AEROGEN INC
Form 10-Q
November 14, 2002

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

ý **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2002

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 0-31913

Aerogen, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0488580**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2071 Stierlin Court, Mountain View, CA	**94043**
(Address of principal executive offices)	(zip code)

Registrant's telephone number, including area code: **(650) 864-7300**

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed 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 ý No o

As of October 31, 2002, there were 20,403,746 shares of the Registrant's Common Stock, par value $0.001, outstanding.

(a development stage enterprise)
Form 10-Q
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Part I. ***Financial Information***

Item 1. Condensed Consolidated Financial Statements

Aerogen, Inc.
(a development stage enterprise)
Condensed Consolidated Balance Sheets
(unaudited; in thousands)

	September 30, 2002	December 31, 2001

ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,824	$ 15,714
Available-for-sale securities	5,994	20,363
Accounts receivable	526	193
Inventories	224	488
Prepaid expenses and other current assets	688	1,201
Total current assets	16,256	37,959
Property and equipment, net	5,397	2,889
Goodwill and other intangible assets, net	1,509	1,362
Other assets	1,249	1,258
Total assets	$ 24,411	$ 43,468
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,202	$ 1,181
Accrued liabilities	1,905	3,321
Total current liabilities	3,107	4,502
Deferred rent	658	223
Other long-term liabilities	224	212
Total liabilities	3,989	4,937
Stockholders' equity:		
Common stock	20	20
Additional paid-in capital	109,483	110,428
Notes receivable from stockholders	(429)	(693)
Deferred stock-based compensation, net	(1,856)	(4,069)
Accumulated other comprehensive gain (loss)	122	(14)
Deficit accumulated during the development stage	(86,918)	(67,141)
Total stockholders' equity	20,422	38,531
Total liabilities and stockholders' equity	$ 24,411	$ 43,468

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aerogen, Inc.

(a development stage enterprise)

Condensed Consolidated Statements of Operations

(unaudited; in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
Revenues:				
Research and development	$ 146	$ 432	$ 180	$ 1,934
Product sales	496	99	608	99
Royalty, fee and other	62	63	187	187
Total revenues	704	594	975	2,220
Costs and expenses:				
Cost of products sold and manufacturing start-up costs	513	134	979	134
Research and development	3,758	5,521	13,728	16,232
Selling, general and administrative	2,186	2,148	6,473	5,878
Litigation Settlement		2,000		2,000
Total costs and expenses	6,457	9,803	21,180	24,244
Loss from operations	(5,753)	(9,209)	(20,205)	(22,024)
Interest income, net	86	473	428	1,924
Net loss	$ (5,667)	$ (8,736)	$ (19,777)	$ (20,100)
Net loss per common share, basic and diluted	$ (0.28)	$ (0.44)	$ (0.98)	$ (1.03)
Shares used in computing net loss per common share, basic and diluted	20,252	19,749	20,141	19,606

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aerogen, Inc.

(a development stage enterprise)

Condensed Consolidated Statements of Cash Flows

(unaudited; in thousands)

	Nine Months Ended September 30,	
	2002	2001
Cash flows from operating activities:		
Net loss	$ (19,777)	$ (20,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	873	968
Amortization of deferred stock-based compensation	1,060	982
Accrued interest on notes receivable from stockholders	(21)	(21)

	Nine Months Ended September 30,	
Amortization of discount on available-for-sale securities	(6)	(77)
Loss on disposal of property and equipment	218	1
Change in inventory reserves	129	
Changes in operating assets and liabilities:		
Accounts receivable	(305)	260
Inventories	148	(388)
Prepaid expenses and other current assets	513	320
Other assets	9	6
Accounts payable	10	180
Accrued liabilities	(1,544)	3,475
Deferred revenues	115	42
Deferred rent	435	
Other long-term liabilities	(6)	43
Net cash used in operating activities	(18,149)	(14,309)
Cash flows from investing activities:		
Acquisition of property and equipment	(3,588)	(828)
Purchases of available-for-sale securities	(5,995)	(15,928)
Proceeds from maturities of available-for-sale securities	20,317	12,358
Net cash provided by (used in) investing activities	10,734	(4,398)
Cash flows from financing activities:		
Proceeds from issuance of common stock	214	224
Repurchase of common stock	(6)	(5)
Repayment of notes receivable from stockholders	285	
Net cash provided by financing activities	493	219
Effect of exchange rate changes on cash	32	(61)
Net decrease in cash and cash equivalents	(6,890)	(18,549)
Cash and cash equivalents, beginning of period	15,714	48,810
Cash and cash equivalents, end of period	$ 8,824	$ 30,261

The accompanying notes are an integral part of these condensed consolidated financial statements.

Aerogen, Inc.

(a development stage enterprise)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business of the Company

Aerogen, Inc. (the "Company" or "Aerogen") was incorporated in November 1991 to develop products using a proprietary aerosol generator. The Company is in the development stage and, since inception, has devoted substantially all of its efforts to developing products, including engaging in research and development activities with and without partners, raising capital, marketing of its initial products and recruiting personnel. The Company has incurred net losses since inception and expects to incur substantial losses for the next several years. To date, the Company has funded its operations primarily through the sale of equity securities, payments from collaboration partners, interest income and debt. The process of developing products will continue to require significant research and development, clinical trials and regulatory approvals. These activities, together with selling, general and administrative expenses, are expected to result in substantial operating losses for the next several years.

These financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The Company requires additional financing and may raise funds by selling shares of its common or preferred stock through private placements or public offerings, by collaborative relationships or other arrangements. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company. Additional equity or debt financing may involve substantial dilution to the Company's stockholders, restrictive covenants or high interest costs. Collaborative arrangements, if necessary to raise additional funds, may require the Company to relinquish rights to certain products, technologies or marketing territories. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the Company's business, operating results and financial condition.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10-01 of Securities and Exchange Commission Regulation S-X. Accordingly, they do not contain all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments (consisting of normal, recurring adjustments) considered necessary for a fair presentation of the Company's interim financial information. These financial statements and notes should be read in conjunction with the audited financial statements and notes thereto of the Company included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001, filed with the Securities and Exchange Commission on March 27, 2002.

