

**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 June 30, 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  No

Applicable Only to Corporate Issuers

The number of outstanding shares of the registrant's Common Stock, \$0.0001 par value, was 55,314,314 as of July 31, 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)

	June 30, 2002	December 31, 2001
	(unaudited)	*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 25,628	\$ 30,814
Short-term investments	310,272	313,542
Accounts receivable	4,848	4,487
Other current assets	13,542	11,998
<b>Total current assets</b>	<b>354,290</b>	<b>360,841</b>
Property and equipment, net	144,031	142,352
Marketable equity securities	329	721
Goodwill	132,021	133,856
Other intangible assets, net	17,723	19,977
Deposits and other assets	8,611	9,494
<b>Total assets</b>	<b>\$ 657,005</b>	<b>\$ 667,241</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,929	\$ 7,685
Accrued research and development	7,584	10,776
Accrued general and administrative	6,798	7,075
Accrued compensation	6,020	5,977
Accrued acquisition costs	—	2,046
Other accrued liabilities	4,356	3,172
Interest payable	4,588	4,588
Capital lease obligation—current	904	807
Deferred revenue	20,656	17,073
<b>Total current liabilities</b>	<b>57,835</b>	<b>59,199</b>
Capital lease obligation—noncurrent	31,804	31,909
Accrued rent	1,997	1,921
Convertible subordinated notes and debentures	299,149	299,149
Other long-term liabilities	4,048	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 June 30, 2002 and December 31, 2001.	40,000	—
Convertible Series B, \$0.0001 par value: 40 shares designated; 40 shares issued and outstanding at June 30, 2002. No shares issued or outstanding at December 31, 2001. Liquidation preference of \$40,000 at June 30, 2002 and \$0 at December 31, 2001.	—	—
Common stock, \$0.0001 par value; 300,000 authorized; 55,263 shares and 55,094 shares issued and outstanding at June 30, 2002 and December 31, 2001, respectively.	6	5
Capital in excess of par value	713,239	712,039
Deferred compensation	(613)	(923)
Accumulated other comprehensive gain	1,290	1,069
Accumulated deficit	(491,750)	(441,877)
<b>Total stockholders' equity</b>	<b>262,172</b>	<b>270,313</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 657,005</b>	<b>\$ 667,241</b>

(\*) The balance sheet at December 31, 2001 has been derived from the audited consolidated 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

See accompanying notes.

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**INHALE THERAPEUTIC SYSTEMS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share information)  
(unaudited)

	Three-Months Ended June 30,		Six-Months Ended June 30,	
	2002	2001	2002	2001
Contract research revenue	\$ 18,828	\$ 16,799	\$ 40,129	\$ 30,896
Product sales	3,423	—	8,868	—
<b>Total revenue</b>	<b>22,251</b>	<b>16,799</b>	<b>48,997</b>	<b>30,896</b>
Operating costs and expenses:				
Cost of goods sold	1,673	—	3,563	—
Research and development	36,551	34,059	78,478	64,330
General and administrative	5,575	4,420	10,956	8,438
Purchased in-process research and development	—	83,600	—	146,260
Amortization of other intangible assets	1,127	432	2,254	758
Amortization of goodwill	—	4,024	—	6,777
<b>Total operating costs and expenses</b>	<b>44,926</b>	<b>126,535</b>	<b>95,251</b>	<b>226,563</b>
Loss from operations	(22,675)	(109,736)	(46,254)	(195,667)
Other income/(expense), net	(599)	(262)	(687)	(340)
Interest income	2,488	7,314	5,287	15,019
Interest expense	(4,031)	(3,110)	(8,219)	(5,847)
Net loss	\$ (24,817)	\$ (105,794)	\$ (49,873)	\$ (186,835)
Basic and diluted net loss per share	\$ (0.45)	\$ (2.05)	\$ (0.90)	\$ (3.64)
Shares used in computing basic and diluted net loss per share	55,216	51,607	55,197	51,330

See accompanying notes

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

	Six-Months Ended June 30,	
	2002	2001
<b>Cash flows used in operating activities:</b>		
Net loss	\$ (49,873)	\$ (186,835)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,144	5,624
Amortization of other intangible assets	2,254	758
Amortization of goodwill	—	6,777
Amortization of debt issuance costs	633	944
Amortization of deferred compensation	310	532
Issuance of common stock for retirement plans	512	—
Stock-based compensation for services rendered	312	480
Purchased in-process research and development	—	146,260

Loss on impairment of marketable equity securities	392	—
<b>Changes in assets and liabilities:</b>		
(Increase) in accounts receivable, other current assets, and other assets	(907)	(700)
Increase/(decrease) in accounts payable and other accrued liabilities	(2,537)	579
Increase in deferred revenue	3,609	11,986
<b>Net cash used in operating activities</b>	<b>(39,151)</b>	<b>(13,595)</b>
<b>Cash flows from investing activities:</b>		
Purchases of short-term investments	(149,541)	(167,820)
Sales of short-term investments	54,768	89,989
Maturities of short-term investments	97,328	263,233
Purchases of property and equipment	(10,320)	(18,286)
Acquisition of Shearwater, net of cash acquired	1,542	(67,246)
Acquisition of Bradford, net of cash acquired	—	(14,805)
<b>Net cash provided by/(used in) investing activities</b>	<b>(6,223)</b>	<b>85,065</b>
<b>Cash flows from financing activities:</b>		
Proceeds from loan and capital lease financing	171	11,424
Payments of loan and capital lease obligations	(360)	(378)
Issuance of preferred stock	40,000	—
Issuance of common stock, net of issuance costs	377	4,614
<b>Net cash provided by financing activities</b>	<b>40,188</b>	<b>15,660</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(5,186)</b>	<b>87,130</b>
Cash and cash equivalents at beginning of period	30,814	136,012
<b>Cash and cash equivalents at end of period</b>	<b>\$ 25,628</b>	<b>\$ 223,142</b>

See accompanying notes.

**INHALE THERAPEUTIC SYSTEMS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**June 30, 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 providing several technologies. The first technology 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, solution enhanced dispersion by supercritical fluids (SEDS™), uses a proprietary processing method known as supercritical fluids processing to develop drug formulations for multiple types of drug delivery.

Our consolidated financial statements include the financial statements of our subsidiaries: Shearwater Corporation ("Shearwater"), Bradford Particle Design Ltd. ("Bradford"), Inhale Therapeutic Systems Deutschland GmbH ("Inhale Germany") and Inhale Therapeutic Systems, U.K. Limited ("Inhale UK"), as well as 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 accompanying unaudited condensed consolidated financial statements of Inhale have been prepared by management in accordance with generally accepted accounting principles for interim financial information and the instructions for Form 10-Q and Article 10 of Regulation S-X. The condensed consolidated balance sheet as of June 30, 2002, the condensed consolidated statements of operations for the three-month periods and the six-month periods ended June 30, 2002 and 2001, and the consolidated statements of cash flows for the six-month periods ended June 30, 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

accounting principles generally accepted in the United States 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.

