AEROGEN INC
Form 10-Q
November 15, 2004

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, 2004

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, Suite 100, 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 (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 5, 2004, there were 4,884,829 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, except per share data)

	September 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,271	$ 762
Accounts receivable	935	445
Inventories, net	893	301
Prepaid expenses and other current assets	1,206	428
Total current assets	23,305	1,936
Property and equipment, net	3,157	3,901
Goodwill and other intangible assets, net	1,896	1,931
Restricted cash		1,200
Other assets	449	608
Total assets	$ 28,807	$ 9,576
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,094	$ 937
Deferred revenue, current	529	500
Convertible debentures, net		1,486
Accrued liabilities	1,903	1,194
Total current liabilities	3,526	4,117
Deferred rent	204	1,658
Deferred revenue, non-current	1,903	1,875
Other long-term liabilities	241	246
Total liabilities	5,874	7,896
Convertible preferred stock		
Convertible preferred stock, par value $0.001: Authorized: 5,000 shares; issued and outstanding: 1,142 shares at September 30, 2004 and no shares at December 31, 2003 (Liquidation preference: $34,260 at September 30, 2004)	12,573	
Stockholders equity:		
Common stock, par value $0.001: Authorized: 95,000 shares; issued and outstanding: 4,870 shares at September 30, 2004 and 4,396 shares at December 31, 2003	5	4

Additional paid-in capital		131,442		110,991
Notes receivable from stockholders		(289)		(280)
Deferred stock-based compensation, net				(264)
Accumulated other comprehensive income		912		700
Accumulated deficit		(121,710)		(109,471)
Total stockholders equity		10,360		1,680
Total liabilities, convertible preferred stock and stockholders equity	$	28,807	$	9,576

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,	
	2004	2003	2004	2003
Revenues:				
Product sales	$ 883	$ 394	$ 2,983	$ 2,660
Research and development				166
Royalty and other	330	125	1,024	375
Total revenues	1,213	519	4,007	3,201
Costs and expenses:				
Cost of products sold	809	249	2,803	1,694
Research and development	3,280	2,891	8,072	9,111
Selling, general and administrative	1,451	1,506	4,780	4,860
Total costs and expenses	5,540	4,646	15,655	15,665
Loss from operations	(4,327)	(4,127)	(11,648)	(12,464)
Interest income (expense), net	79	(127)	(456)	(75)
Other income (expense), net	158	(101)	(135)	265
Net loss	(4,090)	(4,355)	(12,239)	(12,274)
Dividends related to convertible preferred stock	(514)		(13,327)	
Net loss attributable to common stockholders	$ (4,604)	$ (4,355)	$ (25,566)	$ (12,274)
Net loss per share, basic and diluted	$ (0.96)	$ (1.06)	$ (5.47)	$ (3.00)
Weighted - average shares used in computing net loss per share, basic and diluted	4,795	4,105	4,678	4,094

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,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$ (12,239)	$ (12,274)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	926	966
Changes in inventory reserves		8
(Gain) / loss on disposal of property and equipment	755	(25)
Accrued interest on notes receivable from stockholders	(10)	(7)
Amortization of notes discount on convertible notes	522	131
Amortization of premium on available for sales securities		6
Amortization of deferred stock-based compensation	264	763
Changes in operating assets and liabilities:		
Accounts receivable	(491)	(794)
Inventories	(593)	73
Prepaid expenses and other current assets	419	608
Accounts payable	163	(55)
Accrued liabilities	293	(63)
Deferred rent	(1,454)	478
Deferred revenue	57	1,292
Other	24	2
Net cash used in operating activities	(11,364)	(8,891)
Cash flows from investing activities:		
Acquisition of property and equipment	(597)	(285)
Proceeds from maturities of available-for-sale securities		5,615
Net cash provided by (used in) investing activities	(597)	5,330
Cash flows from financing activities:		
Proceeds from issuance of common stock	7	23
Proceeds from issuance of preferred stock and warrants, net	30,928	
Proceeds from issuance of convertible debenture	505	950
Repayment of note receivable from stockholder		165
Net cash provided by financing activities	31,440	1,138
Effect of exchange rate changes on cash	30	(317)
Net increase (decrease) in cash and cash equivalents	19,509	(2,740)
Cash and cash equivalents at beginning of period	762	3,266
Cash and cash equivalents at end of period	$ 20,271	$ 526
Supplemental disclosure of noncash investing and financing activities:		
Conversion of convertible debt and interest into common stock	$ 585	$
Issuance of warrants	$ 6,886	$
Beneficial conversion feature of preferred stock	$ 12,413	$
Conversion of convertible debt and interest into preferred stock	$ 1,567	$
Issuance of stock dividend	$ 913	$

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

Aerogen, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(**Unaudited, tabular amounts in thousands, except per share data**)

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 developing novel drug/device combination aerosol products for treatment of respiratory disorders in the critical care setting. Based on our proprietary OnQ Aerosol Generator (OnQ) for aerosolizing liquids, 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. Since inception, we have financed our operations primarily through equity and convertible debt financings, product revenues, research and development revenues, licensing fees, royalties, 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. On May 12, 2004, we completed a $32.7 million financing providing net proceeds of $30.9 million. As of September 30, 2004, Aerogen had cash, cash equivalents and short-term investments totaling $20.3 million. Cash expenditures for the three months and nine months ended September 30, 2004 were higher than anticipated, primarily due to the absence of OnQ sales revenues during the third quarter from Evo Medical Solutions (Evo, formerly Medical Industries America) related to FDA action taken against Evo during that period. If our average rate of cash expenditures remains constant at the third quarter average rate, then our current cash resources will be insufficient to permit operations beyond November 2005.

As a result of our continued losses and current cash resources, we will need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next twelve 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.

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, 2003, filed with the Securities and Exchange Commission on April 14, 2004.

