

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 20549

**FORM 10-Q**

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

**For the quarterly period ended March 31, 2002**

**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**  
(State of other jurisdiction of  
incorporation or organization)

**94-3134940**  
(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 55,199,484 as of April 30, 2002.

**INHALE THERAPEUTIC SYSTEMS, INC.  
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## PART I: FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

#### INHALE THERAPEUTIC SYSTEMS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except per share information)

	March 31, 2002	December 31, 2001
	(unaudited)	*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 50,729	\$ 30,814
Short-term investments	307,724	313,542
Accounts receivable	4,478	4,487
Other current assets	11,237	11,998
<b>Total current assets</b>	<b>374,168</b>	<b>360,841</b>
Property and equipment, net	143,961	142,352
Marketable equity securities	591	721
Goodwill	133,856	131,588
Other intangibles assets, net	18,850	22,245
Deposits and other assets	9,362	9,494
	<b>\$ 680,788</b>	<b>\$ 667,241</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,203	\$ 7,685
Accrued research and development	10,292	10,776
Accrued general and administrative	6,465	7,075
Accrued compensation	4,659	5,977
Accrued acquisition costs	566	2,046
Other accrued liabilities	4,259	3,172
Interest payable	5,964	4,588
Capital lease obligation—current	855	807
Deferred revenue	20,116	17,073
<b>Total current liabilities</b>	<b>59,379</b>	<b>59,199</b>
Capital lease obligation—noncurrent	31,673	31,909
Accrued rent	1,949	1,921
Convertible subordinated notes and debentures	299,149	299,149
Other long-term liabilities	4,389	4,750
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, 10,000 shares authorized		
Series A, \$0.0001 par value; 3,100 shares designated; no shares issued or outstanding at March 31, 2002 and December 31, 2001.	—	—
Convertible Series B, \$0.0001 par value; 40 shares designated; 40 shares issued and outstanding at March 31, 2002. No shares issued or outstanding at December 31, 2001. Liquidation preference of \$40,000 at March 31, 2002 and \$0 at December 31, 2001.	40,000	—
Common stock, \$0.0001 par value; 300,000 authorized; 55,184 shares and 55,094 shares issued and outstanding at March 31, 2002 and December 31, 2001, respectively.	6	5
Capital in excess of par value	712,571	712,039
Deferred compensation	(748)	(923)
Accumulated other comprehensive gain/(loss)	(647)	1,069
Accumulated deficit	(466,933)	(441,877)
<b>Total stockholders' equity</b>	<b>284,249</b>	<b>270,313</b>
	<b>\$ 680,788</b>	<b>\$ 667,241</b>

See accompanying notes.

(\*) The balance sheet at December 31, 2001 has been derived from the audited financial statements at that date which are included in our Form 10-K for the year ended December 31, 2001 as filed with the Securities and Exchange Commission. This balance sheet does not include all 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 March 31,	
	2002	2001
Contract research revenue	\$ 21,301	\$ 14,097
Product sales	5,445	—
<b>Total revenue</b>	<b>26,746</b>	<b>14,097</b>
Operating costs and expenses:		
Cost of goods sold	1,890	—
Research and development	41,927	30,271
General and administrative	5,381	4,018
Purchased in-process research and development	—	62,660
Amortization of other intangible assets	1,127	326
Amortization of goodwill	—	2,753
<b>Total operating costs and expenses</b>	<b>50,325</b>	<b>100,028</b>
Loss from operations	(23,579)	(85,931)
Other income/(expense), net	(88)	(78)
Interest income	2,800	7,705
Interest expense	(4,189)	(2,737)
Net loss	\$ (25,056)	\$ (81,041)
Basic and diluted net loss per share	\$ (0.45)	\$ (1.59)
Shares used in computing basic and diluted net loss per share	55,143	51,078

*See accompanying notes.*

**INHALE THERAPEUTIC SYSTEMS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
Increase/(Decrease) in Cash and Cash Equivalents  
(in thousands)  
(unaudited)

	Three Months Ended March 31,	
	2002	2001
<b>Cash flows used in operating activities:</b>		
Net loss	\$ (25,056)	\$ (81,041)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3,111	2,373
Amortization of other intangible assets	1,127	326
Amortization of goodwill	—	2,753
Amortization of debt issuance costs	317	513
Amortization of deferred compensation	175	274
Issuance of common stock for retirement plans	249	—
Stock-based compensation for services rendered	30	232
Purchased in-process research and development	—	62,660
Changes in assets and liabilities:		
Increase/(decrease) in accounts receivable, other current assets, and other assets	1,128	(2,169)
Decrease in accounts payable and other accrued liabilities	(2,885)	(73)

Increase in deferred revenue	2,775	1,299
Net cash used in operating activities	(19,029)	(12,853)
<b>Cash flows from investing activities:</b>		
Purchases of short-term investments	(94,714)	(209,294)
Sales of short-term investments	40,408	44,611
Maturities of short-term investments	57,995	140,158
Purchases of property and equipment	(4,720)	(10,119)
Acquisition of Bradford, net of cash acquired	—	(14,805)
Net cash used in investing activities	(1,031)	(49,449)
<b>Cash flows from financing activities:</b>		
Proceeds from loan and capital lease financing	—	3,699
Payments of loan and capital lease obligations	(279)	(186)
Issuance of preferred stock	40,000	—
Issuance of common stock, net of issuance costs	254	2,819
Net cash provided by financing activities	39,975	6,332
Net (decrease)/ increase in cash and cash equivalents	19,915	(55,970)
Cash and cash equivalents at beginning of period	30,814	136,012
Cash and cash equivalents at end of period	\$ 50,729	\$ 80,042

See accompanying notes.

**INHALE THERAPEUTIC SYSTEMS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**March 31, 2002**  
**(unaudited)**

**Note 1—Organization and Summary of Significant Accounting Policies**

**Organization and Basis of Presentation**

We are working to become the world's leading drug delivery company by providing a portfolio of technologies and expertise that will enable our pharmaceutical partners to improve drug performance throughout the drug development process. To fulfill these needs, we are developing several technologies. The first enables inhalation of delivery of a range of drugs, including peptides, proteins and small molecules for treatment of systemic and respiratory diseases. The second technology, advanced PEGylation, is designed to enhance the efficacy and performance of most major drug classes, including macromolecules such as peptides and proteins and smaller sized molecular compounds, and other drugs. A third technology uses a proprietary processing method known as supercritical fluids processing to develop drug formulations for multiple types of drug delivery.

In an effort to capitalize on what we believe is a growing market need for performance-enabling drug delivery technologies, we expanded our technology offerings by acquiring Shearwater Corporation ("Shearwater") and Bradford Particle Design Ltd. ("Bradford") in 2001. These acquisitions have added two additional technologies, advanced PEGylation and Solution Enhanced Dispersion by Supercritical Fluids ("SEDS™") to our portfolio.

We are also the parent company of 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 real estate partnership lessor.

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 and testing activities, scale up manufacturing operations and further expand our late stage clinical and early commercial production facility. 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 March 31, 2002, the condensed consolidated statements of operations for the three-month periods ended March 31, 2002 and 2001, and the consolidated statements of cash flows for the three-month periods ended March 31, 2002 and 2001 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 ("SEC"). 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 for the year ended December 31, 2001, as filed with the SEC.

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 2002 presentation.

### Principles of Consolidation

Our consolidated financial statements include the accounts of the parent company, Inhale Germany, Inhale UK, the financial statements of a real estate partnership created to finance and manage construction of our new lab and office facility, and the accounts of Bradford and Shearwater, acquired during the 2001 fiscal year.

### Significant Concentrations

Cash equivalents and investments are financial instruments that potentially subject us to concentration of risk to the extent of the amounts recorded in the consolidated balance sheet. We limit our concentration of risk by diversifying our investment amount among a variety of industries and issuers. Our professional portfolio managers adhere to this investment policy as approved by our Board of Directors.

We have not experienced significant credit losses from our accounts receivable or collaborative research agreements, and none are currently expected. We perform a regular review of our customer activity and associate credit risks and do not require collateral from our customers.