The results of operations for the three and nine months ended September 30, 2002 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2002, or for any other future period.

Inventories

Inventories are stated at the lower of cost (on a first-in, first-out basis) or market value. Inventories are summarized as follows:

	September 30, 2002	December 31, 2001
	(unaudited; in thousands)	
Raw materials	$ 162	$ 354
Work-in-process	43	99
Finished goods	19	35
Total inventories	$ 224	$ 488

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company's unrealized gains and losses on available-for-sale securities and foreign currency translation gains and losses represent the only components of comprehensive income (loss) that are excluded from the Company's net loss.

Net Loss Per Common Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of vested common shares outstanding for the period. Diluted net loss per share is computed giving effect to all potential dilutive common shares, including options and warrants. Options and warrants are not included in the diluted net loss per share calculations for periods in which the effect would be anti-dilutive.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per common share as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
	(unaudited; in thousands)			
Net Loss per common share, basic and diluted:				
Net Loss	$ (5,667)	$ (8,736)	$ (19,777)	$ (20,100)
Weighted average common shares outstanding	20,274	20,007	20,215	19,967
Less: Weighted average shares subject to repurchase	(22)	(258)	(74)	(361)
Weighted average shares used in computing basic and diluted net loss per common share	20,252	19,749	20,141	19,606

The following outstanding options, common stock subject to repurchase and warrants were excluded from the computation of diluted net loss per share as they had an antidilutive effect:

	September 30,	
	2002	2001
	(unaudited; in thousands)	
Options to purchase common stock	3,078	2,685
Common stock subject to repurchase	15	215
Warrants, based on common stock equivalents	22	32

Note 2 RECENT ACCOUNTING PRONOUNCEMENTS

The Company adopted Statement of Financial Accounting Standards ("SFAS") No.142 "Goodwill and other Intangible Assets" on January 1, 2002. Under the new rules, goodwill is no longer amortized, but is subject to an annual impairment test. The annual goodwill impairment test was completed in the first quarter of 2002 and it was determined that there was no impairment of goodwill at that time.

The following table reconciles the Company's net loss for the three and nine months ended September 30, 2002 and 2001, adjusted, pursuant to SFAS No.142, to exclude goodwill amortization from amounts previously reported:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001

	Three Months Ended September 30,		Nine Months Ended September 30,	
	(unaudited; in thousands, except per share data)			
Reported net loss	$ (5,667)	$ (8,736)	$ (19,777)	$ (20,100)
Add back: Goodwill amortization		91		270
Adjusted net loss	$ (5,667)	$ (8,645)	$ (19,777)	$ (19,830)
Net loss per share, basic and diluted	$ (0.28)	$ (0.44)	$ (0.98)	$ (1.03)
Add back: Goodwill amortization				$ 0.02
Adjusted net loss	$ (0.28)	$ (0.44)	$ (0.98)	$ (1.01)

In April of 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections," which is effective for fiscal years beginning after May 15, 2002. Under SFAS No. 145, gains and losses from the extinguishment of debt should be classified as extraordinary items only if they meet the criteria of Accounting Principles Board Opinion No. 30. SFAS No. 145 also addresses financial accounting and reporting for capital leases that are modified in such a way as to give rise to a new agreement classified as an operating lease. The Company believes that the adoption of SFAS No. 145 will not have a material impact on the consolidated financial position or results of the operations of the Company.

In June of 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities," which is effective for exit or disposal activities initiated after December 31, 2002. SFAS No. 146 supersedes Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." Under SFAS No. 146, a liability is required to be recognized for a cost associated with an exit or disposal activity when the liability is incurred. SFAS No. 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination, or with a retirement or disposal activity covered by FASB Statements No. 143, "Accounting for Asset Retirement Obligations," or SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." The Company believes that the adoption of SFAS No. 146 will not have a material impact on the consolidated financial position or results of the operations of the Company.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

In addition to historical information, this report contains predictions, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results could differ materially from any future performance suggested in this report as a result of many factors, including those referred to in "Factors That May Affect Future Operating Results," at the end of this Item 2. The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes included elsewhere in this report and the information included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001, filed with the Securities and Exchange Commission on March 27, 2002 ("Form 10-K").

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are described in Item 7 of our Form 10-K for the year ended December 31, 2001, and have not changed materially since that date.

Overview

Aerogen was incorporated in November 1991. We specialize in the controlled delivery of drugs to the lungs for respiratory therapy or systemic drug delivery. We are using our technology to develop respiratory products for marketing by us, and we are developing products for ourselves and for collaboration with pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs via the lungs to the bloodstream.

We are in the development stage and, since inception, have devoted substantially all of our efforts to the development of products. We have an accumulated deficit of approximately $86.9 million as of September 30, 2002. We expect to incur significant additional operating losses over the next several years, and cumulative losses may increase, primarily due to the expansion of our research and development activities, an increase in the number and size of clinical trials, the costs associated with marketing recently introduced and additional products and the general expansion of our business activities. We anticipate that our quarterly financial results will fluctuate for the foreseeable future. Therefore, period to period comparisons should not be relied upon as predictive of the results in future periods. Our sources of working capital have been equity financings, research and development revenues, product revenues, interest earned on investments, equipment lease financings and royalties.

Results of Operations

Revenues

Total revenues for the three and nine months ended September 30, 2002 were $0.7 million and $1.0 million, respectively, compared with $0.6 million and $2.2 million for the same periods of 2001. Total revenues include revenue from research and development activities for unrelated third parties, from product sales, and from royalties associated with the licensing of our technology for use outside of the medical field.

Research and development revenues for the three and nine months ended September 30, 2002 were $0.1 million and $0.2 million, respectively, compared with $0.4 million and $1.9 million for the same periods of 2001. The decrease for both the three and nine months ended September 30, 2002 resulted primarily from a lower level of product development activities performed for one partner program with Chiron, Inc. In December 2001, we announced the termination of our development program with Chiron for the aerosol delivery of TOBI®, their proprietary formulation of the antibiotic tobramycin.