### Use of Estimates

Results for any interim period presented are not necessarily indicative of results for any other interim period or for the entire year. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates

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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.

### Reclassifications

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 lessor 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. All significant intercompany accounts and transactions are eliminated in consolidation.

### Significant Concentrations

Cash equivalents and short-term 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 as the source of a significant proportion of our revenue. In the event that this collaboration is 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 assets capitalized. 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 and may incur additional liabilities.

### Cash, Cash Equivalents and Short-term 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,

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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 June 30, 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 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 consists of the following (in thousands):

	June 30, 2002	December 31, 2001
Raw materials	\$ 2,944	\$ 1,805
Work-in process	289	513

\$	4,615	\$	3,201
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## 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 Statement of Financial Accounting Standards ("SFAS") No 142, *Goodwill and Other Intangible Assets*, we stopped the periodic amortization of 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

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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.

SFAS No. 142 requires the disclosure of the effect on net income of the application of this Statement for all periods presented in our Annual Report on Form 10-K for the year ended December 31, 2001. Please see "Note 2—Goodwill and Other Intangible Assets," for further discussion.

## 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.

## Impairment of Long-Lived Assets

We evaluate our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-lived Assets*. Recoverability of assets to be held and used, including assets to be disposed of other than by sale, are measured by a comparison of the carrying amount of any asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceed the fair value of the assets. Assets to be sold are reported at the lower of the carrying amount or fair value less cost to sell.

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## Comprehensive Gain/Loss

Comprehensive gain/loss is comprised of net loss and other comprehensive gain/loss for the three-month and six-month periods ended June 30, 2002 and 2001. Other comprehensive gain/loss included unrealized gains/losses on available-for-sale securities and translation adjustments (in thousands):

	Three-Month Period Ended June 30,		Six-Month Period Ended June 30,	
	2002	2001	2002	2001
Net loss	\$ (24,817)	\$ (105,794)	\$ (49,873)	\$ (186,835)
Change in net unrealized gains/losses on available-for-sale securities	1,074	(2,753)	(494)	(7,758)
Net unrealized loss reclassified into earnings	392		392	
Translation adjustment	471	153	323	50
Comprehensive loss	\$ (22,880)	\$ (108,394)	\$ (49,652)	\$ (194,543)

## Stock-Based Compensation

As permitted by the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, we account for our employee stock options in accordance with Accounting Principles Board Opinion ("APB") No. 25, *Accounting for Stock Issued to Employees* and related interpretations. 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 consists of reimbursement of development costs, reimbursement of certain expenses, payment of clinical supplies and amortization of milestones.

Costs of contract research revenue approximate such revenue and are included in research and development expenses. Product sales are 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.

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## 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 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.

## Segment Reporting

We report segments in accordance with SFAS No 131, *Disclosures About Segments of an Enterprise and Related Information*. SFAS 131 requires the use of a management approach in identifying segments of an enterprise. We are organized and operate as one operating unit.

Our research revenue is derived primarily from clients in the pharmaceutical industry. Contract research revenue from one partner represented 62% and 74% of our revenue for the three-months ended June 30, 2002 and June 30, 2001, respectively, and 61% and 74% for the six-months ended June 30, 2002 and 2001, respectively. Product sales relate to sales by our Shearwater subsidiary of manufactured PEGylated products.

Our accounts receivable balance contains trade receivables from product sales, feasibility agreements and collaborative research agreements. At June 30, 2002, two of our partners represented 27% of our accounts receivable balance, and no one partner had a balance greater than 10% of accounts receivable balance at December 31, 2001.

## 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, outstanding preferred stock 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.

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## Note 2—Goodwill and Other Intangible Assets

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

	June 30, 2002	December 31, 2001
Goodwill	\$ 154,859	\$ 156,694
Accumulated amortization	(22,838)	(22,838)
Net goodwill	132,021	133,856
Other intangible assets:		
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

Total other intangible assets	23,441	23,441
Accumulated amortization of other intangible assets	(5,718)	(3,464)
<b>Net other intangible assets</b>	<b>17,723</b>	<b>19,977</b>
Net goodwill and other intangibles	\$ 149,744	\$ 153,833

The goodwill balance decreased from December 31, 2001, due to certain purchase price adjustments related to our acquisition of Shearwater.

Amortization expense related to other intangible assets totaled \$1.1 million and \$0.4 million during the three months ended June 30, 2002 and 2001, respectively. The estimated aggregate future amortization expense for other intangible assets remaining as of June 30, 2002 is as follows (in thousands):

Remainder of 2002	\$ 2,253
2003	4,507
2004	4,507
2005	4,507
2006	1,949
<b>Total</b>	<b>\$ 17,723</b>

In accordance with SFAS 142 adopted on January 1, 2002, we stopped the periodic amortization of goodwill. SFAS 142 requires disclosure of the effect of the application of this Statement on all periods presented in our Annual Report on Form 10-K for the year ended December 31, 2001. The following table shows the reconciliation of reported net loss adjusted for the adoption of SFAS 142 for each of

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the five years in the period ended December 31, 2001, and three-month and six-month periods ended June 30, 2001 (unaudited, in thousands, except per share data):

	Three-Months Ended June 30,		Six-Months Ended June 30,		Years Ended December 31,				
	2001		2001		2001	2000	1999	1998	1997
Reported net loss	\$ (105,794)	\$ (186,835)	\$ (250,008)	\$ (97,403)	\$ (38,448)	\$ (18,356)	\$ (9,983)		
Add back: Goodwill amortization	3,954	6,661	21,886	312	48				
Add back: Assembled workforce amortization	70	116	593	—	—	—	—	—	—
<b>Adjusted net loss</b>	<b>\$ (101,770)</b>	<b>\$ (180,058)</b>	<b>\$ (227,529)</b>	<b>\$ (97,091)</b>	<b>\$ (38,400)</b>	<b>\$ (18,356)</b>	<b>\$ (9,983)</b>		
<b>Basic net loss per share:</b>									
Reported net loss	\$ (2.05)	\$ (3.64)	\$ (4.71)	\$ (2.32)	\$ (1.13)	\$ (0.58)	\$ (0.36)		
Add back: Goodwill amortization	0.08	0.13	0.41	0.01	—	—	—		
Add back: Assembled workforce amortization	0.00	0.00	0.01	—	—	—	—		
<b>Adjusted net loss</b>	<b>\$ (1.97)</b>	<b>\$ (3.51)</b>	<b>\$ (4.28)</b>	<b>\$ (2.31)</b>	<b>\$ (1.13)</b>	<b>\$ (0.58)</b>	<b>\$ (0.36)</b>		

### Note 3—Business Acquisitions

Bradford 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'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 other intangible assets.

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 six-months ended June 30, 2001 assumes the acquisition of Bradford 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).