The results of operations for the three months ended September 30, 2004 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2004 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, 2004	December 31, 2003
	(in thousands)	
Raw materials	$ 396	$ 228
Work-in-process	204	30
Finished goods	293	43
Net inventories	$ 893	$ 301

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 statements of operations as a cost of products sold. A reconciliation of the changes in the Company s warranty liability for the nine months ended September 30, 2004 and 2003 is as follows (in thousands):

	Nine Months Ended September 30,	
	2004	2003
Warranty accrual at January 1	$ 138	$ 101
Accruals for warranties issued during the period	121	138
Settlements made in kind during the period	(113)	(35)
Warranty accrual at September 30	$ 146	$ 204

Other Comprehensive Loss

Other comprehensive loss generally represents all changes in stockholders equity except those resulting from investments or contributions by stockholders. Foreign currency translation gains and losses represent the only components of comprehensive income that are excluded from the Company s net loss. Total comprehensive loss during the three and nine months ended September 30, 2004 and 2003 consisted of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	$ (4,604)	$ (4,355)	$ (25,566)	$ (12,274)

Net loss attributable to common stockholders				
Foreign currency translation adjustments	26	152	212	(119)
Comprehensive loss	$ (4,578)	$ (4,203)	$ (25,354)	$ (12,393)

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of vested shares outstanding for the period. Diluted net loss per share is computed giving effect to all potentially dilutive shares, including options, convertible debentures, convertible preferred stock and warrants. Options, convertible debentures, convertible preferred stock 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,	
	2004	2003	2004	2003
Net loss attributable to common stockholders	$ (4,604)	$ (4,355)	$ (25,566)	$ (12,274)
Weighted-average common shares outstanding	4,795	4,105	4,678	4,095
Less weighted-average shares subject to repurchase				1
Weighted-average shares used in computing basic and diluted net loss per common share	4,795	4,105	4,678	4,094
Net loss per share, basic and diluted	$ (0.96)	$ (1.06)	$ (5.47)	$ (3.00)

The following outstanding options, warrants, and convertible preferred stock were excluded from the computation of diluted net loss per share as they all had an antidilutive effect:

	September 30,	
	2004	2003
Options to purchase common stock	4,084	492
Warrants	11,772	276
Convertible preferred stock	11,421	

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 FASB Statement No.123. The following provides a reconciliation of net loss and net loss per common share to pro forma net loss and pro forma net loss per common 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,	
	2004	2003	2004	2003
Net loss - as reported	$ (4,604)	$ (4,355)	$ (25,566)	$ (12,274)
Add: stock-based compensation included in reported net loss	49	247	264	747
Deduct: total stock-based employee compensation determined under fair value based method for all awards	(650)	(227)	(972)	(877)
Net loss - pro forma	$ (5,205)	$ (4,335)	$ (26,274)	$ (12,404)
Net loss per share, basic and diluted - as reported	$ (0.96)	$ (1.06)	$ (5.47)	$ (3.00)
Net loss per share, basic and diluted - pro forma	$ (1.09)	$ (1.06)	$ (5.62)	$ (3.03)

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.

Lease Amendments

In March 2004, the Company negotiated a lease amendment with its landlord. Under the terms of the amended lease, Aerogen has relocated to the first floor of its two-story building in Mountain View, CA, and now occupies roughly 32,000 square feet, which is about one half of the building area that the Company had occupied. Under the terms of the lease, Aerogen made aggregate payments during the quarter ended June 30, 2004 totaling $1,625,000 which comprises $75,000 for a new security deposit, $414,000 in past due rent, and $1,136,000 in rent reduction fees, of which $900,000 was funded by relinquishment to the landlord of cash underlying the Company s standby letter of credit. The Company was required to fund up to $140,000 in building access improvements, which are expected to be completed by early November 2004. In addition, the Company issued 50,000 shares of common stock to the landlord. The excess of the value paid to the landlord, including cash, building improvements and stock, over the amounts due, will be amortized as rent expense over the remaining term of the lease. The term of the lease has been shortened and now terminates in February 2009 rather than February 2012.

Future aggregate minimum rental and estimated maintenance commitments for the reduced term of the lease are:

2004	$ 216
2005	867
2006	1,028
2007	1,102
2008	1,152
2009	193
Total future aggregate minimum lease payments	$ 4,558

Financing Events

In January 2004, the Company entered into a loan and securities purchase agreement pursuant to which a convertible debenture (the Carpenter Debenture) and a warrant (the Carpenter Warrant) were issued to the Carpenter 1983 Family Trust UA (the Carpenter Trust), the trustees of which are Aerogen s Chairman and Chief Executive Officer, Dr. Jane Shaw and her husband Peter Carpenter. The Company received approximately $505,000 in gross proceeds in exchange for the Carpenter Debenture and the Carpenter Warrant. The Carpenter Debenture was convertible into 164,258 shares of common stock at a conversion price of $3.044 per share. The Carpenter Warrant is exercisable for 82,129 shares of common stock at an exercise price of $3.044 per share, and expires in January 2008. 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 $263,694. The Carpenter Warrant was assigned an initial value of $154,297, estimated using the Black-Scholes valuation model, and has been classified as equity. The following assumptions were used to determine the fair value of the Carpenter Warrant using the Black-Scholes valuation model: term of four years, risk free rate of 3.25%, volatility of 100%, and a dividend yield of zero. The initial values assigned to both the Carpenter Debenture and the Carpenter Warrant were allocated based on their relative fair values. The discount on the Carpenter Debenture for the beneficial conversion feature and Carpenter Warrant were amortized, using the effective interest method, to interest expense over the original term of the Carpenter Debenture, which had been scheduled to mature on March 1, 2004.

The issuance of the Carpenter Debenture triggered a conversion price and exercise price adjustment on the November 3, 2003 debenture and warrant issued to SF Capital Partners, Ltd. (SF Capital). As a result, the conversion price and exercise price of the November 2003 SF Capital debenture and warrant, respectively, were reduced to $3.044 per share.

During March 2004, SF Capital converted the remaining principal balance and accrued interest on its September 11, 2003 debenture into the Company s common stock. Pursuant to the terms of the debenture, SF Capital elected to have all of its interest paid in the form of common stock. In the aggregate, this debenture and accrued interest was converted into a total of 564,224 shares of the Company s common stock.

On March 12, 2004, SF Capital provided a $300,000 secured bridge loan to support the Company s operations. This secured bridge loan was fully repaid on March 25, 2004.

On March 23, 2004, the Company completed the first closing of a $32.7 million equity financing (the A-1 Financing). The A-1 Financing occurred in two closings, and involved the sale and issuance of 1,142,094 shares of Series A-1 Convertible Preferred Stock (the A-1 Preferred) of the Company that are initially convertible into an aggregate of 11,420,670 shares of common stock of the Company, as well as the issuance of warrants to purchase up to 11,249,390 shares of common stock at an exercise price of $3.25 per share. Under the terms of the A-1 Financing, the Company terminated its Rights Agreement with Mellon Investor Services, LLC on March 19, 2004.

In the first closing, the Company issued 499,981 shares of A-1 Preferred convertible into 4,999,810 shares of common stock, and issued warrants to purchase 4,999,810 shares of common stock, for gross proceeds to the Company of $14,999,430. The warrants were assigned an initial aggregate value of $6,731,678, estimated using the Black-Scholes valuation model, and have been classified as equity. As the warrants relate to preferred stock issuance costs, their valuation was recorded as an issuance cost and as an offset to Convertible Preferred Stock. The warrants expire in March 2009. The following assumptions were used to determine the fair value of the warrants using the Black-Scholes valuation model: term of five years, risk free rate of 2.78%, volatility of 100%, and a dividend yield of zero. The difference between the conversion price and the fair market value of the A-1 Preferred on the commitment date (transaction date) resulted in a beneficial conversion feature of $7,911,870, which was treated as a deemed dividend.