In addition, we are dependent on our partners, vendors and contract manufacturers to provide raw materials, drugs and devices of appropriate quality and reliability and to meet applicable regulatory requirements. Consequently, in the event that supplies are delayed or interrupted for any reason, our ability to develop our products could be impaired, which could have a material adverse effect on our business, financial condition and results of operation.

We are dependent on Pfizer and Aventis as the source of a significant proportion of our revenue. In the event that these collaborations are terminated, our ability to develop and supply our products could be impaired, which could have a material adverse effect on our business, financial condition and results of operation.

Should the Pfizer collaboration be discontinued prior to the launch of inhaleable insulin, we will need to find alternative funding sources to replace the collaborative revenue and will need to reassess the realizability of certain costs capitalized in connection with the commercial scale-up. Additionally, we may have contingent payments to our contract manufacturers to reimburse them for their capital outlay to the extent that they cannot re-deploy their assets.

### Cash, Cash Equivalents and Investments

We consider all highly liquid investments with a maturity from date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include demand deposits held in banks, interest bearing money market funds and repurchase agreements. All other investments are classified as short-term investments. Short-term investments consist of federal and municipal government securities, corporate bonds and commercial paper with A1 or P1 short-term ratings and A+ or better long-term ratings with remaining maturities at date of purchase of greater than 90 days and less than two years.

At March 31, 2002, all investments are designated as available-for-sale and are carried at fair value, with material unrealized gains and losses, if any, reported in stockholders' equity as accumulated other comprehensive gain/loss. The amortized cost of securities is adjusted for amortization of material premiums and accretion of discounts to maturity. Such amortization, if any, is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

### 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 of our Shearwater subsidiary. Inventory is stated at the lower of cost (first-in, first-out method) or market, and consist of the following (in thousands):

	March 31, 2002	December 31, 2001
Raw materials	\$ 2,231	\$ 1,805
Work-in process	1,042	513
Finished goods	404	883
	\$ 3,677	\$ 3,201

### Property and Equipment

Property and equipment are stated at cost. Major improvements are capitalized, while maintenance and repairs are expensed when incurred. Laboratory and other equipment are depreciated using the straight-line method over estimated useful lives of three to seven years. Vehicles are depreciated using the straight-line method over an estimated useful life of five years. Leasehold improvements and buildings, which are subject to the terms of a build-to-suit lease, are depreciated using the straight-line method over the shorter of the estimated useful life or the remaining term of the lease.

We have expensed certain plant design, engineering and validation costs based on our evaluation that it is unclear whether such costs are ultimately recoverable.

## Goodwill

On January 1, 2002, in accordance with a new accounting standard, we stopped amortizing goodwill and adopted a new policy for measuring goodwill for impairment. No impairment of goodwill was recognized in connection with the adoption of this new policy. We currently operate as a single reporting unit and all of our goodwill is associated with the entire company. Under our new policy, goodwill is tested for impairment at least annually, or on an interim basis if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the reporting unit below its carrying value. Goodwill is tested for impairment using a two-step approach. The first step is to compare the fair value of the reporting unit to its carrying amount, including goodwill. If the fair value of the reporting unit is greater than its carrying amount, goodwill is not considered impaired and the second step is not required. If the fair value of the reporting unit is less than its carrying amount, the second step of the impairment test measures the amount of the impairment loss, if any. The second step of the impairment test is to compare the implied fair value of goodwill to its carrying amount. If the carrying amount of goodwill exceeds its implied fair value, an impairment loss is recognized equal to that excess. The implied fair value of goodwill is calculated in the same manner that goodwill is calculated in a business combination, whereby the fair value of the reporting unit is allocated to all of the assets and liabilities of that unit (including any unrecognized intangible assets) as if the reporting unit had been acquired in a business combination and the fair value of the reporting unit was the purchase price. The excess "purchase price" over the amounts assigned to assets and liabilities would be the implied fair value of goodwill.

## Other Intangible Assets

Acquired technology and other intangible assets with definite useful lives are amortized on a straight-line basis over a period of five years. Intangible assets are tested for impairment whenever events or changes in circumstances indicate the carrying amount of the assets may not be recoverable from future undiscounted cash flows. If impaired, the assets are recorded at fair value. Other intangible assets includes proprietary technology, intellectual property, and supplier and customer relationships acquired from third parties or in business combinations.

## Comprehensive Gain/Loss

Comprehensive loss is comprised of net loss and other comprehensive gain/loss for the three-months ended March 31, 2002 and 2001. Other comprehensive gain included unrealized gains/losses on available-for-sale securities and translation adjustments (in thousands):

	March 31,	
	2002	2001
Net loss	\$ (25,056)	\$ (81,041)
Change in net unrealized gains/(losses) on available-for-sale securities	(1,568)	(5,108)
Translation adjustment	(148)	(103)
Comprehensive loss	\$ (26,772)	\$ (86,252)

## Stock-Based Compensation

As permitted by the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, *Accounting for Stock-Based Compensation*, we continue to follow Accounting Principles Board Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees* and related interpretations in accounting for our employee stock option plans. Under APB 25, if the exercise price of our employee stock options equals or exceeds the fair market value of the underlying stock on the date of grant as determined by the closing price of our common stock as quoted on the Nasdaq Stock Market, no compensation expense is recognized.

Stock compensation expense for options granted to non employees has been determined in accordance with SFAS 123 and Emerging Issues Task Force No. 96-18 as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non employees is remeasured as the underlying options vest.

## 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. Payments received from milestone achievements are deferred and recorded as revenue over the next period of continued development. 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 and consists of reimbursement of development costs, reimbursement of certain expenses, payment of clinical supplies and amortization of milestones.

Contract research revenue from one partner represented 60% and 74% of our revenue for the three-months ended March 31, 2002 and March 31, 2001, respectively. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

Product sales relate to sales of PEGylated derivatives. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured. Allowances, if any, are established for estimated product returns and discounts.

## Research and Development

Research and development costs are expensed as incurred and include salaries, benefits, and other operating costs. We perform research and development for others pursuant to feasibility agreements and development and license agreements. Under these feasibility agreements, we are generally reimbursed for the cost of work performed. Feasibility agreements are designed to evaluate the applicability of our technologies to a particular molecule and therefore are generally completed in less than one year. Under our development and license agreements, our partners generally receive an exclusive license to develop, use and sell a dry powder formulation and a suitable delivery device to be

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developed by us for one or more of our partner's macromolecule drugs. Under these development agreements, we will be reimbursed for development costs and may also be entitled to milestone payments when and if certain development milestones are achieved. All of our research and development agreements are generally cancelable by the partner without significant financial penalty.

## Net Loss Per Share

Basic and diluted net loss per common share is computed in accordance with SFAS No. 128, *Earnings Per Share*. Accordingly, the weighted average number of common shares outstanding are used while common stock issuable upon the conversion of debt and common stock equivalents for stock options and warrants are not included in the per share calculation as the effect of their inclusion would be antidilutive.

## Note 2—Goodwill and Other Intangible Assets

Goodwill and other intangible assets consist of the following (in thousands):

	March 31, 2002	December 31, 2001
Goodwill	\$ 156,694	\$ 153,834
Accumulated amortization	(22,838)	(22,246)
<b>Net goodwill</b>	<b>133,856</b>	<b>131,588</b>
Assembled workforce	—	2,860
Core technology	8,100	8,100
Developed product technology	2,900	2,900
Intellectual property	7,301	7,301
Supplier and customer relations	5,140	5,140
<b>Total other intangible assets</b>	<b>23,441</b>	<b>26,301</b>
Accumulated amortization of other intangible assets	(4,591)	(4,056)
<b>Net other intangible assets</b>	<b>18,850</b>	<b>22,245</b>
<b>Net goodwill and other intangibles</b>	<b>\$ 152,706</b>	<b>\$ 153,833</b>

Amortization expense related to intangible assets totaled \$1.1 million and \$0.3 million during the three months ended March 31, 2002 and 2001. The estimated aggregate future amortization expense for intangible assets remaining as of March 31, 2002 is as follows (in thousands):

Remainder of 2002	\$ 3,380
2003	4,507
2004	4,507
2005	4,507
2006	1,949
<b>Total</b>	<b>\$ 18,850</b>

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Given our current cash requirements, we believe that we will have sufficient cash to meet our operating expense requirements for the next 30 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 preclinical 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. Because we are an early stage biotechnology company, we do not qualify to issue investment grade debt or have access to certain credit facilities. As a result, any financing we undertake will likely involve the issuance of equity, convertible debt



instruments or high-yield debt to fund our working capital. To date we have been primarily dependent upon equity and convertible debt financings for capital and have incurred substantial debt as a result of our issuances of subordinated notes and debentures convertible into our common stock. Our substantial debt, the market price of our securities and the general economic climate, among other factors, could have material consequences for the Company's financial position and could affect our sources of short-term and long-term funding. There can be no assurance that additional funds, if and when required, will be available to us on favorable terms, if at all.