	June 30,	
	2002	2001
Total revenues	\$ 48,997	\$ 37,124
Net loss	\$ (49,873)	\$ (106,942)
Net loss per share	\$ (0.90)	\$ (1.96)

#### 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 undepreciated 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 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-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 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

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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 June 30,		Six-Months Ended June 30,	
	2002	2001	2002	2001
<b>Supplemental disclosure of cash flows information:</b>				
Interest paid	\$ 4,286	\$ 4,286	\$ 5,821	\$ 5,821
<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	—	—	—	(125,576)
Cash paid for acquisition of Bradford Particle Design (net of cash received)	\$ —	\$ —	\$ —	\$ 14,805
<b>Non-cash disclosure related to acquisition of Shearwater:</b>				
Tangible assets acquired, net of cash	\$ —	\$ 15,212	\$ —	\$ 15,212
Purchased in-process research and development	—	83,600	—	83,600
Goodwill and other intangible assets acquired	(1,542)	94,619	(1,542)	94,619
Acquisition costs incurred	—	(5,417)	—	(5,417)
Liabilities assumed	—	(6,528)	—	(6,528)
Common stock and options	—	(114,240)	—	(114,240)
Cash paid for acquisition of Shearwater (net of cash received)	\$ (1,542)	\$ 67,246	\$ (1,542)	\$ 67,246

**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

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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 us solely responsible for licensing Enzon's PEG patents, an option for Enzon to license our 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 unfunded research spending in the next three to five years, due to the combination of the completion of scale up and commercial readiness spending, the shifting of infrastructure spending to cost of goods sold for commercial product sales, 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 June 30, 2002, we incurred a cumulative net loss of approximately \$491.8 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 July 2002, we announced an additional collaboration with Chiron Corporation. Based on feasibility work completed by us, we will develop under this recently announced collaboration an inhaled powdered version of PA2794, a proprietary Chiron antibiotic from a class commonly used to treat pulmonary infections.

In July 2002, a product using our PEGylation technology was granted priority review by the U.S. Food and Drug Administration (FDA). The FDA has granted a six-month Priority Review Status of the Biologics License Application (BLA) and New Drug Application (NDA) for Roche's combination therapy of PEGASYS® (PEGinterferon alfa-2a) and Roche ribavirin tablets, for the treatment of chronic hepatitis C in patients without cirrhosis and with cirrhosis with compensated liver disease.

In June 2002, we named inhaleable leuprolide, a peptide, as our first collaborative project in connection with a strategic alliance with Enzon, Inc. announced in January 2002. In November 2001, we announced positive results from a first in human clinical study of inhaleable leuprolide. The 12-person European study suggested that clinical doses of leuprolide could be given as once-a-day single inhalations.

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In June 2002, we also announced that a product using our PEGylation technology, Regeneron's PEGylated AXOKINE(R) for the treatment of obesity, had entered the clinical trials. In addition, Confluent Surgical initiated pivotal trials for the SprayGel adhesion barrier in the US. SprayGel also uses Inhale's PEGylation technology and is already marketed in Europe.

In May 2002, we amended and restated our Employee Stock Purchase Plan to increase the number of shares of common stock authorized for issuance under the Purchase Plan from a total of 300,000 shares to a total of 800,000 shares. This amendment was approved by our shareholders in June 2002.

### 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 reasonably 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

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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.

#### *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. The goodwill balance decreased from December 31, 2001 due to certain purchase price adjustments related to our acquisition of Shearwater. Other intangible assets have been amortized on a straight line basis for the three-months and six-months ended June 30, 2002.

In accordance with a new accounting standard adopted on January 1, 2002, the totals for the three-month and the six-month periods ended June 30, 2002 do not include amortization of goodwill and are comprised solely of amortization of other intangible assets. The total for the three-months and six-months ended June 30, 2001 includes \$0.4 million and \$0.8 million of amortization expense of other intangible assets and \$4.0 million and \$6.8 million of amortization of goodwill. Had amortization of goodwill been continued beyond January 1, 2002, we would have recognized an additional \$7.9 million and \$15.8 million in amortization expense during the three-months and six-months ended June 30, 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.

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## **Results of Operations**

#### *Three-Month and Six-Months Ended June 30, 2002 and 2001*

Revenue for the three-months ended June 30, 2002 was \$22.3 million compared to \$16.8 million for the three-months ended June 30, 2001, an increase of 32%. Revenue for the six-months ended June 30, 2002 was \$49.0 million compared to \$30.9 million for the six months ended June 30, 2001, an increase of 59%. The increase in revenue was primarily due to increased funding of partnered projects and the addition of PEGylation product sales by our Shearwater subsidiary. Pfizer represented approximately 62% and 61% of our revenues for the three-months and six-months ended June 30, 2002. Product sales through our Shearwater subsidiary accounted for 15% and 18% of revenues in the three-months and six-months ended June 30, 2002. Contract research revenue for the three-months and six months ended June 30, 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 \$1.7 million for the three-months ended June 30, 2002 based on product sales of \$3.4 million from our Shearwater subsidiary during the quarter. Cost of goods sold for the six-months ended June 30, 2002 was \$3.6 million based on product sales of \$8.9 million. There were no product sales, and therefore, no cost of goods sold in the three-months or six-months ended June 30, 2001.

Research and development expenses were \$36.6 million for the three-months ended June 30, 2002, as compared to \$34.1 million for the three-months ended June 30, 2001. The 7% increase in 2002 as compared to 2001 was primarily attributable to the addition of our Shearwater subsidiary to our operations and increased spending associated with partner-funded projects. Research and development expenses for the six-months ended June 30, 2002 and 2001 were \$78.5 million and \$64.3 million, an increase of 22%. The additional expenses were attributable to the addition of our Shearwater subsidiary and increased spending associated with partner-funded programs. 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 in the three-months ended March 31, 2002. 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 \$5.6 million for the three-months ended June 30, 2002 as compared to \$4.4 million for the three-months ended June 30, 2001. The 26% increase in general and administrative expenses was primarily due to increased support associated with our manufacturing and development efforts, including administrative staffing, business development and marketing, as well the addition of our Shearwater subsidiary to our operations during the second quarter of 2001. General and administrative expenses increased 30% for the six-months ended June 30, 2002 compared to the same period ended June 30, 2001 from \$8.4 million to \$11.0 million. This increase was primarily due to incremental support associated with our manufacturing and development efforts, including administrative staffing, business development and marketing, as well the addition of our Shearwater subsidiary

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 three-months ended June 30, 2001, we incurred a charge of \$83.6 million for IPR&D related to our Shearwater acquisition. During the six-months ended June 30,

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2001, we incurred charges of \$146.3 million for our acquisitions of Bradford and Shearwater. During the three-months and six-months ended June 30, 2002 we did not incur any IPR&D charges.

