

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2001

or,

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

For the transition period from _____ to _____

Commission File Number: 0-23556

INHALE THERAPEUTIC SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(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 51,504,673 as of April 30, 2001.

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)

| | March 31, 2001 | December 31, 2000 |
|---|-------------------|-------------------|
| | (unaudited) | * |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 80,042 | \$ 136,012 |
| Short-term investments | 373,839 | 348,829 |
| Accounts receivable | 3,333 | 7,234 |
| Other current assets | 7,683 | 968 |
| | <u>464,897</u> | <u>493,043</u> |
| Property and equipment, net | 119,867 | 110,457 |
| Marketable equity securities | 3,444 | 9,140 |
| Goodwill and other intangibles | 87,888 | 4,969 |
| Deposits and other assets | 11,047 | 11,931 |
| | <u>\$ 687,143</u> | <u>\$ 629,540</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | \$ 28,351 | \$ 24,313 |
| Capital lease—current portion | 977 | 977 |
| Deferred revenue | 10,144 | 4,913 |
| | <u>39,472</u> | <u>30,203</u> |
| Total current liabilities | 39,472 | 30,203 |
| Capital lease obligation | 18,791 | 15,269 |
| Convertible subordinated notes and debentures | 299,149 | 299,149 |
| Accrued rent | 2,131 | 2,010 |
| Other long-term liabilities | 7,068 | 5,026 |
| Stockholders' equity: | | |
| Common stock, \$0.0001 par value; 300,000 shares authorized; 51,485 shares and 47,374 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively | 5 | 5 |
| Capital in excess of par value | 594,220 | 465,593 |
| Deferred compensation | (1,553) | (1,827) |
| Accumulated other comprehensive gain | 770 | 5,981 |
| Accumulated deficit | (272,910) | (191,869) |
| | <u>320,532</u> | <u>277,883</u> |
| Total stockholders' equity | 320,532 | 277,883 |
| | <u>\$ 687,143</u> | <u>\$ 629,540</u> |

See accompanying notes.

The balance sheet at December 31, 2000 has been derived from the audited financial statements at that date which are included in the Company's Form 10-K, as amended, for the year ended December 31, 2000 as filed with the Securities and Exchange Commission. This balance sheet does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

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

| | Three Months Ended March 31, | |
|---|------------------------------|--------------------|
| | 2001 | 2000 |
| Contract research revenue | \$ 14,097 | \$ 10,633 |
| Operating costs and expenses: | | |
| Research and development | 30,271 | 21,683 |
| General and administrative | 4,018 | 3,535 |
| Purchased in-process research and development | 62,660 | — |
| Amortization of goodwill and intangible assets | 3,079 | 186 |
| Total operating costs and expenses | 100,028 | 25,404 |
| Loss from operations | (85,931) | (14,771) |
| Other income/(loss) | (78) | — |
| Debt conversion premium, net | — | (15,157) |
| Interest income | 7,705 | 3,627 |
| Interest expense | (2,737) | (2,531) |
| Net loss | \$ (81,041) | \$ (28,832) |
| Basic and diluted net loss per share | \$ (1.59) | \$ (0.76) |
| Shares used in basic and diluted net loss per share calculation | 51,078 | 38,068 |

See accompanying notes.

INHALE THERAPEUTIC SYSTEMS, INC.
Increase/(Decrease) in Cash and Cash Equivalents
(in thousands)
(unaudited)

| | Three Months Ended March 31, | |
|--|------------------------------|------------|
| | 2001 | 2000 |
| Cash flows from operating activities: | | |
| Net cash used in operations | \$ (12,832) | \$ (1,890) |
| Cash flows from investing activities: | | |
| Acquisition of Bradford Particle Design, plc, net of cash | (14,825) | — |
| Purchases of short-term investments, net of sales and maturities | (24,525) | (101,298) |
| Purchases of property and equipment, net | (10,119) | (13,583) |
| Other investing activities | (21) | (115) |
| Net cash used in investing activities | (49,490) | (114,996) |
| Cash flows from financing activities: | | |
| Proceeds from capital lease financing | 3,699 | — |
| Payments of capital lease and equipment financing obligations | (186) | (18) |
| Payments of debt conversion premium, net | — | (16,569) |
| Issuance of convertible subordinated debentures and notes, net | — | 222,439 |
| Issuance of common stock, net of issuance costs | 2,839 | 7,382 |
| Net cash provided by financing activities | 6,352 | 213,234 |
| Net increase/(decrease) in cash and cash equivalents | (55,970) | 96,348 |

| | | |
|--|-----------|------------|
| Cash and cash equivalents at beginning of period | 136,012 | 33,430 |
| Cash and cash equivalents at end of period | \$ 80,042 | \$ 129,778 |

See accompanying notes.