In accordance with a new accounting standard adopted on January 1, 2002, we stopped amortizing goodwill. The following pro forma information for the three months ended March 31, 2001 presents net loss and loss per common share adjusted to exclude goodwill amortization expense of \$2.8 million recognized during the period (in thousands):

	<u>March 31, 2001</u>
Net loss:	
As reported	\$ (81,041)
Pro forma	(78,288)
Basic and diluted, net loss per common share:	
As reported	\$ (1.59)
Pro forma	(1.53)

### Note 3—Business Acquisitions

Bradford Particle Design and Shearwater's results of operations included in the following pro forma financial information are derived from their unaudited financial statements for the years ended December 31, 2001 and 2000, respectively. Bradford Particle Design'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.

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The unaudited pro forma results of our 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 transactions 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 quarter ended March 31, 2001 assumes the acquisition of Bradford Particle Design and Shearwater has been accounted for using the purchase method of accounting as of January 1, 2001 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. Pro forma results of operation include the adoption of SFAS 142 as of January 1, 2001 (unaudited, in thousands, except per share information).

	<u>Pro Forma Three Months Ended March 31,</u>	
	<u>2002</u>	<u>2001</u>
Total revenues	\$ 26,746	\$ 16,384
Net loss	\$ (25,056)	\$ (23,762)
Net loss per share	\$ (0.45)	\$ (0.49)

### Note 4—Contingencies

In August 2000, we entered into supply agreements with two contract manufacturers to provide for the manufacturing of our inhalation device. Under the terms of the agreements, we may be obligated to reimburse both parties for the actual unamortized and unrecovered portion of any equipment procured or facilities established and the interest accrued for their capital overlay in the event that inhaleable insulin does not gain FDA approval to the extent that the contract manufacturers cannot re-deploy the assets. At the present time, it is not possible to estimate the loss that will occur should inhaleable insulin not be approved.

### Note 5—Preferred Stock

The Company has authorized 10,000,000 shares of Preferred Stock, each share having a par value of \$0.0001. Three million one hundred thousand (3,100,000) shares of Preferred Stock are designated Series A Junior Participating Preferred Stock (the "Series A Preferred Stock") and forty thousand (40,000) shares of Preferred Stock are designated as Series B Convertible Preferred Stock (the "Series B Preferred Stock").

#### Series A Preferred Stock

On June 1, 2001 the Board of Directors of the Company approved the adoption of a Share Purchase Rights Plan (the "Plan"). Terms of the Plan provide for a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of the Company's Common Stock (the "Common Shares"). The Rights have certain anti-takeover effects and will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by the Company's Board of Directors. The dividend distribution was payable on June 22, 2001 (the "Record

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Date") to the stockholders of record on that date. Each Right entitles the registered holder to purchase from the Company one one-hundredth of a share of Series A Preferred Stock at a price of \$225.00 per one one-hundredth of a share of Series A Preferred Stock (the "Purchase Price"), subject to adjustment. Each one one-hundredth of a share of Series A Preferred Stock has designations and powers, preferences and rights, and the qualifications, limitations and restrictions which make its value approximately equal to the value of a Common Share.



The Rights are not exercisable until the Distribution Date (as defined in the Certificate of Designation for the Series A Preferred Stock). The Rights will expire on June 1, 2011, unless the Rights are earlier redeemed or exchanged by the Company. Each share of Series A Preferred Stock will be entitled to a minimum preferential quarterly dividend payment of \$1.00 but will be entitled to an aggregate dividend of 100 times the dividend declared per Common Share. In the event of liquidation, the holders of the Series A Preferred Stock would be entitled to a minimum preferential liquidation payment of \$100 per share, but would be entitled to receive an aggregate payment equal to 100 times the payment made per Common Share. Each share of Series A Preferred Stock will have 100 votes, voting together with the Common Shares. Finally, in the event of any merger, consolidation or other transaction in which Common Shares are exchanged, each share of Series A Preferred Stock will be entitled to receive 100 times the amount of consideration received per Common Share. Because of the nature of the Series A Preferred Stock dividend and liquidation rights, the value of one one-hundredth of a share of Series A Preferred Stock should approximate the value of one Common Share. The Series A Preferred Stock ranks junior to the Series B Preferred Stock and would rank junior to any other series of the Company's preferred stock. Until a Right is exercised, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

### Series B Convertible Preferred Stock

In connection with a strategic alliance with Enzon, Inc., we entered into a Preferred Stock Purchase Agreement pursuant to which we sold to Enzon and Enzon purchased from us forty thousand (40,000) shares of non-voting Series B Preferred Stock at a purchase price of one thousand dollars (\$1,000) per share for an aggregate purchase price of forty million dollars (\$40,000,000). A Certificate of Designation filed with the Secretary of State of Delaware sets forth the rights, privileges and preferences of the Series B Preferred Stock. Pursuant to the Certificate of Designation, the Series B Preferred Stock does not have voting rights. The Series B Preferred Stock is convertible, in whole or in part, into that number of shares of the Company's Common Stock (the "Conversion Shares") equal to the quotient of \$1,000 per share divided by the Conversion Price. The "Conversion Price" shall initially be equal to \$22.79 per share or 125% of the Closing Price and at no time can the Preferred Stock convert into shares of Common Stock at a discount to the Closing Price. The "Closing Price" equals \$18.23 per share and was based upon the average of the Company's closing bid prices as listed on the Nasdaq National Market for the twenty (20) trading days preceding the date of the closing of the transaction.

The Series B Preferred Stock is convertible at the option of the holder after the first anniversary of the original issuance of the Series B Preferred Stock (the "Original Issue Date") or, if earlier, upon a Change in Control (as defined in the Certificate of Designation). Except with respect to an automatic conversion as described below, the Conversion Price shall be equal to 125% of the Closing Price until

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the third anniversary of the Original Issue Date. Upon the third anniversary of the Original Issue Date, the Conversion Price shall be adjusted to be equal to either (i) the Closing Price, in the event that the average of the closing bid prices of Inhale's Common Stock as quoted on the Nasdaq National Market for the twenty (20) trading days preceding the third anniversary of the original issuance (the "Future Price") is less than or equal to the Closing Price; (ii) the Future Price (as defined above) if the Future Price is greater than the Closing Price but less than 125% of the Closing Price; or (iii) 125% of the Closing Price if the Future Price is equal to or greater than 125% of the Closing Price.

To the extent not previously converted, the Series B Preferred Stock will automatically convert into shares of Inhale Common Stock, based on the then effective Conversion Price, upon the earliest of (i) the fourth anniversary of the Original Issue Date; (ii) immediately prior to an Asset Transfer or Acquisition (as defined in the Certificate of Designation); or (iii) with the consent of the holders of a majority of the then outstanding Series B Preferred Stock immediately prior to a liquidation, dissolution or winding up of Inhale. In the event of an automatic conversion pursuant to an asset transfer, acquisition or liquidation, the adjustment mechanism described above will be applied immediately prior to the automatic conversion.

