

AEROGEN INC  
Form 10-Q  
May 13, 2004

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2004

OR

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

For the transition period from            to

Commission File Number: 0-31913

**Aerogen, Inc.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or  
organization)

**33-0488580**

(I.R.S. Employer Identification No.)

**2071 Stierlin Court, Suite 100, Mountain View, CA**

(Address of principal executive offices)

**94043**

(zip code)

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

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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  No

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

As of April 30, 2004, there were 4,783,695 shares of the Registrant's Common Stock, par value \$0.001, outstanding.

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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)

	March 31, 2004	December 31, 2003
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 12,635	\$ 762
Accounts receivable	513	445
Inventories, net	324	301
Prepaid expenses and other current assets	622	428
Total current assets	14,094	1,936
Property and equipment, net	3,735	3,901
Goodwill and other intangible assets, net	1,872	1,931
Restricted cash	900	1,200
Other assets	632	608
Total assets	\$ 21,233	\$ 9,576
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 565	\$ 937
Deferred revenue, current	500	500
Convertible debentures, net	1,550	1,486
Accrued liabilities	2,934	1,194
Total current liabilities	5,549	4,117
Deferred rent	145	1,658
Deferred revenue, non-current	1,928	1,875
Other long-term liabilities	238	246
Total liabilities	7,860	7,896
Redeemable convertible preferred stock		
Redeemable convertible preferred stock, par value \$0.001:		

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Authorized: 5,000 shares; issued and outstanding:

500 shares at March 31, 2004 and no shares at December 31, 2003

8,072

(Liquidation preference: \$14,999 and \$0 at March 31, 2004 and December 31, 2003, respectively)

Stockholders' equity:

Common stock, par value \$0.001:

Authorized: 95,000 shares; issued and outstanding:

4,780 shares at March 31, 2004 and 4,396 shares at December 31, 2003

5

4

Additional paid-in capital

118,735

110,991

Notes receivable from stockholders

(283)

(280)

Deferred stock-based compensation, net

(147)

(264)

Accumulated other comprehensive income

817

700

Accumulated deficit

(113,826)

(109,471)

Total stockholders' equity

5,301

1,680

Total liabilities, redeemable convertible preferred stock

and stockholders' equity

\$

21,233

\$

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)

	<b>Three Months Ended March 31,</b>	
	<b>2004</b>	<b>2003</b>
<b>Revenues:</b>		
Product sales	\$ 849	\$ 1,278
Research and development		165
Royalty and other	250	125
Total revenues	1,099	1,568
<b>Costs and expenses:</b>		
Cost of products sold	737	834
Research and development	1,933	3,205
Selling, general and administrative	2,005	1,904
Total costs and expenses	4,675	5,943
Loss from operations	(3,576)	(4,375)
Interest income (expense), net	(560)	38
Other income (expense), net	(219)	40
Net loss	(4,355)	(4,297)
Dividends related to convertible preferred stock	(7,932)	
Net loss attributable to common stockholders	\$ (12,287)	\$ (4,297)
Net loss per share, basic and diluted	\$ (2.76)	\$ (1.05)
Weighted - average shares used in computing net loss per share, basic and diluted	4,456	4,079

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

## Aerogen, Inc.

## Condensed Consolidated Statements of Cash Flows

(unaudited; in thousands, except per share data)

	Three Months Ended March 31	
	2004	2003
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,355)	\$ (4,297)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	291	334
Changes in inventory reserves		8
Disposal of property and equipment		(25)
Accrued interest on notes receivable from stockholders	(3)	(1)
Amortization of notes discount		6
Amortization of deferred stock-based compensation	117	278
Amortization of discount on convertible notes	522	
Changes in operating assets and liabilities:		
Accounts receivable	72	(420)
Inventories	19	(100)
Prepaid expenses and other current assets	128	(970)
Accounts payable	(443)	(308)
Accrued liabilities	1,921	210
Deferred rent	(1,513)	61
Deferred revenue	53	(208)
Other	(102)	1,201
Net cash used in operating activities	(3,293)	(4,231)
<b>Cash flows from investing activities:</b>		
Acquisition of property and equipment	(59)	(140)
Proceeds from maturities of available-for-sale securities		5,599
Net cash provided by (used in) investing activities	(59)	5,459
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of preferred stock and warrants, net	14,644	
Proceeds from issuance of convertible debenture	505	
Proceeds from issuance of debenture	300	
Repayment of debenture	(300)	
Net cash provided by financing activities	15,149	
Effect of exchange rate changes on cash	76	(17)
Net increase in cash and cash equivalents	11,873	1,211



