AEROGEN INC
Form 10-Q
November 14, 2003

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, 2003

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

Indicate by check mark whether the Registrant is an accelerated filed (as defined in Rule 12b-2 of the Exchange Act): Yes o No ý

As of November 10, 2003, there were 4,165,971 shares of the Registrant s Common Stock, par value $0.001, outstanding.

Aerogen, Inc.

Form 10-Q

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Part I. **Financial Information**

Item 1. **Condensed Consolidated Financial Statements**

Aerogen, Inc.

Condensed Consolidated Balance Sheets

(unaudited; in thousands)

	September 30, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 526	$ 3,266
Available-for-sale securities		5,621
Accounts receivable, net	1,756	903
Inventories, net	314	374
Prepaid expenses and other current assets	338	934
Total current assets	2,934	11,098
Property and equipment, net	4,651	5,251
Goodwill and other intangible assets, net	1,783	1,612
Restricted cash	1,200	1,200
Other assets	35	33
Total assets	$ 10,603	$ 19,194
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 953	$ 973
Convertible debt	950	
Discounts on convertible debt	(819)	
Accrued liabilities	1,543	1,446
Total current liabilities	2,627	2,419
Deferred long-term revenue	1,200	
Deferred rent	1,304	826
Other long-term liabilities	227	205
Total liabilities	5,358	3,450
Stockholders equity:		
Common stock	4	4
Additional paid-in capital	110,236	109,513
Notes receivable from stockholders	(276)	(434)
Deferred stock-based compensation, net	(507)	(1,520)
Accumulated other comprehensive income	114	233
Accumulated deficit	(104,326)	(92,052)
Total stockholders equity	5,245	15,744
Total liabilities and stockholders equity	$ 10,603	$ 19,194

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

Aerogen, Inc.

Condensed Consolidated Statements of Operations

(unaudited; in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	**2002**	**2003**	**2002**
Revenues:				
Product sales	$ 394	$ 496	$ 2,660	$ 608
Research and development		146	166	180
Royalty	125	62	375	187
Total revenues	519	704	3,201	975
Costs and expenses:				
Cost of products sold	249	513	1,694	979
Research and development	2,891	3,758	9,111	13,728
Selling, general and administrative	1,506	2,186	4,860	6,473
Total costs and expenses	4,646	6,457	15,665	21,180
Loss from operations	(4,127)	(5,753)	(12,464)	(20,205)
Interest income/(expense), net	(127)	85	(75)	425
Other income/(expense), net	(101)	1	265	3
Net loss	$ (4,355)	$ (5,667)	$ (12,274)	$ (19,777)
Net loss per share, basic and diluted	$ (1.06)	$ (1.40)	$ (3.00)	$ (4.91)
Weighted - average shares used in computing net loss per share, basic and diluted	4,105	4,050	4,094	4,028

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

Aerogen, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited; in thousands)

	Nine Months Ended September 30,	
	2003	**2002**
Cash flows from operating activities:		
Net loss	$ (12,274)	$ (19,777)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	966	873
Amortization of deferred stock-based compensation	763	1,060
Accrued interest on notes receivable from stockholders	(7)	(21)
Amortization of discount on convertible notes	131	
Amortization of premium / (discount) on available for sale securities	6	(6)
(Gain) / loss on disposal of property and equipment	(25)	218
Change in inventory reserves	8	129
Changes in operating assets and liabilities:		
Accounts receivable	(794)	(305)
Inventories	73	148
Prepaid expenses and other current assets	608	513
Other assets	2	9
Accounts payable	(55)	10
Accrued liabilities	(63)	(1,544)
Deferred revenues	1,292	115
Deferred rent	478	435
Other long-term liabilities		(6)
Net cash used in operating activities	(8,891)	(18,149)
Cash flows from investing activities:		
Acquisition of property and equipment	(285)	(3,588)
Purchases of available-for-sale securities		(5,995)
Proceeds from maturities of available-for-sale securities	5,615	20,317
Net cash provided by investing activities	5,330	10,734
Cash flows from financing activities:		
Proceeds from issuance of common stock	23	214
Proceeds from issuance of convertible debt	950	
Repurchase of common stock		(6)
Repayment of note receivable from stockholders	165	285
Net cash provided by financing activities	1,138	493
Effect of exchange rate changes on cash	(317)	32

Net (decrease) in cash and cash equivalents		(2,740)		(6,890)
Cash and cash equivalents, beginning of period		3,266		15,714
Cash and cash equivalents, end of period	$	526	$	8,824

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

Aerogen, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(**Unaudited**)

Note 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business of the Company

Aerogen, Inc. (Aerogen the Company or we) was incorporated in November 1991. We are a specialty pharmaceutical company focusing on respiratory therapy in the acute care setting. Our core technology is our proprietary OnQ Aerosol Generator. Using our technology, we are developing respiratory products for marketing by us, and products in collaboration with, and for marketing by, pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs through the lungs to the bloodstream. The Company s recurring net losses from operations and negative cash flows from operations, in light of the Company s current liquidity and capital resources, raise substantial doubt regarding the Company s ability to continue as a going concern for a reasonable period of time. Since inception, we have financed our operations primarily through debt and equity financings, product revenues, research and development revenues, and the interest earned on related proceeds. The process of developing our products will continue to require significant research and development, clinical trials and regulatory approvals. These activities, together with manufacturing, selling, general and administrative expenses, are expected to result in substantial operating losses for the next several years.