In the event of our Company's liquidation, dissolution or winding down, either voluntary or involuntary, following the payment of any distributions due the holders of any class of capital stock or series of preferred stock that ranks senior to the Series B Preferred Stock, the holders of the Series B Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of our assets or surplus funds to the holders of our Common Stock or any class of capital stock or series of preferred stock that does not rank senior to or on parity with the Series B Preferred Stock, an amount per share (as adjusted for any combinations, consolidations, stock distributions or stock dividends with respect to the Series B Preferred Stock) equal to up to \$1,000.

### Note 6—Supplemental Cash Flow Data (in thousands):

	Three months ended March 31,	
	2002	2001
<b>Supplemental disclosure of cash flows information:</b>		
Interest paid	\$ 1,535	\$ 1,535
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Issuance of common stock in connection with acquisitions	\$ —	\$ 5,576
<b>Non-cash disclosure related to acquisition of Bradford Particle Design:</b>		
Tangible assets acquired, net of cash	\$ —	\$ 2,100
Purchased in-process research and development	—	62,660
Goodwill and other intangible assets acquired	—	80,108
Acquisition costs incurred	—	(4,000)
Liabilities assumed	—	(487)
Common stock and options issued	—	(125,576)
Cash paid for acquisition of Bradford Particle Design (net of cash received)	\$ —	\$ 14,805

## **Note 7—Agreement with Alliance Pharmaceutical**

In March 2002, we announced the expansion of our agreement with Alliance Pharmaceutical Corp. regarding the PulmoSphere® particle and particle technology, aspects of which we initially acquired from Alliance in November 1999. The PulmoSphere® technology is a particle formation method designed to enhance the performance of drugs delivered via the lung in propellant-based metered-dose inhalers and dry powder inhalers. As a result of the supplemental agreement we have paid to Alliance \$5.25 million in exchange for rights beyond inhaleable applications and other considerations, which was recorded as an expense in the three months ended March 31, 2002. Under the terms of the supplemental agreement, we have the right to use the PulmoSphere® technology for alternative methods of delivery in addition to inhaleable applications. Further, Alliance assigned five new patent applications covering methods of producing microparticles to us. Alliance retains the rights to use the technology on products to be instilled directly into the lung, and obtains the rights to commercialize up to four products administered with inhalers, two of which will be royalty-free. We will pay Alliance future milestone or royalty payments on a reduced number of products developed by us or our licenses utilizing the technology. In addition we have the right to purchase chemicals used in the production process for drugs using the PulmoSphere® technology.

## **Note 8—Cross Platform Strategic Alliance**

In January 2002, we announced a strategic alliance with Enzon that includes an agreement making Inhale solely responsible for licensing Enzon's PEG patents, an option for Enzon to license Inhale's PEGylation patents, an agreement to explore the development of non-invasive delivery of single-chain antibody products via the pulmonary route and settlement of a patent infringement litigation originally filed by Enzon against Shearwater. As part of this broad alliance, we entered into a collaboration to develop three products using our Inhance™ inhaleables technology and/or SEDS™ technology. Under the terms of this collaboration, we will be responsible for the development of drug formulations for the agreed upon pharmaceutical agents as well as clinical and commercial manufacturing of the drug formulation and device combination. Enzon will be responsible for the clinical development and worldwide commercialization of the system. Inhale will receive research and development funding, milestone payments as the program progresses through further clinical testing, and royalty payments once the product is commercialized. As part of this alliance, Enzon made a \$40.0 million investment in our preferred stock.

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## **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Overview**

We are working to become the world's leading drug delivery company by providing a portfolio of technologies and expertise that will enable our pharmaceutical partners to improve drug performance throughout the drug development process. We have been unprofitable since inception and expect to incur substantial operating losses over at least the next few years as we expand testing activities and manufacturing operations, and as we further expand our late stage clinical and early commercial production facility. Nonetheless, we do anticipate a decrease in un-funded research spending in the next three to five years, due to the combination of scale-up completion and infrastructure-shifting for inhaled insulin, and the anticipated partnering of Inhale-funded projects. To date, except for sales from three 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 March 31, 2002, we incurred a cumulative net loss of approximately \$466.9 million. The sources of our working capital have been equity offerings and convertible 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. To date we have been primarily dependent upon equity and convertible debt financings to fund our working capital.

We have generally been compensated for research and development expenses during initial feasibility work performed under collaborative arrangements. In a typical collaboration, our partner will provide the drug, fund clinical and formulation development and market the resulting commercial product. We will supply the drug delivery approach or drug formulation and receive revenues from drug compound manufacturing and other manufacturing activities, as well as royalties from sales of most commercial products. In addition, for products using our Inhance™ inhaleables technology, we expect to receive revenues from the supply of our device for the product along with any applicable drug processing. Partners that enter into collaborative agreements generally fund research and development through expense reimbursements and/or payments as we achieve certain key development and regulatory milestones. 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 other drug delivery systems. There can be no assurance that we can generate sufficient product or contract research revenue to become profitable or to sustain profitability.

### **Recent Developments**

In March 2002, we announced the expansion of our agreement with Alliance Pharmaceutical Corp. regarding the PulmoSphere® particle and particle technology, aspects of which we initially acquired from Alliance in November 1999. The PulmoSphere® technology is a particle formation method designed to enhance the performance of drugs delivered via the lung in propellant-based metered-dose inhalers and dry powder inhalers. As a result of the supplemental agreement we have paid to Alliance \$5.25 million in exchange for rights beyond inhaleable applications and other considerations. Under the terms of the supplemental agreement, we have the right to use the PulmoSphere® technology for alternative methods of delivery in addition to inhaleable applications. Further, Alliance assigned five new patent applications covering methods of producing microparticles to us. Alliance retains the rights to use the technology on products to be instilled directly into the lung, and obtains the rights to commercialize up to four products administered with inhalers, two of which will be royalty-free. We will pay Alliance future milestone or royalty payments on a reduced number of products developed by us or our licenses utilizing the technology. In addition we have the right to purchase chemicals used in the production process for drugs using the PulmoSphere® technology.

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In January 2002, we announced a strategic alliance with Enzon that includes an agreement making Inhale solely responsible for licensing Enzon's PEG patents, an option for Enzon to license Inhale's PEGylation patents, an agreement to explore the development of non-invasive delivery of single-chain antibody products via the pulmonary route and settlement of a patent infringement litigation originally filed by Enzon against Shearwater. As part of this broad alliance, we entered into a collaboration to develop three products using our Inhance™ inhaleables technology and/or SEDS™ technology. Under the terms of this collaboration, we will be responsible for the development of drug formulations for the agreed upon pharmaceutical agents as well as clinical and commercial manufacturing of the drug formulation and device combination. Enzon will be responsible for the clinical development and worldwide commercialization of the

system. Inhale will receive research and development funding, milestone payments as the program progresses through further clinical testing, and royalty payments once the product is commercialized. As part of this alliance, Enzon made a \$40.0 million investment in our preferred stock.

In January 2002, Biogen announced that it does not plan to further develop inhaleable Avonex® for multiple sclerosis at this time, but is working with us to evaluate other potential indications for the inhaled formulation or other opportunities for collaboration.

In January 2002, we filed a Schedule TO with the SEC announcing our offer to certain Inhale employees to exchange certain options to purchase shares of our common stock granted prior to July 24, 2001 with exercise prices greater than or equal to \$25.00 per share currently outstanding under Inhale's 2000 Non-Officer Equity Incentive Plan, as amended (the "Eligible Options"), for replacement options (the "Replacement Options") to purchase shares of common stock to be granted under our 2000 Non-Officer Plan Equity Incentive Plan. We conducted the exchange with respect to the Eligible Options on a one-for-two (1:2) basis. If an employee accepted this offer with respect to any Eligible Option, such employee also was obligated to exchange all options to acquire Inhale common stock granted to such employee on or after July 24, 2001 (the "Mandatory Exchange Options"). We conducted the exchange with respect to Mandatory Exchange Options on a one-for-one (1:1) basis. On March 18, 2002, we filed an Amendment No. 2 to Schedule TO announcing that 90 employees participated in the exchange offer, exchanging 1,217,500 Eligible Options and 78,170 Mandatory Exchange Options to purchase shares of our common stock. We intend to issue Replacement Options to purchase 686,920 shares of Common Stock on August 26, 2002 at an exercise price equal to the closing price of our common stock as reported on the Nasdaq National Market on the last market trading day prior to the date of grant.