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Cash and cash equivalents at beginning of period		762		3,266
Cash and cash equivalents at end of period	\$	12,635	\$	4,477
<b>Supplemental disclosure of noncash investing and financing activities:</b>				
Conversion of convertible debt and interest into common stock	\$	585	\$	
Issuance of warrants	\$	6,886	\$	
Beneficial conversion feature of preferred stock	\$	7,912	\$	

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

**Aerogen, Inc.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**Note 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Organization and Business of the Company**

Aerogen, Inc. ( Aerogen, the Company or we ) was incorporated in November 1991. We are a specialty pharmaceutical company focusing on respiratory therapy in the acute care setting. 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. As of March 31, 2004, Aerogen had cash and cash equivalents of approximately \$12.6 million. On March 23, 2004, we completed a first closing of a \$32.7 million financing for gross proceeds of \$15.0 million. The second closing for gross proceeds of \$17.7 million was approved by stockholders at our annual meeting held on May 10, 2004.

**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 March 31, 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:

	March 31, 2004	December 31, 2003
	(in thousands)	
Raw materials	\$ 131	\$ 228
Work-in-process	64	30
Finished goods	129	43
Net inventories	\$ 324	\$ 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 statement of operations as a cost of products sold. A reconciliation of the changes in the Company's warranty liability for the three months ending March 31, 2004 is as follows (in thousands):

Warranty accrual at January 1, 2004	\$ 138
Accruals for warranties issued during the period	30
Settlements made in kind during the period	(36)
Warranty accrual at the March 31, 2004	\$ 132

**Other Comprehensive Income**

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

**Net Loss Per Share**

Basic net loss per share is computed by dividing the net loss attributable to common shareholders 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.

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

	Three Months Ended	
	2004	March 31, 2003
Net loss per share, basic and diluted:	(in thousands)	
Net loss	\$ (4,355)	\$ (4,297)
Deemed dividend on preferred stock	(7,912)	
Accrued dividend on preferred stock	(20)	
Net loss attributable to common shareholders	\$ (12,287)	\$ (4,297)
Weighted-average common shares outstanding	4,456	4,081
Less weighted-average shares subject to repurchase		(2)
Weighted-average shares used in computing basic and diluted net loss per common share	4,456	4,079

The following outstanding options, common stock subject to repurchase, warrants, convertible debentures and convertible preferred stock (on an as-converted basis) were excluded from the computation of diluted net loss per share as they all had an antidilutive effect:

	2004	March 31, 2003
	(in thousands)	
Options to purchase common stock	453	561
Common stock subject to repurchase		1
Warrants	5,522	4
Convertible debentures	493	
Convertible preferred stock	5,000	

#### 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:







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

	<b>Years Ending December 31, (in thousands)</b>	
2004	\$	706
2005		867
2006		1,028
2007		1,102
2008		1,152
2009		193
Total minimum payments	\$	5,048

#### 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, as amended, is convertible into 164,258 shares of common stock on or before May 14, 2004 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. 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 Carpenter Warrant expires in four years. 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 the relative fair values of the Carpenter Debenture and Carpenter Warrant. The discount on the Carpenter Debenture for the beneficial conversion feature and Carpenter Warrant are being amortized, using the effective interest method, to interest expense over the term of the Carpenter Debenture, which matured on March 1, 2004. Total interest expense recognized relating to the beneficial conversion feature and the Carpenter Warrant discount was \$ 417,991 for the three month period ended March 31, 2004.

There were two convertible secured debentures, each with an associated warrant, issued to SF Capital Partners, Ltd. (SF Capital) during September and November 2003, all of which were subject to a conversion price and exercise price adjustment provision. The conversion price and exercise price adjustment provision was triggered for the November 3, 2003 SF Capital debenture and warrant when the Company issued the \$0.5 million Carpenter Debenture with a conversion price less than the initial conversion price of the November 2003 SF Capital debenture. As a result, the conversion price and exercise price of the November 2003 SF Capital debenture and warrant, respectively, have been reduced to \$3.044 per share.