On May 12, 2004, the Company completed the second and final closing of the A-1 Financing. In the second closing, the Company issued 642,113 shares of A-1 Preferred convertible into 6,421,130 shares of common stock, and issued warrants to purchase 6,249,580 shares of common stock, for gross proceeds to the Company of $17,696,430. The warrants were assigned an initial aggregate value of $7,188,249, estimated using the Black-Scholes valuation model, and have been classified as equity. As the warrants relate to preferred stock issuance costs, their valuation was recorded as an issuance cost and as an offset to Convertible Preferred Stock. The warrants expire in March 2009. The following assumptions were used to determine the fair value of the warrants using the Black-Scholes valuation model: term of five years, risk free rate of 3.13%, volatility of 100%, and a dividend yield of zero. The difference between the conversion price and the fair market value of the A-1 Preferred on the commitment date (transaction date) resulted in a beneficial conversion feature of $4,500,911, which was treated as a deemed dividend.

As part of the A-1 Financing, SF Capital and the Carpenter Trust exchanged the outstanding secured convertible debentures previously issued to them for an aggregate of 52,232 shares of A-1 Preferred at the second closing. Under the terms of the A-1 Financing, SF Capital retained both of its warrants originally issued in connection with both of its 2003 debentures, and also received

a new warrant to acquire 350,770 shares of common stock at an exercise price of $3.25 per share in connection with its debenture exchange into A-1 Preferred. The Carpenter Trust retained its warrant originally issued in connection with the Carpenter Debenture, but it did not receive a new warrant in connection with the exchange of the Carpenter Debenture into A-1 Preferred.

Series A-1 Convertible Preferred Stock Preferences

For a complete review of the A-1 Preferred, refer to the Company s definitive Proxy Statement for its Annual Meeting of Stockholders, filed with the SEC on April 19, 2004. Below is a summary of sections of the terms of the A-1 Preferred.

Liquidation Rights

In the event of any liquidation, dissolution or winding up of the Company, the holders of A-1 Preferred shall be entitled to receive $30.00 per share (as adjusted for any stock splits, dividends, combinations or other recapitalizations) (the Series A-1 Stated Value) plus any unpaid dividends, on a pro rata basis, in preference to any distribution made to the common stock (the Liquidation Preference). Once the Liquidation Preference has been paid in full, any remaining proceeds shall be distributed ratably between the holders of the A-1 Preferred and common stock, with the holders of A-1 Preferred deemed to hold that number of shares of common stock into which the shares of A-1 Preferred are then convertible. The holders of a majority in interest of the A-1 Preferred, including the Lead Investor (so long as it owns at least 80,000 shares of A-1 Preferred) (the Requisite Holders), may elect to treat an acquisition of the Company as a liquidation.

Dividends

Each holder of A-1 Preferred is entitled to receive cumulative dividends in preference to any dividend on the common stock at the rate of 6% of the Series A-1 Stated Value per share, paid quarterly in arrears on the first day of January, April, July and October in each year (the Preferred Dividends). The Preferred Dividends will be paid, at the Company s election, out of legally available funds or through the issuance of shares of common stock. For the nine months ended September 30, 2004 cumulative dividends of $913,000 have been accrued on the A-1 Preferred, these dividends all had been or were in the process of being paid through the issuance of an aggregate of 361,638 shares of the Company s common stock.

Conversion; Anti-Dilution Protection

The holder of any share or shares of A-1 Preferred shall have the right, at the holder s option at any time, to convert any such shares of A-1 Preferred into such number of fully paid and nonassessable shares of common stock as is obtained by: (i) multiplying the number of shares of A-1 Preferred to be converted by the Series A-1 Stated Value and adding to such product the amount of any accrued but unpaid dividends with respect to such shares of A-1 Preferred to be converted; and (ii) dividing the result obtained pursuant to clause (i) above by the Series A-1 Conversion Price then in effect. As of the date of this report, the Series A-1 Conversion Price is $3.00.

If the Company issues or sells any common stock, or is deemed to have issued or sold common stock by issuing or selling options or other convertible securities, for consideration per share less than the Series A-1 Conversion Price in effect immediately prior to the time of such issue or sale, then the then-existing Series A-1 Conversion Price shall be reduced to the lowest price per share at which any share of common stock was issued or sold or deemed to be issued or sold. However, the Company shall not be required to make any adjustment of the Series A-1 Conversion Price in the case of the following issuances of shares of common stock from and after March 23, 2004 (each an Excluded Issuance): (i) issuances upon the exercise of any options or convertible securities granted, issued and outstanding on March 23, 2004; (ii) issuances upon the grant or exercise of any stock or options which may hereafter be granted or exercised under any employee benefit plan, stock option plan or

restricted stock plan of the Company in existence on March 23, 2004, so long as the issuance of such stock or options is approved by a majority of the independent members of the Board or a majority of the members of a committee of independent directors established for such purpose; (iii) issuances of securities as consideration for a merger or consolidation with, or purchase of assets from, a non-affiliated third party or in connection with any strategic partnership or joint venture with a non-affiliated third party with which the Company will enter into technology agreements (the primary purpose of any such action is not to raise equity capital); (iv) shares of common stock issuable upon conversion of A-1 Preferred or as payment-in-kind dividends on the A-1 Preferred; (v) shares of common stock issued or issuable as a result of any stock split, combination, dividend, distribution, reclassification, exchange or substitution for which an equitable adjustment is provided for; and (vi) shares of common stock issued (or issuable upon exercise, exchange or conversion of rights, options or warrants outstanding from time to time) which the Requisite Holders expressly elect in writing to treat as an Excluded Issuance.

The conversion of A-1 Preferred into common stock is limited so that no share may be converted that would cause the holder of such share (or such stockholder s affiliates) to beneficially own more than 4.99% of the Company s

then-outstanding common stock, provided that such stockholder may waive the provision upon 61 days written notice to the Company.

Voting Rights

The holders of A-1 Preferred are entitled to vote together with the holders of common stock as a single class. Each share of A-1 Preferred shall have the number of votes equal to the number of shares of common stock into which such share of A-1 Preferred is convertible.