Research and development revenues can be expected to vary from period to period based on the activities requested by partner companies in any particular period and, therefore, are not predictable. Based on agreements we currently have in place, we would expect research and development revenues for 2002 to be lower than those for 2001.

Product sales for the three and nine months ended September 30, 2002 were $0.5 million and $0.6 million compared with $0.1 million and $0.1 million for the same respective periods of 2001. Product sales were significantly influenced by the launch of our second product, the Aeroneb® Professional Nebulizer System ("Aeroneb Pro") in June 2002. Our first product, the Aeroneb® Portable Nebulizer System ("Aeroneb Portable"), was launched in June 2001. The quarter ended September 30, 2002 showed stronger product sales than in prior quarters, and we expect that product sales will continue to increase.

Royalty, fee and other revenues were approximately $62,000 and $187,000, for the three and nine month periods ended September 30, for both 2002 and 2001. Royalties represent a minimum royalty obligation associated with licensing our aerosol generator technology to a consumer product company for limited usage outside the medical field.

Cost of Products Sold and Manufacturing Start-up Costs

Cost of products sold and manufacturing start-up costs for the three and nine months ended September 30, 2002 were $0.5 million and $1.0 million, respectively, compared with $0.1 million and $0.1 million for the same respective periods of 2001. Cost of products sold for the three and nine months ended September 30, 2002 include costs associated with the start-up of manufacturing production in the Company's new facility in Mountain View. As product sales volumes increase, we expect to see increasing cost of product sales. In the third quarter ended September 30, 2002, however, we saw improvements in cost of sales as a percent of revenue, both over the prior year and prior quarters. The introduction of Aeroneb® Pro, which contributes higher gross margins than the Aeroneb® Portable, contributed significantly to this improvement. During the three months ending September 30, 2002, we have seen yield improvements in the manufacturing process, resulting in lower costs per unit. As the Aeroneb Pro volumes increase, and as the manufacturing process matures, we anticipate further improvements to the cost of sales as a percent of product sales.

As detailed in our previous quarterly reports on Form 10-Q, effective April 2002, we implemented a price reduction on the Aeroneb Portable to enhance our competitive position in the home nebulizer market. In the nine months ending September 30, 2002, we took a net $0.1 million charge to cost of products sold to reduce inventories to estimated market value and accrue future losses on purchase commitments based on the reduced selling price.

Research and Development Expenses

Research and development expenses capture our own research and development projects, as well as the costs related to research and development activities for our partners. Research and development expenses for partner activities approximate our revenues from those partners. Research and development expenses include salaries and benefits for scientific and development personnel, laboratory supplies, consulting services, clinical expenses and the expenses associated with the development of manufacturing processes, including related overhead. Research and development spending may increase significantly over the next several years as we enter new clinical trials, expand our research and development activities to support our products and those which we develop in our collaborations. Future research and development and clinical expenditures cannot be predicted reliably, as they depend, in part, upon our success in expanding existing development collaborations, entering into new partnering agreements, potential changes in our partner's priorities, and the level of internally funded research and development efforts.

Research and development expenses for the three and nine months ended September 30, 2002 were $3.8 million and $13.7 million, respectively, compared with $5.5 million and $16.2 million for the same periods of 2001. The decrease in research and development expenses of $1.7 million for the three months ended September 30, 2002, as compared with the same period of 2001, was primarily due to a decrease in payroll and related expenses of $0.9 million associated with the reduction in force in June 2002; non-payroll related expenses for professional services, materials, and machining services for the development of the clinical version of the inhaled insulin product and clinical trials decreased by $0.5 million; non-payroll related expenses for professional and machining services associated with our development of clinical devices for respiratory products decreased by $0.4 million; deferred compensation decreased by $0.1 million; non-payroll related expenses for professional services, machining services, and materials for several other programs decreased by $0.5 million. These decreases were partially offset by incremental rent and information technology expenses, primarily associated with our newly leased facility, which were approximately $0.6 million higher, in comparison with the same period in the prior year.

The decrease in research and development expenses of $2.5 million for the nine months ended September 30, 2002, as compared with the same period of 2001, was primarily due to decreases in non-payroll related expenses for professional design services, insulin formulation, and clinical studies, associated with our clinical version design of the inhaled insulin product and clinical trials of $1.4 million; decreases in non-payroll related expenses for professional design services associated with our development of clinical devices for respiratory products of $1.2 million; decreases in payroll related expenses of $1.4 million including stock-based compensation of $0.3 million; decreases in non-payroll related expenses for professional design services, machining, and materials for several other programs of $0.6 million; offset by increased rent and information technology expenses, primarily associated with our newly leased facility, of $2.1 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three and nine months ended September 30, 2002 were $2.2 million and $6.5 million, respectively, compared with $2.1 million and $5.9 million for the same periods of 2001. The increase for the three months ended September 30, 2002 of $0.1 million compared with the same period of 2001 was due to $0.1 million of increased rent and information technology expenses, primarily associated with our newly leased facility, increased stock-based compensation costs of $0.1 million, an increase in professional marketing services of $0.2 million; partially offset by a decrease of $0.2 million in payroll related expenses associated with the reduction in force in June 2002, and by the cessation of goodwill amortization of $0.1 million.

The increase of $0.6 million for the nine months ended September 30, 2002, compared with the same period of 2001, was due to $0.5 million of increased rent and information technology expense primarily associated with our newly leased facility; increased payroll related expenses of $0.6 million, including stock-based compensation of $0.4 million; these increases were partially offset by the cessation of goodwill amortization of $0.3 million; decrease in professional services of $0.1 million and decreases in other miscellaneous expenses of $0.1 million.

Litigation Settlement

The litigation settlement charge of $2.0 million for the three and nine month periods ended September 30, 2001 resulted from the settlement of a lawsuit brought by the Company against Becton Dickinson and Company ("BD"). The settlement amount was paid in two equal installments, one in October of 2001 and the other in February of 2002. As the result of this settlement, we now own all of the intellectual property developed by either party under the now terminated development agreement between the parties, and BD retains a non-exclusive license to certain technology developed by BD under said agreement for use outside of the field of inhaled insulin.