In June 2001, we completed our acquisition of Shearwater in exchange for approximately 4.0 million shares or options to acquire shares of our common stock and cash of \$72.5 million. Of the total purchase consideration of \$192.2 million, \$108.6 million was allocated to the assets acquired based on their fair value on the date of acquisition, including \$94.6 million in goodwill and other intangible assets. Approximately \$83.6 million of the purchase price was allocated to IPR&D, which was determined to have no alternative future use and was charged as an expense during the three-months ended June 30, 2001.

In January 2001, we acquired all of the outstanding share capital of Bradford 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 three-months ended March 31, 2001.

Amortization of other intangible assets expenses were \$1.1 million for the three-months ended June 30, 2002 as compared to \$0.4 million for the three-months ended June 30, 2001. For the six-months ended June 30, 2002 and 2001, amortization of other intangible assets expenses were \$2.3 million and \$0.8 million, respectively. The increase in amortization and other intangible assets expenses in the three-month and six-month periods ended June 30, 2002 as compared to 2001, respectively, was associated with the amortization of intangible assets in connection with the acquisition of our Shearwater subsidiary in the second half of 2001.

There was no amortization of goodwill for the three-months and six-months ended June 30, 2002 as compared to \$4.0 million and \$6.8 million for the three-months and six-months ended June 30, 2001. The decrease was associated with the adoption of new accounting standards on January 1, 2002 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. Since January 1, 2002, we have periodically evaluated 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. No impairment charges have been recorded for the three-months or six-months ended June 30, 2002.

Other income/(expense), net, was (\$0.6) million and (\$0.3) million for the three-months ended June 30, 2002 and 2001, respectively. For the six-months ended June 30, 2002 and 2001, other income/(expense), net, was (\$0.7) million and (\$0.3) million, respectively. The increase from 2001 to 2002 can primarily be attributed to a (\$0.4) million realized loss on our marketable equity securities due to impairment.

Interest income was \$2.5 million for the three-months ended June 30, 2002, as compared to \$7.3 million for the three-months ended June 30, 2001. Interest income was \$5.3 million during the six-months ended June 30, 2002, compared to \$15.0 million earned during the six-months ended June 30, 2001. The 66% and 65% decrease in interest income in the three-months and six-months ended June 30, 2002 from the same period in 2001, respectively, were primarily due to our lower cash and investment balances and lower interest rates in the first six-months of 2002 as compared to the same periods in 2001.

Interest expense was \$4.0 million for the three-months ended June 30, 2002, as compared to \$3.1 million for the three-months ended June 30, 2001. Interest expense was \$8.2 million and \$5.8, respectively, million for the six-months ended June 30, 2002 and 2001. The 30% and 41% increase in

interest expense for the three-months and six-months ended June 30, 2002, from comparable periods ended June 30, 2001, relates primarily to the interest expense on our capital lease obligation associated with our build-to-suit lease.

## 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 June 30, 2002, we had cash, cash equivalents and short-term investments of approximately \$335.9 million.

Our operations used cash of \$39.2 million in the six-months ended June 30, 2002 as compared to \$13.6 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 \$6.1 million for the six-months ended June 30, 2002 from \$5.6 million for the six-months ended June 30, 2001, due to the inclusion of Shearwater and the build-to-suit lease with our real estate partnership lessor. Amortization of other intangible assets increased for the six-months ended June 30, 2002 as compared to the six-months ended June 30, 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 six-months ended June 30, 2002 due to the adoption of SFAS 142; however, we had amortization of goodwill expense of \$6.8 million in the six-months ended June 30, 2001. We did not incur any purchased in-process research and development for the six-months period ended June 30, 2002; however we did incur charges of \$146.3 million for the six-months ended June 30, 2001 associated with our acquisitions of Bradford Particle Design and Shearwater. The change in accounts payable and other accrued liabilities for the six-months ended June 30, 2002, as compared to the six-months ended June 30, 2001 was related to a \$3.0 million payment to Enzon to cover expenses incurred in connection with defending litigation involving our branched PEG patents. The change in deferred revenue for the six-months ended June 30, 2002 as compared to the six-months ended June 30, 2001 was primarily due to the timing of partner payments in 2001.

Cash flows used in investing activities were \$6.2 million for the six-months ended June 30, 2002 as compared to \$85.1 million cash inflow for the six-months ended June 30, 2001. We purchased property and equipment of approximately \$10.3 million and \$18.3 million during the six-months ended June 30, 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. The change in maturities of short-term investments for the six-months ended June 30, 2002, compared to the six-months ended June 30, 2001 was primarily attributable to an increase in cash requirements to support the acquisitions of Shearwater and Bradford in 2001. In connection with our acquisition of Shearwater in June 2001, we paid net cash of \$67.2 million for the six-months ended June 30, 2001, which represents cash paid to Shearwater shareholders of \$72.5 million, net of Shearwater's cash balance of \$5.3 million. The remainder of the Shearwater acquisition was non-cash in nature. For the six-months ended June 30, 2002, we received \$1.5 million for a purchase price adjustment of Shearwater. Also, in connection with our acquisition of Bradford, we paid net cash of \$14.8 million for the six-months ended June 30, 2001, which represents cash paid to Bradford shareholders of \$20.4 million, net of Bradford cash balance of \$5.6 million. The remainder of the Bradford acquisition was non-cash in nature.

Cash flows from financing activities were \$40.2 million for the six-months ended June 30, 2002 as compared to \$15.7 million for the six-months ended June 30, 2001. The cash inflow in 2002 was related to our strategic alliance with Enzon entailing a \$40.0 million investment in our preferred stock (see

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Consolidated Financial Statements Note 8—Cross Platform Strategic Alliance). In 2001 we received \$11.4 million from the loan and capital lease financing of our real estate lessor for the construction of our San Carlos lab and office facility.

We believe that research and development expenses should continue at current levels or higher through at least the next couple of years. Research and development expenses 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) commercial readiness 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.

Given our current cash requirements, we believe that we will have sufficient cash to meet our operating expense requirements for the next three years. 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. Of our convertible subordinated notes and debentures, \$7.8 million and \$291.4 million mature in 2006 and 2007, respectively. 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.

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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 35 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. Our SEDS™ supercritical fluids technology, obtained through our acquisition of Bradford Particle Design, 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™ 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 inhaleables technology requires the development of:

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

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;
- corporate partners with marketing rights may choose to devote fewer resources to the marketing of our products than they do to products of their own development; and

- there are risks related to the ability of our distributors and corporate partners to pay us.

Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts.

In October 2001, Eli Lilly and Company, our collaborative partner with respect to a Phase I program for an inhaleable product for the treatment of osteoporosis, Fortéo™, notified us that the program will not be funded in 2002. Lilly further informed us that other than on-going stability work, additional activities with respect to the program will be suspended. 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® 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 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 or our partners 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 or our partners 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 three products using our advanced PEGylation technology for specific use in the United States. Further, two additional products using PEGylation have been approved in Europe and other countries. In addition, our partners have submitted for approval to the FDA two NDAs using our PEGylation technology and we plan to manufacture and market other potential products. Even though we have obtained regulatory approval for three 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.