As long as at least 200,000 shares of A-1 Preferred are outstanding, the consent of the Requisite Holders shall be required to take or agree to any of the following actions: (1) amend, alter or repeal any of the provisions of the Company s Amended and Restated Certificate of Incorporation, Bylaws or the Certificate of Designations, or in any way change the preferences, privileges, rights or powers with respect to the A-1 Preferred or reclassify any class of stock, including, without limitation, by way of merger or consolidation; (2) authorize, create, designate, issue or sell any (A) class or series of capital stock (including shares of treasury stock), (B) rights, options, warrants or other securities convertible into or exercisable or exchangeable for capital stock or (C) any debt security which by its terms is convertible into or exchangeable for any capital stock or has any other equity feature or any security that is a combination of debt and equity, which capital stock, in each case, is senior to or pari passu with the A-1 Preferred; (3) increase the number of authorized shares of A-1 Preferred authorize the issuance of or issue any shares of A-1 Preferred (other than in connection with the payment of Preferred Dividends); (4) increase or decrease the number of authorized shares of any class of capital stock of the Company; (5) agree to any restriction on the Company s ability to satisfy its obligations hereunder to holders of A-1 Preferred the Company s ability to honor the exercise of any rights of the holders of A-1 Preferred; (6) declare or pay any dividend or make any distribution on shares of capital stock of the Company (except with respect to shares of A-1 Preferred), or redeem, purchase or otherwise acquire for value, or set apart money or other property for any mandatory purchase or analogous fund for the redemption, purchase or acquisition of any shares of capital stock of the Company (except with respect to the repurchase of shares of common stock held by employees, officers or directors of the Company, which has been approved by the Company s Board of Directors); (7) consummate an acquisition or enter into an agreement with respect to an acquisition; (8) materially change the nature or scope of the business of the Company to a business other than the manufacturing or formulation of devices or drugs for aerosol delivery; (9) consummate or agree to make any sale, transfer, assignment, pledge, lease, license or similar transaction by which the Company grants on an exclusive basis any rights to any of the Company s intellectual property other than intellectual property relating to the Company s insulin program or the licensing of any of the Company s intellectual property to a ventilator manufacturer for incorporation into such manufacturer s ventilator technology; (10) create, incur, assume or suffer to exist, any lien, charge or other encumbrance on any of its properties or assets, other than liens of carriers, warehousemen, artisans, bailees, mechanics and materialmen incurred in the ordinary course of business securing sums not overdue; or (11) agree to do any of the foregoing.

Note 2 - RECENT ACCOUNTING PRONOUNCEMENTS

None.

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, 2003, filed with the Securities and Exchange Commission (SEC) on April 14, 2004 (Form 10-K).

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are described in Item 7 of the Form 10-K for the year ended December 31, 2003, and have not changed materially since that date.

Overview

Aerogen, Inc. (Aerogen, the Company or we) was incorporated in November 1991. We are a specialty pharmaceutical company developing novel drug/device combination aerosol products for treatment of respiratory disorders in the critical care setting. Based upon our proprietary OnQ Aerosol Generator, 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 the period ended September 30, 2004, we had two nebulizer products on the market. We have an accumulated deficit of approximately $121.7 million as of September 30, 2004. In 2002, we generated significant revenues from our planned principal operations and thus exited the development stage. We will, however, continue to devote substantial efforts to the development of current and future products. 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 primarily been equity financings, convertible debentures, product revenues, research and development revenues, license fees, royalties, and interest earned on investments.

On May 12, 2004, we completed a financing for gross proceeds of $32.7 million. As of September 30, 2004, Aerogen had cash, cash equivalents and short-term investments totaling $20.3 million. Cash expenditures for the three months and nine months ended September 30, 2004 were higher than anticipated, primarily due to the absence of OnQ sales revenues during the third quarter from Evo related to FDA action taken against Evo during that period. If our average rate of cash expenditures remains constant at the third quarter average rate, then our current cash resources will be insufficient to permit operations beyond November 2005.

As a result of our continued losses and current cash resources, we will need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next twelve 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.

Results of Operations

Revenues

Total revenues for the three months ended September 30, 2004 were $1.2 million, compared with $0.5 million for the same period of 2003. Total revenues for the nine months ended September 30, 2004 were $4.0 million, compared with $3.2 million for the same period of 2003. Total revenues include revenues from product sales, research and development activities for unrelated third parties, royalties on gross sales of licensed products, and royalties associated with the licensing of our technology for use outside the medical field.

Product sales for the three months ended September 30, 2004 were $0.9 million, compared with $0.4 million for the same period of 2003. Product sales for the nine months ended September 30, 2004 were $3.0 million compared with $2.7 million for the same period of 2003. The increase in product sales for the three month period year over year was due solely to the sales of the Aeroneb® Professional Nebulizer System (Aeroneb Pro), as there were no sales of our OnQ Aerosol Generators to Evo Medical Solutions (Evo formerly Medical Industries America) during the quarter ended September 30, 2004. The increase in sales for the nine months ended September 30, 2004, as compared with the same period of 2003, was due to the sales of our OnQ Aerosol Generators to Evo over the first six months of 2004 partially offset by lower Aeroneb Pro Sales.

There were no research and development revenues for the three months ended September 30, 2004 or 2003. Research and development revenues for the nine months ended September 30, 2003 were $166,000 . 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 2004 to be lower than those for 2003.

Royalty revenues were $0.3 million and $0.1 million, for the three months ended September 30, 2004 and 2003, respectively. Royalty revenues for the nine months ended September 30, 2004 were $1.0 million compared with $0.4 million for the same period of 2003. The increase over the three months and nine months ended September 30, 2003 was due to up-front payments associated with the September 2003 commercial agreement with Evo, which resulted in amortized quarterly revenues of $125,000 relating to the $2.5 million upfront payment which is being amortized ratably over the five-year term of the agreement. Additionally, we have recognized royalties on Evo s sales of the Aeroneb® Go Nebulizer (Aeroneb Go) products and accessories. No royalty revenues from the Aeroneb Go were recognized during the same periods of 2003. Other royalties represent a minimum royalty obligation associated with licensing our aerosol generator technology to a consumer product company for use in the fields of air fresheners and insect repellants in the amount of $125,000 per quarter.

Cost of Products Sold

Cost of products sold for the three months ended September 30, 2004 was $0.8 million, compared with $0.2 million for the

same period in 2003. Cost of products sold for the nine months ended September 30, 2004 was $2.8 million, compared to $1.7 million for the same period in 2003. Cost of products sold increased as a percent of product sales for the three and nine months ended September 30, 2004 as compared to the same periods in 2003, primarily due to the commencement of sales in January 2004 of a lower-margin Aeroneb Go product under a contract supply agreement with Evo. Our lower margins on these sales are offset by the royalties we receive on Evo s subsequent sales. Additionally, an increased amount of costs related to the manufacturing scale-up of this new component have continued in the quarter ended September 30, 2004.