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In 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, the September 11, 2003 SF Capital debenture and accrued interest was converted into a total of 564,224 shares of the Company's common stock.

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 entailed the sale and issuance of 1,142,094 shares of Series A-1 Convertible Preferred Stock of the Company that are initially convertible into an aggregate of 11,420,940 shares of common stock of the Company, as well as the issuance of warrants to purchase 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 Series A-1 Convertible Preferred Stock 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 \$6,730,000, 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 as an offset to Convertible Preferred Stock. 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%, volatility of 100%, and a dividend yield of zero. The difference between the accounting conversion price of the preferred stock and the fair market value of the underlying common stock on the commitment date (transaction date) resulted in a beneficial conversion feature of \$7,912,000, which was treated as a deemed dividend on the preferred stock. The initial values assigned to both the convertible preferred stock and the warrants were allocated based on the relative fair values of the preferred stock and the warrants.

We were granted a waiver from the Nasdaq stockholder approval requirements for the first closing, which was subject to a 10-day stockholder notice requirement. The balance of the Series A-1 Convertible Preferred Stock and warrants were issued in a second closing, which was approved by Aerogen's stockholders at the Company's Annual Meeting held on May 10, 2004.

As part of the A-1 Financing, SF Capital and the Carpenter Trust agreed to exchange the outstanding secured convertible debentures previously issued to them for an aggregate of 52,232 shares of Series A-1 Convertible Preferred Stock. The debentures issued to SF Capital and the Carpenter Trust were amended to extend the maturity of such debentures to June 1, 2004. Under the terms of the A-1 Financing, SF Capital will retain both of its warrants originally issued in connection with both 2003 debentures, and also received a new warrant to purchase 350,770 shares of common stock at an exercise price of \$3.25 per share in connection with its debenture exchange into Series A-1 Convertible Preferred Stock at the second closing. The Carpenter Trust will retain its warrant originally issued in connection with the Carpenter Debenture, but it will not receive a new warrant in connection with the exchange of the Carpenter Debenture into Series A-1 Convertible Preferred Stock at the second closing. Additionally, on March 12, 2003, SF Capital provided a \$300,000 secured bridge loan (the SF Capital Bridge) to support the Company's operations through the first closing. The SF Capital Bridge has been repaid out of the proceeds of the first closing of the A-1 Financing.

On March 19, 2004, the Company filed a certificate of designation authorizing 1,572,685 shares of Series A-1 Preferred stock.

## Series A-1 Preferred Stock Preferences

### Liquidation Rights

In the event of any liquidation, dissolution or winding up of the Company, the holders of Series A-1 Convertible 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 Series A-1 Convertible Preferred and common stock, with the holders of Series A-1 Convertible Preferred deemed to hold that number of shares of common stock into which the shares of Series A-1 Convertible Preferred are then convertible. The holders of a majority in interest of the Series A-1 Convertible Preferred, including the Lead Investor (so long as it owns at least 80,000 shares of Series A-1 Convertible Preferred) (the Requisite Holders ), may elect to treat an acquisition of the Company as a liquidation.

Because such liquidation events could require the Company to redeem the convertible preferred stock and are outside the control of the Company, the convertible preferred stock is classified outside of stockholder s equity in the accompanying balance sheet.

### Dividends

Each holder of Series A-1 Convertible 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. Accrued dividends, whether or not paid, will increase net loss attributable to common stockholders.

### Conversion; Anti-Dilution Protection

The holder of any share or shares of Series A-1 Convertible Preferred shall have the right, at the holder s option at any time, to convert any such shares of Series A-1 Convertible Preferred into such number of fully paid and nonassessable shares of common stock as is obtained by: (i) multiplying the number of shares of Series A-1 Convertible 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 Series A-1 Convertible 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. The Series A-1 Conversion Price shall initially be \$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 Corporation in existence on March 23, 2004, so long as the issuance of such stock or options is approved by a

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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 Series A-1 Convertible Preferred or as payment-in-kind dividends on the Series A-1 Convertible 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 Series A-1 Convertible 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 Series A-1 Convertible Preferred are entitled to vote together with the holders of common stock as a single class. Each share of Series A-1 Convertible Preferred shall have the number of votes equal to the number of shares of common stock into which such share of Series A-1 Convertible Preferred is convertible.