INHALE THERAPEUTIC SYSTEMS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2001

(Unaudited)

1. Organization and Basis of Presentation

Inhale Therapeutic Systems, Inc. was incorporated in the State of California in July 1990 and reincorporated in the State of Delaware in July 1998. During 2000, we created two wholly-owned subsidiaries: Inhale Therapeutic Systems Deutschland GmbH, incorporated in the Federal Republic of Germany; and Inhale Therapeutic Systems UK Limited, incorporated in the United Kingdom and consolidated the financial statements of a special purpose entity lessor. Since inception, we have been engaged in the development of systems for the pulmonary delivery of macromolecule drug therapies for systemic and local lung applications. The scope of our technology has expanded with the recent acquisition of Bradford Particle Design, plc ("Bradford"), a United Kingdom Company, which provides additional pulmonary capabilities as well as other routes of drug delivery including oral and injectable.

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

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

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

We have prepared the accompanying unaudited condensed consolidated financial statements in accordance with generally accepted accounting principles for interim financial information, the instructions for Form 10-Q and Article 10 of Regulation S-X. The condensed consolidated balance sheet as of March 31, 2001 and the related condensed consolidated statements of operations and cash flows for the three month periods ended March 31, 2001 and 2000, are unaudited but include all adjustments (consisting only of normal recurring adjustments) which we consider necessary for a fair presentation of the financial position at such dates and the operating results and cash flows for those periods. Although we believe that the disclosures in these financial statements are adequate to make the information presented not misleading, certain information normally included in financial statements and related footnotes prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the "Commission"). The accompanying financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K, as amended, for the year ended December 31, 2000, as filed with the Commission.

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

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

2. Principles of Consolidation

Our consolidated financial statements include the accounts of Inhale Therapeutic Systems, Inc., our wholly owned subsidiaries, the financial statements of a special purpose entity created to finance and manage construction of our new lab and office facility and the accounts of Bradford, our recently acquired subsidiary (See Note 6 "Acquisition of Bradford Particle Design, plc). All significant intercompany balances and transactions have been eliminated.

3. Comprehensive Loss

Other comprehensive gains and losses consist primarily of unrealized gains or losses on available-for-sale securities. For the three-month period ended March 31, 2001, we recorded unrealized losses of approximately \$5.1 million, consisting of approximately \$5.7 million of losses relating to our investment in Alliance Pharmaceutical, Inc. and approximately \$0.6 million of gains in other available-for-sale investments. For the three-month period ended March 31, 2000, we recorded unrealized gains of approximately \$8.2 million, consisting of approximately \$8.3 million of gains relating to our investment in Alliance and approximately \$0.1 million of losses in other available for sale investments.

4. Revenue Recognition

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

Contract research revenue from one partner represented 74% of our revenue in the three-month period ended March 31, 2001. Contract research revenue from one partner accounted for 66% of our revenue in the three-month period ended March 31, 2000. Costs of contract research revenue approximate such revenue and are included in operating costs and expenses.

5. Net Loss Per Share

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

6. Acquisition of Bradford Particle Design, plc.

In January 2001, we acquired all of the outstanding share capital of Bradford in exchange for approximately 3.75 million newly issued shares of our common stock and approximately \$20.4 million in cash. The acquisition was accounted for under the purchase method of accounting. Of the total purchase consideration of \$152.1 million, \$89.4 million was allocated to the assets acquired based on their fair value on the date of acquisition, including \$85.8 million in goodwill and other intangible assets and estimated acquisitions costs of \$4.0 million. Approximately \$62.7 million of the purchase price was allocated to in-process research and development ("IPR&D") which was charged to expense in the quarter ended March 31, 2001. At the date of the acquisition, we concluded that the IPR&D technology had no alternative future use and did not qualify for capitalization. The results of operations for Bradford for the period from January 31, 2001 through March 31, 2001 are included in Inhale's condensed consolidated income statement for the quarter ended March 31, 2001.