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 generally 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 partner collaborations. Future research and development and clinical expenditures cannot be predicted reliably, as they depend, in part, upon our success in expanding partner collaborations, entering into new partnering agreements, potential changes in our partner s priorities, and the level of our internally funded research and development efforts.

Research and development expenses for the three months ended September 30, 2004 were $3.3 million, compared with $2.9 million for the same period of 2003. The increase in research and development expenses of $0.4 million for the three months ended September 30, 2004, as compared with the same period of 2003, was primarily due to $1.1 million of spending related to preparations for a Phase 2 clinical trial for our aerosolized antibiotic product, offset by reduced facility related spending of $0.3 million, and a decrease of $0.4 million in research and development spending related to absorbed manufacturing costs as we begin commercial operations and increase our sales.

Research and development expenses for the nine months ended September 30, 2004 were $8.1 million compared with $9.1 million for the same period of 2003. The decrease in research and development expenses of $ 1.0 million for the nine months ended September 30, 2004, as compared with the same period of 2003, was primarily due to reduced payroll and related expenses of $0.7 million associated with reductions in force in 2003 and reduced facility related expenses of $0.6 million, and a decrease of $1.2 million in research and development spending related to absorbed manufacturing costs as we begin commercial operations and increase our sales. These reductions were partially offset by increased spending of $1.5 million related to preparations for a Phase 2 clinical trial for our aerosolized antibiotic product.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $1.5 million for each of the three-month periods ended September 30, 2004 and 2003. Selling, general and administrative expenses for the nine months ended September 30, 2004 were $4.8 million, compared with $4.9 million for the same period of 2003. For the nine months ended September 30, 2004, as compared with the same period in 2003, selling, general and administrative expenses decreased by $0.1 million due to a decrease in deferred stock compensation of $0.3 million and a decrease of $0.3 million in selling and marketing expenses, offset by an increase in outside legal expenses of $0.5 million.

Interest and Other Income (Expense), Net

Net interest income for the three months ended September 30, 2004 was $79,000 compared with $127,000 of net interest expense for the same period in 2003. Interest income was higher due to the higher balances in interest earning accounts in 2004 compared to the same period in 2003. The decrease in interest expense was due to $0.1 million of imputed interest on the beneficial conversion feature of a debenture and the imputed value of a warrant issued September 2003.

Net interest expense for the nine months ended September 30, 2004 was $0.5 million, compared with $0.1 million for the same period of 2003. The growth in interest expense is primarily due to imputed interest resulting from the beneficial conversion feature of the convertible debentures, and the imputed value associated with the warrants, that were issued to SF Capital during the second half of 2003 and to the Carpenter Family Trust in the first quarter of 2004, all of which totaled $0.5 million in the first quarter of 2004.

Other income and expense for the three months ended September 30, 2004 consisted of income of $158,000, compared with an expense of $101,000 for the same period of 2003. Other income and expense for the nine months ended September 30, 2004 consisted of an expense of $135,000 compared with income of $265,000 for the same period of 2003. The change in other income and expense for both the three and nine month periods are solely due to change in the currency exchange rate between the Eurodollar and the United States dollar, and the resulting impact on intercompany balances.

Dividend Related to Beneficial Conversion Feature of Preferred Stock

Upon the first closing of the Series A-1 Convertible Preferred Stock offering on March 23, 2004, the aggregate difference between the conversion price and the fair market value of the common stock underlying the Series A-1 Convertible Preferred Stock on the commitment date (transaction date) resulted in a beneficial conversion feature of $7,911,870 which was treated as a deemed dividend in the three months ended March 31, 2004. Upon the second closing of the Series A-1 Convertible Preferred Stock offering on May 12, 2004, the aggregate difference between the conversion price and the fair market value of the common stock underlying the Series A-1 Convertible Preferred Stock on the commitment date (transaction date) resulted in a beneficial conversion feature of $4,500,911 which was also treated as a deemed dividend. For the nine months ended September 30, 2004 the total beneficial conversion feature was $12,412,781 and was treated as deemed dividends.

In addition to the deemed dividends, during the three and nine months ended September 30, 2004 stock dividends to holders of the Series A-1 Convertible Preferred Stock were declared with a market value of $514,000 and $913,000, respectively. The combined value of the deemed dividends and the stock dividends appears on the Statements of Operations as dividends of $13,327,000 related to convertible preferred stock.

The common stock warrants issued in connection with the Series A-1 Convertible Preferred Stock offering were assigned an initial aggregate value of $13,919,927, estimated using the Black-Scholes valuation model, and have been classified as equity. The warrants expire in five years. The following assumptions were used to determine the fair value of the warrants using the Black-Scholes valuation model: term of five years, risk free rate of 2.78% for the first closing and 3.13% for the second closing, volatility of 100%, and a dividend yield of zero.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through equity and convertible debt financings, product revenues, research and development revenues, licensing fees, royalties, and the interest earned on related proceeds. We have received approximately $130.2 million in aggregate net proceeds from sales of our common and preferred stock through September 30, 2004, including approximately $44.5 million of net proceeds from our initial public offering in November 2000 and $31.4 million of total net proceeds from the sale of Series A-1 Convertible Preferred stock in March and May 2004. In September and November 2003, we raised $2.0 million through the issuance of convertible notes, and, in January 2004, an additional $0.5 million was raised through the issuance of a convertible note. We also received a short-term loan of $300,000 during March 2004.

As of September 30, 2004, we had cash and cash equivalents of approximately $20.3 million. Net cash used in operating activities during the nine months ended September 30, 2004 was $11.4 million, resulting primarily from the net loss for the period of $12.2 million. We had additional uses of cash resulting from increases in accounts receivable of $0.5 million due to higher sales volume and increases in royalty receivables of $0.6 million in inventory balances of OnQ Aerosol Generators, and payments totaling $1.5 million made to the landlord for changes in the lease, comprised of past due rent, security deposit and rent reduction fees. These uses were partially offset by non-cash related charges of $0.3 million of amortized deferred stock-based compensation, depreciation of $0.9 million, amortization of note discounts of $0.5 million, and disposal of property and equipment of $0.8 million due to the consolidation into the first floor of our Mountain View facility and the subsequent write-off of the leasehold improvements that had been made to the second floor.

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. Additional uses resulted from increases in accounts receivable of $0.8 million due to sales increases. 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, an increase in deferred rent of $0.5 million, a decrease of $0.6 million in prepaid expenses and other current

assets, and an increase in deferred revenue of $1.3 million.