These condensed consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The continued operation of the Company is dependent on our ability to obtain adequate funding and eventually establish profitable operations. As of September 30, 2003, we had $0.5 million in cash and cash equivalents. During the first nine months of 2003, our operating cash expenditures averaged $1.4 million per month, which were partially offset by cash collections of trade receivables averaging $0.4 million per month, resulting in a net cash utilization of approximately $1.0 million per month. As a result of our continued losses and current cash resources, we will need to raise additional funds through public or private financings, sale of certain of our assets, collaborative relationships or other arrangements within the next few months in order to continue as a going concern. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to either certain of our products or technologies or desirable marketing territories, or all of these. We are pursuing efforts to raise such additional funds; however, if we are not successful, we may have to curtail significantly, or cease entirely, our operations, and/or seek bankruptcy protection.

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, 2002, filed with the Securities and Exchange Commission on March 31, 2003 (Form 10-K).

The results of operations for the nine months ended September 30, 2003 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2003, 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, 2003	December 31, 2002
	(in thousands)	
Raw materials	$ 226	$ 333
Work-in-process	45	31
Finished goods	43	10
Net inventories	$ 314	$ 374

Warranty

The Company offers a warranty of certain products and records a liability for the estimated future costs associated with warranty claims, which is based on historical experience and the Company s estimated level of future costs. Warranty costs are reflected in the statement of operations as a cost of products sold. A reconciliation of the changes in the Company s warranty liability for the nine months ending September 30, 2003 follows (in thousands):

Warranty accrual at January 1, 2003	$	101
Accruals for warranties issued during the period		138
Settlements made in kind during the period		(35)
Warranty accrual at September 30, 2003	$	204

Convertible Debenture and Warrants

In September 2003, the Company entered into a loan and securities purchase agreement pursuant to which a convertible debenture (the Debenture) and a warrant (the Warrant) were issued to SF Capital Partners, Ltd., (SF Capital). The Company received approximately $950,000 in cash in gross proceeds in exchange for the Debenture and the Warrant. The Debenture is convertible into 542,857 shares of common stock on or before December 31, 2003 at a conversion price of $1.75 per share. The Warrant is exercisable for 271,428 shares of common stock at an exercise price of $1.75 per share. The terms of the Debenture and Warrant preclude SF Capital from converting or exercising such securities if such conversion or exercise would result in SF Capital and its affiliates owning in excess of 9.999% of the Company s outstanding stock. The difference between the conversion price and the fair market value of the common stock on the commitment date (transaction date) resulted in a beneficial conversion feature recorded on the Debenture of $592,473. The Warrant was assigned an initial value of $357,527, estimated using the Black-Scholes valuation model, and has been classified as equity. The Warrant expires in four years. The following assumptions were used to determine the fair value of the Warrant using the Black-Scholes valuation model: term of four years, risk free rate of 3.28%, volatility of 100%, and a dividend yield of zero. The initial values assigned to both the Debenture and the Warrant were allocated based on the relative fair values of the Debenture and Warrant. The discount on the Debenture for the beneficial conversion feature and Warrant are being amortized to interest expense, using the effective interest method, over the term of the Debenture, which matures on December 31, 2003. Total interest expense recognized relating to the beneficial conversion feature and the Warrant discount was $130,606 for the three and nine month periods ended September 30, 2003.

Other Comprehensive Income

Other comprehensive income 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 that are excluded from the Company s net loss. The components of other comprehensive income which are excluded from net loss are not significant, individually or in the aggregate, and therefore, no separate statement of comprehensive loss has been presented.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted - average number of vested shares outstanding for the period. Diluted net loss per share is computed giving effect to all potential dilutive 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 share as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(in thousands)			
Net loss per share, basic and diluted:				
Net loss	$ (4,355)	$ (5,667)	$ (12,274)	$ (19,777)
Weighted average shares outstanding	4,105	4,054	4,095	4,043
Less: Weighted average shares subject to repurchase		4	1	15
Weighted average shares used in computing basic and diluted net loss per share	4,105	4,050	4,094	4,028

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

	September 30,	
	2003	2002
	(in thousands)	
Options to purchase common stock	492	616
Common stock subject to repurchase		3
Warrants	276	4

Accounting for Stock-based Compensation

The Company accounts for stock-based compensation using the intrinsic value method under Accounting Principles Board Opinion No. 25 (APB No. 25), Accounting for Stock Issued to Employees, and related interpretations and complies with the disclosure requirements of Statement of Financial Accounting Standards No. 148 (SFAS No. 148), Accounting for Stock-Based Compensation, Transition and Disclosure an amendment of SFAS Statement No.123. The following provides a reconciliation of net loss and net loss per share to proforma net loss and proforma net loss per share as if the Company had applied the fair value recognition provisions of SFAS No. 123 Accounting for Stock-Based Compensation to all employee awards:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net loss - as reported	$ (4,355)	$ (5,667)	$ (12,274)	$ (19,777)
Add: employee stock-based compensation included in reported net loss	247	295	747	1,046
Deduct : total stock-based employee compensation determined under fair value based method for all awards	(227)	(532)	(877)	(1,715)
Net loss - proforma	$ (4,335)	$ (5,904)	$ (12,404)	$ (20,446)
Net loss per share, basic and diluted - as reported	$ (1.06)	$ (1.40)	$ (3.00)	$ (4.91)
Net loss per share, basic and diluted - proforma	$ (1.06)	$ (1.46)	$ (3.03)	$ (5.08)