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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™ Technologies*

We acquired our advanced PEGylation and supercritical fluids technologies through our acquisitions of Shearwater and Bradford Particle Design, respectively. Except for our three approved products or two 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.

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### *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.

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### **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;
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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™ technology and the advanced PEGylation technology we are developing through our acquisitions of Bradford Particle Design and Shearwater, respectively. Some of our competitors with regard to inhaleables technology include AeroGen, Inc., Alkermes, Inc. and Aradigm Corporation. Aerogen and Aradigm are working on liquid drug delivery systems, and Alkermes is working on a dry powder delivery system. 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™ 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™ supercritical fluids technologies, and we plan to file additional patent applications. We currently have 296 issued U.S. and foreign patents that cover certain aspects of our technology and we have a number of patent applications pending. There is a risk that many of the patents applied for will not issue, or that any patents that issue or have issued will not be valid and enforceable. Enforcing our patent rights would be time consuming and costly.

Our access or our partners' access to the drugs to be formulated using our technologies will affect our ability to develop and commercialize our technology. Many drugs, including powder formulations of certain drugs that are presently under development by us, and our drug formulation technologies are subject to issued and pending U.S. and foreign patents that may be owned by competitors. We know that there are issued patents and pending patent applications relating to the formulation and delivery

of 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.

**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

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- 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 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.

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**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 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 June 30, 2002 we have an accumulated deficit of approximately \$491.8 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 three years. 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 July 31, 2002, based on closing prices on the Nasdaq National Market, our stock price ranged from \$5.86 to \$19.47. We expect it to remain volatile. A variety of factors may have a significant effect on the market price of our common stock, including:

- clinical trial results or product development delays;
- announcement or termination of collaborative relationships by us or our competitors;
- fluctuations in our operating results;
- developments in patent or other proprietary rights;
- announcements of technological innovations or new therapeutic products;
- governmental regulation;
- 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 June 30, 2002, we had approximately \$337.0 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 June 30, 2002 we had cash, cash equivalents and short-term investments valued at approximately \$335.9 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

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- 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 reported market risks since December 31, 2001.

**PART II: OTHER INFORMATION**

**Item 1. Legal Proceedings—None**

**Item 2. Changes in Securities and Use of Proceeds—None**

**Item 3. Defaults upon Senior Securities—None**

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

A. The annual meeting of the stockholders was held on June 25, 2002.

B. The following matters were voted upon at the annual meeting:

1. To elect the following directors to hold office until the 2005 Annual Meeting of Stockholders:

Nominee	In Favor	Withheld
Ajit S. Gill	45,555,063	398,612
Melvin Perelman, Ph.D.	45,702,860	250,815

2. To approve the amendment of our Employee Stock Purchase Plan, as amended and restated, to increase the aggregate number of shares of common stock authorized for issuance under the plan by 500,000 shares.

For	Against	Abstain	Broker Non-Vote
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3. To ratify the selection of Ernst and Young LLP as our independent auditors for the fiscal year ending December 31, 2002.

For	Against	Abstain	Broker Non-Vote
44,912,293	1,009,745	31,637	0

**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.
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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.

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- 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.
- 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.

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- 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.
- 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.
- 10.38(22) Fourth Amendment, effective June 22, 2001, to the 1996 Nonqualified Stock Option Plan of Shearwater Corporation.
- 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.
- 10.43(26) Inhale Therapeutic Systems, Inc., Employee Stock Purchase Plan, as amended and restated.
- 99.1(26) Certification of Officers.

- (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.

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- (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.
  - (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.
  - (26) Filed herewith.

(b) Reports on Form 8-K for the three-month period ending June 30, 2002:

None.

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**INHALE THERAPEUTIC SYSTEMS  
EMPLOYEE STOCK PURCHASE PLAN**

**ADOPTED BY THE BOARD OF DIRECTORS FEBRUARY 10, 1994  
APPROVED BY STOCKHOLDERS FEBRUARY 18, 1994  
AMENDED AND RESTATED MAY 10, 2002  
APPROVED BY STOCKHOLDERS JUNE 25, 2002**

**1. PURPOSE.**

(a) The purpose of the Plan is to provide a means by which Employees of the Company and certain designated Related Corporations may be given an opportunity to purchase shares of the Common Stock of the Company.

(b) The Company, by means of the Plan, seeks to retain the services of such Employees, to secure and retain the services of new Employees and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Related Corporations.

(c) The Company intends that the Purchase Rights be considered options issued under an Employee Stock Purchase Plan.

**2. DEFINITIONS.**

(a) "**Board**" means the Board of Directors of the Company.

(b) "**Code**" means the Internal Revenue Code of 1986, as amended.

(c) "**Committee**" means a committee appointed by the Board in accordance with Section 3(c) of the Plan.

(d) "**Common Stock**" means the common stock of the Company.

(e) "**Company**" means Inhale Therapeutic Systems, a Delaware corporation.

(f) "**Contributions**" means the payroll deductions, and other additional payments specifically provided for in the Offering, that a Participant contributes to fund the exercise of a Purchase Right. A Participant may make additional payments into his or her account, if specifically provided for in the Offering, and then only if the Participant has not already had the maximum permitted amount through payroll deductions withheld during the Offering.

(g) "**Corporate Transaction**" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company;

(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the

merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(h) "**Director**" means a member of the Board.

(i) "**Eligible Employee**" means an Employee who meets the requirements set forth in the Offering for eligibility to participate in the Offering, provided that such Employee also meets the requirements for eligibility to participate set forth in the Plan.

(j) "**Employee**" means any person, including Officers and Directors, who is employed for purposes of Section 423(b)(4) of the Code by the Company or a Related Corporation. Neither service as a Director nor payment of a director's fee shall be sufficient to make an individual an Employee of the Company or a Related Corporation.

(k) "**Employee Stock Purchase Plan**" means a plan that grants Purchase Rights intended to be options issued under an "employee stock purchase plan," as that term is defined in Section 423(b) of the Code.

(l) "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

(m) "**Fair Market Value**" means the value of a security, as determined in good faith by the Board. If the security is listed on any established stock exchange or traded on the Nasdaq National Market or the Nasdaq SmallCap Market, the Fair Market Value of the security, unless otherwise determined by the Board, shall be the closing sales price (rounded up where necessary to the nearest whole cent) for such security (or the closing bid, if no sales were reported) as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the relevant security of the Company) on the Trading Day prior to the relevant determination date, as reported in *The Wall Street Journal* or such other source as the Board deems reliable.

(n) "**Offering**" means the grant of Purchase Rights to purchase shares of Common Stock under the Plan to Eligible Employees.

(o) "**Offering Date**" means a date selected by the Board for an Offering to commence.

(p) "**Officer**" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(q) "**Participant**" means an Eligible Employee who holds an outstanding Purchase Right granted pursuant to the Plan.