For the nine months ended September 30, 2004, net cash used in investing activities was $0.6 million, consisting primarily of property and equipment acquisitions associated with process improvements. For the nine months ended September 2003, net cash provided by investing activities was $5.3 million, 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 financing activities was $31.4 million for the nine months ended September 30, 2004, consisting of $30.9 million in net proceeds from issuance of Series A-1 Convertible Preferred Stock and associated common stock warrants, and $0.8 million in net proceeds from the issuance of debentures and convertible debentures, partially offset by the repayment of a $0.3 million debenture. Net cash provided by financing activities for the nine months ending September 30, 2003 was $1.1 million, resulting from the issuance of a convertible debenture in the amount of $950,000, receipt of $165,000 in repayment of a note receivable by a stockholder, and proceeds from issuance of common stock in the amount of $23,000.

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.

As of September 30, 2004, Aerogen had cash, cash equivalents and short-term investments totaling $20.3 million. Cash expenditures for the three months and nine months ended September 30, 2004 were higher than anticipated, primarily due to the absence of OnQ sales revenues during the third quarter from Evo related to FDA action taken against Evo during that period. If our average rate of cash expenditures remains constant at the third quarter average rate, then our current cash resources will be insufficient to permit operations beyond November 2005.

As a result of our continued losses and current cash resources, we will need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next twelve 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.

Recent Accounting Pronouncements

None.

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. Additional risks that we do not yet know of, or that we currently believe are immaterial, may also impair our business. 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.

In order for any of our drug products to complete Phase 3 clinical trials, we will most likely need capital in excess of our current cash resources.

We expect our current cash and cash equivalents will allow continued operations through approximately the end of the third quarter of 2005. Our cash resources will be insufficient to complete Phase 3 clinical trials for any of our products, and may be insufficient to complete all of our anticipated Phase 2 clinical trials. Sufficient cash to complete our Phase 2 and 3 trials may be provided from strategic partnerships, such as from out-licensing and partnering of our insulin product, or from product sales in excess of our expectations. There can be no guarantee, however, that these capital resources will materialize in sufficient magnitude or at all, or that product sales will meet our expectations. In the alternative, the Company will have to raise significant capital through the sale of convertible debt, convertible securities, and/or common stock, and there can be no guarantee that such capital will be available on favorable terms, if at all, and could result in significant dilution to our current stockholders.

Our recent equity financing has resulted in a concentration of ownership.

Twelve investors in our Series A-1 Convertible Preferred Stock (The A-1 Preferred) own equity securities that, if all such securities were converted into common stock, would represent ownership of approximately 86% of the outstanding common shares of the Company. While each of these investors is contractually prohibited from owning more than 4.99% of the Company s common stock at any one time, any investor can

waive this limitation as to the shares it holds upon 61 days written notice to the Company. As few as eleven of the A-1 Preferred investors, or investors to whom the A-1 securities are resold, could acquire in excess of 50% of the voting securities of the Company without exceeding this limitation. On November 3, 2004 the Xmark Funds delivered to us a written waiver of this limitation, thereby permitting the conversion of any or all of their A-1 Preferred into common stock at any time on or after January 3, 2005. Based upon the number of the Company's common shares outstanding as of November 5, 2004, if the Xmark Funds were to convert all of their A-1 Preferred, and no other holder of A-1 Preferred were to convert, then the total number of shares of outstanding Aerogen common stock would increase to at least 6,570,425 shares, of which the Xmark Funds would own at least 1,685,596 shares, or 25.65%. To our knowledge, the A-1 Preferred investors have not acted as a group in seeking, negotiating, or making their investment in the Company, and consider themselves to be independent investors. Due to the termination of our rights plan, there can be no assurance that further concentration of ownership will not occur, or that these securities will not be resold to different investors who may or may not act as a group.

The conversion of our Series A-1 Convertible Preferred Stock into common stock and the exercise of common stock warrants issued to the Series A-1 Convertible Preferred investors may depress the price of our common stock and will substantially dilute the ownership interests of existing common stockholders.

If the A-1 Preferred stockholders were to exercise all of the common stock warrants they hold and convert all of the shares of A-1 Preferred they owned as of November 5, 2004, they would own approximately 22,670,330 shares of our common stock, in addition to any other shares such stockholders may now or in the future own. Furthermore, as of November 5, 2004, a total of 361,638 shares of Aerogen common stock have been issued, or are in the process of being issued, to the A-1 Preferred stockholders in satisfaction of Aerogen s quarterly dividend obligation to them for the quarters ended March 31, June 30 and September 30, 2004. If the A-1 Preferred stockholders exercise the warrants or convert our preferred stock into shares of common stock and sell the shares into the market, such sales could have a negative effect on the market price of our common stock and will dilute the holdings of our existing common stockholders. The Company may choose to pay the cumulative quarterly dividend on the A-1 Preferred in shares of common stock instead of cash, in which case more dilution will result. Dilution or the potential for dilution also could materially impair our ability to raise capital through the future sale of equity securities. As a result of the issuance of the A-1 Preferred and warrants, the Company recorded a charge in the first and second quarters of 2004 related to the beneficial conversion feature of the preferred stock in the amount of $7.9 million and $4.5 million, respectively. If the

Company were to issue additional equity securities in a future financing transaction at a per share price lower than the current conversion price of the A-1 Preferred, then the conversion price of the A-1 Preferred would automatically adjust downward to be equal to the common stock equivalent price of the newly-issued securities, and an additional deemed dividend charge would be recorded. Any such charge would reduce stockholders equity and the amount of net income available to common stockholders. While the Company currently has no plans to issue securities in a manner that would trigger these anti-dilution provisions, it may elect to do so in the future. The full details of these anti-dilution provisions are contained in the Series A-1 Convertible Preferred Stock Certificate of Designation, which was filed on the Company s Form 8-K on March 23, 2004 and incorporated by reference herein.

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

We have never been profitable. Through September 30, 2004, we have incurred an accumulated deficit of approximately $121.7 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:

- 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;

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

allocation of our resources, particularly when they are limited;

the costs and expenses relating to any litigation;

the ability to successfully identify and consummate appropriate collaborations with corporate partners; and

our manufacturing, development and marketing partners changing priorities and resources.

We have a significant backlog of unfilled orders for our products that may adversely impact our distributors ability or willingness to sell our products.

Due to our extremely limited cash resources at the end of 2003 and during the first quarter of 2004, we were at times unable to procure critical components and/or manufacturing services necessary to satisfy customer demand for our products, most of whom were unable to provide cash payments in a timeframe that resolved our procurement issues. Compounding this limitation, orders in the same time period exceeded our expectations. As a result, we accumulated a backlog of orders that were not completely filled by the end of the second quarter of 2004. As of September 30, 2004, the value of this backlog was less than 15% of our revenues for the quarter, but there can be no guarantee that future backlogs will not be more material, or that customer dissatisfaction related to delays in order fulfillment will not adversely affect future orders and sales.