Interest Income, Net

Interest income, net for the three and nine months ended September 30, 2002 was $0.1 million and $0.4 million, respectively, compared with $0.5 million and $1.9 million for the same periods of 2001. The decrease in interest income, net was primarily due to lower average cash, cash equivalents and investment balances resulting from cash used in operations and capital expenditures and, to a lesser extent, to lower interest rates. The Company currently has no outstanding debt.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through equity financings, research and development revenues and the interest earned on these funds. We have received approximately $98.2 million aggregate net proceeds from sales of our common and preferred stock through September 30, 2002, including approximately $44.5 million of net proceeds from our initial public offering ("IPO").

As of September 30, 2002, we had cash, cash equivalents and available-for-sale securities of approximately $14.8 million. Net cash used in operating activities during the nine months ended September 30, 2002 was $18.1 million resulting primarily from the net loss for the period of $19.8 million; decreased accounts payable and accrued liabilities of $1.5 million primarily due to payments to BD of $1.0 million for the settlement, and to payments of move related charges of $0.3 million; these uses were partially offset by non-cash related charges of approximately $2.3 million and a reduction in prepaid expenses of $0.5 million. Net cash used in operating activities for the nine months ended September 30, 2001 was $14.3 million resulting primarily from the net loss for the period of $20.1 million; partially offset by non-cash related charges of approximately $2.0 million and an increase in accounts payable and accrued liabilities of $3.7 million due primarily to accruals for the BD settlement of $2.0 million.

Net cash provided by investing activities was $10.7 million for the nine months ended September 30, 2002, consisting primarily of proceeds from maturing available-for-sale securities over purchases of securities of $14.3 million, partially offset by $3.6 million of property and equipment acquisitions, primarily associated with leasehold improvements to our newly leased facility and equipment associated with the process improvements. Net cash used in investing activities was $4.4 million for the nine months ended September 30, 2001, consisting primarily of $3.6 million for net purchases of available-for-sale securities and acquisition of $0.8 million of property and equipment.

Cash provided by financing activities for the nine months ending September 30, 2002 of $0.5 million included $0.2 million of proceeds from the issuance of common stock which was comparable with the same period of 2001. In addition, repayment of notes receivable from stockholders provided $0.3 million for the nine months ending September 30, 2002, compared with no repayments in the same period of 2001.

The development of our technology and products requires a commitment of substantial funds to conduct the costly and time-consuming product development and clinical trials that are required to mature and expand our technology and products, and to bring any such products to market. Our future capital requirements and operating expenses will depend on many factors including, but not limited to: research and development activities; the timing, cost, extent and results of clinical trials; our success in licensing drugs for use in our products; regulatory approvals; the status of competitive products; marketing and manufacturing costs associated with commercialization of products; costs involved in obtaining and maintaining patents; and our ability to enter into collaborative agreements.

Based upon our current internal analyses, which do not include potential upfront payments or offsets to ongoing expenses to us associated with anticipated partnering arrangements, we believe that our cash, cash equivalents and available-for-sale securities will be sufficient to meet our capital

requirements into the second quarter of 2003. We will most likely need to secure additional funds through partner collaborations, sales of our securities, borrowing, or other sources of capital. There can be no assurance that we will be able to enter into such collaborations or raise additional funds on terms favorable to the Company.

Recent Accounting Pronouncements

In April of 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 145 ("SFAS 145"), "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections," which is effective for fiscal years beginning after May 15, 2002. Under SFAS 145, gains and losses from the extinguishment of debt should be classified as extraordinary items only if they meet the criteria of Accounting Principles Board Opinion No. 30. SFAS 145 also addresses financial accounting and reporting for capital leases that are modified in such a way as to give rise to a new agreement classified as an operating lease. The Company believes that the adoption of SFAS 145 will not have a material impact on the consolidated financial position or results of the operations of the Company.

In June of 2002, the FASB issued SFAS No. 146 ("SFAS 146"), "Accounting for Costs Associated with Exit or Disposal Activities," which is effective for exit or disposal activities initiated after December 31, 2002. SFAS No. 146 supersedes Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." Under SFAS 146, a liability is required to be recognized for a cost associated with an exit or disposal activity when the liability is incurred. SFAS 146 applies to costs associated with an exit activity that does not involve an entity newly acquired in a business combination or with a retirement or disposal activity covered by FASB Statements No. 143, "Accounting for Asset Retirement Obligations," or SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." The Company believes that the adoption of SFAS No. 146 will not have a material impact on the consolidated financial position or results of the operations of the Company.

Factors That May Affect Future Operating Results

Our business and the value of our stock are subject to a number of risks, many of which are set out below. If any of these risks actually materialize, our business, financial condition or operating results could be materially adversely affected, which would likely have a corresponding impact on the value of our common stock. These risk factors should be reviewed carefully.

We are a development stage company and many of our products are in research and development stages, which makes it difficult to evaluate our business and prospects.

Our Company must be evaluated in light of the uncertainties and complexities present in a development stage company. Other than the Aeroneb Portable Nebulizer System which was introduced in 2001, and the Aeroneb Professional Nebulizer System in 2002, our products are in the research or development stages. Before we can begin to sell our Aerodose® inhaler products commercially, we will need to invest in substantial, additional development activities, including the conduct of clinical trials. To further develop such products, we will need to address engineering and design issues, including ensuring that our products deliver a consistent and predictable amount of drug to the lung and that they can be manufactured successfully. We cannot assure that:

- our research and development efforts will be successful;
- any of our inhaler products will prove safe and effective;
- we will obtain regulatory clearance or approval to sell any additional products; or
- any of our existing or future products can be manufactured in commercial quantities or at an acceptable cost or marketed successfully.

We have a history of losses, anticipate future losses and may never achieve or maintain profitability.

We have never been profitable. Through September 30, 2002, we have incurred a cumulative deficit of approximately $86.9 million. We expect to continue to incur substantial losses over at least the next several years as we:

- expand our research and development efforts;
- expand our preclinical and clinical testing activities;
- expand our manufacturing efforts, including our commercial production capability; and
- build our sales and marketing capabilities and launch our inhaler products.