The above pro forma disclosures may not be representative of the pro forma effect in future years because options vest over several years and additional grants may be made each year.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force (EITF) Issue No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, which require that such equity instruments are recorded at their fair value on the measurement date, which is typically the date of grant. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

Note 2 - RECENT ACCOUNTING PRONOUNCEMENTS

In April 2003, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS No. 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The adoption of SFAS No. 149 did not have a material impact on the Company s consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS No. 150 establishes standards for how companies classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires companies to classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective beginning second quarter of fiscal 2004. The Company does not expect the adoption of SFAS No. 150 to have a material impact on its consolidated financial statements.

Note 3 SUBSEQUENT EVENTS

On September 30, 2003, the Company entered into an agreement with Medical Industries America, Inc. (MIA) for manufacturing and marketing of the Aeroneb® Go Nebulizer (Aeroneb Go). Under the terms of the agreement, MIA will have the exclusive right to manufacture and market the Aeroneb Go in the home care market in the United States and certain countries worldwide, including the major markets of Europe and Japan. During October, Aerogen received upfront payments totaling $2.5 million for these distribution rights and for the sale of certain equipment. Aerogen will also manufacture and supply OnQ Aerosol Generators to MIA under a transfer price agreement and will receive royalties from MIA on MIA s gross sales

of the Aeroneb Go and its accessories over the life of the agreement.

On October 24, 2003, the Company entered into an agreement with our landlord, EOP-Shoreline Technology Park, L.L.C. (EOP) to defer a portion of the base rent due under the lease relating to the Company s offices in Mountain View, California for the 24-month period, ending on June 30, 2005. This agreement allows the Company to repay the deferred portion on a monthly basis, plus 10% interest per annum on the unpaid portion, beginning on July 1, 2005 until the deferred portion is paid in full. In consideration of this agreement, we issued EOP 60,000 shares of the Company s common stock.

In a special meeting held on October 30, 2003, the stockholders approved a reverse stock split of our common stock, to allow any whole number of outstanding shares between and including four and eight to be combined into one share of our common stock, and to authorize our Board of Directors to select and file one such amendment. Immediately following the special meeting, the Company s Board of Directors approved a five-for-one reverse stock split. On October 31, 2003, we filed an amended and restated Certificate of Incorporation effecting the five-for-one reverse stock split. All references in the Company s financial statements to common shares, common share price, and per share amounts have been adjusted retroactively to give the effect of this stock split.

The stockholders also approved the second closing of a convertible debenture financing with SF Capital. On November 3, 2003, SF Capital purchased a secured convertible debenture (the Second Debenture) with a face amount of $1,000,000. The Second Debenture bears interest at a rate of 10% per annum, is due March 1, 2004, and is convertible into common stock at a conversion price of $3.28 per share. If fully converted, the principal amount of the Second Debenture would result in the issuance of 304,878 shares of common stock. SF Capital also received a four-year Warrant (the Second Warrant) to purchase up to 152,439 shares of common stock at an exercise price of $3.28 per share. The terms of the Second Debenture and Second Warrant preclude SF Capital from converting or exercising such securities if such conversion or exercise would result in SF Capital and its affiliates owning in excess of 9.999% of the Company s outstanding stock.

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, 2002, filed with the Securities and Exchange Commission on March 31, 2003 (Form 10-K).

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are described in Item 7 of the Company s Annual Report on Form 10-K for the year ended December 31, 2002, and have not changed materially since that date.

Overview

Aerogen was incorporated in November 1991. We are a specialty pharmaceutical company focusing on respiratory therapy in the acute care setting. Our core technology is our proprietary OnQ Aerosol Generator. Using our technology, we are developing respiratory products for marketing by us, and products in collaboration with, and for marketing by, pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs through the lungs to the bloodstream.

In 2002, Aerogen, Inc. generated significant revenues from our planned principal operations and hence we exited the development stage. However, we will continue to devote substantial efforts to the development of current and future products. We currently market nebulizer products which include the Aeroneb® Portable

Nebulizer System (Aeroneb Portable) and the Aeroneb® Professional Nebulizer System (Aeroneb Pro) and have recently announced an exclusive marketing partner for the Aeroneb Go nebulizer, our next generation home nebulizer that will replace the Aeroneb Portable. We have an accumulated deficit of approximately $104 million as of September 30, 2003. The continued existence of the Company is dependent on the Company s ability to obtain adequate funding and eventually establish profitable operations.

As of September 30, 2003, we had $0.5 million in cash and cash equivalents. During the first nine months of 2003, our operating cash expenditures averaged $1.4 million per month, which were partially offset by cash collections of trade receivables averaging $0.4 million per month, resulting in a net cash utilization of approximately $1.0 million per month. As a result of our continued losses and current cash resources, we will need to raise additional funds through public or private financings, sale of certain of our assets collaborative relationships or other arrangements within the next few months in order to continue as a going concern. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to either certain of our products or technologies or desirable marketing territories, or all of these. We cannot be certain that such additional funding will be available on terms attractive to us, or at all. Furthermore, additional equity or debt financing may involve substantial dilution to our existing stockholders, restrictive covenants or high interest rates. We are pursuing efforts to raise such additional funds; however, if we are not successful, we may have to curtail significantly, or cease entirely, our operations, and/or seek bankruptcy protection.