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.

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 reproducible 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/device combination 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, future nebulizer products 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 reproducible 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/device combination products are not successful, drug products using our technology or inhalers may not be commercialized.

Before either we or our partners can file for regulatory approval for the commercial sale of combination products using our technology or inhalers, the United States 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/device combinations which will require clinical testing. To date, we have completed limited clinical trials using prototype devices. 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 three products, and limited clinical supplies of other products. We currently produce all of the OnQ Aerosol Generators for our products, partnered or not, in a single facility. We plan to continue using 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 of our products ourselves, or we may use contract manufacturers for the final assembly of 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.

Our Aerodose® inhaled insulin product is 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 2a) 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 secured 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 not yet resumed our work on that product, and do not expect to re-start the program until we have an acceptable partner 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.

Of our drug/device combination products currently under active development, our amikacin product is the most advanced, and is the only one to have completed a human clinical trial.

Our ability to become a successful specialty pharmaceutical company depends upon our ability to commercialize our own combination drug/device products, the majority of which will incorporate our Pulmonary Drug Delivery System (PDDS). Although our PDDS leverages the basic technology platform of the Aeroneb Pro, and our initial version of this device, the Pro II Clinical, Nebuliser System has been CE marked for clinical use in Europe, the PDDS has not been approved as a commercial product. Our lead product in development, a PDDS drug combination product incorporating the aminoglycoside amikacin, has only completed one small Phase 2 clinical trial. The development of this product will require, at a minimum, a second Phase 2 clinical trial and a Phase 3 clinical trial program in order to support a New Drug Application (NDA), which must be filed with the FDA to obtain approval prior to marketing the product in the United States. If these clinical trials fail to meet their objectives, or are halted for safety reasons, we may be required to suspend further development of this product, conduct additional clinical trials, or return to an earlier stage of research and development. Any or all of these possible outcomes could materially impair our ability to raise additional capital on attractive economic terms, if at all.

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.

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 certain 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 PDDS. 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 Pro and the Aeroneb Go 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 Evo, are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with Quality System Regulation (QSR). 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 on a Form FDA-483 (Form-483). One addressed the manner in which Aerogen records documented in-process acceptance test results and the other addressed the calibration standard operating procedure (SOP) and equipment that was no longer in use, but had exceeded its calibration period. We submitted a timely response to the FDA, which was accepted and the Form-483 was closed.

All medical devices marketed in the European Union are required to bear the CE Mark. Aerogen, Evo and certain Aerogen subcontractors are required to comply with the Medical Device Directive (MDD) and comply with ISO, the International Organization for Standards, to meet the quality standards. ISO is a worldwide network of national standards institutes. ISO has developed ISO 13485 in order to assist companies in implementing and operating quality management systems to meet the MDD.

As of May 2004, the Galway, Ireland, and Mountain View, California, facilities successfully obtained certification to ISO 13485:2003. If Aerogen, Evo or Aerogen s subcontractors fail to maintain compliance with QSRs, ISO 13485 or other international regulatory requirements, we may be required to among other things recall product or cease all or part of our operations until we comply with the regulations. We cannot be certain that our facilities, or those of Evo and/or our subcontractors, will be found to comply on an ongoing basis with the QSRs, ISO or other international regulatory requirements.

Evo was the subject of an FDA inspection that was completed in early July 2004, and pursuant to which Evo received a Form-483 with ten observations, and which was followed by a warning letter concerning the Aeroneb Go. In response to the warning letter, Evo voluntarily suspended shipments of the Aeroneb Go until a risk mitigation plan could be developed and presented to the FDA. Similarly, Aerogen voluntarily suspended shipments of OnQ Aerosol Generators to Evo, which resulted in no revenues from OnQ Aerosol Generator sales to Evo during the quarter ended September 30, 2004. Evo has developed a risk mitigation plan that has been reviewed by the FDA, which includes enhanced patient education as to the importance of cleaning the device in accordance with the manufacturer s directions for use and the importance of having spare batteries and a backup device available if the user-patient is treating a life-threatening disease, the stocking of replacement handsets at distributors and customer support for rapid-turnaround of reported failures, as well as the provision of a back-up handset to certain identified, high-risk patients. Evo s implementation of the risk mitigation plan is structured according to the FDA s regulations for a Class II, firm-initiated recall, and updates are being forwarded to the FDA.

In [October] 2004, Evo resumed Aeroneb Go shipments incorporating their existing inventory of OnQ Aerosol Generators in accordance with their risk mitigation plan. Aerogen has initiated several design and manufacturing changes to enhance the inherent durability of the OnQ Aerosol Generator, and which we believe will make it more resistant to user misuse. Aerogen is diligently working to validate and implement these changes prior to the expected depletion of the existing inventories of OnQ Aerosol Generators. We cannot assure that these changes will be implemented in a timely fashion, or if implemented, will be successful in enhancing the durability and reliability of the device. During the quarter ended September 30, 2004, a reserve of $75,000 against cost of goods sold was established for potential costs related to Aerogen s support of the Evo risk mitigation plan, but we cannot assure that this reserve will be adequate to cover all expenses that are or will be related to the recall.

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.

We rely on several, sole-source outside manufacturing service providers and raw material suppliers. If one or more of these outside vendors becomes unable to supply us, we may be unable to locate an alternate supplier, which may adversely impact our ability to sell our products.

We outsource production of many components of our products to manufacturers in the United States and elsewhere. Generally, there is more than one potential supplier for these components, but some are manufactured to our specifications and an interruption in supply could adversely affect our ability to manufacture and supply our products. The brazing and overmolding processes used in assembly of our OnQ Aerosol Generators are conducted at third party facilities. Even though we have qualified second suppliers for each of these services, loss of the use of the primary facilities could result in significant delays in our supply of components while we ramp up production at the second sites and/or establish alternate provider sites. Palladium, which we use in our OnQ aperture plate, is expensive and is subject to price volatility. The palladium plating bath chemicals we use to manufacture our OnQ Aerosol Generators are formulated by a single supplier.

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. The Aeroneb Pro is not currently reimbursed by insurance or government entities, which may limit its market penetration. In addition, future changes to Medicare reimbursement policies for nebulizers and/or the drugs used with them, particularly as a result of the Medicare Prescription Drug Improvement and Modernization Act of 2003, may limit the market penetration of the Aeroneb Go in the United States

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

We currently compete with device and medical equipment companies for sales of our nebulizer products; as we introduce our drug products, we will compete with pharmaceutical and biotechnology companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in developing non-invasive drug delivery dosage forms. In the area of systemic drug delivery, competing non-invasive alternatives to injectable drug delivery include oral, buccal, intranasal, transdermal and colonic absorption dosage forms. We also compete with entities producing and developing injectable dosage forms. Several of these entities are working on sustained-release injectable systems. While these systems still require injections, the lower number of injections could allow these products to compete effectively with non-invasive therapies.