As long as at least 200,000 shares of Series A-1 Convertible 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 Series A-1 Convertible 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 Series A-1 Convertible Preferred; (3) increase the number of authorized shares of Series A-1 Convertible Preferred or authorize the issuance of or issue any shares of Series A-1 Convertible 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 Series A-1 Convertible Preferred or the Company's ability to honor the exercise of any rights of the holders of Series A-1 Convertible 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 Series A-1 Convertible 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*

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*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 on April 14, 2003 ( 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 focusing on respiratory therapy in the acute 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 March 31, 2004, we had two nebulizer products on the market. We have an accumulated deficit of approximately \$113.8 million as of March 31, 2004. In 2002, we generated significant revenues from our planned principal operations and thus exited the development stage. However, we will 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.

As of March 31, 2004, we had \$12.6 million in cash and cash equivalents. On March 23, 2004, we completed a first closing of a \$32.7 million financing for gross proceeds of \$15.0 million. The second closing for gross proceeds of \$17.7 million was approved by stockholders at our annual meeting held on May 10, 2004. In January 2004, we announced a furlough of nine employees, seven of which were subsequently terminated on March 22, 2004.

### **Results of Operations**

#### **Revenues**

Total revenues for the three months ended March 31, 2004 were \$1.1 million, compared with \$1.6 million for the same period of 2003. Total revenues include revenues from product sales, research and development activities for unrelated third parties, royalties associated with the licensing of our technology for use outside of the medical field and other revenues.

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Product sales for the three months ended March 31, 2004 were \$0.8 million, compared with \$1.3 million for the same period of 2003. Product sales were lower for the three months ending in March 31, 2004 as product shipments were curtailed during the quarter in an effort to conserve working capital. As a result, the value of our backlog as of March 31, 2004 was approximately \$492,000. Product sales were influenced during the first three months of 2004 as sales of our OnQ Aerosol Generators to Medical Industries America Inc. ( MIA ) under a transfer pricing arrangement began to ramp up.

There were no research and development revenues for the three months ended March 31, 2004, compared with \$165,000 for the same period of 2003. The revenues for the three months ended March 31, 2003 resulted from product development activities performed under partner agreements signed in late 2002, which completed in 2003. There are currently no revenue-bearing partner agreements effective for 2004. 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.

Royalty and other revenues were \$250,000 and \$125,000, for the three month periods ended March 31, 2004 and 2003, respectively. The increase in royalty and other revenue in 2004 over 2003 was due to up-front payments associated with the September 2003 commercial agreement with MIA, which resulted in the amortization of \$125,000 of a \$2.5 million upfront payment which is being amortized ratably over the five year



term of the agreement; additionally, MIA will pay us royalties on its gross sales of the Aeroneb® Go and MIA's sales of accessories. First commercial shipments occurred in the United States in January 2004. No royalty revenues were recognized during the quarter ended March 31, 2004. 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.

#### **Cost of Products Sold**

Cost of products sold for the three months ended March 31, 2004 and 2003 were \$0.7 million and \$0.8 million, respectively. We began to realize yield improvements in our manufacturing processes during the three month period ending March 31, 2003, resulting in lower costs per unit. However, cost of goods sold, as a percentage of product sales revenue, increased in the first three months ended March 31, 2004 as compared to the same period of 2003, primarily as a result of the temporary decrease in product sales volumes. As the manufacturing processes mature, and as we see volumes increase, we anticipate further improvements in the cost of products sold as a percentage of product sales revenue.

#### **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 partners priorities, and the level of our internally funded research and development efforts.

Research and development expenses for the three months ended March 31, 2004 were \$1.9 million, compared with \$3.2 million for the same period of 2003. The decrease in research and development expenses of \$1.3 million for the three months ended March 31, 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 a furlough of six research and development employees in January 2004, five of whom were subsequently terminated in March 2004; reduced facility related expense of \$0.4 million due to changes in facility space utilization; and non-payroll related expenses for professional services, machining services, and materials for several other programs totaling \$0.2 million.

#### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses for the three months ended March 31, 2004 were \$2.0 million, compared with \$1.9 million for the same period of 2003. The increase for the three months ended March 31, 2004 of \$0.1 million compared with the same period of 2003 was primarily due to: increased facility related expense of \$0.3 million due to changes in facility space utilization, increases in legal expenses of \$0.3 million, and increases in taxes of \$0.1 million; partially offset by reductions in payroll and related expenses of \$0.2 million associated with reductions in force in 2003 and a furlough of three employees from sales and administration, two of whom were subsequently terminated in

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March 2004, reductions in stock based compensation of \$0.1 million, reductions in marketing and selling programs of \$0.2 million, and other reductions of \$0.2 million.

### **Interest and Other Income (Expense), Net**

Net interest expense for the three months ending March 31, 2004 was \$0.6 million compared with \$0.1 million of net interest income in 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 in 2003 and to the Carpenter Family Trust in 2004, all of which totaled \$0.5 million.

### **Dividend Related to Beneficial Conversion Feature of Preferred Stock**

The issuance of the Series A-1 Convertible Preferred Stock resulted in the recognition of a beneficial conversion feature in the amount of \$7,912,000. The beneficial conversion feature, which is accounted for as a deemed dividend on the preferred stock, arises from the difference between the value of the consideration allocated to the preferred stock in the transaction and the value of the underlying common stock on the date of closing.

### **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 \$113.9 million in aggregate net proceeds from sales of our common and preferred stock through March 31, 2004, including approximately \$44.5 million of net proceeds from our initial public offering in November 2000. In the year ended December 31, 2003, we raised \$2.0 million through the issuance of convertible notes, and, in the first three months ended March 31, 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 March 31, 2004, we had cash and cash equivalents of approximately \$12.6 million. Net cash used in operating activities during the three months ended March 31, 2004 was \$3.3 million, resulting primarily from the net loss for the period of \$4.4 million and a net decrease in accounts payable of \$0.4 million as we settled with past-due vendors. These uses were partially offset by non-cash related charges of approximately \$0.3 million in depreciation and amortization, \$0.5 million in amortization of discounts on convertible notes and \$0.1 million in amortization of deferred stock-based compensation. Additionally, accrued liabilities increased by \$1.9 million primarily due to the payment obligations associated with the restructuring of our lease, which payments must be made during the quarter ending June 30, 2004, partially offset by the decrease in deferred rent of \$1.5 million associated with the same lease restructuring agreement. Net cash used in operating activities during the three months ended March 31, 2003 was \$4.2 million resulting primarily from: the net loss for the period of \$4.3 million; increases in accounts receivable of \$0.4 million; increases in inventories of \$0.1 million; and net decreased accounts payable and accrued liabilities of \$0.1 million. These uses were partially offset by non-cash related charges of approximately \$0.3 million in depreciation and amortization and \$0.3 million in amortization of deferred stock-based compensation. Additionally, in the period ending March 31, 2003 the changes in prepaid expenses, other current assets and other assets were the result of changing a long-term investment into a current investment, which changes substantially offset one another.

Net cash used in investing activities was \$59,000 for the three months ended March 31, 2004, consisting primarily of property and equipment acquisitions associated with process improvements. Net cash provided by investing activities was \$5.5 million for the three months ended March 31, 2003, consisting primarily of proceeds from maturing available-for-sale securities of \$5.6 million, partially offset by \$0.1 million of property and equipment acquisitions associated with process improvements.

Net cash provided by financing activities was \$15.1 million for the three months ended March 31, 2004, consisting of \$14.6 million in net proceeds from issuance of Series A-1 Convertible Preferred Stock and common stock warrants and \$0.8 million in net proceeds from the issuance of debentures and convertible debentures, partially offset by repayment of debentures for \$0.3 million. No cash was provided by financing activities for the three months ending March 31, 2003.

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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.

The continued operation of the Company is dependent on our ability to obtain adequate funding and eventually establish profitable operations. On March 23, 2004, we completed a first closing of a \$32.7 million financing for gross proceeds of \$15.0 million. The net proceeds from this first closing provided us with funds to continue operations through approximately April 2005. The second closing for gross proceeds of \$17.7 million was approved by stockholders at our annual meeting held on May 10, 2004.

#### **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.**

Even with the stockholder's approval of the second closing of the \$ 17.7 million equity financing, our cash resources will most likely 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 clinical trials may be provided from strategic partnerships, such as from out-licensing and partnering of our insulin product, and 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 shareholders.