We expect to incur significant additional operating losses over the next several years and expect cumulative losses to increase, primarily due to the costs associated with the manufacturing and marketing of our products, the expansion of our research and development activities and the general expansion of our business activities. We anticipate that our quarterly 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 debt and equity financings, product revenues, research and development revenues, royalty revenues, interest earned on investments and, to a small extent, equipment lease financings.

Results of Operations

Revenues

Total revenues for the three months ended September 30, 2003 were $0.5 million, compared with $0.7 million for the same period of 2002. Total revenues for the nine months ended September 30, 2003 were $3.2 million, compared with $1.0 million for the same period of 2002. Total revenues include revenues from product sales, research and development activities for unrelated third parties, and royalties associated with the licensing of our technology for use outside the medical field.

Product sales for the three months ended September 30, 2003 were $0.4 million, compared with $0.5 million for the same period of 2002, and $1.0 million for the three months ended June 30, 2003. Product orders were lower for the three month period ended September 30, 2003 than for the prior three month period ended June 30, 2003 due to the completion of pipeline stocking of Aeroneb Pro during the first six months of 2003, cyclical purchasing patterns of Aerogen's distribution partners and to their expressed concerns regarding the Company s near-term financial viability. The decrease in sales for the three months ended September 30, 2003 compared with 2002, also primarily resulted from the phasing out of our Aeroneb Portable product, which will be replaced by the Aeroneb Go product that has been limited to a test market as of September 30, 2003 and lower sales of Aeroneb Pro.

Product sales for the nine months ended September 30, 2003 were $2.7 million compared with $0.6 million for the same period of 2002. The increase in product sales for the nine months ended September 30, 2003 over 2002 was primarily due to the increased sales of the Aeroneb Pro.

There was no research and development revenue for the three months ended September 30, 2003 compared with $0.1 million for the same period of 2002. Research and development revenues for the three months ended September 30, 2002 resulted from the completion of one program and our recognition of the associated deferred revenue. Research and development revenues for the nine months ended September 30, 2003 were $166,000 compared with $180,000 for the same period of 2002. 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 expect research and development revenues for 2003 to be lower than those for 2002.

Royalty revenues were $125,000 and $62,500, for the three month periods ended September 30, 2003 and 2002, respectively. Royalty revenues for the nine months ended September 30, 2003 were $375,000 compared with $187,000 for the same period of 2002. These royalties represent a minimum royalty obligation associated with licensing our aerosol generator technology to a consumer product company for use in the delivery of air fresheners and insect repellants. The increase from the three months and nine months ended September 30, 3002 was due to an increase in the minimum royalty payable under the agreement with the consumer product company. The first product covered by the agreement was launched in one country outside of the United States in January 2003 and in several cities in the United States in March 2003.

Cost of Products Sold

Cost of products sold for the three months ended September 30, 2003 and 2002 was $0.2 million and $0.5 million, respectively. Cost of products sold for the nine months ended September 30, 2003 was $1.7 million compared with $1.0 million for the same period of 2002. During the fourth quarter of 2002 and the first nine months of 2003, yield improvements in manufacturing processes resulted in lower costs per unit and improvements in cost of products sold as a percent of product sales. As Aeroneb Pro volumes increase and the manufacturing processes mature, we anticipate further improvements to the cost of products sold as a percent of product sales. For the nine months ended September 30, 2002, cost of products sold included costs associated with the start-up of manufacturing production in our facility in Mountain View, California.

Research and Development Expenses

Research and development expenses include 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, all including related overhead. Research and development spending may increase significantly over the next several years as we undertake new clinical trials and 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 collaborations, entering into new partnering agreements, potential changes in our partners priorities, and the level of internally funded research and development efforts.

Research and development expenses for the three months ended September 30, 2003 were $2.9 million, compared with $3.8 million for the same period of 2002. The decrease in research and development expenses of $0.9 million for the three months ended September 30, 2003, as compared with the same period of 2002, was primarily due to: reduced payroll and related expenses of $0.6 million associated with reductions in force in 2002 and early 2003; reduced expenses for professional services, materials and machining services for the development of the commercial version of our Aerodose® insulin product inhaler and clinical trials of $0.2 million; reduced expenses for professional services, machining services, and materials for several other programs totaling $0.1 million; partially offset by $0.1 million in expenses for amikacin Phase 2 clinical trials.

Research and development expenses for the nine months ended September 30, 2003 were $9.1 million, compared with $13.7 million for the same period of 2002. The decrease in research and development expenses of $4.6 million for the three months ended September 30, 2003, as compared with the same period of 2002, was primarily due to: reduced payroll and related expenses of $2.5 million associated with reductions in force in 2002 and early 2003; reduced expenses of $1.1 million for professional services, materials and machining services for the development of the commercial version of our Aerodose insulin product inhaler and clinical trials; reduced expenses for professional and machining services associated with our development of clinical devices for respiratory products of $0.3 million; reduced expenses for professional services, machining services, and materials for several other programs totaling $0.7 million; and reduced facility related expenses of $0.2 million due to dual facilities in early 2002; partially offset by $0.2 million of expenses for amikacin Phase 2 clinical trials.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2003 were $1.5 million, compared with $2.2 million for the same period of 2002. The decrease for the three months ended September 30, 2003 of $0.7 million compared with the same period of 2002 was primarily due to: decreases in payroll and related expenses of $0.2 million associated with reductions in force in 2002 and early 2003; expenses for professional services associated with marketing research of $0.3 million; expenses for professional services associated with marketing and selling our Aeroneb products of $0.2 million; and other expenses of $0.1 million, partially offset by an increase in outside legal expenses of $0.1 million.