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 and drug/device combinations. Our pending patent applications, and those that 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 all 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, (USPTO), to determine the priority of inventions. Although we prevailed in a 1999 interference proceeding before the USPTO, that granted to Aerogen all but one of the independent claims of Bespak s 5,261,601 patent, we entered into a cross-license agreement with 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 a patent licensed to PARI GmbH. While the suit has not yet been formally initiated by the German regional court, we believe that it is without merit and intend 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. In July 2004, the Federal Patent Court in Munich, Germany ruled in favor of Aerogen by nullifying all contested claims of this patent, which is owned by The Technology Partnership plc (TTP) of Hertfordshire, England, and is licensed to PARI, GmbH of Munich, Germany. The Court ordered TTP to pay Aerogen s legal expenses related to this nullity action to the maximum extent allowed under German law. During October 2004, TTP requested, and was granted, a three-month extension of time to file an appeal of this decision. Additionally, during October 2004 TTP formally served Aerogen with the infringement suit that PARI had advised Aerogen in April 2003 had already been filed in Munich, Germany. Although the infringement suit claims that Aerogen infringes solely on the patent claims that have since been ruled null and void, there can be no guarantee that an appeals court will not reverse the nullity ruling and again provide PARI with the legal standing to reassert their infringement suit.

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, which 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, by our partner companies or by 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.

Item 3. Quantitative and Qualitative Disclosures 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 United States dollars using the average currency exchange rate in effect for that period, and assets and liabilities are translated into United States 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 United States 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 United States 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

As of the end of the period covered by 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 Securities and Exchange Commission (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 adverse changes in our internal controls or in other factors that could significantly affect those controls during the period covered by this report. We did, however, complete the implementation of an Enterprise Resource Planning (ERP) software system in both our Mountain View, CA and Galway, Ireland facilities. This system now enables the Company to electronically process all accounting transactions for both the parent and subsidiary, including general ledger, purchasing, payables, inventory and receivables management, and provides full electronic audit trail capability and reporting for all such transactions.

Part II. Other Information

Item 1. Legal Proceedings

In April 2003, PARI notified Aerogen that it had filed a patent infringement suit in the District Court of Mannheim, Germany, alleging that Aerogen s commercially available Aeroneb Pro nebulizer infringes European Patent 0 615 470 in Germany. In May 2003, we filed an action in the German Patent Office requesting that the patent in question be rendered null and void. On July 22, 2004, the Federal Patent Court in Munich, Germany ruled in favor of Aerogen by nullifying all contested claims of this patent, which is owned by The Technology Partnership plc (TTP) of Hertfordshire, England, and is licensed to PARI, GmbH of Munich, Germany. The Court ordered TTP to pay Aerogen s legal expenses related to this nullity action to the maximum extent allowed under German law. During October 2004, TTP requested, and was granted, a three-month extension of time to file an appeal of this decision, and TTP formally served Aerogen with the infringement suit that PARI had

claimed during April 2003 had already been filed in Munich, Germany. Although the infringement suit claims that Aerogen infringes solely on the patent claims that have since been ruled null and void, there can be no guarantee that an appeals court will not reverse the nullity ruling and again provide PARI with the legal standing to reassert their infringement suit.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

In accordance with the terms of the Series A-1 Preferred, Aerogen has issued quarterly dividends in the form of Aerogen common stock to the holders of the A-1 Preferred, commencing with the quarter ended March 31, 2004 through the quarter ended September 30, 2004. The total number of common shares issued and issuable pursuant to these dividends was 361,638 shares as of September 30, 2004. The issuance of these shares 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.

None.

Item 6. Exhibits

We have filed, or incorporated by reference, the exhibits listed on the accompanying Exhibit Index immediately following the signature page of this report.

Exhibit List

No.	Note	Description of Exhibit Document
3.2	(7)	Amended and Restated Certificate of Incorporation of Aerogen, Inc.
3.2.1	(8)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Aerogen, Inc.
3.4	(1)	Amended and Restated Bylaws of Aerogen, Inc.
4.5	(9)	Warrant dated as of September 9, 2003, issued by the Company to SF Capital Partners, Ltd. (SF Capital)
4.7	(8)	Warrant dated as of November 3, 2003, issued by the Company to SF Capital
4.13	(10)	Warrant, dated as of January 23, 2004, issued by the Company in favor of the Carpenter 1983 Family Trust UA
4.14	(11)	Purchase Agreement, dated March 11, 2004, by and between the Company, Xmark Fund L.P., Xmark Fund, Ltd. and other investors
4.15	(11)	Certificate of Designations, Preferences and Rights of Series A-1 Preferred Stock of the Company, dated March 19, 2004
4.16	(11)	Form of Warrant
4.17	(11)	Registration Rights Agreement, date as March 22, 2004, by and between the Company and the Investors named in the Purchase Agreement
4.18	(11)	Amendment to Purchase Agreement and Waiver, dated as of March 19, 2004, by and between the Company and certain of the Investors named in the Purchase Agreement
4.19	(11)	Amendment No. 2 to Rights Agreement, dated as of March 19, 2004, by and between the Company and Mellon Investor Services LLC as Rights Agent
31.1		Certification required by Rules 13a-15(3) and 15d-15(e)
31.2		Certification required by Rules 13a-15(3) and 15d-15(e)
32.1		Certification required by Section 13a-14(b) or Rule 15d-14(b) of the Securities and Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of The United States Code (18 U.S.C. § 1350).

(1) Incorporated by reference to our Registration Statement on Form S-1 No. 333-44470 filed on August 25, 2000
(7) Incorporated by reference to our Form 10-Q for the quarter ended June 30, 2002 filed on August 11, 2002
(8) Incorporated by reference to our Form 10-Q for the quarter ended September 30, 2003 filed on November 14, 2003
(9) Incorporated by reference to our Current Report on Form 8-K filed on October 7, 2003
(10) Incorporated by reference to our Current Report on Form 8-K filed on February 5, 2004
(11) Incorporated by reference to our Current Report on Form 8-K filed on March 26, 2004

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 15, 2004	By:	/s/ JANE E. SHAW Jane E. Shaw, Ph.D. *Chairman and Chief Executive Officer*
Dated: November 15, 2004	By:	/s/ ROBERT S. BREUIL Robert S. Breuil *Chief Financial Officer*