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The following table summarizes the values assigned to Bradford's goodwill and intangible assets and their current net carrying value on our balance sheet at March 31, 2001.

| | Amount | Useful Life |
|--|----------------|----------------|
| | (in thousands) | (months) |
| Goodwill | \$ 78,605 | 60 |
| Intellectual property | 4,130 | 60 |
| Workforce-in-place | 840 | 36 |
| Customer relations | 2,240 | 60 |
| | <hr/> | |
| Total goodwill and intangible assets acquired | 85,815 | |
| Less accumulated amortization | (2,879) | |
| | <hr/> | |
| Net goodwill and intangible assets at March 31, 2001 | \$ 82,936 | |

Bradford's results of operations included in these pro forma financial statements are derived from its unaudited financial statements for the three months ended March 31, 2001 and 2000 respectively. Bradford's financial statements included in the pro forma information as of all dates and for all periods presented have been adjusted, where appropriate, to present Bradford's financial position and results of operations in accordance with generally accepted accounting principles in the United States.

The unaudited pro forma net loss and loss per share amounts do not include a charge for purchased research and development of \$62.7 million. The pro forma results also reflect amortization of goodwill and other intangible assets.

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

The following unaudited pro forma results of operations of the company for the three-month periods ended March 31, 2001 and 2000, respectively, assumes the acquisition of Bradford has been accounted for using the purchase method of accounting as of January 1, 2000 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.

| | Three Months Ended March 31, 2000 Pro Forma | | Three Months Ended March 31, 2001 Pro Forma |
|--|---|----|---|
| | (unaudited) | | (unaudited) |
| <i>(in thousands, except loss per share)</i> | | | |
| Contract research revenue | \$ 13,347 | \$ | 14,185 |
| Net loss | \$ (29,242) | \$ | (20,456) |
| Net loss per share | \$ (0.70) | \$ | (0.40) |

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This Management's Discussion and Analysis of Financial Condition and Results of Operations for the three months ended March 31, 2001 and 2000 should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations included in Inhale's Annual Report on Form 10-K, as amended, for the year ended December 31, 2000. The following discussion contains forward-looking statements that involve risk and uncertainties. Inhale's actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this section and under the heading "Risk Factors" as well as those discussed in Inhale's Annual Report on Form 10-K, as amended, for the year ended December 31, 2000.

Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date hereof. Inhale undertakes no obligation to publicly release the results of any revision to these forward-looking statements which may be made to reflect events or circumstances occurring after the date hereof or to reflect the occurrence of unanticipated events.

Overview

Since our inception in July 1990, we have been engaged in the development of a drug delivery system to deliver a wide range of drugs, including peptides, proteins, nucleic acids and other molecules, by inhalation to the deep lung. As part of our long-term goal to be the pre-eminent provider of drug delivery solutions, we have recently expanded our development of drug delivery to include additional pulmonary capabilities and other methods of delivery. Through our acquisition of Bradford we have acquired additional technology and collaborations relating to the development of a proprietary process for making drug particles using a technique known as supercritical fluids. This process is broadly applicable across a wide range of molecules that can be delivered by oral, injectable and pulmonary routes. We have been unprofitable since inception and expect to incur significant and increasing additional operating losses over the next several years primarily due to increasing research and development expenditures and expansion of late stage clinical and early stage commercial manufacturing facilities. To date, we have not sold any commercial products and do not anticipate receiving revenue from product sales or royalties in the near future. For the period from inception through March 31, 2001, we incurred a cumulative net loss of approximately \$272.9 million. Our sources of working capital have been equity and debt financings, revenues from development contracts and short-term research and feasibility agreements, financings of equipment acquisitions and tenant improvements and interest earned on investments of cash.

We have generally been compensated for research and development expenses during initial feasibility work performed under collaborative arrangements. Partners that enter into collaborative agreements generally pay for some or all research and development expenses and make additional payments to us as we achieve certain key milestones. We expect to receive royalties from our partners based on their revenues received from product sales, and under certain agreements to receive revenue from the manufacturing of powders and the supply of devices. In certain cases, we may enter into collaborative agreements under which our partners would manufacture or package powders or supply inhalation devices, thereby potentially limiting one or more sources of revenue for us. To achieve and sustain profitable operations, we, alone or with others, must successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products utilizing our pulmonary 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.

In January 2001 we issued 3,752,456 shares of our common stock to the holders of all of the existing issued ordinary share capital of Bradford. We issued these shares as partial consideration for

the acquisition of the outstanding share capital of Bradford in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended, pursuant to Regulation D and Regulation S promulgated under the Act. For each share of Bradford's common stock we issued 1.8354 new shares of our common stock and paid approximately \$9.80 cash, for an aggregate cash payment of approximately \$20.4 million.