Selling, general and administrative expenses for the nine months ended September 30, 2003 were $4.9 million, compared with $6.5 million for the same period of 2002. The decrease for the nine months ended September 30, 2003 of $1.6 million compared with the same period of 2002 was primarily due to decreases in payroll and related expenses of $1.0 million associated with reductions in force in 2002 and early 2003; deferred stock based compensation of $0.2 million; expenses for professional services associated with marketing research of $0.3 million expenses for professional services associated with marketing our Aeroneb products of $0.3 million; travel expenses of $0.1 million; and other expenses of $0.1 million, partially offset by an increase in outside legal expenses of $0.4 million.

Interest and Other Income, Net

Net interest expense for the three months ended September 30, 2003 was $0.1 million compared with $0.1 million of net interest income for the same period of 2002. Net interest expense for the nine months ended September 30, 2003 was $0.1 million compared with $0.4 million of net interest income for the same period of 2002. The decrease in interest income for the three and nine months 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. Interest expense was $0.1 million for the three and nine months ended September 30, 2003, primarily due to imputed interest on the beneficial conversion feature of the Debenture and the value associated with the Warrant issued to SF Capital. There was no interest expense for the same periods of 2002.

Other income and expense, primarily comprising foreign currency translation losses, was $0.1 million for the three months ended September 30, 2003 compared with a minimal gain for the same period of 2002. Other income and expense, for the nine months ended September 30, 2003 primarily consisted of currency translation gains, which were $0.3 million for the nine months ended September 30, 2003 compared with $3,000 for the same period of 2002.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through debt and equity financings, product sales, research and development revenues and the interest earned on these funds. We have received approximately $98.5 million aggregate net proceeds from sales of our common and preferred stock through September 30, 2003, including approximately $44.5 million of net proceeds from our initial public offering (IPO) in November 2000.

As of September 30, 2003, we had cash and cash equivalents of approximately $0.5 million. Net cash used in operating activities during the nine months ended September 30, 2003 was $8.9 million resulting primarily from the net loss for the period of $12.3 million; increases in accounts receivable of $0.8 million; decreases in prepaid expenses and other current assets of $0.6 million; and net decreased accounts payable and accrued liabilities of $0.1 million. These uses were partially offset by non-cash related charges of approximately $1.0 million in depreciation and amortization; $0.8 million in amortization of deferred stock-based compensation; increases in deferred rent of $0.5 million; and increases in deferred revenue of $1.3 million. Net cash used in operating activities for the nine months ended September 30, 2002, was $18.1 million resulting primarily from the net loss for the period of $19.8 million and decreased accounts payable and accrued liabilities of $1.5 million, partially reduced by non-cash related charges of approximately $2.3 million and a reduction in prepaid expenses of $0.5 million.

Net cash provided by investing activities was $5.3 million for the nine months ended September 30, 2003, consisting primarily of proceeds from maturing available-for-sale securities of $5.6 million, partially offset by $0.3 million of property and equipment acquisitions associated with process improvements. Net cash provided by investing activities was $10.7 million for the nine months ended September 30, 2002, consisting primarily of $14.3 million from proceeds from maturities of available-for-sale securities, net of purchases, partially offset by the acquisition of $3.6 million of leasehold improvements and equipment.

Net cash provided by financing activities for the nine months ending September 30, 2003 was $1.1 million, including the issuance of a convertible debenture that provided gross proceeds of $950,000; repayment of notes receivable from stockholders provided $165,000 and proceeds from issuance of common stock provided $23,000. For the nine months ending September 30, 2002, financing activities provided $0.5 million including $285,000 of repayment of notes receivable from stockholders, and $208,000 from the issuance of common stock.

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.

We need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next few months in order to continue as a going concern. We cannot be certain that such additional funding will be available on terms attractive to us, or at all. Furthermore, additional equity or debt financing may involve substantial dilution to our existing stockholders, restrictive covenants or high interest rates. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to either certain of our products or technologies or desirable marketing territories, or all of these. We may also explore other potential options, such as a merger or sale. If our efforts are unsuccessful, we will have to significantly curtail, or cease entirely our operations and/or seek bankruptcy protection. Even if we are successful at raising funds to continue our operations, our cash requirements may increase in the future because of our research and development efforts, including clinical trials, capital expenditures and the manufacture and marketing of our products.

On September 30, 2003, the Company entered into an agreement with Medical Industries America, Inc. (MIA) for manufacturing and marketing of the Aeroneb Go nebulizer. Under terms of the agreement, Aerogen received upfront payments totaling $2.5 million for distribution rights and for the sale of certain equipment. Aerogen will also manufacture and supply the core components to MIA over the life of the agreement. The $2.5 million from MIA was received by Aerogen in installments prior to October 20, 2003.

