June 30, 2001 of $5.3 million. (See Purchased In-process Research and Development).

Cash flows from financing activities were $19.6 million for the nine-months ended September 30, 2001, as compared to $218.6 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 our technologies, development of drug formulations, process development for the manufacture and filling of powders and devices, marketing and general and administrative costs and starting up commercial operations. 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 the next 29 months. We plan to continue to invest 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 us 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.

If our drug delivery and formulation technologies are not commercially feasible, then our revenues and results of operations will be impacted negatively.

We are in an early stage of development. There is a risk that our drug delivery and drug 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. We are currently using the advanced PEGylation technology platform we recently acquired through our acquisition of Shearwater in the development of 15 drugs. While we have incorporated our PEGylation technology in two products that the FDA approved for use 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. We recently acquired our supercritical fluids technology through our acquisition of Bradford Particle Design, which is also primarily in an early stage of feasibility. This technology represents a new method of manufacturing drug particles and is still in research and development, with only one formulation having entered human clinical testing.

Other companies have tested many of the underlying drug compounds contained in our drug formulations in humans 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 we and our collaborative partners may not be able to produce any of our potential products 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.

If our research and development efforts are delayed or unsuccessful, then we may be delayed or unsuccessful in commercializing our products and our business will suffer.

Except for our products that have already been approved by the FDA or submitted for approval by the FDA, our product candidates are still in research and development, including preclinical testing and clinical trials. Preclinical testing and clinical trials are long, expensive and uncertain processes. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage in the process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in later stage clinical trials, even after promising results in earlier trials.

Any clinical trial may fail to produce results satisfactory to us, our collaborative partners or the FDA. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be repeated or a program to be terminated. We typically rely on collaborative partners and third-party clinical investigators to conduct our clinical trials and, as a result, we may face additional delaying factors outside our control.

We do not know if any of our research and development efforts, including preclinical testing or clinical trials will adhere to our planned schedules or be completed on a timely basis or at all. Typically, there is a high rate of attrition for product candidates in preclinical and clinical trials. If our research and development efforts are unsuccessful or substantially delayed, our results of operations will be adversely affected.

If our drug delivery and formulation technologies are not efficient, then our products may not be competitive.

We may not be able to achieve the total system efficiency needed to be competitive with alternative routes of delivery or formulation technologies. We determine total system efficiency by the amount of drug loss during manufacture, in the delivery device, in reaching the site at which the drug is absorbed into the

bloodstream, 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 drug is commercially feasible. We would not consider a drug to be a good candidate for development and commercialization using our inhaleables technology if 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 and the solvents which maybe incorporated in the manufacturing process 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 technology results in very low efficiency in manufacturing of drug powders.

If our drug formulations are not stable, then we will not be able to commercialize our products.

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 effectively with our delivery device for deep lung delivery using our inhaleables technology or through other methods of drug delivery 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 drug formulation and the type and amount of ingredients that are used in the formulation. Since our drug formulation technology is new and largely unproven, we do not know if our drug formulations will retain the physical and chemical properties of injected drugs. 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.

If our drug delivery and formulation technologies are not safe, then we may not obtain regulatory approval of our products or adequately develop or market our products.

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. Since most of our products are in early stage of testing and have not completed clinical trials we cannot be certain that these products, and our technology that developed these products, are safe or will not produce unacceptable adverse side effects. 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.

If our drug delivery and formulation technologies do not provide consistent doses of medicine, then we will not be able to develop and commercialize our products.

We may not be able to provide reproducible dosing of stable formulations of drug compounds. Reproducible dosing is the ability to deliver a consistent and predictable amount of drug into the bloodstream over time both for a single patient and across patient groups. Reproducible dosing 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. Since all of our technologies are still in development and, for the most part, are yet to be commercialized, we cannot be certain that we will 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.

If our collaborative partners that we depend on to obtain regulatory approvals and commercialization of our products are not successful, and if such collaboration fails, then our product development or commercialization of our products may be delayed or unsuccessful.