To achieve and sustain profitability, we must, alone or with others, develop, obtain regulatory approval for, manufacture, market and sell products. We cannot assure that we will generate sufficient product revenues, royalties or research and development revenues to become profitable or to sustain profitability.

We most likely will need additional capital. If we cannot secure additional funding on acceptable terms, we may be required to slow our progress, curtail our operations significantly or sell rights to some of our technologies, products, or other assets.

As of September 30, 2002, our cash, cash equivalents and available-for-sale securities are expected to support the continuation of our current operations into the second quarter of 2003. We will need to secure additional funds to finance those operations beyond the second quarter of 2003. Our cash requirements may even increase in the future because of our research and development efforts, including clinical trials, capital expenditures and the manufacture and marketing of our products. We may need to seek additional funding through collaborations or through public or private equity

financings. Based on the current capital markets, we cannot assure that additional financing will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs. Arrangements with collaborative partners may require us to relinquish rights to some of our technologies or products.

Our stock price may be volatile.

The market prices for securities of many companies in the life sciences industry have historically been highly volatile, and the market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. Prices for our common stock may be influenced by many factors, including:

market conditions relating to the life sciences industry;

investor perception of us as a company;

securities analysts' recommendations;

delays in the development, regulatory approval or commercialization of our products;

announcements of technological innovations or new commercial products by us, our partners or competitors;

failure to establish new collaborative relationships or termination of existing collaborative relationships;

developments or disputes concerning patent or intellectual property rights;

regulatory and pricing developments in both the United States and foreign countries;

public concern as to the safety of drugs and drug delivery technologies;

period-to-period fluctuations in financial results; or

economic and other external factors.

Our common stock is currently trading at a market price significantly below the initial public offering price; there can be no assurance that the price will recover to the initial public offering price or that it will increase in the future.

Our common stock may be delisted from The Nasdaq National Market, which may adversely affect the market liquidity and market price of our common stock.

Our common stock is currently listed on the Nasdaq National Market and has had, since July 1, 2002, closing bid prices of less than $1.00 per share on all but three days. Nasdaq rules do not permit listed companies to maintain closing bid prices below $1.00 per share for more than 30 consecutive trading days. Following the 30th consecutive trading day in which a listed stock closes with a bid price below $1.00 per share, Nasdaq rules require that the stock's bid price close above $1.00 for any 10 consecutive trading days during the subsequent 90 calendar days in order to avoid delisting action.

In November 2002, we received notice from Nasdaq Stock Market Inc., that our common stock would be delisted from the Nasdaq National Market on November 19, 2002 because the stock had not closed with a bid price of above $1.00 per share for at least 10 consecutive trading days during the preceding 90 calendar days. We intend to request a written appeal hearing before a Nasdaq Listing Qualifications Panel to review the delisting determination. If our appeal is unsuccessful, we may apply to transfer our common stock for trading on the Nasdaq Small Cap Market.

If we fail to meet the qualification to transfer to The Nasdaq Small Cap Market, or fail to continue to meet the listing requirements under The Nasdaq Small Cap Market, the trading of our common stock is likely to be conducted on the OTC Bulletin Board or in the over-the-counter market in what is commonly referred to as the "pink sheets," any of which may have an adverse affect on the market price of our common stock and on the ability of stockholders and investors to buy and sell the common stock. If delisting occurs, stockholders may lose some or all of their liquidity and/or value.

Our technology in Aerodose inhalers is relatively unproven, so they may not work effectively or safely enough to commercialize.

Since our pulmonary drug delivery technology is new and relatively unproven, many of our products are currently in the research, development or clinical stages. Extensive additional testing will need to be performed to demonstrate that:

drugs may be safely and effectively delivered using our technology;

our inhalers are safe across a range of drugs and formulations;

our products consistently deliver accurate and predictable amounts of drug over time; and

drug formulations are stable in our products.

If our products do not prove to be safe and effective, we may be required to abandon some or all of them. If we cannot develop new products, our business will suffer.

If clinical trials of our products are not successful, products using our Aerodose inhalers or Aeroneb nebulizers may not be commercialized.

Before either we or our partners can file for regulatory approval for the commercial sale of products using our Aerodose inhalers, the Food and Drug Administration, ("FDA"), and other governmental agencies in other countries will require extensive clinical trials to demonstrate product safety and efficacy. We are developing drug/inhaler and drug/nebulizer combinations, each of which will require clinical testing. To date, we have completed limited clinical trials using prototype Aerodose inhalers and Aeroneb nebulizers. If we do not successfully complete appropriate clinical trials, we will not be able to commercialize our products. The results of initial clinical trials do not necessarily predict the results of more extensive clinical trials. Furthermore, we cannot be certain that clinical trials of our products will demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials.

We have limited manufacturing experience and may not be able to manufacture our products in commercially sustainable quantities. We will depend on key suppliers and contract manufacturers, and their failure to supply us may delay or prevent commercialization of our products.

We have built our own manufacturing capabilities to produce key components of our products. We have manufactured only limited quantities of our first two products, and limited clinical supplies of other products. We currently plan to produce all of our aerosol generators for our products, partnered or not. We plan to use contract manufacturers to produce certain other key components and subassemblies of our products. We may assemble some or all of our products ourselves, or we may use contract manufacturers for the final assembly of some or all of our products. We do not have long-term supply contracts with most of our key suppliers or contract manufacturers. In addition, most of them are currently our sole source of supply. We may not be able to enter into, or maintain, satisfactory contracts or arrangements. In addition, manufacturing of our products could be delayed by supply problems at our suppliers or contract manufacturers. If we need to qualify a new supplier, there could be significant delay, and a regulatory filing could be required before we could use the new supplier to

provide material for our products. There can be no assurance that we, or our contract manufacturers, can successfully manufacture in high volumes in a timely manner, at an acceptable cost, or at all. We cannot assure that:

- the design of our products will permit their manufacture on a commercially sustainable scale;
- manufacturing and quality control problems will not arise as we attempt to scale-up production; or
- any scale-up of production can be achieved in a timely manner or at a commercially reasonable cost.

