AEROGEN INC
Form 10-Q/A
April 18, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q/A

(Mark One)

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

For the quarterly period ended June 30, 2004

OR

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

For the transition period from to

Commission File Number: 0-31913

Aerogen, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0488580**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2071 Stierlin Court, Suite 100, Mountain View, CA	**94043**
(Address of principal executive offices)	(zip code)

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 (the Exchange Act) during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ý No o

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

As of August 2, 2004, there were 4,784,506 shares of the Registrant s Common Stock, par value $0.001, outstanding.

EXPLANATORY NOTE

The purpose of this Amendment No. 1 to Aerogen s Form 10-Q for the quarter ended June 30, 2004 is to restate our financial statements to correct an error in the accounting for warrants to purchase common stock issued during fiscal 2004 as further discussed in Note 2 to the condensed consolidated financial statements. No attempt has been made in the Form 10-Q/A to modify or update any disclosures except as required to reflect the impact of this restatement.

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)

	June 30, 2004 (Restated)	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,821	$ 762
Accounts receivable	972	445
Inventories, net	569	301
Prepaid expenses and other current assets	721	428
Total current assets	27,083	1,936
Property and equipment, net	2,954	3,901
Goodwill and other intangible assets, net	1,858	1,931
Restricted cash		1,200
Other assets	583	608
Total assets	$ 32,478	$ 9,576
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 554	$ 937
Deferred revenue, current	961	500
Convertible debentures, net		1,486
Accrued liabilities	1,347	1,194
Total current liabilities	2,862	4,117
Deferred rent	174	1,658
Deferred revenue, non-current	2,002	1,875
Warrant liability	17,558	
Other long-term liabilities	236	246
Total liabilities	22,832	7,896
Redeemable convertible preferred stock		
Redeemable convertible preferred stock, par value $0.001: Authorized: 5,000 shares; issued and outstanding: 1,142 shares at June 30, 2004 and no shares at December 31, 2003, respectively) (Liquidation preference: $34,260 at June 30, 2004)	16,351	
Stockholders equity (deficit):		
Common stock, par value $0.001: Authorized: 95,000 shares; issued and outstanding:	5	4

4,785 shares at June 30, 2004 and 4,396 shares at December 31, 2003		
Additional paid-in capital	111,779	110,991
Notes receivable from stockholders	(286)	(280)
Deferred stock-based compensation, net	(48)	(264)
Accumulated other comprehensive income	886	700
Accumulated deficit	(119,041)	(109,471)
Total stockholders equity (deficit)	(6,705)	1,680
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 32,478	$ 9,576

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

Aerogen, Inc.

Condensed Consolidated Statements of Operations

(unaudited; in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004 (Restated)	2003	2004 (Restated)	2003
Revenues:				
Product sales	$ 1,251	$ 989	$ 2,100	$ 2,267
Research and development				165
Royalty and other	444	125	694	250
Total revenues	1,695	1,114	2,794	2,682
Costs and expenses:				
Cost of products sold	1,257	611	1,994	1,445
Research and development	2,859	3,015	4,792	6,220
Selling, general and administrative	1,324	1,450	3,329	3,354
Total costs and expenses	5,440	5,076	10,115	11,019
Loss from operations	(3,745)	(3,962)	(7,321)	(8,337)
Interest income (expense), net	25	14	(535)	52
Increase in warrant liability	(361)		(1,421)	
Other income (expense), net	(74)	326	(293)	366
Net loss	(4,155)	(3,622)	(9,570)	(7,919)
Dividends related to convertible preferred stock	(5,628)		(12,088)	
Net loss attributable to common stockholders	$ (9,783)	$ (3,622)	$ (21,658)	$ (7,919)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.05)	$ (0.88)	$ (4.69)	$ (1.94)
Weighted - average shares used in computing net loss per share attributable to common stockholders, basic and diluted	4,783	4,097	4,620	4,088

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

Aerogen, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited; in thousands)