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:

- 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. In October 2001, Eli Lilly and Company, our collaborative partner with respect to a Phase I program for an inhaleable product for the treatment of osteoporosis, Fortéo,™ notified us that the program will not be funded in 2002. Lilly further informed us that other than on-going stability work, additional activities with respect to the program will be suspended. If the collaborative program with Lilly is not reinitiated, or other significant collaborations are suspended or terminated, our ability to successfully commercialize certain of our proposed products would be significantly and negatively impacted. If these efforts fail, our product development or commercialization of products could be delayed.

If we fail to establish future successful collaborative relationships, then our financial results may suffer and our product development efforts may be delayed or unsuccessful.

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 the timing of drug development programs under existing collaborative agreements with our corporate partners will continue to affect our revenues from such agreements. 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.

If we do not obtain regulatory approval for our products on a timely basis, then our revenues and results of operations may be affected negatively.

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 FDA mandated or equivalent foreign authorities review process. 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. The FDA has approved two products using our advanced PEGylation technology for specific use in the U.S. In addition, our partners have submitted for approval to the FDA three NDAs using our PEGylation technology and we plan to manufacture and market other potential products. Even though we have obtained regulatory approval for two products, these products and our manufacturing processes are subject to continued review by the FDA and other regulatory authorities. Even if we receive regulatory approval of a product, 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 products 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.

In July 2001, Pfizer, our collaborative partner in the development of inhaleable insulin for the treatment of Type 1 and Type 2 diabetes announced that based upon its active discussions with the FDA regarding the requirements for a NDA for this product, its schedule for the filing of an NDA may be delayed beyond its original proposed schedule. The delay in the filing of this NDA may result in a delay in the approval of the NDA by the FDA, if such approval is received at all. Any material delay in the regulatory approval of this product or failure to receive regulatory approval of this product would negatively impact our results of operations.

If our technologies cannot be integrated successfully to bring products to market, then our ability to develop, obtain approval of or market our products may be delayed or unsuccessful.

We may not be able to integrate all of the relevant technologies to provide complete drug delivery and formulation systems. In particular, our development of 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 development efforts may face similar challenges relating to the integration of drug formulation, processing, packaging and delivery device technologies. At the same time we must:

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

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

If we are not able to manufacture our products in commercially feasible quantities, then we will not be able to successfully commercialize our products.

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 rely 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 products using our inhaleables technology 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 maintain arrangements with our 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

We recently acquired our advanced PEGylation and supercritical fluids technologies 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 and if such suppliers fail to provide when required, then our product development efforts may be delayed or unsuccessful.

We have agreed to subcontract the manufacture of our inhalation 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 inhalation device and which can meet the requirements of cGMP. We are not certain 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' 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 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.

If the market does not accept products using our drug delivery and formulation technologies, then our revenues and results of operations will be adversely affected.

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, then 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 regulatory agencies approve our proposed products 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.

If our competitors develop and sell better drug delivery and formulation technologies, then our products or technologies may be uncompetitive or obsolete and our revenues and results of operations will be adversely affected.

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. Some of our competitors with regard to inhaleables technology include AeroGen, Inc., Alkermes, Inc. and Aradigm Corporation. Aerogen and Aradigm are working on liquid drug delivery systems, and Alkermes is working on a dry powder delivery system. Some of our competitors with regard to advanced PEGylation technology include Enzon, Inc. and Valentis, Inc., as well as several pharmaceutical and biotechnology

companies with in-house PEGylation expertise. Some of our competitors with regard to supercritical fluids technology include Alkermes, Inc., Battelle Memorial Institute, AstraZeneca PLC, Ethypharm SA, Ferro Corp., Lavipharm SA, Phasex Corporation and Rx Connectics. Some of these companies license or provide the technology to other companies, while others are developing the technology for internal use. 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.

If any of our patents are invalid or pending patents are not valid, then we may lose key intellectual property right protection. If our products infringe on third-party's rights, then we will suffer adverse effects on our ability to develop and commercialize products as well as our revenues and results of operations.

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 219 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. Enzon is seeking compensatory and treble damages, attorneys' fees and permanent injunction against infringement of its two patents. To date, Enzon has not specified an

amount of damages it is seeking with respect to its claims. The litigation with respect to this matter has been bifurcated, such that damages, if any, will be determined once a judgment has been rendered with respect to the merits of Enzon's claims. 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 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 we formulate 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 our partners provide such access, there is a risk that third parties will accuse, and possibly a court or a governmental agency will determine, our partners or us to be infringing a third-party's patent rights, and we 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.