### **Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements which have been prepared in conformity with accounting principles generally accepted in the United States. It 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.

We consider certain accounting policies related to revenue recognition, business combinations and accrued liabilities to be critical to our business operations and the understanding of our results of operations:

#### ***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 and consists of reimbursement of development costs, reimbursement of certain expenses, payment of clinical supplies and amortization of milestones. Payments received for milestones achieved are deferred and recorded as revenue over the next period of continued development.

Revenue from product sales is recorded when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collectability is reasonable assured. Allowances, if any, are established for estimated product returns and discounts. Because we have only recently begun selling a limited number of products through the acquisition of our subsidiaries, we do not have substantial experience in establishing allowances for returns and discounts.

#### ***Business Combinations***

##### ***Purchased In-Process Research and Development ("IPR&D")***

IPR&D expense is determined based on an analysis using risk-adjusted cash flows expected to be generated by products that may result from in-process technologies purchased in connection with acquisitions or business combinations. This analysis includes forecasting future cash flows that are expected to result from the progress made on each in-process project prior to the purchase dates. Cash flows are 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 adjusting these revenues to reflect the probability of advancing to the next stage of the FDA approval process. The forecast data in the analysis is 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 is based on assumptions, which management believes 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. Appropriate operating expenses are deducted from forecasted net revenues or on a product-by-product basis to establish a forecast of net returns on the completed portion of the in-process technology. Finally, net returns are 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 include the products phase of development, type of molecule under development, likelihood of regulatory approval, manufacturing process capability, scientific rationale, preclinical safety and efficacy data, target product profile, and development plan. In addition to the product specific risk factors, a discount rate is used for the purchase valuation, which represents a considerable risk premium to our weighted average cost of capital. The valuations used to estimate IPR&D require us to use significant estimates and assumptions that if changed, may result in a different valuation for IPR&D. Valuations for our acquisitions were completed by independent third-party consulting firms in accordance with SEC guidelines and reviewed with our external audit firm.

##### ***Impairment of Goodwill and Other Intangible Assets***

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 was effective for any business combinations initiated after June 30, 2001 and also include the criteria for the recognition of intangible assets separately from goodwill. SFAS 142 was effective for fiscal years beginning after December 15, 2001 and requires 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 intangible assets acquired in transactions completed before July 1, 2001 will be reassessed and the remaining amortization periods adjusted accordingly. Effective January 1, 2002, consistent with the new business combination accounting rules, assembled workforce was reclassified as goodwill and is subject to an impairment assessment. We periodically evaluate whether changes have occurred that would require revision of the remaining estimated useful life of these assets or otherwise render the assets unrecoverable. If such an event occurred, we would determine whether the goodwill or other intangible assets are impaired. To date, no such impairment losses have been recorded. Other intangible assets have been amortized on a straight line basis for the quarter ended March 31, 2002.

In accordance with a new accounting standard adopted on January 1, 2002, the total for the three-months ended March 31, 2002 does not include amortization of goodwill and is comprised solely of amortization of intangible assets. The total for the three-months ended March 31, 2001 includes \$0.3 million of amortization expense of other intangible assets and \$2.8 million of amortization of goodwill. Had amortization of goodwill been continued beyond January 1, 2002, we would have recognized an additional \$7.9 million in amortization expense during the three months ended March 31, 2002.

### ***Accrued Liabilities***

Certain accrued liabilities reflect management's best estimates based on our specific historical experience and understanding of industry practice. We record a reserve for these matters when an adverse outcome is probable and the amount of the potential liability is reasonably estimable.

### **Results of Operations**

#### *Period ending March 31, 2002 and 2001*

Revenue was \$26.7 million for the three-months ended March 31, 2002 compared to \$14.1 million for the three-months ended March 31, 2001. Revenue increased 90% in 2002 from 2001 levels due to expansion of our existing collaborative agreement with Pfizer and revenues from our newly acquired subsidiaries in 2001. Pfizer represented approximately 60% of our revenues for the quarter ended March 31, 2002. Product sales through our Shearwater subsidiary accounted for 20% of revenues in the first quarter of 2002. Contract research revenue for the period ended March 31, 2002 and 2001 also included reimbursed research and development expenses as well as the amortization of deferred up-front signing and progress payments received from our collaborative partners. Contract revenues are expected to fluctuate from year to year, and future contract revenues cannot be predicted accurately. The level of contract revenues depends in part upon future success in obtaining new collaborative agreements, timely completion of feasibility studies, the continuation of existing collaborations and achievement of milestones under current and future agreements. Product sales are dependent upon regulatory approval of new products for sale and adoption of current products in the market and cannot be accurately predicted.

Cost of goods sold is associated with product sales and was \$1.9 million for the three-months ended March 31, 2002 based on product sales of \$5.4 million from our Shearwater subsidiary during the quarter.

Research and development expenses were \$41.9 million for the three-months ended March 31, 2002, as compared to \$30.3 million for the three-months ended March 31, 2001. The 39% increase in 2002 as compared to 2001 was primarily attributed 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 preparation for commercial production, as well as the

addition of Shearwater to our operations in the second quarter of 2001. In addition, we made a one-time payment of \$5.3 million to Alliance for the rights beyond inhaleable applications for PulmoSphere® technology and other considerations. We expect un-funded research, development and process development spending to decrease in the next three to four years due to the combination of scale-up completion and infrastructure-shifting for inhaled insulin, and the anticipated partnering of Inhale-funded projects.

General and administrative expenses were \$5.4 million for the three-months ended March 31, 2002 as compared to \$4.0 million for the three-months ended March 31, 2001. The 34% increase in general and administrative expenses was due primarily to increased support associated with our manufacturing and development efforts, including administrative staffing, business development and marketing, as well the addition of Shearwater to our operations during the second quarter of 2001.

Amortization of other intangible assets expenses were \$1.1 million for the three-months ended March 31, 2002 as compared to \$0.3 million for the three-months ended March 31, 2001. The increase in 2002 as compared to 2001 was associated with the amortization of intangibles assets in connection with our acquisition of Shearwater in the second half of 2001.

There were no amortization of goodwill expenses for the three-months ended March 31, 2002 as compared to \$2.8 million for the three-months ended March 31, 2001. The decrease was associated with the adoption of new accounting standard with respect to business combinations. Goodwill and certain other intangible assets are no longer amortized and are subject to an impairment test at least annually. The useful lives of recognized intangible assets acquired in transactions will regularly be reassessed and the remaining amortization periods adjusted accordingly. We performed the required impairment tests of goodwill and other intangible assets as of January 1, 2002 and none of the assets were determined to be impaired. Consequently, no impairment charges were recorded for the three-months ended March 31, 2002.

Other income/(expense) was unchanged at \$0.1 million of expense for the three-months ended March 31, 2002 and 2001.

Interest income was \$2.8 million for the three-months ended March 31, 2002 as compared to \$7.7 million for the three-months ended March 31, 2001. The 64% decrease in interest income in 2002 from 2001 was primarily due to our lower cash and investment balances and lower interest rates in the first quarter of 2002 as compared to the same period in 2001. Interest expense was \$4.2 million for the three months ended March 31, 2002, as compared to \$2.8 million for the three-months ended March 31, 2001. The 53% increase in interest expense primarily relates to the interest expense associated with our build-to-suit lease.

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

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 quarter ended March 31, 2001, we incurred a charge of \$62.7 million for IPR&D for the Bradford Particle Design acquisition. During the quarter ended March 31, 2002 we did not incur any IPR&D charges.

In January 2001, we acquired all of the outstanding share capital of Bradford Particle Design 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 \$80.1 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.

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## Liquidity and Capital Resources

We have financed our operations primarily through public and private placements of our debt and equity securities, revenues from development contracts and short-term research and feasibility agreements, financing of equipment acquisitions and tenant improvements, and interest income earned on our investments of cash. We do not utilize off-balance sheet financing arrangements as a source of liquidity or financing. At March 31, 2002, we had cash, cash equivalents and short-term investments of approximately \$358.5 million.