	Six Months Ended June 30	
	2004 (Restated)	**2003**
Cash flows from operating activities:		
Net loss	$ (9,570)	$ (7,919)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	576	645
Increase in warrant liability	1,421	
Changes in inventory reserves		8
Disposal of property and equipment	755	(25)
Accrued interest on notes receivable from stockholders	(6)	(6)
Amortization of notes discount	522	
Amortization of premium on available for sales securities		6
Amortization of deferred stock-based compensation	215	515
Amortization of discount on convertible notes		
Changes in operating assets and liabilities:		
Accounts receivable	(396)	299
Inventories	(230)	58
Prepaid expenses and other current assets	926	337
Accounts payable	(41)	(213)
Accrued liabilities	(42)	(165)
Deferred rent	(1,484)	123
Deferred revenue	180	(208)
Other	(100)	(3)
Net cash used in operating activities	(7,274)	(6,548)
Cash flows from investing activities:		
Acquisition of property and equipment	(141)	(230)
Proceeds from maturities of available-for-sale securities		5,599
Net cash provided by (used in) investing activities	(141)	5,369
Cash flows from financing activities:		
Proceeds from issuance of common stock	6	23
Proceeds from issuance of preferred stock and warrants, net	30,928	
Proceeds from issuance of convertible debenture	505	
Repayment of note receivable from stockholder		65
Net cash provided by financing activities	31,439	88
Effect of exchange rate changes on cash	35	(478)
Net increase in cash and cash equivalents	24,059	(1,569)
Cash and cash equivalents at beginning of period	762	3,266
Cash and cash equivalents at end of period	$ 24,821	$ 1,697
Supplemental disclosure of noncash investing and financing activities:		
Conversion of convertible debt and interest into common stock	$ 585	$
Beneficial conversion feature of preferred stock	$ 11,689	$

Conversion of convertible debt and interest into preferred stock	$	1,567	$	
Issuance of stock dividend	$	399	$	

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

Aerogen, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

Note 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business of the Company

Aerogen, Inc. (Aerogen, the Company or we) was incorporated in November 1991. We are a specialty pharmaceutical company 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. On March 23, 2004, we completed a first closing of a $32.7 million financing for gross proceeds of $15.0 million. The second and final closing was completed on May 12, 2004 providing gross proceeds of $17.7 million. As of June 30, 2004, Aerogen had cash and cash equivalents of approximately $24.8 million.

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 June 30, 2004 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2004, or for any other future period.

Inventories

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

	June 30, 2004	December 31, 2003
Raw materials	$ 242	$ 228
Work-in-process	69	30
Finished goods	258	43
Net inventories	$ 569	$ 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 six months ending June 30, 2004 is as follows (in thousands):

	Six Months Ended June 30	
	2004	2003
Warranty accrual at January 1	$ 138	$ 101
Accruals for warranties issued during the period	45	118
Settlements made in kind during the period	(62)	(23)
Warranty accrual at June 30	$ 121	$ 196

Other Comprehensive Income

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

	Three Months Ended June 30		Six Months Ended June 30	
	2004 (Restated)	2003	2004 (Restated)	2003
Net loss	$ (4,155)	$ (3,622)	$ (9,570)	$ (7,919)
Foreign currency translation adjustments	69	(281)	186	(271)
Comprehensive loss	$ (4,086)	$ (3,903)	$ (9,384)	$ (8,190)

Net Loss Per Share

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004 (Restated)	2003	2004 (Restated)	2003
Net loss	$ (4,155)	$ (3,622)	$ (9,570)	$ (7,919)
Deemed dividend on preferred stock	(5,249)		(11,689)	
Accrued dividend on preferred stock	(379)		(399)	
Net loss attributable to common stockholders	$ (9,783)	$ (3,622)	$ (21,658)	$ (7,919)
Weighted-average common shares outstanding	4,783	4,098	4,620	4,089
Less weighted-average shares subject to repurchase		1		1
Weighted-average shares used in computing basic and diluted net loss per share attributable to common stockholders	4,783	4,097	4,620	4,088
Net loss per share attributable to common stockholders, basic and diluted	$ (2.05)	$ (0.88)	$ (4.69)	$ (1.94)

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

	June 30,	
	2004	2003
Options to purchase common stock	3,863	509
Warrants	11,772	4
Convertible preferred stock	11,421	