On October 24, 2003, the Company entered into an agreement with its landlord to defer a portion of the base rent due for the premises during a 24-month period, ending on June 30, 2005, and to allow us to repay the deferred portion of such base rent at a later date. For this consideration, we agreed to repay the deferred portion on a monthly basis, plus 10% interest per annum on the unpaid portion, beginning on July 1, 2005 until the deferred portion is paid in full. In consideration of this agreement, we issued 60,000 shares of the Company s common stock to our landlord.

On October 30, 2003, our stockholders approved a second closing of the convertible debenture financing with SF Capital, including the issuance of a convertible debenture and warrant to purchase our common stock. On November 3, 2003, SF Capital purchased a secured convertible debenture (the Second Debenture) with a face amount of $1,000,000 that bears interest at a rate of 10% per annum and is due March 1, 2004. The Second Debenture is convertible into common stock at a conversion price of $3.28 per share. If fully converted, the principal amount of the debenture would result in the issuance of 304,878 shares of our common stock (the Second Warrant). SF Capital also received a four-year warrant to purchase up to 152,439 shares of our common stock at an exercise price of $3.28 per share. The terms of the Second Debenture and

Second Warrant preclude SF Capital from converting or exercising such securities if such

conversion or exercise would result in SF Capital and its affiliates owning in excess of 9.999% of the Company s outstanding stock.

Recent Accounting Pronouncements

In April 2003, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS No. 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. SFAS No. 149 is effective for contracts entered into or modified after September 30, 2003 and for hedging relationships designated after September 30, 2003. The adoption of SFAS No. 149 did not have a material impact on the Company s consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS No. 150 establishes standards for how companies classify and measures certain financial instruments with characteristics of both liabilities and equity. It requires companies to classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS No. 150 is effective beginning second quarter of fiscal 2004. The Company does not expect the adoption of SFAS No. 150 to have a material impact on its consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

RISK FACTORS

This offering involves a high degree of risk. You should carefully consider the following risk factors, in addition to other information included or incorporated by reference in this prospectus, before making an investment decision. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and you may lose all or part of your investment.

We need additional capital. If we cannot secure additional funding on acceptable terms within the next few months, we may not be able to continue as a going concern.

As of September 30, 2003, we had $0.5 million in cash, cash equivalents and short-term investments. Since September 30, 2003, we have received an aggregate of $2.5 million in payments from Medical Industries America (MIA) in connection with the agreement announced in October 2003 with MIA in relation to the Aeroneb® Go nebulizer. In addition, on November 3, 2003, we received gross proceeds of $1,000,000 from SF Capital Partners, Ltd. in connection with the issuance of a convertible debenture and associated warrant. During the first nine months of 2003, our operating cash expenditures averaged $1.4 million per month, which were partially offset by cash collections of trade receivables averaging $0.4 million per month, resulting in a net cash utilization of approximately $1.0 million per month. We need to raise additional funds through public or private financings, sale of certain of our assets, collaborative relationships or other arrangements within the next few months in order to continue as a going concern. We cannot be certain that such additional funding will be available on terms attractive to us, or at all. Furthermore, additional equity or debt financing may involve

substantial dilution to our existing stockholders, restrictive covenants or high interest rates. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to either certain of our products or technologies or desirable marketing territories, or all of these. We may also explore other potential options, such as a merger or sale. If our efforts are unsuccessful, we will have to significantly curtail, or cease entirely, our operations and/or seek bankruptcy protection. Even if we are successful at raising funds to continue our operations, our cash requirements may 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 have a history of losses, anticipate future losses and may never achieve or maintain profitability.

We have never been profitable. Through September 30, 2003, we have incurred an accumulated deficit of approximately $104 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 products currently being developed.

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

Our operating results may fluctuate significantly and may fail to meet the expectations of investors.

We expect that our operating results may fluctuate in the future, and may vary from investors expectations, depending on a number of factors described in this Risk Factors section including:

- the availability of additional funding and the terms of any such funding;

the success of any restructuring actions we have taken or may take in the future;

changes in domestic and international economic, business, regulatory, industry and political conditions;

demand for our existing products and any we may introduce in the future;

timing of the introduction of new products and enhancements of existing products;

allocation of our resources, particularly when they are limited; and

the costs and expenses relating to any litigation.

Our 2002 reductions in force and our January 2003 restructuring may not be sufficient to accomplish our goals.

In January and June 2002, we engaged in reductions in force in order to reduce our operating expenses. In December 2002, we began a restructuring that included the suspension of development of our Aerodose insulin inhaler product, and a workforce reduction in January 2003. While these changes were designed to reduce spending, align resources with long-term growth opportunities and preserve cash, there can be no assurances that we will realize any of these expected benefits to the extent needed. Further, we cannot predict whether we will need to engage in additional restructuring actions, which may impact our operating results.

Our stock price may continue to 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, including those of our competitors;
- period-to-period fluctuations in financial results; and

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 increase in the future or will recover to the initial public offering price.