Results of Operations

Revenue in the first quarter of 2001 was \$14.1 million compared to \$10.6 million in the first quarter of 2000, an increase of approximately 33%. The increase in revenue was primarily due to the expansion of our existing collaborative agreements and includes activities associated with the manufacture of Phase III clinical supplies for the insulin program. Revenue for the first quarter of 2001 and 2000 was comprised of reimbursed research and development expenses as well as the amortization of the pro-rata portion of up-front signing and progress payments received from our collaborative partners. Recognition of up-front signing and progress payments is based on actual period of continued involvement. Costs of contract research revenue approximate such revenue and are included in research and development expenses.

Research and development expenses increased to approximately \$30.3 million in the first quarter of 2001 from \$21.7 million in the corresponding period of 2000, an increase of approximately 40%. The increase was due to increased spending related to the scale-up of technologies and the continuing development of manufacturing capabilities for both inhalation devices and drug powders in order to support Phase III inhaleable insulin clinical trials and commercial operations, the expansion of our partnered projects, as well as our internally funded projects. We expect research, development and process development spending to increase over the next few years as we expand our development efforts under collaborative agreements and scale up our commercial manufacturing facility.

General and administrative expenses increased to \$4.0 million in the first quarter of 2001 from \$3.5 million in the first quarter of 2000, an increase of approximately 14%. The increase in such expenses in 2001 was due primarily to costs associated with supporting our increased manufacturing and development efforts, including administrative staffing, business development and marketing activities. General and administrative expenses are expected to continue to increase over the next few years as we expand our operations

Interest income was \$7.7 million in the first quarter of 2001, compared to \$3.6 million in the first quarter of 2000. The 114% increase reflects larger cash and investment balances available for the entire 2001 quarter, compared to only a portion of the year 2000 quarter, the issuance of our convertible subordinated notes in February 2000, as well as higher available interest rates. Interest expense was \$2.7 million in the first quarter of 2001, compared to \$2.5 million in the first quarter of 2000. In addition, in the first quarter of 2000, we paid approximately \$15.2 million of a conversion premium to holders of the Company's convertible subordinated debentures issued in October 1999, to convert \$98.7 million aggregate principal amount of outstanding convertible subordinated debentures into approximately 6.2 million shares of Inhale's common stock.

Acquired In-process Research and Development

In January 2001 we acquired all of the outstanding share capital of Bradford in exchange for approximately 3.75 million in newly issued shares of our common stock and approximately \$20.4 million in cash. Of the total purchase consideration of \$152.1 million, \$89.4 million was allocated to the assets acquired based on their fair value on the date of acquisition, including \$85.8 million in goodwill and other intangible assets. Approximately \$62.7 million of the purchase price was

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. At March 31, 2001, we had cash, cash equivalents and short-term investments of approximately \$453.9 million.

Our operations used cash of \$12.8 million in the three months ended March 31, 2001, as compared to \$1.9 million used in the three months ended March 31, 2000. These amounts differed from our net operating losses in these periods principally due to increased depreciation and amortization charges and debt conversion incentives. In addition, we recorded a \$62.7 million of IPR&D charges in the quarter ended March 31, 2001. (See "Acquired In-process Research and Development" above).

We purchased property and equipment of \$10.1 million during the three months ended March 31, 2001, compared to \$13.6 million for the corresponding period in 2000. The decrease in purchased property and equipment reflects completion of the first phase of construction of a new San Carlos lab and office facility, balanced by continued investment in our commercial manufacturing facilities, including device manufacturing at third-party contract manufacturers, and expansion of our San Carlos powder processing facilities. Also, in connection with our acquisition of Bradford, we paid net cash of \$14.8 million, which represents cash paid to Bradford shareholders of \$20.4 million, net of Bradford's cash balance of \$5.6 million. The remainder of the acquisition costs was non-cash in nature (See "Acquired In-process Research and Development" above).

Cash flows from financing activities were \$6.4 million for the quarter ending March 31, 2001 as compared to \$213.2 million for the same period in 2000 due primarily to the issuance of convertible subordinated notes which netted approximately \$222.4 million. Also in February 2000, we paid a debt conversion premium of approximately \$15.2 million to convert \$98.7 million of our 6³/₄% convertible subordinated debentures sold in October 1999, into approximately 6.2 million shares of common stock.

We expect our cash requirements to continue at an accelerated rate due to expected increases in costs associated with further research and development of our technologies, development of drug formulations, process development for the manufacture and filling of powders and devices for our deep lung drug delivery system, marketing and general and administrative costs. These expenses include debt service costs, increases in personnel and personnel related costs, purchases of capital equipment, investments in technologies, inhalation device prototype construction and facilities expansion, including the completion of our manufacturing facility and start-up of commercial operations. In addition, the balance of our convertible subordinated debentures and notes will come due in 2006 and 2007, respectively.