Failure to address these issues adequately could delay or prevent clinical testing and commercialization of our products.

Our inhaled insulin product currently is our most mature product in development for systemic drug delivery, and there are many uncertainties that could cause the product to be delayed or not to reach the market at all.

We have only completed four small clinical trials (two Phase 1 and two Phase 2) of our Aerodose insulin inhaler product. Early studies generally focus on the safety of a product rather than its effectiveness in treating the disease. We cannot be sure that the results of these and/or other additional clinical trials will prove the safety and effectiveness of our product. We have not yet signed an agreement with a marketing partner to fund the additional development and clinical trials necessary to obtain regulatory approval and to commercialize the product. We cannot assure that we will be able to enter into a satisfactory agreement with a marketing partner, and we currently do not have sufficient funds to conduct the necessary development and clinical programs ourselves.

We may not be able to develop certain products if we do not enter into additional collaborative relationships or gain access to compounds from third parties.

Our strategy depends partially on our ability to enter into collaborative relationships with partners to conduct the clinical trials, manufacturing, marketing and sales activities necessary to commercialize products. To develop products to be marketed by us, we will need to purchase or license, and possibly reformulate and package, drugs for use with our Aerodose inhalers and Aeroneb nebulizers. We cannot assure that we will be able to establish these kinds of arrangements on favorable terms, or at all, or that our existing or future collaborative arrangements will be successful.

If our products do not gain commercial acceptance, we will not generate significant revenue.

Our success in commercializing our products depends on many factors, including acceptance by healthcare professionals and patients. Their acceptance of our products will depend largely on our ability to demonstrate that our products can compete with alternative delivery systems with respect to:

- safety;

efficacy;

the benefits associated with pulmonary delivery;

ease of use; and

price.

We cannot be sure that our products will compete effectively, or that we, or our partners, will be able to successfully market any products in a timely manner.

If we are unable to develop a successful sales and marketing program, we will not be able to sustainably commercialize our products.

We currently have a very limited sales and marketing staff, and many of our competitors have substantial sales and marketing infrastructure. We rely on third party distributors to sell our products. Our success in commercializing our respiratory products in the United States will depend on our ability to develop and execute a successful sales and marketing program. There can be no assurance that our first two products, the Aeroneb Portable Nebulizer System and the Aeroneb Professional Nebulizer System, will be successful, and, in any event, these products are not expected to generate revenues sufficient enough to solely support the Company's operations in the foreseeable future. We will initially have financial losses resulting from the marketing expenditures necessary to launch the products. Successful worldwide commercialization will depend upon finding effective marketing partners for our products outside the United States.

Our corporate partners may not commercialize our products or may develop products that compete against our products.

Our business model includes collaborations with pharmaceutical and biotechnology companies. There can be no assurance that we will be able to enter into arrangements that result in successful commercial products. Even if we do enter into such arrangements, we will depend on corporate partners to commercialize the products developed in collaboration with us. If any of our existing or future corporate partners do not complete the development and commercialization of products to which they have obtained rights from us, our business could be impaired. In the drug delivery industry, it is common for corporate partners to conduct feasibility studies with multiple partners. There can be no assurance that our existing or future corporate partners will continue to choose our technology over their own technology or that of our competitors. Collaboration agreements generally provide that the partner can terminate the agreement at any time; for example, Chiron terminated our arrangement for an Aerodose TOBI product in December 2001.

If we are unable to attract and retain the highly skilled personnel necessary for our business, we may not be able to develop our products successfully.

Because of the specialized nature of our business, we depend upon qualified scientific, engineering, technical and managerial personnel. In particular, our business and prospects depend in large part upon the continued employment of Dr. Jane E. Shaw, our Chairman and Chief Executive Officer. We do not have an employment agreement with Dr. Shaw. Even with the recent downturn in the global economy, there is intense competition for qualified personnel in our business. In addition, our location in northern California makes recruiting qualified personnel from outside the San Francisco Bay area more difficult, due to the very high cost of housing, the demand for skilled workers and the relatively low unemployment rates. Therefore, we may not be able to attract and retain the qualified personnel necessary to grow our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical, engineering and managerial personnel in a timely manner, would harm our research and development programs and our business.

Our ability to market and sell our products depends upon receiving regulatory approvals, which we may not obtain.

Our products are subject to extensive regulation by the FDA, state and local government agencies, and by international regulatory authorities. These agencies regulate the development, testing, manufacture, labeling, storage, approval, advertising, promotion, sale and distribution of medical devices, drugs and biologics. If we, or our partners, fail to obtain regulatory clearances to develop or to market our products, our business will be harmed and we, or our collaborative partners, will not be able to market and sell our products. Even if granted, regulatory approvals may include significant

limitations on the uses for which products may be tested or marketed. Once obtained, required approvals may be withdrawn, or we may not remain in compliance with regulatory requirements. The process for obtaining necessary regulatory approvals for drugs and biologics is generally lengthy, expensive and uncertain. Obtaining and maintaining foreign regulatory approvals in multiple countries is expensive, and we cannot be certain that we will receive approvals in any foreign country in which we or our partners plan to market our products. If we or our partners fail to obtain regulatory approval in the United States or in any foreign country in which we plan to market our products, our revenues will be lower. The regulatory approval process for many of our products is unclear because our products may be classified as medical devices, drugs or biologics. As a result, we may experience greater regulatory uncertainty and longer approval timelines.

If our manufacturing facilities do not meet federal, state and international manufacturing standards, we may not be able to sell our products in the United States or internationally.

Our manufacturing facilities are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with QSR (Quality System Regulation). We moved into a new facility in Mountain View, California during the second quarter of 2002. Prior to transferring product manufacturing to this facility, we underwent a successful inspection by the FDA, which was completed in May 2002. Our registration was received in August 2002.