Our operations used cash of \$19.0 million in the three-months ended March 31, 2002 as compared to \$12.8 million for the corresponding period in 2001. These amounts differed from our net operating losses in these periods due to several factors. Depreciation expense increased to \$3.1 million for the three-months ended March 31, 2002 from \$2.4 million for the three-months ended March 31, 2001, due to the inclusion of Shearwater and the build-to-suit lease with our real estate partnership lessor. In addition, the increase in accounts receivable, other current assets, and other assets is largely due to the addition of Shearwater's inventory of \$3.7 million for the three-months ended March 31, 2002. Amortization of other intangible assets increased for the three-months ended March 31, 2002 as compared to the three-months ended March 31, 2001, due to the amortization of intangible assets acquired in connection with the acquisition of Shearwater. We did not incur any amortization expense of goodwill for the three-months ended March 31, 2002 due to the adoption of SFAS 142; however, we had amortization of goodwill expense of \$2.8 million in the three-months ended March 31, 2001. We did not incur any purchased in-process research and development for the three-months period ended March 31, 2002; however we did incur charges of \$62.7 million for the three-months ended March 31, 2001 associated with our acquisition of Bradford Particle Design.

Cash flows used in investing activities were \$1.0 million for the three-months ended March 31, 2002 as compared to \$49.4 million for the three-months ended March 31, 2001. We purchased property and equipment of approximately \$4.7 million and \$10.1 million during the quarters ended March 31, 2002 and 2001, respectively. The decrease in purchased property and equipment in 2002 as compared to 2001, reflects completion of the second 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 Particle Design, we paid net cash of \$14.8 million for the three-months ended March 31, 2001, which represents cash paid to Bradford Particle Design shareholders of \$20.4 million, net of Bradford Particle Design's cash balance of \$5.6 million. The remainder of the Bradford Particle Design acquisition was non-cash in nature.

Cash flows from financing activities were \$40.0 million for the three-months ended March 31, 2002 as compared to \$6.3 million for the three-months ended March 31, 2001. The increase in 2002 was related to our strategic alliance with Enzon entailing a \$40.0 million investment in our preferred stock (see Note 8—Cross Platform Strategic Alliance).

Research and development expenses should continue at current levels or higher through the next couple of years and are associated with three general categories: (i) collaborative agreements under which spending is reimbursed by our partners; (ii) spending attributed to internally funded programs, and (iii) scale-up and infrastructure costs associated with commercial operations for our drug and third-party device manufacturing. We expect our cash requirements to continue at a comparable rate due to expected activities in these areas. Research and development costs will be dependent upon the number of collaborative agreements we are engaged in, the number of Inhale funded projects and the timing of our transition to commercial manufacturing of our San Carlos operations. In addition, we expect expenses associated with personnel and personnel related costs, purchases of capital equipment, investments in technologies, inhalation device prototype construction and facilities to increase or decrease depending upon the needs and progress of our business.

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## RISK FACTORS

*The following risk factors should be read carefully in connection with evaluating our business. Any of the following risks could materially and adversely affect our business, operating results or financial condition.*

### **If our drug delivery 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 technologies will not be commercially feasible. Even if our drug delivery 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 30 drugs. While we have incorporated our PEGylation technology in three products that the FDA approved for use and in two 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 SEDS<sup>(TM)</sup> 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 preclinical 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 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 drug delivery 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 inhaleables or SEDS<sup>(TM)</sup> technologies or obtain regulatory approval of such products.

**If our drug delivery 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 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 an 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 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 inhalables 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.

Compound stability, 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 drug delivery 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;

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- 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<sup>(TM)</sup>, 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. In January 2002, Biogen, our collaborative partner with respect to a Phase I program for an inhaleable product for the treatment of multiple sclerosis, announced that it does not plan to further develop inhaleable Avonex<sup>®</sup> for multiple sclerosis at this time. If the collaborative programs with Lilly or Biogen are 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 United States. 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 current 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, it had decided to include an increased level of controlled, long-term safety data in its proposed NDA with respect to inhaled insulin and that it expected to complete this additional study in 2002. Any 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 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.**

#### *Advanced PEGylation and SEDS<sup>TM</sup> 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. At this time, our existing facilities are large enough for most commercial scale manufacturing to meet current demand. In the future, we may have to expand our facilities if we are not 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. 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.

#### *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 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. Our device is still in clinical testing and production scale-up work is underway. Further design and development work is underway to enable commercial manufacturing and additional work may be required to optimize the device for regulatory approval, field reliability or other issues that may be important to its commercial success. Additional design and development work may lead to a delay in regulatory approval, efforts to seek regulatory approval for any product that incorporates the device or the time the device could be ready for commercial launch. 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 manufacturers 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.

**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 Pharma to manufacture biosynthetic recombinant insulin. Under the terms of their agreement, Pfizer and Aventis Pharma agreed to construct a jointly owned manufacturing plant in Frankfurt, Germany. Until its completion, Pfizer will provide us with insulin from Aventis Pharma's existing plant.

We have also entered into an exclusive agreement with one supplier for a significant portion of the PEG polymer chains we use in our products that incorporate PEGylation technology. NOF Corporation is our predominate supplier of 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 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 new drug delivery technologies 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 technologies similar to the SEDS<sup>(TM)</sup> 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 inhalables 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. Our competitors with regard to advanced PEGylation technology include Valentis, Inc., Mountain View Pharmaceuticals, Inc. and SunBio PEG-SHOP, as well as several pharmaceutical and biotechnology companies with in-house PEGylation expertise. Some of our competitors with regard to SEDS<sup>(TM)</sup> technology include Alkermes, Battelle Memorial Institute, Ethypharm SA, Ferro Corp., Lavipharm SA, Phasex Corporation and RxKinetics. 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 advanced PEGylation and SEDS<sup>(TM)</sup> supercritical fluids technologies, and we plan to file additional patent applications. We currently have 284 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.

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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 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.

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. We cannot predict with certainty the eventual outcome of any pending litigation or potential future 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 a substantial portion 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.**

Over the past year, the western United States (and California in particular) has experienced episodes of diminished electrical power supply, and it is possible that this situation could 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 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.

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**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 us 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 acquisitions 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

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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 March 31, 2002 we have an accumulated deficit of approximately \$466.9 million. We expect to continue to incur substantial and potentially increasing 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. Many of our potential products are in the early stages of development except for our three approved products using our PEGylation technology. Except for our approved advanced 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 technologies. There is 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 30 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. In addition, as an early stage biotechnology company, we do not qualify to issue investment grade debt and therefore any financing we do undertake will likely involve

the issuance of equity, convertible debt instruments or high-yield debt. These sources of capital may not be available to us in the event additional financing is required. 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 April 30, 2002, based on closing prices on the Nasdaq National Market, our stock price ranged from \$7.87 to \$35.47. 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 us 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 March 31, 2002, we had approximately \$335.2 million in long-term obligations. Our substantial indebtedness has and will continue to impact us by:

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

Currently, we are not generating sufficient cash flow to satisfy the annual debt service payments on our outstanding subordinated convertible debentures and subordinated convertible notes. This may require us to use a portion of the proceeds from the sales of these securities to pay interest or borrow additional funds or sell additional equity to meet our debt service obligations. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result, which would negatively impact our future prospects. As of March 31, 2002 we had cash, cash equivalents and short-term investments valued at approximately \$358.5 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 report includes forward-looking statements and if these statements are incorrect or inaccurate, our actual results may differ.**

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

There have been no material changes in the reported market risks since December 31, 2001.

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## PART II: OTHER INFORMATION

### Item 1. Legal Proceedings

On January 8, 2002, we announced that we had formed a broad strategic alliance with Enzon, Inc. that included entering into a settlement agreement with Enzon whereby the two companies agreed to settle the patent infringement suit related to Enzon's branded PEG technology filed in 1998 by Enzon against Shearwater. Under the terms of this agreement, Enzon received a \$3 million payment from Inhale to cover expenses incurred in connection with defending the branched PEG patents and Inhale will receive licensing access to the patents under a cross-license agreement.