We may incur material litigation costs which may adversely affect our business and results of operations.

Substantially all of the litigation to which we are currently subjected to or have been subjected to relates to our patent and intellectual property rights. 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. In addition, Enzon is seeking compensatory and treble damages, attorneys' fees and permanent injunction against infringement of certain of its patents, any or all of which could have a material adverse effect on our financial condition. To date, Enzon has not specified an amount of damages it is seeking with respect to its claims. The litigation with respect to this matter has been bifurcated, such that damages, if any, will be determined once a judgment has been rendered with respect to the merits of Enzon's claims. 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.

If earthquakes and other catastrophic events strike, our business may be negatively affected.

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 which are applicable to us and may affect our revenues and results of operations.

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, all of which must be successfully managed. 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 some or all of these factors effectively, our business could grow too slowly or too quickly to be successfully sustained, thereby resulting in material adverse effects on our business, financial condition and results of operations.

If we do not effectively integrate personnel and operations relating to our acquisitions of Bradford Particle Design and Shearwater, our business and management may suffer disruptions.

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 and as such, we may need to restate our financial statements which may alter our operating results.

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 we reflected these acquisitions 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. We may face risks relating to difficult integrations of personnel, technology and operations, uncertainty whether any integration will be successful and whether earnings will be negatively affected, and potential distractions to our management with respect to these acquisitions. In addition, our earnings may suffer because of acquisition-related costs.

We expect to continue to lose money for the next few years and may not reach profitability if our products do not generate sufficient revenue.

We have never been profitable and, through September 30, 2001, we have an accumulated deficit of approximately $405.6 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.

If we cannot raise additional capital our financial condition may suffer.

We anticipate that our existing capital resources will enable us to maintain currently planned operations through the next 29 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 November 1, 2001, based on closing prices on the Nasdaq National Market, our stock price ranged from $11.01 to $55.19. 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.

If we do not generate sufficient cash flow through increased revenues or raising additional capital, then we may not be able to meet our debt obligations.

As of September 30, 2001, we had approximately $338.0 million in long-term obligations, which represents an increase of approximately $17.0 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 September 30 2001, we had cash and short-term investments valued at approximately $353.0 million.

Anti-takeover provisions in our charter documents and under Delaware law may make it more difficult to remove our management. Further, these provisions may make it more difficult to acquire a large portion of our securities, to initiate a tender offer or a proxy contest or to acquire us, even though such events may be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws could make it more difficult for a third party to remove our management. Further, these provisions may make it more difficult to acquire a

large portion of our securities, to initiate a tender offer or a proxy contest or 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 removing our management. Further, they may discourage, delay or prevent a third party from acquiring a large portion of our securities, initiating a tender offer or proxy contest or acquiring us, even if our stockholders might receive a premium for their shares in the acquisition over then current market prices.

This prospectus includes forward-looking statements and if these statements are incorrect or inaccurate, our actual results may differ.

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 o 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 do not intend to update any forward-looking statements except as required by law or applicable regulations.

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 several years. Accordingly, fluctuations in interest rates can lead to fluctuations in the fair value of such instruments. We have not entered into financial derivatives to reduce its exposure to interest rate risks.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

(a)

There have been no material developments during the third quarter of 2001 related to our outstanding lawsuit with Enzon, Inc.

We are currently party to various legal proceedings involving employment disputes and from time to time, we are also subject to claims in the ordinary course of business. While management, including internal counsel, currently believes that the ultimate outcome of any outstanding proceeding, individually and in the aggregate, will not have a material adverse effect on our financial position or overall trends in results of operations, litigation is subject to inherent uncertainties. The estimate of the potential impact on our financial position or overall results of operations for the above legal proceedings could change in the future.