Given our current cash requirements, we believe that we will have sufficient cash to meet our operating expense requirements for at least the next 29 months. However, we plan to continue to invest heavily in our growth and the need for cash will be dependent upon the timing of these investments. Our capital needs will depend on many factors, including continued scientific progress in our research and development arrangements, potential acquisitions of technologies or business operations, progress with preclinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs of developing and the rate of scale-up of our powder processing and packaging technologies, the timing and cost of our late stage clinical and early commercial production facility, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, the need to acquire licenses to new technologies and the status of competitive products. To satisfy our long-term needs, we intend to seek additional funding, as necessary, from corporate partners and from the sale of securities. There can be no assurance that additional funds, if and when required, will be available to us on favorable terms, if at all.

RISK FACTORS

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

We do not know if our deep lung and other drug delivery technologies are commercially feasible.

We are in an early stage of development. There is a risk that our deep lung and other drug delivery technologies will not be commercially feasible. Even if our deep lung and other delivery technologies are commercially feasible, they may not be commercially accepted across a range of large and small molecule drugs. We have tested twelve deep lung delivery formulations in humans, but many of our potential formulations have not been tested in humans. In particular, the technology recently acquired through our acquisition of Bradford is primarily in the early stage of feasibility, with only one formulation in clinical testing.

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

We do not know if our deep lung and other drug delivery technologies are efficient.

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

We do not know if our deep lung and other drug formulations are stable.

We may not be able to identify and produce powdered formulations of drugs that retain the physical and chemical properties needed to work with our delivery device for deep lung delivery. Formulation stability is the physical and chemical stability of the drug over time and under various storage, shipping and usage conditions. Formulation stability will vary with each deep lung or other formulation and the type and amount of ingredients that are used in the formulation. Problems with powdered drug stability in particular would negatively impact our ability to develop and market our potential deep lung delivery products or obtain regulatory approval.

We do not know if our deep lung and other drug delivery technologies are safe.

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

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We do not know if our deep lung and other drug delivery technologies provide consistent doses of medicine.

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

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

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

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

Because we are in the business of developing technology for delivering drugs to the lungs, producing improved particles 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. If our partner fails to do any of these things, we cannot complete the development of the product.

We may not obtain regulatory approval for our products on a timely basis, or at all.

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

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

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

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

We may not be able to integrate all of the relevant technologies to provide complete deep lung or other drug delivery system. In particular, our integrated approach to systems development for deep lung drug delivery relies upon several different but related technologies:

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

Other drug delivery technologies that we are developing including supercritical fluids, present 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 therapeutic products using our deep lung and other delivery technologies.

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

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

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

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

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

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

Supercritical fluids. The supercritical fluids technology we recently acquired through our acquisition of Bradford is still in research and development and it represents a new method of particle manufacturing. Only one product has entered human clinical testing. There is no assurance that this technology will accomplish its objective of reducing the manufacturing process to a single step to overcome certain problems inherent in multi-stage manufacturing technology for certain conventional drugs. There is no assurance that pharmaceutical manufacturers will be willing to introduce new manufacturing methods into their operations including the development and regulatory risk that is inherent in any new process. Adoption of this technology will depend on many factors including:

- the benefits that this technology provides versus existing alternatives
- the ability to scale-up this technology; and
- the development of alternative competitive processes.

For late stage clinical trials and initial commercial production, we intend to use one or more contract manufacturers to produce our drug delivery devices. There is a risk that we will not be able to establish or maintain arrangements with our potential contract manufacturers or effectively scale-up production of our drug delivery devices through contract manufacturers. Our failure to do so would negatively impact our revenues and results of operations. Additionally, any sudden or protracted interruption in our operations or the operations of our contract manufacturers could result in loss of product in the process of being developed or manufactured. A number of factors could cause interruptions, including equipment malfunctions or failures, or damage to a facility due to a natural disaster, or the unavailability of energy due to rolling blackouts or other disruptions in the supply of energy to our facilities. Because our manufacturing processes and those of our contract manufactures are very complex and subject to lengthy governmental approval processes, alternative qualified production sources or capacity may not be available on a timely basis or at all. Disruptions or delays in our manufacturing processes or those of our contract manufacturers for existing or new products could result in increased costs, loss of revenues or market share, or damage to our reputation.