### Item 2. Changes in Securities and Use of Proceeds

#### *Sale of Series B Preferred Stock to Enzon*

In connection with the formation of the strategic alliance referenced above, Inhale and Enzon also entered into a Preferred Stock Purchase Agreement (the "Purchase Agreement") effective January 7, 2002, pursuant to which Inhale sold to Enzon and Enzon purchased from Inhale forty thousand (40,000) shares of non-voting Series B Convertible Preferred Stock (the "Preferred Stock") at a purchase price of one thousand dollars (\$1,000) per share of Preferred Stock for an aggregate purchase price of forty million dollars (\$40,000,000). The Preferred Stock was issued in a private placement exempt from the registration requirements of the Securities Act of 1933 (the "Act") pursuant to an exemption under Section 4(2) of the Act.

Pursuant to the Certificate of Designation filed with the Secretary of State of Delaware on January 7, 2002, the Preferred Stock does not have voting rights and the consent of the holders of the Preferred Stock is not required (except to the extent required by law or otherwise expressly stated in the Certificate of Designation) for taking any corporate action. The Preferred Stock is convertible, in whole or in part, into that number of shares of common stock (the "Conversion Shares") equal to the quotient of \$1,000 per share divided by the Conversion Price. The "Conversion Price" shall initially be equal to \$22.79 per share or 125% of the Closing Price and at no time can the Preferred Stock convert into shares of Common Stock at a discount to the Closing Price. The "Closing Price" equals \$18.23 per share and was based upon the average of the Company's closing bid prices as listed on the Nasdaq National Market for the twenty (20) trading days preceding the date of the closing of the transaction.

The Preferred Stock is convertible at the option of the holder after the first anniversary of the original issuance of the Preferred Stock (the "Original Issue Date") or, if earlier, upon a Change in Control (as defined in the Certificate of Designation). Except with respect to an automatic conversion as described below, the Conversion Price shall be equal to 125% of the Closing Price until the third anniversary of the Original Issue Date. Upon the third anniversary of the Original Issue Date, the Conversion Price shall be adjusted to be equal to either (i) the Closing Price, in the event that the average of the closing bid prices of Inhale's Common Stock as quoted on the Nasdaq National Market for the twenty (20) trading days preceding the third anniversary of the original issuance (the "Future Price") is less than or equal to the Closing Price; (ii) the Future Price (as defined above) if the Future Price is greater than the Closing Price but less than 125% of the Closing Price; or (iii) 125% of the Closing Price if the Future Price is equal to or greater than 125% of the Closing Price.

To the extent not previously converted, the Preferred Stock will automatically convert into shares of our Common Stock, based on the then effective Conversion Price, upon the earliest of (i) the fourth anniversary of the Original Issue Date; (ii) immediately prior to an Asset Transfer or Acquisition (as defined in the Certificate of Designation); or (iii) with the consent of the holders of a majority of the then outstanding Series B Preferred Stock immediately prior to a liquidation, dissolution or winding up of Inhale. In the event of an automatic conversion pursuant to an Asset Transfer, Acquisition or liquidation, the adjustment mechanism described above will be applied immediately prior to the

automatic conversion. Pursuant to the terms of the Purchase Agreement, we have agreed to register the shares of common stock issuable upon conversion of the Preferred Stock for resale under certain circumstances.

#### *Stock Option Exchange Program*

On January 25, 2002, we filed a Schedule TO with the SEC announcing our offer to certain Inhale employees to exchange certain options to purchase shares of our common stock granted prior to July 24, 2001 with exercise prices greater than or equal to \$25.00 per share currently outstanding under Inhale's 2000 Non-Officer Equity Incentive Plan, as amended (the "Eligible Options"), for replacement options (the "Replacement Options") to purchase shares of common stock to be granted under our 2000 Non-Officer Plan Equity Incentive Plan. We conducted the exchange with respect to the Eligible Options on a one-for-two (1:2) basis. If an employee accepted this offer with respect to any Eligible Option, such employee also was obligated to exchange all options to acquire Inhale common stock granted to such employee on or after July 24, 2001 (the "Mandatory Exchange Options"). We conducted the exchange with respect to Mandatory Exchange Options on a one-for-one (1:1) basis. On March 18, 2002, we filed an Amendment No. 2 to Schedule TO announcing that 90 employees participated in the exchange offer, exchanging 1,217,500 Eligible Options and 78,170 Mandatory Exchange Options to purchase shares of our common stock. We intend to issue Replacement Options to purchase 686,920 shares of common stock on August 26, 2002 at an exercise price equal to the closing price of our common stock as reported on the Nasdaq National Market on the last market trading day prior to the date of grant.

#### **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 here with 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(15)	Recommended Offer, dated December 21, 2000, by Cazenove & Co. on behalf of Inhale Therapeutic Systems, Inc. for Bradford Particle Design plc.
2.3(20)	Agreement and Plan of Merger and Reorganization, dated May 22, 2001, by and among Inhale Therapeutic Systems, Inc., Shearwater Corporation, Square Acquisition Corp., J. Milton Harris and Puffinus, L.P.
2.4(20)	Amendment to Agreement and Plan of Merger and Reorganization, dated June 21, 2001, by and among Inhale Therapeutic Systems, Inc., Shearwater Corporation, Square Acquisition Corp., J. Milton Harris and Puffinus, L.P.
3.1(1)	Certificate of Incorporation of Inhale Therapeutic Systems, Inc.
3.2(1)	Bylaws of Inhale Therapeutic Systems, Inc.
3.3(13)	Certificate of Amendment of the Amended Certificate of Incorporation of Inhale Therapeutic Systems, Inc.
3.4(19)	Certificate of Designation of Series A Junior Participating Preferred Stock of Inhale Therapeutic Systems, Inc.

3.5(24)	Certificate of Designation of Series B Convertible Preferred Stock of Inhale Therapeutic Systems, Inc.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5.
4.2(2)	Restated Investor Rights Agreement, dated April 29, 1993, as amended October 29, 1993, by and among Inhale Therapeutic Systems, Inc. and certain other persons named therein.
4.3(3)	Stock Purchase Agreement, dated January 18, 1995, by and between Inhale Therapeutic Systems, Inc. and Pfizer Inc.
4.4(8)	Form of Purchase Agreement, dated January 28, 1997, by and among Inhale Therapeutic Systems, Inc. and the individual Purchasers.
4.5(9)	Stock Purchase Agreement, dated December 8, 1998, by and between Inhale Therapeutic Systems, Inc. and Capital Research and Management Company.
4.6(11)	Purchase Agreement, dated October 6, 1999, by and among Inhale Therapeutic Systems, Inc., Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc.
4.7(11)	Resale Registration Rights Agreement, dated October 13, 1999, by and among Inhale Therapeutic Systems, Inc., Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc.
4.8(11)	Indenture, dated October 13, 1999, by and between Inhale Therapeutic Systems, Inc., as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
4.9(11)	Form of Inhale Registration Rights Agreement, dated January 25, 2000, by and between Inhale Therapeutic Systems, Inc. and Selling Shareholder.
4.10(12)	Purchase Agreement, dated February 2, 2000, by and among Inhale Therapeutic Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.11(12)	Resale Registration Rights Agreement, dated February 8, 2000, by and among Inhale Therapeutic Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
4.12(12)	Indenture, dated February 8, 2000, by and between Inhale Therapeutic Systems, Inc., as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
4.13(13)	Specimen common stock certificate.
4.14(14)	Specimen warrants to purchase shares of common stock.
4.15(16)	Purchase Agreement, dated October 11, 2000, by and among Inhale Therapeutic Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith



- Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
- 4.16(16) Resale Registration Rights Agreement, dated October 17, 2000, by and among Inhale Therapeutic Systems, Inc., Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities, Inc., Lehman Brothers Inc. and U.S. Bancorp Piper Jaffray Inc.
- 4.17(16) Indenture, dated October 17, 2000, by and between Inhale Therapeutic Systems, Inc., as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee.
- 4.18(19) Rights Agreement, dated as of June 1, 2001, by and between Inhale Therapeutic Systems, Inc. and Mellon Investor Services LLC.
- 4.19(19) Form of Right Certificate.