(r) "**Plan**" means this Inhale Therapeutic Systems Employee Stock Purchase Plan, as amended and restated May 10, 2002.

(s) "**Purchase Date**" means one or more dates during an Offering established by the Board on which Purchase Rights shall be exercised and as of which purchases of shares of Common Stock shall be carried out in accordance with such Offering.

(t) "**Purchase Period**" means a period of time specified within an Offering beginning on the Offering Date or on the next day following a Purchase Date within an Offering and ending on a Purchase Date. An Offering may consist of one or more Purchase Periods.

(u) "**Purchase Right**" means an option to purchase shares of Common Stock granted pursuant to the Plan.

(v) "**Related Corporation**" means any parent corporation or subsidiary corporation, whether now or hereafter existing, as those terms are defined in Sections 424(e) and (f), respectively, of the Code.

(w) "**Securities Act**" means the Securities Act of 1933, as amended.

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(x) "**Trading Day**" means any day the exchange(s) or market(s) on which shares of Common Stock are listed, whether it be any established stock exchange, the Nasdaq National Market, the Nasdaq SmallCap Market or otherwise, is open for trading.

### 3. ADMINISTRATION.

(a) The Board shall administer the Plan unless and until the Board delegates administration to a Committee, as provided in Section 3(c). Whether or not the Board has delegated administration, the Board shall have the final power to determine all questions of policy and expediency that may arise in the administration of the Plan.

(b) The Board (or the Committee) shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine when and how Purchase Rights to purchase shares of Common Stock shall be granted and the provisions of each Offering of such Purchase Rights (which need not be identical).

(ii) To designate from time to time which Related Corporations of the Company shall be eligible to participate in the Plan.

(iii) To construe and interpret the Plan and Purchase Rights, and to establish, amend and revoke rules and regulations for the administration of the Plan. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.

(iv) To amend the Plan as provided in Section 15.

(v) Generally, to exercise such powers and to perform such acts as it deems necessary or expedient to promote the best interests of the Company and its Related Corporations and to carry out the intent that the Plan be treated as an Employee Stock Purchase Plan.

(c) The Board may delegate administration of the Plan to a Committee of the Board composed of two (2) or more members of the Board. If administration is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board, subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may abolish the Committee at any time and revert in the Board the administration of the Plan. If administration is delegated to a Committee, references to the Board in this Plan and in the Offering document shall thereafter be deemed to be to the Board or the Committee, as the case may be.

### 4. SHARES OF COMMON STOCK SUBJECT TO THE PLAN.

Subject to the provisions of Section 14 relating to adjustments upon changes in securities, the shares of Common Stock that may be sold pursuant to Purchase Rights shall not exceed in the aggregate eight hundred thousand (800,000) shares of Common Stock. If any Purchase Right granted under the Plan shall for any reason terminate without having been exercised, the shares of Common Stock not purchased under such Purchase Right shall again become available for issuance under the Plan.

### 5. GRANT OF PURCHASE RIGHTS; OFFERING.

(a) The Board may from time to time grant or provide for the grant of Purchase Rights to purchase shares of Common Stock under the Plan to Eligible Employees in an Offering (consisting of one or more Purchase Periods) on an Offering Date or Offering Dates selected by the Board. Each Offering shall be in such form and shall contain such terms and conditions as the Board shall deem

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appropriate, which shall comply with the requirement of Section 423(b)(5) of the Code that all Employees granted Purchase Rights shall have the same rights and privileges. The terms and conditions of an Offering shall be incorporated by reference into the Plan and treated as part of the Plan. The provisions of separate Offerings need not be identical, but each Offering shall include (through incorporation of the provisions of this Plan by reference in the document comprising the Offering or otherwise) the period during which the Offering shall be effective, which period shall not exceed twenty-seven (27) months beginning with the Offering Date, and the substance of the provisions contained in Sections 6 through 9, inclusive.

(b) If a Participant has more than one Purchase Right outstanding under the Plan, unless he or she otherwise indicates in agreements or notices delivered hereunder: (i) each agreement or notice delivered by that Participant shall be deemed to apply to all of his or her Purchase Rights under the Plan, and (ii) a Purchase Right with a lower exercise price (or an earlier-granted Purchase Right, if different Purchase Rights have identical exercise prices) shall be exercised to the fullest possible extent before a Purchase Right with a higher exercise price (or a later-granted Purchase Right if different Purchase Rights have identical exercise prices) shall be exercised.

## 6. ELIGIBILITY.

(a) Purchase Rights may be granted only to Employees of the Company or, as the Board may designate as provided in Section 3(b), to Employees of a Related Corporation. Except as provided in Section 6(b), an Employee shall not be eligible to be granted Purchase Rights under the Plan unless, on the Offering Date, such Employee has been in the employ of the Company or the Related Corporation, as the case may be, for such continuous period preceding such Offering Date as the Board may require, but in no event shall the required period of continuous employment be greater than two (2) years. In addition, the Board may provide that no Employee shall be eligible to be granted Purchase Rights under the Plan unless, on the Offering Date, such Employee's customary employment with the Company or the Related Corporation is more than twenty (20) hours per week and more than five (5) months per calendar year.

(b) The Board may provide that each person who, during the course of an Offering, first becomes an Eligible Employee shall, on a date or dates specified in the Offering which coincides with the day on which such person becomes an Eligible Employee or which occurs thereafter, receive a Purchase Right under that Offering, which Purchase Right shall thereafter be deemed to be a part of that Offering. Such Purchase Right shall have the same characteristics as any Purchase Rights originally granted under that Offering, as described herein, except that:

(i) the date on which such Purchase Right is granted shall be the "Offering Date" of such Purchase Right for all purposes, including determination of the exercise price of such Purchase Right;

(ii) the period of the Offering with respect to such Purchase Right shall begin on its Offering Date and end coincident with the end of such Offering; and

(iii) the Board may provide that if such person first becomes an Eligible Employee within a specified period of time before the end of the Offering, he or she shall not receive any Purchase Right under that Offering.

(c) No Employee shall be eligible for the grant of any Purchase Rights under the Plan if, immediately after any such Purchase Rights are granted, such Employee owns stock possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of the Company or of any Related Corporation. For purposes of this Section 6(c), the rules of Section 424(d) of the Code shall apply in determining the stock ownership of any Employee, and stock which such

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Employee may purchase under all outstanding Purchase Rights and options shall be treated as stock owned by such Employee.

(d) As specified by Section 423(b)(8) of the Code, an Eligible Employee may be granted Purchase Rights under the Plan only if such Purchase Rights, together with any other rights granted under all Employee Stock Purchase Plans of the Company and any Related Corporations, do not permit such Eligible Employee's rights to purchase stock of the Company or any Related Corporation to accrue at a rate which exceeds twenty five thousand dollars (\$25,000) of Fair Market Value of such stock (determined at the time such rights are granted, and which, with respect to the Plan, shall be determined as of their respective Offering Dates) for each calendar year in which such rights are outstanding at any time.