Item 2. Changes in Securities

(a)

None

Item 3. Defaults upon Senior Securities—None

Item 4. Submission of Matters to a Vote of Security Holders—None

Item 5. Other Information—None

Item 6. Exhibits and Reports on Form 8-K

(a)

The following exhibits are filed herewith or incorporated by reference:

Exhibit Number		Exhibit Index
2.1	(1)	Agreement and Plan of Merger by and 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 the Registrant for Bradford Particle Design, plc.
2.3	(21)	Agreement and Plan of Merger and Reorganization, dated May 22, 2001, by and among the Registrant, Shearwater Corporation, Square Acquisition Corp., J. Milton Harris and Puffinus, L.P.

2.4	(21)	Amendment to Agreement and Plan of Merger and Reorganization, dated June 21, 2001, by and among the Registrant, Shearwater Corporation, Square Acquisition Corp., J. Milton Harris and Puffinus, L.P.
3.1	(1)	Certificate of Incorporation of the Registrant.
3.2	(1)	Bylaws of the Registrant.
3.3	(14)	Certificate of Amendment of the Amended Certificate of Incorporation of the Registrant.
4.1		Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	(2)	Restated Investor Rights Agreement, dated April 29, 1993, as amended October 29, 1993, by and among the Registrant and certain other persons named therein.
4.3	(3)	Stock Purchase Agreement, dated January 18, 1995, by and between the Registrant and Pfizer Inc.
4.4	(9)	Form of Purchase Agreement, dated January 28, 1997, by and among the Registrant and the individual Purchasers.
4.5	(10)	Stock Purchase Agreement, dated December 8, 1998, by and between the Registrant and Capital Research and Management Company.
4.6	(12)	Purchase Agreement, dated October 6, 1999, by and among the Registrant, Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc.
4.7	(12)	Registration Rights Agreement, dated October 13, 1999, by and among the Registrant, Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc.
4.8	(12)	Indenture, dated October 13, 1999, by and between the Registrant, as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
4.9	(12)	Form of Inhale Registration Rights Agreement, dated January 25, 2000, by and between the Registrant and Selling Shareholder.
4.10	(13)	Purchase Agreement, dated February 2, 2000, by and among the Registrant, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.11	(13)	Resale Registration Rights Agreement, dated February 8, 2000, by and among the Registrant, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.12	(13)	Indenture, dated February 8, 2000, by and between the Registrant, as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
4.13	(14)	Specimen common stock certificate.
4.14	(15)	Specimen warrants to purchase shares of common stock.

4.15	(17)	Purchase Agreement, dated October 11, 2000, by and among the Registrant, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.16	(17)	Resale Registration Rights Agreement, dated October 17, 2000, by and among the Registrant, Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities, Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.17	(17)	Indenture, dated October 17, 2000, by and between the Registrant, as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
4.18	(20)	Certificate of Designation of Series A Junior Participating Preferred Stock.
4.19	(20)	Rights Agreement, dated as of June 1, 2001, by and between the Registrant and Mellon Investor Services LLC.
4.20	(20)	Form of Right Certificate.
10.1	(4)	The Registrant's 1994 Equity Incentive Plan, as amended.
10.2	(7)	The Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended.
10.3	(2)	The Registrant's 1994 Employee Stock Purchase Plan, as amended.
10.4	(2)	Standard Industrial Lease, dated September 17, 1992, as amended September 18, 1992, by and between the Registrant and W.F. Batton & Co., Inc.
10.5	(2)	Addendum IV to Lease dated September 17, 1992, dated April 1, 1994, by and among the Registrant, W.F. Batton and Marie A. Batton.
10.6	(6)	Amendment Agreement Number One to Lease dated September 17, 1992, dated October 20, 1995, by and between the Registrant and W.F. Batton & Co., Inc.
10.7	(6)	Amendment Agreement Number Two to Lease dated September 17, 1992, dated November 15, 1995, by and among the Registrant, 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 to Lease dated September 17, 1992, dated February 14, 1996, by and between the Registrant and Batton Trust.
10.9	(11)	Amendment Agreement Number Four to Lease dated September 17, 1992, dated September 15, 1996, by and between the Registrant and Batton Trust.
10.10	(2)	Sublicense Agreement, dated September 13, 1991, by and between the Registrant and John S. Patton.
10.11	(5)	Stock Purchase Agreement, dated March 1, 1996, by and between the Registrant and Baxter World Trade Corporation.
10.12	(8)	Sublease and Lease Agreement, dated October 2, 1996, by and between the Registrant and T.M.T. Associates L.L.C. ("Landlord").