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- 4.20(24) Stock Purchase Agreement, dated January 7, 2002, by and between Inhale Therapeutic Systems, Inc. and Enzon, Inc.
- 10.1(6) Inhale Therapeutic Systems, Inc.'s 1994 Non-Employee Directors' Stock Option Plan, as amended.
- 10.2(2) Inhale Therapeutic Systems, Inc.'s 1994 Employee Stock Purchase Plan, as amended and restated.
- 10.3(2) Standard Industrial Lease, dated September 17, 1992, as amended September 18, 1992, by and between Inhale Therapeutic Systems, Inc. and W.F. Batton & Co., Inc.
- 10.4(2) Addendum IV to Lease dated September 17, 1992, dated April 1, 1994, by and among Inhale Therapeutic Systems, Inc., W.F. Batton and Marie A. Batton.
- 10.5(5) Amendment Agreement Number One to Lease dated September 17, 1992, dated October 20, 1995, by and between Inhale Therapeutic Systems, Inc. and W.F. Batton & Co., Inc.
- 10.6(5) Amendment Agreement Number Two to Lease dated September 17, 1992, dated November 15, 1995, by and among Inhale Therapeutic Systems, Inc., 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").
- 10.7(10) Amendment Agreement Number Three to Lease dated September 17, 1992, dated February 14, 1996, by and between Inhale Therapeutic Systems, Inc. and Batton Trust.
- 10.8(10) Amendment Agreement Number Four to Lease dated September 17, 1992, dated September 15, 1996, by and between Inhale Therapeutic Systems, Inc. and Batton Trust.
- 10.9(2) Sublicense Agreement, dated September 13, 1991, by and between Inhale Therapeutic Systems, Inc. and John S. Patton.
- 10.10(4) Stock Purchase Agreement, dated March 1, 1996, by and between Inhale Therapeutic Systems, Inc. and Baxter World Trade Corporation.
- 10.11(7) Sublease and Lease Agreement, dated October 2, 1996, by and between Inhale Therapeutic Systems, Inc. and T.M.T. Associates L.L.C. ("Landlord").
- 10.12(10) First Amendment to Sublease and Lease Agreement dated October 2, 1996, dated October 30, 1996, by and between Inhale Therapeutic Systems, Inc. and Landlord.
- 10.13(10) Letter Agreement amending Sublease and Lease Agreement dated October 2, 1996, dated April 9, 1997, by and between Inhale Therapeutic Systems, Inc. and Landlord.
- 10.14(10) Third Amendment to Sublease and Lease Agreement dated October 2, 1996, dated April 16, 1997, by and between Inhale Therapeutic Systems, Inc. and Landlord.
- 10.15(10) Fourth Amendment to Sublease and Lease Agreement dated October 2, 1996, dated November 5, 1997, by and between Inhale Therapeutic Systems, Inc. and Landlord.
- 10.16(12) Sublease, dated November 3, 1999, by and between Webvan Group, Inc., as sublessor, and Inhale Therapeutic Systems, Inc., as sublessee.
- 10.17(14) Inhale Therapeutic Systems, Inc.'s 2000 Equity Incentive Plan, as amended.
- 10.18(14) Inhale Therapeutic Systems, Inc.'s Stock Option Agreement issued in accordance with Inhale Therapeutic Systems, Inc.'s 2000 Equity Incentive Plan, as amended.

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- 10.19(14) Agreement for the Contribution of 201 Industrial Road Project, made and entered into as of September 14, 2000, by and among Inhale Therapeutic Systems, Inc., Inhale 201 Industrial Road, L.P., a California limited partnership and Bernardo Property Advisors, Inc., a California corporation.
- 10.20(14) Agreement of Limited Partnership of Inhale 201 Industrial Road, L.P., a California limited partnership, made and entered into September 14, 2000, by and among SCIMED PROP III, Inc., a California corporation, as general partner, 201 Industrial Partnership, a California general partnership, as limited partner and Inhale Therapeutic Systems, Inc., as limited partner.
- 10.21(14) Build-To-Suit Lease, made and entered into as of September 14, 2000, by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale Therapeutic Systems, Inc., as Tenant.
- 10.22(14) Amendment to Lease, dated October 3, 2000, by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale Therapeutic Systems, Inc., as Tenant.
- 10.23(14) Parking Lease Agreement, entered into as of September 14, 2000, by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale Therapeutic Systems, Inc., as Tenant.
- 10.24(23) Inhale Therapeutic Systems, Inc.'s 2000 Non-Officer Equity Incentive Plan.
- 10.25(17) Inhale Therapeutic Systems, Inc.'s Stock Option Agreement issued in accordance with Inhale Therapeutic Systems, Inc.'s 2000 Non-Officer Equity Incentive Plan.
- 10.26+(18) Manufacturing and Supply Agreement by and among Inhale Therapeutic Systems, Inc., Tech Group North America and Bespak Europe, LTD.
- 10.27(21) The Bradford Particle Design plc Approved Employee Share Option Scheme.
- 10.28(21) Form of The Bradford Particle Design plc Approved Employee Share Option Scheme Option Certificate.
- 10.29(21) The Bradford Particle Design plc Unapproved Employee Share Option Scheme.
- 10.30(21) Form of The Bradford Particle Design plc Unapproved Employee Share Option Scheme Option Certificate.
- 10.31(21) Form of Agreement Granting an Enterprise Management Incentives Option.
- 10.32(21) Agreement Granting Options, dated November 5, 1999, by and between Mr. Joseph F. Bohan and Bradford Particle Design plc.
- 10.33(21) Agreement Granting Options, dated October 27, 2000, by and between Mr. Joseph F. Bohan and Bradford Particle Design plc.
- 10.34(22) Shearwater Corporation 1996 Nonqualified Stock Option Plan.
- 10.35(22) Amendment, effective May 22, 1998, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
- 10.36(22) Second Amendment, effective February 26, 2000, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
- 10.37(22) Third Amendment, effective October 5, 2000, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.

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10.39(22)	Form of Shearwater Corporation Nonqualified Stock Option Agreement.
10.40(22)	Form of June 2001 Amendment to Shearwater Corporation Nonqualified Stock Option Agreement.
10.41(25)	Inhale Therapeutic Systems, Inc. 401(k) Retirement Plan.
10.42(25)	Non-Standardized Adoption Agreement No. 001 for use with Inhale Therapeutic Systems, Inc. 401(k) Retirement Plan.

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+ Confidential treatment with respect to specific portions are omitted and filed separately with the SEC.

- (1) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.
- (2) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-1 (No.33-75942), as amended.
- (3) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-1 (No.33-89502), as amended.
- (4) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.
- (5) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Annual Report on Form 10-K for the year ended December 31, 1995.
- (6) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.
- (7) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.
- (8) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-3 (No. 333-20787).
- (9) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-3 (No. 333-68897), as amended.
- (10) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999.
- (11) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-3 (No. 333-94161), as amended.
- (12) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Annual Report on Form 10-K for the year ended December 31, 1999.
- (13) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.
- (14) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000.
- (15) Incorporated by reference to the indicated exhibit in Inhale Therapeutic Systems, Inc.'s Current Report on Form 8-K, filed on January 11, 2001.

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- (16) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-3 (No. 333-53678), filed on January 12, 2001.
  - (17) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-54078), filed on January 19, 2001.
  - (18) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Annual Report on Form 10-K, as amended, for the year ended December 31, 2000.
  - (19) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Current Report on Form 8-K, filed on June 4, 2001.
  - (20) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Current Report on Form 8-K, filed on July 10, 2001.
  - (21) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-55032), filed on February 6, 2001.
  - (22) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-67342), filed on August 10, 2001.
  - (23) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-71936), filed on October 19, 2001.
  - (24) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Current Report on Form 8-K, filed on January 8, 2002.
  - (25) Incorporated by reference to Inhale Therapeutic Systems, Inc.'s Registration Statement on Form S-8 (No. 333-76638), filed on January 11, 2002.