We depend on sole or exclusive suppliers for our inhalation device and bulk drugs.

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

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

We do not know if the market will accept our deep lung or other drug delivery systems.

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

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

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

If our products are not cost effective, government and private insurance plans may not pay for them.

In both domestic and foreign markets, sales of our products under development will depend in part upon the availability of reimbursement from third-party payors, such as government health administration authorities, managed care providers, private health insurers and other organizations. In addition, such third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Legislation and regulations affecting the pricing of pharmaceuticals may change before our proposed products are approved for marketing. Adoption of such legislation and regulations could further limit reimbursement for medical products. A government or third-party payor decision to not provide adequate coverage and reimbursements for our products would limit market acceptance of such products.

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

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

Integration of personnel and operations relating to our acquisition of Bradford may disrupt our business and management

Our acquisition of Bradford 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 often decide to pursue other opportunities. In addition, there may be complications if we

attempt to integrate any of the technology acquired from Bradford 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. In particular, because Bradford 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 such an acquisition may not uncover all the potential problems or liabilities we may have assumed in the transaction. 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.

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 acquisition. In addition, our earnings may suffer because of acquisition-related costs.

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

We have never been profitable and, through March 31, 2001, we have an accumulated deficit of approximately \$272.9 million. We expect to continue to incur substantial and increasing losses over at least the next several years as we expand our research and development efforts, testing activities and manufacturing operations, and as we further expand our late stage clinical and early commercial production facility. All of our potential products are in research or in the early stages of development except for our insulin collaboration. We have generated no revenues from approved product sales. Our revenues to date have consisted primarily of payments under short-term research and feasibility agreements and development contracts. To achieve and sustain profitable operations, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, introduce, market and sell products using our deep lung and other drug delivery systems. There is a risk that we will not generate sufficient product or contract research revenue to become profitable or to sustain profitability.

We may need to raise additional capital that may not be available.

We anticipate that our existing capital resources will enable us to maintain currently planned operations through at least the next 29 months. However, this expectation is based on our current operating plan, which is expected to change as a result of many factors, and we may need additional funding sooner than anticipated. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in dilution to our stockholders.

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

Our patents may not protect our products and our products may infringe on third-party patent rights.

We have filed patent applications covering certain aspects of our device, powder processing technology, powder formulations and deep lung route of delivery for certain molecules as well as for other drug delivery technology, and we plan to file additional patent applications. We currently have 115 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 will affect our ability to develop and commercialize our technology. Many drugs, including powder formulations of certain drugs that are presently under development by us, are subject to issued and pending U.S. and foreign patents that may be owned by competitors. We know that there are issued patents and pending patent applications relating to the deep lung and other forms of delivery of large molecule drugs, including several for which we are developing deep lung or other delivery formulations, including supercritical fluid technology. 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 are to be formulated by us for deep lung and other forms of delivery. There is a risk that our partners will not be able to provide access to such drug candidates. Even if such access is provided, there is a risk that our partners or we will be accused of, or determined to be, infringing a third-party's patent rights and will be prohibited from working with the drug or be found liable for damages that may not be subject to indemnification. Any such restriction on access to drug candidates or liability for damages would negatively impact our revenues and results of operations.

Our competitors may develop and sell better drug delivery systems.

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

Investors should be aware of industry-wide risks.

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

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

We expect our stock price to remain volatile.

Our stock price is volatile. In the last twelve-month period ending May 1, 2001, based on closing prices on the Nasdaq National Market, our stock price ranged from \$17.125 to \$56.375. We expect it to remain volatile. A variety of factors may have a significant effect on the market price of our common stock, including:

- fluctuations in our operating results;
- announcements of technological innovations or new therapeutic products;

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

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

Our indebtedness may result in future liquidity problems.

As of March 31, 2001, we had approximately \$322.8 million in long-term obligations, which represents an increase of \$3.5 million from the fiscal year-ended December 31, 2000. This increased indebtedness has and will continue to impact us by:

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

Currently, we are not generating sufficient cash flow to satisfy the annual debt service payments that will be required as a result of the consummation of sale of the notes. This may require us to use a portion of the proceeds from the sales of the notes to pay interest or borrow additional funds or sell additional equity to meet our debt service obligations. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result, which would negatively impact our future prospects. As of March 31, 2001, we had cash and short-term investments valued at approximately \$453.9 million.