We also are required to comply with ISO 9001/EN46001 in order to produce products for sale in the European Union. ISO, the International Organization for Standardization, is a worldwide federation of national standards bodies. ISO has developed the ISO 9000 family of standards to assist companies in implementing and operating quality management systems. ISO 9001/EN46001 provides the requirements for a quality management system that a company must meet in order for our products to satisfy applicable regulatory requirements. We received ISO 9001/EN46001 certification for our Sunnyvale facility in July 2000. In August 2002, we passed the surveillance audit, updating our ISO 9001/EN46001 certification for our Mountain View facility.

If we fail to maintain our compliance with QSR requirements, ISO 9001/EN46001 or other international regulatory requirements, we may be required to cease all or part of our operations until we comply with the regulations. We cannot be certain that our facilities will be found to comply on an ongoing basis with QSR, ISO 9001/EN46001 or other international regulatory requirements.

The State of California requires that we maintain a license to manufacture medical devices, and our facilities and manufacturing processes may be inspected from time to time to monitor compliance with the applicable regulations. We are subject to licensing requirements and periodic inspections by the California Department of Health Services, the County of Santa Clara and various environmental agencies. If we are unable to maintain a license following any future inspections, we will be unable to manufacture or ship any products.

Our products may not be commercially viable if government health administration authorities, private health insurers or other third-party payors do not provide adequate reimbursement for the cost of our products.

In both domestic and foreign markets, sales of our potential products will depend, in part, on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. There is significant uncertainty about the reimbursement status of newly approved healthcare products. We cannot assure that any of our products will be reimbursed by third-party payors. In addition, we cannot assure that our products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of health care products may change before our products are approved for marketing, and any such changes could further limit reimbursement. Our first commercial products, the Aeroneb Portable Nebulizer System and the Aeroneb Professional Nebulizer System, are not currently reimbursed by insurance or government entities, which may limit their market penetration.

Our competitors may be more successful in developing competing technologies and gaining market acceptance.

We compete with pharmaceutical, biotechnology and drug delivery companies, research organizations, individual scientists and nonprofit organizations engaged in the development and commercialization of drug delivery systems and new drug research and testing. We are aware of a number of companies currently seeking to develop pulmonary delivery devices and other non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems and infusion systems. Many of these companies and entities have greater research and development, manufacturing, marketing, financial and managerial resources and experience than we do. Accordingly,

our competitors may succeed in developing competing technologies and products, obtaining regulatory approval for products or gaining market acceptance more rapidly than we can. If competitors bring effective products to market before we do, there is a risk that we may not be able to gain significant market share because our competitors may have firmly established their products in the market. It is also possible that a competitor may develop a technology or product that renders our technology or products obsolete.

We may be unable to effectively protect our intellectual property, which could enable third parties to use our technology and impair our ability to compete effectively.

Our ability to compete effectively depends in part on developing and maintaining the proprietary aspects of our aerosolization technology. We cannot assure that the patents we have obtained, or any patents we may obtain as a result of our pending United States or international patent applications and, in particular, our vibratory aerosolization technology, which is technology that aerosolizes liquids by vibrating a metal plate that contains holes, will provide any competitive advantages for our products. We also cannot assure that those patents will not be successfully challenged, invalidated or circumvented in the future. In addition, we cannot assure that competitors, many of which have substantial resources and have made substantial investments in competing technologies, have not already applied for, or obtained, or will not seek to apply for and obtain, patents that will prevent, limit or interfere with our ability to make, use and sell our products either in the United States or in international markets. Patent applications are maintained in secrecy for a period after filing. We may not be aware of all of the patents and patent applications potentially adverse to our interests.

A number of pharmaceutical, medical device and other companies, as well as universities and research institutions, have filed patent applications or have issued patents relating to methods and apparatuses for aerosolization and pulmonary drug delivery. We have become aware of, and may

become aware of in the future, patent applications and issued patents that relate to certain aspects of the technology employed in our products, including certain aspects of vibratory aerosolization technology. Our pending patent applications, and those we may file in the future, may not result in patents being issued. We do not believe that our products currently infringe any valid and enforceable claims of the issued patents that we have reviewed. However, if third-party patents or patent applications contain claims infringed by our products and such claims are ultimately determined to be valid, we may not be able to obtain licenses to those patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. Our inability to do either would have a material adverse effect on our business, financial condition, results of operations and prospects. We cannot assure that we will not have to defend ourselves in court against allegations of infringement of third-party patents, or that such defense would be successful.

In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. We require our employees and key consultants to execute confidentiality agreements upon the commencement of employment or a consulting relationship with us. We cannot assure that employees or consultants will not breach these agreements, that we would have adequate remedies for any breach or that our trade secrets will not otherwise become known to or be independently developed by competitors.

We may become subject to patent litigation, which would be costly to defend and could invalidate our patents.

The pharmaceutical and medical device industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in these industries have used intellectual property litigation to gain a competitive advantage. We cannot assure that we will not become subject to patent infringement claims or litigation or interference proceedings declared by the United States Patent and Trademark Office, the USPTO, to determine the priority of inventions. In 1999, we settled a patent interference with United States Patent No. 5,261,601, assigned to Bespak. The settlement provided for a cross-license between us and Bespak, as a result of which Bespak has a license to certain of our technology, including the right to sublicense. The scope of the granted license was limited to products employing technology which was disclosed by Bespak in United States Patent No. 5,261,601.

Our patent position involves complex legal and factual questions and is generally uncertain. Legal standards relating to the validity and scope of patent claims in the biotechnology and pharmaceutical field are evolving. Defending and prosecuting intellectual property suits, USPTO interference proceedings and related legal and administrative proceedings are costly and time-consuming. Further litigation may be necessary to enforce our patents, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings will be costly and will result in significant diversion of effort by technical and management personnel. An adverse determination in any of the litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties, require us to license disputed rights from third parties or require us to cease using such technology, which would have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

Patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, and could include ongoing royalties. We cannot assure that we can obtain the necessary licenses on satisfactory terms, if at all.

If we were successfully sued for product liability, we could face substantial liabilities that may exceed our resources.