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

Twelve Series A-1 investors own equity securities that, if all such securities were converted into common stock, would represent ownership of 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, as few as eleven of these investors, or investors to whom the A-1 securities are resold, could

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acquire in excess of 50% of the voting securities of the Company without exceeding this limitation. To our knowledge, the Series A-1 investors have not acted as a group in seeking, negotiating, or making their investment in the Company, have not acted as a group since making their investment, 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.

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

We have never been profitable. Through March 31, 2004, we have incurred an accumulated deficit of approximately \$113.8 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; and

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 currently have a backlog of orders that we believe will not be completely filled until late in the second quarter of 2004, assuming that new orders in the second quarter of 2004 do not materially exceed our revised expectations. As of April 13, 2004, the value of this backlog was approximately \$524 thousand.



**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 products will prove safe and effective;

we will obtain regulatory clearance or approval to sell any additional products; or

any of our existing or future products can be manufactured in commercial quantities or at an acceptable cost or marketed successfully.

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

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

drugs may be safely and effectively delivered using our technologies;

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

our products consistently deliver accurate and 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 products are not successful, drug products using our inhalers or nebulizers may not be commercialized.**

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

**We have limited experience manufacturing our technology. We depend on key suppliers and contract manufacturers, and their failure to supply us may delay or prevent commercialization of our products.**

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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 our 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.

**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<sup>®</sup> inhalers and Aeroneb<sup>®</sup> nebulizers. We cannot assure that we will be able to establish these kinds of arrangements on favorable terms, or at all, or that our existing or future collaborative arrangements will be successful.

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

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

safety;

efficacy;

the benefits associated with pulmonary delivery;

ease of use; and

price.

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

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

We currently have a small sales and marketing staff and modest marketing budget, and many of our competitors have substantial sales and marketing infrastructures and significant marketing budgets. We rely on third party distributors to sell our products, some of which have limited experience in the markets that we are trying to access. Our success in commercializing our respiratory products in the United States and worldwide will depend on our and our partners' ability to develop and execute a successful sales and marketing effort. There can be no assurance that our current products, which include the Aeroneb® Professional Nebulizer and the Aeroneb® Go Nebulizer 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 MIA, 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. 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 483 was closed.

All medical devices marketed in the European Union are required to bear the CE Mark. Aerogen, MIA 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.

In May of 2004, the Mountain View facility successfully obtained certification to ISO 13485:2003. If Aerogen, MIA 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 MIA and/or our subcontractors, will be found to comply on an ongoing basis with the QSRS, ISO or other international regulatory requirements.

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

**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 process used in assembly of our OnQ Aerosol Generators is conducted at a third party's facilities. Loss of the use of those facilities would result in several months' delay in our supply of components while we establish an alternative brazing site. 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. One of our first commercial products, the Aeroneb Pro, is not currently reimbursed by insurance or government entities, which may limit its market penetration.

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

We 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. 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 key consultants to execute confidentiality agreements upon the commencement of employment or a consulting relationship with us. We cannot assure that employees or consultants will not breach these agreements, that we would have adequate remedies for any breach or that our trade secrets will not otherwise become known to or be independently developed by competitors.

**We have in the past and may become in the future subject to patent litigation, which has been and may be costly to defend and could invalidate our patents.**

The pharmaceutical and medical device industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in these industries have used intellectual property litigation to gain a competitive advantage. We cannot assure that we will not become subject to, whether within or outside of the United States, patent infringement claims or litigation or interference proceedings declared by the United States Patent and Trademark Office, ( 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 Bepak's 5,261,601 patent, we entered into a cross-license agreement with Bepak, as a result of which Bepak 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 Bepak 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 Aeronob 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.

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 changes in our internal controls or in other factors that could significantly affect those controls during the period covered by this report.

**Part II. Other Information**

**Item 1. Legal Proceedings**

There were no new legal proceedings or material developments regarding existing legal proceedings in the quarter ending March 31, 2004.

**Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities.**

On January 23, 2004, we closed a convertible debt financing, that resulted in gross proceeds of \$505,133 from the Carpenter 1983 Family Trust UA (the Carpenter Trust). The trustees of the Carpenter Family Trust are Aerogen's Chairman and Chief Executive Officer, Dr. Jane Shaw and her husband Peter Carpenter. Under the terms of the debt financing, we issued the Carpenter Trust a secured convertible debenture with a face amount of \$500,000 that bears interest at a rate of 10% per annum and, as amended, is due June 1, 2004. The conversion price of the debenture is \$3.044. The Carpenter Trust also purchased a warrant, exercisable on or after July 26, 2004 for 82,129 shares of common stock at an exercise price of \$3.044 per share, which expires in January 2008.

On March 11, 2004, we signed definitive documents for a \$32.7 million equity financing (the A-1 Financing) with Xmark Fund, L.P. and Xmark Fund, Ltd. (Xmark) and other accredited investors. The A-1 Financing entailed the sale and issuance, in two closings, of 1,142,094 shares of Series A-1 Convertible Preferred Stock initially convertible into 11,420,940 shares of the Company's common stock, and warrants to purchase 11,249,390 shares of common stock at an exercise price of \$3.25 per share.

On March 23, 2004, the Company completed the first closing of the A-1 Financing, resulting in the sale and issuance of 499,981 shares of Series A-1 Convertible Preferred Stock and warrants to purchase 4,999,810 shares of the Company's common stock, in exchange for gross proceeds of \$14,999,430. The second closing of the A-1 Financing was approved at Aerogen's annual meeting of stockholders on May 10, 2004 and Aerogen has issued an additional 642,113 shares of Series A-1 Convertible Preferred Stock and warrants to purchase 6,249,580 shares of common stock for gross proceeds of approximately \$17.7 million and the exchange of all outstanding secured convertible debentures. Under the terms of the A-1 Financing, the Company terminated the Rights Agreement between it and Mellon Investor Services LLC as Rights Agent, dated as of June 5, 2001, as amended February 24, 2003, pursuant to Amendment No. 2 to Rights Agreement dated as of March 19, 2004.

As part of the A-1 Financing, SF Capital and the Carpenter Trust agreed to exchange the outstanding secured convertible debentures previously issued to them for an aggregate of 52,232 shares of Series A-1 Convertible Preferred Stock. SF Capital also received a warrant to purchase 350,770 shares of common stock at an exercise price of \$3.25 per share in connection with its debt exchange.

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The issuances of the Series A-1 Convertible Preferred Stock, convertible debentures, warrants and common stock described in this section titled Sales of Unregistered Securities were exempt from registration under Section 4(2) of the Securities Act of 1933, as amended (the Act), and Regulation D of the General Rules and Regulations under the Act.

**Item 3. Defaults Upon Senior Securities.**

None.

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

Not applicable.

**Item 5. Other Information.**

On May 5, 2004, the Company filed a current report on Form 8-K with a press release announcing the Company's earnings for the three months ended March 31, 2004. The financial statements in this press release correctly showed a Net Loss of \$4.4 million; however, the Net Loss Per Share was incorrectly shown as \$0.98 per share. The Net Loss Per Share was inaccurate because it did not reflect a deemed dividend related to the issuance of our Series A-1 Convertible Preferred Stock (see *Dividend Related to Beneficial Conversion Feature of Preferred Stock* for a complete description of this deemed dividend). The difference between the conversion price and the fair market value of the underlying common stock on the commitment date (transaction date) resulted in a beneficial conversion feature of \$7,912,000 which has been treated as a deemed dividend. Including this deemed dividend, the Net Loss Attributable to Shareholders was \$12.3 million, or \$2.76 per share, as reported in this Form 10-Q. Additionally, the appropriate presentation of the convertible preferred stock has been determined to be outside permanent stockholder's equity, therefore the balance sheet included in this Form 10-Q has been updated to reflect \$8,072,000 of convertible preferred stock in the mezzanine, with a corresponding reduction of stockholders' equity from \$13,373,000 to \$5,301,000.

**Item 6. Exhibits and Reports on Form 8-K**

(a) Exhibits.

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.
3.5	(6)	Amendment to Rights Agreement dated as of February 24, 2003, by and between Aerogen, Inc. and Mellon Investor Services, LLC, as Rights Agent
4.2	(1)	Warrant, dated October 14, 1997, to purchase Series C preferred stock of Aerogen, Inc. issued to Venture Lending & Leasing II, Inc.
4.3	(1)	Warrant, dated October 14, 1997, to purchase Series C preferred stock of Aerogen, Inc. issued to Venture Lending & Leasing, Inc.