A Potential New Accounting Pronouncement Could Impact Our Financial Position and Results of Operations

The Financial Accounting Standards Board is expected to issue a new accounting standard on Business Combinations in June 2001. If the proposed accounting standard is adopted, it would require that goodwill not be amortized, but rather be subject to an impairment test. In addition, separately identified and recognized intangibles resulting from business combinations completed prior to the adoption of the proposed accounting standard that do not meet the new criteria for

separate recognition of intangible assets will be subsumed into goodwill upon adoption. If adopted, the proposed accounting standard could have a significant impact on our financial position and results of operations.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in the reported market risks since December 31, 2000.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings—Not Applicable

Item 2. Changes in Securities and Use of Proceeds

In January 2001, we issued 3,752,456 shares of our common stock to the holders of all of the existing issued ordinary share capital of Bradford. We issued these shares as consideration for the acquisition of the outstanding share capital of Bradford in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933, as amended (the "Act") and/or Regulation D or Regulation S promulgated under the Act. For each share of Bradford common stock we issued 1.8354 new shares of our common stock and paid approximately \$9.80 cash, for an aggregate cash payment of approximately \$20.4 million. The acquirers relying upon the exemption from registration afforded by Regulation S signed forms of acceptances indicating, respectively, their intent to acquire the securities for investment only and not with a view to distribution, and also indicated that if they were an individual, then they were residents of the United Kingdom, or if they were a corporation, limited liability company or other entity, then the offices of the Bradford shareholder in which its investment decision was made was located in the United Kingdom. The acquirers relying upon the exemption from registration afforded by Regulation D signed forms of acceptances indicating respectively their intent to acquire the securities for investment only and not with a view to distribution, and also represented that they were "accredited investors" as that term is defined under Rule 501 of Regulation D. Appropriate legends are affixed to the shares issued in this transaction. Cazenove & Co. served as financial advisor and broker to the Company in connection with the acquisition of Bradford and received \$650,000 in payment of certain fees. On February 5, 2001, a shelf registration statement for these shares of common stock was declared effective by the SEC.

Item 3. Defaults upon Senior Securities—None

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

Item 5. Other Information—None

Item 6. Exhibits and Reports on Form 8-K

(a)

The following exhibits are filed here with or incorporated by reference:

| Exhibit Number | Exhibit Index |
|----------------|---|
| 2.1 | (1) Agreement and Plan of Merger between Inhale Therapeutic Systems, a California corporation, and Inhale Therapeutic Systems (Delaware), Inc., a Delaware corporation. |
| 2.2 | (16) Recommended Offer, dated December 21, 2000 by Cazenove & Co. on behalf of Inhale Therapeutic Systems, Inc. for Bradford Design plc. |
| 3.1 | (1) Certificate of Incorporation of Inhale. |
| 3.2 | (1) Bylaws of Inhale. |
| 3.3 | (14) Certificate of Amendment of the Amended Certificate of Incorporation. |
| 4.1 | Reference is made to Exhibits 3.1, 3.2 and 3.3. |
| 4.2 | (2) Restated Investor Rights Agreement among Inhale and certain other persons named therein, dated April 29, 1993, as amended October 29, 1993. |
| 4.3 | (3) Stock Purchase Agreement between Inhale and Pfizer Inc., dated January 18, 1995. |
| 4.4 | (9) Form of Purchase Agreement between Inhale and the individual Purchasers, dated January 28, 1997. |

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| 4.5 | (10) Stock Purchase Agreement between Inhale and Capital Research and Management Company, dated December 8, 1998. |
| 4.6 | (12) Purchase Agreement among Inhale and Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc. dated October 6, 1999. |
| 4.7 | (12) Registration Rights Agreement among Inhale and Lehman Brothers Inc., Deutsche Bank Securities Inc. and U.S. Bancorp Piper Jaffray Inc., dated October 13, 1999. |
| 4.8 | (12) Indenture between Inhale as Issuer and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated October 13, 1999. |
| 4.9 | (12) Form of Inhale Registration Rights Agreement, between Inhale and Selling Shareholder, dated January 25, 2000. |
| 4.10 | (13) Purchase Agreement among Inhale and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated February 2, 2000. |
| 4.11 | (13) Resale Registration Rights Agreement among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., |