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

Our common stock is currently listed on the Nasdaq SmallCap Market and, between July 1, 2002 and November 3, 2003, had a closing bid price 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. Nasdaq granted us a grace period until November 3, 2003 to regain compliance with this requirement. On October 30, 2003, we received stockholder approval for, and on October 31, 2003 we effected, a reverse stock split of our common stock at a ratio of one-for-five. While our closing bid price has exceeded $1.00 per share since November 3, 2003, we cannot be certain that it will remain at that level or, even if it does, that we will be able to avoid being delisted from the Nasdaq SmallCap Market. While a reverse stock split may be an effective means for increasing the bid price of our common stock, the resulting reduced liquidity may adversely impact the attractiveness of our stock to investors.

If we are unable to meet all of the requirements of the Nasdaq SmallCap Market, our stock may be delisted and 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, 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.

Many of our products are in research and development stages, which makes it difficult to evaluate our business and prospects.

Many of our products are in the research or development stages. Before we can begin to commercialize our new products, we will need to invest in substantial additional activities, generally including the conduct of clinical trials. To further develop our products, we will need to obtain additional funds and 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, nebulizer or drug 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.

Our technologies are relatively unproven, so they may not work effectively or safely enough to commercialize inhalers, nebulizers or drug-containing products.

Since our pulmonary drug delivery technologies are 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 technologies;
- our inhalers and nebulizers 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 drug products are not successful, drug products using our inhalers or nebulizers may not be commercialized.

Before either we or our partners can file for regulatory approval for the commercial sale of combination products using our inhalers or our nebulizers, the United Stated 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 inhalers and 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 experience manufacturing our technology. We 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 produce all of our aerosol generators for our products, partnered or not, in a single facility. We plan to use contract manufacturers to produce certain other key components and subassemblies of our products, many of which are produced in unique facilities and/or with unique tooling. 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 or redesign the

product, 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.

During 2002, our Aerodose inhaled insulin product was our most mature product in development for systemic drug delivery; however, we have suspended development of that product.

We have 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. During 2002, we did not sign an agreement with a marketing partner to fund the additional development and clinical trials necessary to obtain regulatory approval and to commercialize the product; therefore we have stopped our work on that product, and do not expect to re-start the program until we have an acceptable partner or sufficient funding to pay for additional clinical trials. We cannot assure that we will ever 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.

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 or approval 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. A longer than expected regulatory process, additional or significant changes in regulatory requirements, or more expensive clinical studies than we anticipate, may cause us to stop development of particular products, which we did with our albuterol and ipratropium inhaler products.

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 and fund 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 effort, we will not be able to sustainably commercialize our products.

We currently have a small sales and marketing staff and modest marketing budget, and many of our competitors have substantial sales and marketing infrastructures and significant marketing budgets. We rely on third party distributors to sell our products, some of which have limited experience in the markets that we are trying to access. Our success in commercializing our respiratory products in the United States and worldwide will depend on our and our partners ability to develop and execute a successful sales and marketing effort. There can be no assurance that our current products, which include the Aeroneb® Portable Nebulizer System, the Aeroneb® Professional Nebulizer System, and the Aeroneb®Go (not yet cleared for marketing in the U.S.) will be successful. 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 and sales expenditures necessary to launch and grow the products. Our distribution and marketing partners have significant discretion in allocating and applying their selling and marketing efforts, so we have limited ability to predict or manage the end-user acceptance of our products, and there can be no guarantee that we can meet demand that rises sharply as a result of our partners selling and/or marketing efforts.

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.

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. 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.

If our manufacturing facilities, or those of our subcontractors and/or licensees, 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, and those of our subcontractors and manufacturing licensee Medical Industries America (MIA), 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. We received our registration in August 2002. We registered with the FDA an additional manufacturing site in Galway, Ireland, in April 2003. In September 2003, the site in Galway underwent an inspection by the FDA. Two observations were noted. One addressed the manner in which Aerogen records documented in-process acceptance test results and the other addressed the Calibration SOP and equipment that was no longer in use, but had exceeded its calibration period. We submitted a timely response to the FDA Form 483. The FDA has not yet informed us as to the adequacy of our response.

Aerogen, MIA, and Aerogen s subcontractors are also are required to comply with ISO 9001/EN46001 in order to manufacture 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.

In May of 2003, the Mountain View facility successfully obtained certification to ISO 13485: 1996. If Aerogen, MIA or Aerogen s subcontractors fail to maintain compliance with QSR requirements, ISO 9001/EN46001, ISO 13485 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, or those of MIA and/or our subcontractors, will be found to comply on an ongoing basis with QSR, ISO or other international regulatory requirements.

The State of California requires that we maintain a license to manufacture medical devices at our Mountain View facility, 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. Similar requirements exist in other jurisdictions where our products are manufactured.

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. One of our first commercial products, the Aeroneb Pro, is not currently reimbursed by insurance or government entities, which may limit its 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 be sure 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 have in the past and may become in the future subject to patent litigation, which has been and may 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, whether within or outside of the United States, 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. Additionally, in

April 2003, we received notice that a German patent infringement suit had been filed by PARI GmbH in the regional court in Munich, Germany alleging that Aerogen s Aeroneb Pro product infringes the patent in question. While the suit has not yet been formally initiated by the German regional court, we believe that it is without merit and intends to vigorously defend against all allegations in the suit. In May 2003, we filed an action in the German patent office requesting that the patent in question be rendered null and void.

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 and amended in early 2003), 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 15, 2003, our executive officers, directors and entities affiliated with our directors beneficially owned, 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 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Based upon their evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) are, as of September 30, 2003, sufficiently effective to ensure that information required to be disclosed by us in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and Form 10-Q.