Researching, developing and commercializing medical devices and pharmaceutical products entail significant product liability risks. The use of our products in clinical trials, and the commercial sale of

our products may expose us to liability claims. These claims might be made directly by consumers or by our partner companies or others selling such products. Companies often address the exposure of this risk by obtaining product liability insurance. Although we currently have product liability insurance, we cannot assure that we can maintain such insurance or obtain additional insurance on acceptable terms in amounts sufficient to protect our business or at all. A successful claim brought against us in excess of our insurance coverage would have a material adverse effect on our business.

We use hazardous and toxic materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our operations involve the use of hazardous and toxic materials and generate hazardous, toxic and other wastes. In particular, we use a special metal alloy to build our aerosol generators a component of which is regulated as a hazardous material. The risk of accidental contamination or injury from hazardous and toxic materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result, and this liability could exceed our resources. Our operations could be shut down by government officials if we were not in compliance with environmental laws.

We have implemented anti-takeover measures that could discourage or prevent a takeover, even if an acquisition would be beneficial to stockholders.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law and of our stockholder rights plan adopted in 2001, could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions also may discourage bids at a premium over the market price of our common stock and may adversely affect both the market price of our common stock and the voting rights of our stockholders.

Concentration of ownership among our existing executive officers, directors and entities affiliated with our directors may prevent new investors from influencing significant corporate decisions.

As of September 30, 2002, our executive officers, directors and entities affiliated with our directors beneficially own, in the aggregate, approximately 28% of the outstanding common stock. As a result, these stockholders may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of the Company, and will make some transactions difficult or impossible without the support of these stockholders.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Interest rate risk

Interest rate risk represents the risk of loss that may impact our financial position, operating results or cash flows due to changes in interest rates. This exposure is directly related to our normal operating activities. We invest only in United States government and related agency securities and money markets. These investments are generally of a short-term nature. As a result, other than changes in interest income due to changes in interest rates, we do not believe that near-term changes in interest rates will have a material effect on our future results of operations.

Exchange rate risk

Due to our Irish operations, we have market risk exposure to adverse changes in foreign currency exchange rates. The revenues and expenses of our subsidiary, Aerogen (Ireland) Limited, are denominated in Eurodollars. At the end of each period, the revenues and expenses of

our subsidiary are translated into U.S. dollars using the average currency exchange rate in effect for that period, and

assets and liabilities are translated into U.S. dollars using the exchange rate in effect at the end of that period. Fluctuations in exchange rates therefore impact our financial condition and results of operations, as reported in U.S. dollars. Additionally, we occasionally have market risk exposure to adverse changes in foreign currency exchange rates associated with foreign vendors who require payment in their functional currencies. To date, we have not experienced any significant negative impact as a result of fluctuations in foreign currency markets. As a policy, we do not engage in speculative or leveraged transactions, nor do we hold financial instruments for trading or hedging purposes.

As we expand our overseas operations, our operating results may, become subject to more significant fluctuations based on changes in exchange rates of foreign currencies in relation to the U.S. dollar. We will periodically analyze our exposure to currency fluctuations and we may adjust our policies to allow for financial hedging techniques to minimize exchange rate risk.

Item 4. Controls and Procedures

Within 90 days prior to the filing date of this report, we carried out an evaluation, under the supervision and the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective and timely in alerting them to material information required to be included in our periodic SEC reporting. It should be noted that the design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

In addition, we reviewed our internal controls, and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of their last evaluation.

Part II. Other Information

Item 1. Legal Proceedings

None.

Item 2. Changes in Securities and Use of Proceeds

In November 2000, the Securities Exchange Commission declared our Registration Statement on Form S-1 effective. We completed our initial public offering, including the exercise of the underwriters' over-allotment option of a total of 4,140,000 shares, at an initial public offering price of $12.00 per share, for aggregate cash proceeds of approximately $49.7 million. The managing underwriters of the offering were Chase Securities Inc., CIBC World Markets Corporation and SG Cowen Securities Corporation.

In connection with the offering, we paid a total of approximately $3.5 million in underwriting discounts and commissions and $1.7 million in other offering costs and expenses. After deducting the underwriting discounts and commissions and the offering costs and expenses, our net proceeds from the offering, including the over-allotment option, were approximately $44.5 million.

The proceeds from the offering were used for research and development, clinical activities, marketing and manufacturing expenditures for existing and future products, capital expenditures and general corporate purposes beginning in January of 2001. As of September 30, 2002, the cumulative cash used in operations since the IPO has exceeded the proceeds from the IPO.

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)

Exhibits.

Exhibit Number	Description of Document
3.2(1)	Amended and Restated Certificate of Incorporation of Aerogen, Inc.
3.4(2)	Amended and Restated Bylaws of Aerogen, Inc.
99.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference from the exhibit with corresponding number from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, filed August 13, 2002.

(2) Incorporated by reference to the Company's Registration Statement on Form S-1 (No. 333-44470), filed August 25, 2000.

(b)

Reports on Form 8-K.

None.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Aerogen, Inc.

(Registrant)

Dated: November 13, 2002	By:	/s/ JANE E. SHAW
		Jane E. Shaw, Ph.D. *Chairman and Chief Executive Officer*
Dated: November 13, 2002	By:	/s/ ROBERT S. BREUIL
		Robert S. Breuil *Chief Financial Officer*

CERTIFICATIONS

I, Jane E. Shaw, certify that:

1.
I have reviewed this quarterly report on Form 10-Q of Aerogen, Inc.;

2.
Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3.
Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4.
The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

(a)
designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

(b)
evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

(c)
presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5.
The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

(a)
all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b)

any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6.

The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: November 13, 2002

/s/ JANE E. SHAW

Jane E. Shaw, Ph.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

I, Robert S. Breuil, certify that:

1.

I have reviewed this quarterly report on Form 10-Q of Aerogen, Inc.;

2.

Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3.

Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4.

The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

(a)

designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

(b)

evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

(c)

presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5.

The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

(a)

all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b)

any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6.

The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: November 13, 2002

/s/ ROBERT S. BREUIL

Robert S. Breuil
Chief Financial Officer
(Principal Financial Officer)

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CERTIFICATIONS