Accounting for Stock-based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004 (Restated)	2003	2004 (Restated)	2003
Net loss as reported	$ (4,155)	$ (3,622)	$ (9,570)	$ (7,919)
Add: stock-based compensation included in reported net loss	99	237	215	500
Deduct : total stock-based employee compensation determined under fair value based	(145)	(342)	(320)	(650)

method for all awards							
Net loss	proforma	$ (4,201)	$ (3,727)	$ (9,675)	$ (8,069)		
Net loss per share attributable to common stockholders, basic and diluted	as reported	$ (2.05)	$ (0.18)	$ (4.69)	$ (0.39)		
Net loss per share attributable to common stockholders, basic and diluted	proforma	$ (2.05)	$ (0.18)	$ (4.71)	$ (0.39)		

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

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123

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

Lease Amendments

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

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

		Years Ending December 31,
2004	$	706
2005		867
2006		1,028
2007		1,102
2008		1,152
2009		193
Total minimum payments	$	5,048

Note 2 RESTATEMENT

On March 9, 2005, the Company issued a press release and filed a Current Report on Form 8-K announcing that an error had been identified relating to the classification of the warrants issued in connection with the Company s Series A-1 Convertible Preferred Stock financing (see NOTE 3). The Company has reclassified the warrants from equity and preferred stock, where they were originally recorded, to a liability. The liability is adjusted to its fair value at the end of each reporting period. This fair value adjustment resulted in $361,000 and $1,421,000 increases in net loss for the three and six month periods ended June 30, 2004, respectively.

Originally, the proceeds from the Series A-1 Convertible Preferred Stock (the A-1 Preferred) financings on March 23, 2004 and May 12, 2004 were allocated on a pro rata basis using the estimated fair market value of the warrants and A-1 Preferred. Under the Company s revised accounting, however, proceeds are first allocated to the warrant liability based on its fair market value, and then residual proceeds are allocated to the A-1 Preferred. This change in allocation has the result of substantially reducing the proceeds allocated to the A-1 Preferred. A beneficial

conversion feature (BCF) is recorded as a dividend to the preferred stockholders based on the difference between the proceeds allocated to the preferred stock and the transaction date fair market value of the common stock issuable upon conversion, in an amount not to exceed the proceeds allocated to the preferred stock in the transaction. As a result of the change in proceeds allocated to the preferred, the deemed dividend increased by $748,000 for the three months ended June 30, 2004, and decreased by $724,000 for the six months ended June 30, 2004.

Consequently, the condensed consolidated financial statements for the second quarter of 2004 are restated in this Form 10-Q/A. These restated condensed consolidated financial statements reflect adjustments relating to the classification and valuation of the warrants.

The principal effects of these adjustments on the accompanying condensed consolidated financial statements are as follows:

	Condensed Consolidated Balance Sheet June 30, 2004	
	As restated	As Previously reported
Warrant liability	$ 17,558	$
Total liabilities	22,832	5,274
Redeemable convertible preferred stock	16,351	12,573
Additional paid-in capital	111,779	131,694
Accumulated deficit	(119,041)	(117,620)
Total stockholders equity (deficit)	(6,705)	14,631

	Condensed Consolidated Statement of Operations for the three months ended June 30, 2004		Condensed Consolidated Statement of Operations for the six months ended June 30, 2004	
	As restated	As Previously reported	As restated	As Previously reported
Decrease in warrant liability	$ (361)	$	$ (1,421)	$
Net loss	(4,155)	(3,794)	(9,570)	(8,149)
Dividends related to convertible preferred stock	(5,628)	(4,881)	(12,088)	(12,812)
Net loss attributable to common stockholders	(9,783)	(8,675)	(21,658)	(20,961)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.05)	$ (1.81)	$ (4.69)	$ (4.54)

NOTE 3 FINANCING EVENTS

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

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

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

In the aggregate, this debenture and accrued interest was converted into a total of 564,224 shares of the Company s common stock.

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

On March 23, 2004, the Company completed the first closing of a $32.7 million equity financing (the A-1 Financing). The

A-1 Financing occurred in two closings, and involved the sale and issuance of 1,142,094 shares of Series A-1 Convertible Preferred Stock (the A-1 Preferred) of the Company that are initially convertible into an aggregate of 11,420,940 shares of common stock of the Company, as well as the issuance of warrants to purchase up to 11,249,390 shares of common stock at an exercise price of $3.25 per share. Under the terms of the A-1 Financing, the Company terminated its Rights Agreement with Mellon Investor Services, LLC on March 19, 2004.