Changes in Internal Controls over Financial Reporting. In addition, we reviewed our internal controls, and there were no changes in our internal controls over financial reporting during the quarter ended September 30, 2003 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. 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.

Part II. **Other Information**

Item 1. Legal Proceedings

In April 2003, we received notice that a German patent infringement suit had been filed by PARI in the regional court in Munich, Germany alleging that Aerogen s Aeroneb Pro product infringes the patent in question. While the suit has not yet been formally initiated by the German regional court, the Company believes that it is without merit and intends to vigorously defend against all allegations in the suit. In May 2003, the Company filed an action in the German patent office requesting that the patent in question be rendered null and void.

Item 2. Changes in Securities and Use of Proceeds

On September 10, 2003, the Company closed the first round of a two round convertible debt financing, which resulted in gross proceeds to Aerogen of approximately $950,000 from SF Capital Partners, Ltd (SF Capital).

Under the terms of the investment, SF Capital purchased a secured convertible debenture with a face value of approximately $950,000 that bears interest at a rate of 10% per annum and is due December 31, 2003, at a conversion price of $1.75 per share, as adjusted for our five-for-one reverse stock split. If fully converted, the debenture would result in the issuance of approximately 542,857 shares of common stock. SF Capital also received a four-year warrant to purchase up to approximately 271,428 shares of common stock at an exercise price of $1.75 per share. The issuance of the debenture and warrant to SF Capital was exempt from registration under Section 4(2) of the Securities Act of 1933, as amended.

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

On September 30, 2003, we entered into an agreement with Medical Industries America, Inc. (MIA) for manufacturing and marketing of Aerogen's Aeroneb Go nebulizer. Under the terms of the agreement, MIA will have the exclusive right to manufacture and market the Aeroneb Go nebulizer in the home care market in the United States and certain countries worldwide, including Japan and the major markets of Europe. We have received upfront payments totaling $2.5 million for these distribution rights and for the sale of certain equipment. We will also manufacture and supply OnQ Aerosol Generators to MIA under a transfer price agreement and will receive royalties from MIA on MIA s gross sales of the Aeroneb Go nebulizer and its accessories over the life of the agreement.

On October 24, 2003, we entered into an agreement with our landlord, EOP-Shoreline Technology Park, L.L.C. EOP) to defer a portion of the base rent due under the lease for our offices in Mountain View, California for the 24-month period, ending on June 30, 2005. This agreement allows us to repay the deferred portion on a monthly basis, plus 10% interest per annum on the unpaid portion, beginning on July 1, 2005 until the deferred portion is paid in full. In consideration of this agreement, we issued EOP 60,000 shares of our common stock.

In a special meeting held on October 30, 2003, our stockholders approved a reverse stock split of our common stock, to allow any whole number of outstanding shares between and including four and eight to be combined into one share of our common stock, and to authorize our Board of Directors to select and file one such amendment. Immediately following the special meeting, our Board of Directors approved a five-for-one reverse stock split. On October 31, 2003, we filed an amended and restated Certificate of Incorporation effecting the five-for-one reverse stock split. All references in our financial statements to common shares, common share price, and per share amounts have been adjusted retroactively to give the effect of this stock split.

Our stockholders also approved the second closing of a convertible debt financing with SF Capital Partners, Ltd. On November 3, 2003, SF Capital purchased a secured convertible debenture (the Second Debenture) with a face amount of $1,000,000. The Second Debenture bears interest at a rate of 10% per annum, is due March 1, 2004, and is convertible into common stock at a conversion price of $3.28 per share. If fully converted, the principal amount of the Second Debenture would result in the issuance of 304,878 shares of our common stock. SF Capital also received a four-year warrant (the Second Warrant) to purchase up to 152,439 shares of our common stock at an exercise price of $3.28 per share.

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.
3.2.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Aerogen, Inc.
3.4(2)	Amended and Restated Bylaws of Aerogen, Inc.
4.1(3)	Debenture dated as of September 9, 2003, issued by the Company to SF Capital.
4.2(4)	Warrant dated as of September 9, 2003, issued by the Company to SF Capital.
4.3	Debenture dated as of November 3, 2003, issued by the Company to SF Capital.
4.4	Warrant dated as of November 3, 2003, issued by the Company to SF Capital.
10.17(5)	Distribution and supply agreement, dated as of September 30, 2003, between the Company and Medical Industries America, Inc.
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certifications required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 to Title 18 of the United States Code (18 U.S.C. 1350)

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(1) Incorporated by reference to 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.

(3) Incorporated by reference to Exhibit 10.15 of the Company s Report on Form 8-K filed on October 7, 2003.

(4) Incorporated by reference to Exhibit 10.16 of the Company s Report on Form 8-K filed on October 7, 2003.

(5) Confidential treatment has been requested for portions of this exhibit.

(b) Reports on Form 8-K.

During the quarter ended September 30, 2003, we filed on August 4, 2003 one Current Report on Form 8-K concerning our press release announcing our financial results for the quarter ended June 30, 2003.

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 14, 2003	By:	/s/ JANE E. SHAW Jane E. Shaw, Ph.D. *Chairman and Chief Executive Officer*
Dated: November 14, 2003	By:	/s/ ROBERT S. BREUIL Robert S. Breuil *Chief Financial Officer*

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