- dated February 8, 2000.
- 4.12 (13) Indenture between Registrant as Issuer and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated February 8, 2000.
- 4.13 (14) Specimen common stock certificate.
- 4.14 (15) Specimen warrants to purchase shares of common stock.
- 4.15 (17) Purchase Agreement among Inhale and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated October 11, 2000.
- 4.16 (17) Resale Registration Rights Agreement among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Deutsche Bank Securities, Inc., Lehman Brothers Inc., and U.S. Bancorp Piper Jaffray Inc., dated October 17, 2000.
- 4.17 (17) Indenture between Registrant, as Issuer, and Chase Manhattan Bank and Trust Company, National Association, as Trustee, dated October 17, 2000.
- 10.1 (4) Registrant's 1994 Equity Incentive Plan, as amended.
- 10.2 (7) Registrant's 1994 Non-Employee Directors' Stock Option Plan, as amended.
- 10.3 (2) Registrant's 1994 Employee Stock Purchase Plan, as amended.
- 10.4 (2) Standard Industrial Lease between Inhale and W.F. Batton & Co., Inc., dated September 17, 1992, as amended September 18, 1992.
- 10.5 (2) Addendum IV dated April 1, 1994 to Lease dated September 17, 1992, between Inhale and W.F. Batton and Marie A. Batton, dated September 17, 1992.
- 10.6 (6) Amendment Agreement Number One, dated October 20, 1995, to Lease dated September 17, 1992, between Inhale and W.F. Batton & Co., Inc.
- 10.7 (6) Amendment Agreement Number Two, dated November 15, 1995, to Lease, dated September 17, 1992, between Registrant and W.F. Batton and Marie A. Batton, Trustees of the W.F. Batton and Marie A. Batton Trust UTA dated January 12, 1998 ("Batton Trust").

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- 10.8 (11) Amendment Agreement Number Three, dated February 14, 1996, to Lease, dated September 17, 1992, between Registrant and Batton Trust.
- 10.9 (11) Amendment Agreement Number Four, dated September 15, 1996, to Lease, dated September 17, 1992, between Registrant and Batton Trust.
- 10.10 (2) Sublicense Agreement between Inhale and John S. Patton, dated September 13, 1991.
- 10.11 (5) Stock Purchase Agreement between Inhale and Baxter World Trade Corporation, dated March 1, 1996.
- 10.12 (8) Sublease and Lease Agreement, dated October 2, 1996, between Inhale and T.M.T. Associates L.L.C. ("Landlord").
- 10.13 (11) First Amendment, dated October 30, 1996, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
- 10.14 (11) Letter Agreement, dated April 9, 1997, amending Sublease and Lease Agreement, dated October 2, 1996, between Inhale and Landlord.
- 10.15 (11) Third Amendment, dated April 16, 1997, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
- 10.16 (11) Fourth Amendment, dated November 5, 1997, to Sublease and Lease Agreement, dated October 2, 1996, between Registrant and Landlord.
- 10.17 (13) Sublease by and between Webvan Group, Inc., as sublessor and Registrant, as sublessee, dated November 3, 1999.
- 10.18 (15) Registrant's 2000 Equity Incentive Plan
- 10.19 (15) Registrant's Stock Option Agreement issued in accordance with Inhale's 2000 Equity Incentive Plan.
- 10.20 (15) Agreement for the Contribution of 201 Industrial Road Project made and entered into as of September 14, 2000 by and among Inhale, Inhale 201 Industrial Road, L.P., a California limited partnership and Bernardo Property Advisors, Inc., a California corporation.
- 10.21 (15) Agreement of Limited Partnership of Inhale 201 Industrial Road., L.P., a California limited partnership made and entered into September 14, 2000, by and among SCIMED PROP III, Inc., a California corporation, as general partner, 201 Industrial Partnership, a California general partnership, as limited partner, and Inhale, as limited partner.
- 10.22 (15) Build-To-Suit Lease made and entered into as of September 14, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
- 10.23 (15) Amendment to Lease dated October 3, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
- 10.24 (15) Parking Lease Agreement entered into as of September 14, 2000 by and between Inhale 201 Industrial Road, L.P., a California limited partnership, as Landlord, and Inhale, as Tenant.
- 10.25 (18) Registrant's 2000 Non-Officer Equity Incentive Plan
- 10.26 (18) Registrant's Stock Option Agreement issued in accordance with Inhale's 2000 Non-Officer Equity Incentive Plan

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- 10.27 (19) Manufacturing and Supply Agreement among Inhale, Tech Group North America, Bepak Europe, LTD. Incorporated by reference to the indicated exhibit in Inhale's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998.
- (2) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-1 (No. 33-75942), as amended.
- (3) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-1 (No. 33-89502), as amended.
- (4) Incorporated by reference to the indicated exhibit in Inhale's Registration Statement on Form S-8 (No. 33-59735).

[Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS](#)

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