(e) Officers of the Company and any designated Related Corporation, if they are otherwise Eligible Employees, shall be eligible to participate in Offerings under the Plan. Notwithstanding the foregoing, the Board may provide in an Offering that Employees who are highly compensated Employees within the meaning of Section 423(b)(4)(D) of the Code shall not be eligible to participate.

## 7. PURCHASE RIGHTS; PURCHASE PRICE.

(a) On each Offering Date, each Eligible Employee, pursuant to an Offering made under the Plan, shall be granted a Purchase Right to purchase up to that number of shares of Common Stock purchasable either with a percentage or with a maximum dollar amount, as designated by the Board, but in either case not exceeding fifteen percent (15%), of such Employee's Earnings (as defined by the Board in each Offering) during the period that begins on the Offering Date (or such later date as the Board determines for a particular Offering) and ends on the date stated in the Offering, which date shall be no later than the end of the Offering.

(b) The Board shall establish one (1) or more Purchase Dates during an Offering as of which Purchase Rights granted pursuant to that Offering shall be exercised and purchases of shares of Common Stock shall be carried out in accordance with such Offering.

(c) In connection with each Offering made under the Plan, the Board may specify a maximum number of shares of Common Stock that may be purchased by any Participant on any Purchase Date during such Offering. In connection with each Offering made under the Plan, the Board may specify a maximum aggregate number of shares of Common Stock that may be purchased by all Participants pursuant to such Offering. In addition, in connection with each Offering

that contains more than one Purchase Date, the Board may specify a maximum aggregate number of shares of Common Stock that may be purchased by all Participants on any given Purchase Date under the Offering. If the aggregate purchase of shares of Common Stock issuable upon exercise of Purchase Rights granted under the Offering would exceed any such maximum aggregate number, then, in the absence of any Board action otherwise, a pro rata allocation of the shares of Common Stock available shall be made in as nearly a uniform manner as shall be practicable and equitable.

- (d) The purchase price of shares of Common Stock acquired pursuant to Purchase Rights shall be not less than the lesser of:
  - (i) an amount equal to eighty-five percent (85%) of the Fair Market Value of the shares of Common Stock on the Offering Date; or
  - (ii) an amount equal to eighty-five percent (85%) of the Fair Market Value of the shares of Common Stock on the applicable Purchase Date.

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## 8. PARTICIPATION; WITHDRAWAL; TERMINATION.

(a) A Participant may elect to authorize payroll deductions pursuant to an Offering under the Plan by completing and delivering to the Company, within the time specified in the Offering, an enrollment form (in such form as the Company may provide). Each such enrollment form shall authorize an amount of Contributions expressed as a percentage of the submitting Participant's Earnings (as defined in each Offering) during the Offering (not to exceed the maximum percentage specified by the Board). Each Participant's Contributions shall be credited to a bookkeeping account for such Participant under the Plan and shall be deposited with the general funds of the Company except where applicable law requires that Contributions be deposited with a third party. To the extent provided in the Offering, a Participant may begin such Contributions after the beginning of the Offering. To the extent provided in the Offering, a Participant may thereafter reduce (including to zero) or increase his or her Contributions.

(b) During an Offering, a Participant may cease making Contributions and withdraw from the Offering by delivering to the Company a notice of withdrawal in such form as the Company may provide. Such withdrawal may be elected at any time prior to the end of the Offering, except as provided otherwise in the Offering. Upon such withdrawal from the Offering by a Participant, the Company shall distribute to such Participant all of his or her accumulated Contributions (reduced to the extent, if any, such deductions have been used to acquire shares of Common Stock for the Participant) under the Offering, and such Participant's Purchase Right in that Offering shall thereupon terminate. A Participant's withdrawal from an Offering shall have no effect upon such Participant's eligibility to participate in any other Offerings under the Plan, but such Participant shall be required to deliver a new enrollment form in order to participate in subsequent Offerings.

(c) Purchase Rights granted pursuant to any Offering under the Plan shall terminate immediately upon a Participant ceasing to be an Employee for any reason or for no reason (subject to any post-employment participation period required by law) or other lack of eligibility. The Company shall distribute to such terminated or otherwise ineligible Employee all of his or her accumulated Contributions (reduced to the extent, if any, such deductions have been used to acquire shares of Common Stock for the terminated or otherwise ineligible Employee) under the Offering.

(d) Purchase Rights shall not be transferable by a Participant otherwise than by will or the laws of descent and distribution, or by a beneficiary designation as provided in Section 13 and, during a Participant's lifetime, shall be exercisable only by such Participant.

(e) Unless otherwise specified in an Offering, the Company shall have no obligation to pay interest on Contributions.

## 9. EXERCISE.

(a) On each Purchase Date during an Offering, each Participant's accumulated Contributions shall be applied to the purchase of shares of Common Stock up to the maximum number of shares of Common Stock permitted pursuant to the terms of the Plan and the applicable Offering, at the purchase price specified in the Offering. No fractional shares shall be issued upon the exercise of Purchase Rights unless specifically provided for in the Offering.

(b) If any amount of accumulated Contributions remains in a Participant's account after the purchase of shares of Common Stock and such remaining amount is less than the amount required to purchase one share of Common Stock on the final Purchase Date of an Offering, then such remaining amount shall be held in such Participant's account for the purchase of shares of Common Stock under the next Offering under the Plan, unless such Participant withdraws from such next Offering, as provided in Section 8(b), or is not eligible to participate in such Offering, as provided in Section 6, in which case such amount shall be distributed to such Participant after the final Purchase Date, without

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interest. If the amount of Contributions remaining in a Participant's account after the purchase of shares of Common Stock is at least equal to the amount required to purchase one (1) whole share of Common Stock on the final Purchase Date of the Offering, then such remaining amount shall be distributed in full to such Participant at the end of the Offering.

(c) No Purchase Rights may be exercised to any extent unless the shares of Common Stock to be issued upon such exercise under the Plan are covered by an effective registration statement pursuant to the Securities Act and the Plan is in material compliance with all applicable federal, state, foreign and other securities and other laws applicable to the Plan. If on a Purchase Date during any Offering hereunder the shares of Common Stock are not so registered or the Plan is not in such compliance, no Purchase Rights or any Offering shall be exercised on such Purchase Date, and the Purchase Date shall be delayed until the shares of Common Stock are subject to such an effective registration statement and the Plan is in such compliance, except that the Purchase Date shall not be delayed more than twelve (12) months and the Purchase Date shall in no event be more than twenty-seven (27) months from the Offering Date. If, on the Purchase Date under any Offering hereunder, as delayed to the maximum extent permissible, the shares of Common Stock are not registered and the Plan is not in such compliance, no Purchase Rights or any Offering shall be exercised and all Contributions accumulated during the Offering (reduced to the extent, if any, such deductions have been used to acquire shares of Common Stock) shall be distributed to the Participants.