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- 4.4 (9) Loan and Securities Purchase, dated as of September 9, 2003, by and between the Company and SF Capital Partners, Ltd. ( SF Capital ).
- 4.5 (9) Warrant dated as of September 9, 2003, issued by the Company to SF Capital
- 4.6 (8) Debenture dated as of November 3, 2003, issued by the Company to SF Capital
- 4.7 (8) Warrant dated as of November 3, 2003, issued by the Company to SF Capital
- 4.8 (10) Amendment to Secured Convertible Debenture, dated January 7, 2004, by and between the Company and SF Capital
- 4.9 (10) Amendment No. 2 to Secured Convertible Debenture and Consent, dated as of January 20, 2004, by and between the Company and SF Capital
- 4.10 (10) Loan and Securities Purchase Agreement, dated as of January 23, 2004, by and between the Company and the Carpenter 1983 Family Trust UA (the Trust )
- 4.11 (10) Debenture, dated as of January 23, 2004, issued by the Company in favor of the Trust.
- 4.12 (10) Registration Rights Agreement, dated as of January 23, 2004, by and between the Company and the Trust
- 4.13 (10) Warrant, dated as of January 23, 2004, issued by the Company in favor of the Trust

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- 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, dated as of 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
- 4.20 (11) Amendment to Secured Convertible Debentures, dated as of March 1, 2004, by and between the Company and SF Capital
- 4.21 (11) Amendment No. 1 to Secured Convertible Debenture and Consent, dated as of March 1, 2004, by and between the Company and the Carpenter Trust
- 4.22 (11) Secured Debenture, dated March 12, 2004, issued by the Company to SF Capital
- 4.23 (11) Amendment No. 1 to Security Agreement, dated as of March 11, 2004, by and between the Company and SF Capital
- 4.24 (11) Amendment No. 1 to IP Security Agreement, dated as of March 11, 2004, by and between the Company and SF Capital
- 10.12 (5) Form of lease agreement between EOP-Shoreline Technology Park, L.L.C. and Aerogen, Inc. for the premises located at 2071 Stierlin Court, Mountain View, California
- 10.12.1 (12) Lease amendment, dated November 6, 2003, between CA-Shoreline Technology Park, LP and Aerogen.
- 10.12.2 (12) Lease amendment, dated March 9, 2004, between CA-Shoreline Technology Park, LP and Aerogen.
- 10.17 (8)\* Distribution and supply agreement, dated as of September 30, 2003, between the Company and Medical Industries America Inc.
- 31.1 Certification required by Rule 13a-14(a) or Rule 15d-14(a)
- 31.2 Certification required by Rule 13a-14(a) or Rule 15d-14(a)
- 32.1 Certification required by Rule 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. Section 1350).

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- (1) Incorporated by reference to our Registration Statement on Form S-1 No. 333-44470 filed on August 25, 2000.
  - (5) Incorporated by reference to our Form 10-Q for the quarter ended September 30, 2001 filed on November 13, 2001.
  - (6) Incorporated by reference to our Current Report on Form 8-K filed on February 25, 2003.
  - (7) Incorporated by reference to our Form 10-Q for the quarter ended June 30, 2002 filed on August 13, 2002.
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- (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.
  
- (12) Incorporated by reference to our Form 10-K/A for the year ended December 31, 2003 filed on May 10, 2004.

\* Previously requested confidential treatment as to specific portions, which portions were omitted and filed separately with the Securities and Exchange Commission.

- (b) Reports on Form 8-K.

On February 5, 2004, we filed a current report on Form 8-K relating to the closing of the convertible debt financing with the Carpenter Trust. On March 26, 2004, we filed a current report on Form 8-K relating to the signing of definitive agreements for, and first closing of, the \$32.7 million equity financing with Xmark and other investors.

**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: May 13, 2004

By:

/s/ JANE E. SHAW  
Jane E. Shaw, Ph.D.  
*Chairman and Chief Executive Officer*

Dated: May 13, 2004

By:

/s/ ROBERT S. BREUIL  
Robert S. Breuil  
*Chief Financial Officer*



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