10.13	(11)	First Amendment to Sublease and Lease Agreement dated October 2, 1996, dated October 30, 1996, by and between the Registrant and Landlord.
10.14	(11)	Letter Agreement amending Sublease and Lease Agreement dated October 2, 1996, dated April 9, 1997, by and between the Registrant and Landlord.
10.15	(11)	Third Amendment to Sublease and Lease Agreement dated October 2, 1996, dated April 16, 1997, by and between the Registrant and Landlord.
10.16	(11)	Fourth Amendment to Sublease and Lease Agreement dated October 2, 1996, dated November 5, 1997, by and between the Registrant and Landlord.
10.17	(13)	Sublease, dated November 3, 1999, by and between Webvan Group, Inc., as sublessor, and the Registrant, as sublessee.
10.18	(15)	The Registrant's 2000 Equity Incentive Plan.
10.19	(15)	The Registrant's Stock Option Agreement issued in accordance with the Registrant'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 the Registrant, 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 the Registrant, 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 the Registrant, 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 the Registrant, 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 the Registrant, as Tenant.
10.25	(24)	The Registrant's 2000 Non-Officer Equity Incentive Plan.
10.26	(24)	The Registrant's Stock Option Agreement issued in accordance with the Registrant's 2000 Non-Officer Equity Incentive Plan.
10.27+	(19)	Manufacturing and Supply Agreement by and among the Registrant, Tech Group North America and 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, dated November 5, 1999, by and between Mr. Joseph F. Bohan and Bradford Particle Design plc.
99.7	(22)	Agreement Granting Options, dated October 27, 2000, by and between Mr. Joseph F. Bohan and Bradford Particle Design plc.
99.8	(23)	Shearwater Corporation 1996 Nonqualified Stock Option Plan.
99.9	(23)	Amendment, effective May 22, 1998, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
99.10	(23)	Second Amendment, effective February 26, 2000, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
99.11	(23)	Third Amendment, effective October 5, 2000, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
99.12	(23)	Fourth Amendment, effective June 22, 2001, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
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 Agreement.

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

(1)

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

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

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

(4)
Incorporated by reference to the Registrant's Registration Statement on Form S-8 (No. 333-59735).

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

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

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

(8)
Incorporated by reference to the indicated exhibit in the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.

(9)
Incorporated by reference to the Registrant's Registration Statement on Form S-3 (No. 333-20787).

(10)
Incorporated by reference to the indicated exhibit in the Registrant's Registration Statement on Form S-3 (No.333-68897), as amended.

(11)
Incorporated by reference to the indicated exhibit in the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.

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

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

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

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

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

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

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

(19)
Incorporated by reference to the Registrant's Annual Report on Form 10-K, as amended, for the year ended December 31, 2000.

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

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

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

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

(24)
Incorporated by reference to the Registrant's Registration Statement on Form S-8 (No. 333-71936), filed on October 19, 2001.

(b)

Reports on Form 8-K.

Current Report on Form 8-K, filed July 10, 2001, announcing the consummation of the acquisition of Shearwater Corporation, an Alabama corporation, through the merger of Shearwater with and into a wholly-owned subsidiary of the Registrant.

Current Report on Form 8-K/A, filed August 10, 2001, providing certain financial information in connection with the acquisition of Shearwater Corporation.

Current Report on Form 8-K/A, filed October 4, 2001, providing certain additional financial information in connection with the acquisition of Shearwater Corporation.

Current Report on Form 8-K/A, filed October 4, 2001, providing certain additional financial information relating to in-process research and development costs in connection with the acquisition of Bradford Particle Design plc.

Current Report on Form 8-K, filed October 25, 2001, announcing the Registrant's financial results for the third quarter and nine months ended September 30, 2001 and providing additional information with respect to the status of certain of its collaborative arrangements.

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.

DATE: November 13, 2001

INHALE THERAPEUTIC SYSTEMS, INC.

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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