## 10. COVENANTS OF THE COMPANY.

The Company shall seek to obtain from each federal, state, foreign or other regulatory commission or agency having jurisdiction over the Plan such authority as may be required to issue and sell shares of Common Stock upon exercise of the Purchase Rights. If, after commercially reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of shares of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell shares of Common Stock upon exercise of such Purchase Rights unless and until such authority is obtained.

#### **11. USE OF PROCEEDS FROM SHARES OF COMMON STOCK.**

Proceeds from the sale of shares of Common Stock pursuant to Purchase Rights shall constitute general funds of the Company.

#### **12. RIGHTS AS A STOCKHOLDER.**

A Participant shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, shares of Common Stock subject to Purchase Rights unless and until the Participant's shares of Common Stock acquired upon exercise of Purchase Rights are recorded in the books of the Company (or its transfer agent).

#### **13. DESIGNATION OF BENEFICIARY.**

(a) A Participant may file a written designation of a beneficiary who is to receive any shares of Common Stock and/or cash, if any, from the Participant's account under the Plan in the event of such Participant's death subsequent to the end of an Offering but prior to delivery to the Participant of such shares of Common Stock or cash. In addition, a Participant may file a written designation of a beneficiary who is to receive any cash from the Participant's account under the Plan in the event of such Participant's death during an Offering.

(b) The Participant may change such designation of beneficiary at any time by written notice to the Company. In the event of the death of a Participant and in the absence of a beneficiary validly designated under the Plan who is living at the time of such Participant's death, the Company shall

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deliver such shares of Common Stock and/or cash to the executor or administrator of the estate of the Participant, or if no such executor or administrator has been appointed (to the knowledge of the Company), the Company, in its sole discretion, may deliver such shares of Common Stock and/or cash to the spouse or to any one or more dependents or relatives of the Participant, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.

#### **14. ADJUSTMENTS UPON CHANGES IN SECURITIES; CORPORATE TRANSACTIONS.**

(a) If any change is made in the shares of Common Stock, subject to the Plan, or subject to any Purchase Right, without the receipt of consideration by the Company (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by the Company), the Plan shall be appropriately adjusted in the type(s), class(es) and maximum number of shares of Common Stock subject to the Plan pursuant to Section 4(a), and the outstanding Purchase Rights shall be appropriately adjusted in the type(s), class(es), number of shares and purchase limits of such outstanding Purchase Rights. The Board shall make such adjustments, and its determination shall be final, binding and conclusive. (The conversion of any convertible securities of the Company shall not be treated as a "transaction not involving the receipt of consideration by the Company.")

(b) In the event of a Corporate Transaction, then: (i) any surviving or acquiring corporation may continue or assume Purchase Rights outstanding under the Plan or may substitute similar rights (including a right to acquire the same consideration paid to stockholders in the Corporate Transaction) for those outstanding under the Plan, or (ii) if any surviving or acquiring corporation does not continue or assume such Purchase Rights or does not substitute similar rights for Purchase Rights outstanding under the Plan, then, the Participants' accumulated Contributions shall be used to purchase shares of Common Stock within ten (10) business days prior to the Corporate Transaction under the ongoing Offering, and the Participants' Purchase Rights under the ongoing Offering shall terminate immediately after such purchase.

#### **15. AMENDMENT OF THE PLAN.**

(a) The Board at any time, and from time to time, may amend the Plan. However, except as provided in Section 14 relating to adjustments upon changes in securities and except as to amendments solely to benefit the administration of the Plan, to take account of a change in legislation or to obtain or maintain favorable tax, exchange control or regulatory treatment for Participants or the Company or any Related Corporation, no amendment shall be effective unless approved by the stockholders of the Company to the extent stockholder approval is necessary for the Plan to satisfy the requirements of Section 423 of the Code or other applicable laws or regulations.

(b) It is expressly contemplated that the Board may amend the Plan in any respect the Board deems necessary or advisable to provide Employees with the maximum benefits provided or to be provided under the provisions of the Code and the regulations promulgated thereunder relating to Employee Stock Purchase Plans and/or to bring the Plan and/or Purchase Rights into compliance therewith.

(c) The rights and obligations under any Purchase Rights granted before amendment of the Plan shall not be impaired by any amendment of the Plan except: (i) with the consent of the person to whom such Purchase Rights were granted, or (ii) as necessary to comply with any laws or governmental regulations (including, without limitation, the provisions of the Code and the regulations promulgated thereunder relating to Employee Stock Purchase Plans).

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#### **16. TERMINATION OR SUSPENSION OF THE PLAN.**



(a) The Board in its discretion may suspend or terminate the Plan at any time. Unless sooner terminated, the Plan shall terminate at the time that all of the shares of Common Stock reserved for issuance under the Plan, as increased and/or adjusted from time to time, have been issued under the terms of the Plan. No Purchase Rights may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) Any benefits, privileges, entitlements and obligations under any Purchase Rights while the Plan is in effect shall not be impaired by suspension or termination of the Plan except (i) as expressly provided in the Plan or with the consent of the person to whom such Purchase Rights were granted, (ii) as necessary to comply with any laws, regulations, or listing requirements, or (iii) as necessary to ensure that the Plan and/or Purchase Rights comply with the requirements of Section 423 of the Code.

#### **17. EFFECTIVE DATE OF PLAN.**

The Plan shall become effective as determined by the Board, but no Purchase Rights shall be exercised unless and until the Plan has been approved by the stockholders of the Company within twelve (12) months before or after the date the Plan is adopted by the Board.

#### **18. MISCELLANEOUS PROVISIONS.**

(a) The Plan and Offering do not constitute an employment contract. Nothing in the Plan or in the Offering shall in any way alter the at will nature of a Participant's employment or be deemed to create in any way whatsoever any obligation on the part of any Participant to continue in the employ of the Company or a Related Corporation, or on the part of the Company or a Related Corporation to continue the employment of a Participant.

(b) The provisions of the Plan shall be governed by the laws of the State of California without resort to that state's conflicts of laws rules.

#### QuickLinks

[Exhibit 10.43](#)

[INHALE THERAPEUTIC SYSTEMS EMPLOYEE STOCK PURCHASE PLAN  
ADOPTED BY THE BOARD OF DIRECTORS FEBRUARY 10, 1994 APPROVED BY STOCKHOLDERS FEBRUARY 18, 1994 AMENDED AND  
RESTATED MAY 10, 2002 APPROVED BY STOCKHOLDERS JUNE 25, 2002](#)

**CERTIFICATION**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C § 1350, as adopted), Ajit S. Gill, Chief Executive Officer and President of Inhale Therapeutic Systems, Inc. (the "Company"), and Brigid A. Makes, Vice President, Finance and Administration and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2002, to which this Certification is attached as Exhibit 99.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: August 14, 2002

/s/ AJIT S. GILL

/s/ BRIGID A. MAKES

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Ajit S. Gill  
*Chief Executive Officer and President*

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

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QuickLinks

[Exhibit 99.1](#)