In the first closing, the Company issued 499,981 shares of A-1 Preferred convertible into 4,999,810 shares of common stock, and issued warrants to purchase 4,999,810 shares of common stock, for gross proceeds to the Company of $14,999,430. As a result of certain rights provided to the investors in the A-1 Financing, the warrants to purchase common stock are accounted for as a liability and marked to market at each period-end date. The aggregate fair value of the warrants of $8,200,000was recorded as a liability, and the remaining net proceeds of $6,440,000 were recorded as preferred stock. The warrants expire in March 2009. The difference between the conversion price and the fair market value of the A-1 Preferred on the commitment date (transaction date) resulted in a beneficial conversion feature of $6,440,000, which is treated as a deemed dividend.

On May 12, 2004, the Company completed the second and final closing of the A-1 Financing. In the second closing, the Company issued 642,113 shares of A-1 Preferred convertible into 6,421,130 shares of common stock, and issued warrants to purchase 6,249,580 shares of common stock, for gross proceeds to the Company of $17,696,000. As a result of certain rights provided to the investors in the A-1 Financing, the warrant to purchase common stock are accounted for as a liability and marked to market at each period-end date. The aggregate fair value of the warrants of $7,937,000 was recorded as a liability, with the remaining net proceeds of $9,397,000 were recorded as preferred stock. The warrants expire in May 2009. The difference between the conversion price and the fair market value of the A-1 Preferred on the commitment date (transaction date) resulted in a beneficial conversion feature of $5,249,000, which is treated as a deemed dividend.

The fair value of the warrants and the corresponding liability is re-measured at each reporting period with any change in the fair value being recorded as a non-operating item in the statement of operations. The aggregate fair value of the warrants increased during the three and six months ended June 30, 2004, which resulted in the Company recording a loss of $361,000 and $1,421,000, respectively, for the three and six months ended June 30, 2004. The fair value of the warrant is determined at each reporting period using a valuation model which takes into consideration a variety of assumption, including stock price, stock volatility and the risk free rate.

As part of the A-1 Financing, SF Capital and the Carpenter Trust exchanged the outstanding secured convertible debentures previously issued to them for an aggregate of 52,232 shares of A-1 Preferred at the second closing. Under the terms of the A-1 Financing, SF Capital retained both of its warrants originally issued in connection with both of its 2003 debentures, and also received a new warrant to acquire 350,770 shares of common stock at an exercise price of $3.25 per share in connection with its debenture exchange into A-1 Preferred. The Carpenter Trust retained its warrant originally issued in connection with the Carpenter Debenture, but it did not receive a new warrant in connection with the exchange of the Carpenter Debenture into A-1 Preferred.

Series A-1 Convertible Preferred Stock Preferences

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

Liquidation Rights

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

Dividends

Each holder of Series A-1 Convertible Preferred Stock 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.

In the event the Company pays a dividend on the Common Stock, the holders of the A-1 Preferred are entitled to a dividend equal to the dividend that would have been payable to such holder if the shares of Series A-1 Preferred Stock had been converted into Common Stock.

Conversion; Anti-Dilution Protection

The holder of any share or shares of Series A-1 Convertible Preferred Stock shall have the right, at the holder s option at any time, to convert any such shares of Series A-1 Convertible Preferred Stock 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 Stock 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 Stock 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 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 Stock or as payment-in-kind dividends on the Series A-1 Convertible Preferred Stock; (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 Stock 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 Stock are entitled to vote together with the holders of Common stock as a single class. Each share of Series A-1 Convertible Preferred Stock 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 Stock is convertible.

As long as at least 200,000 shares of Series A-1 Convertible Preferred Stock 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 Stock 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 Stock; (3) increase the number of authorized shares of Series A-1 Convertible Preferred Stock or authorize the issuance of or issue any shares of Series A-1 Convertible Preferred Stock (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 Stock or the Company s ability to honor the exercise of any rights of the holders of Series A-1 Convertible Preferred Stock; (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 Stock), or redeem, purchase or otherwise acquire for value, or set apart money or other property for any mandatory purchase or analogous fund for the redemption, purchase or acquisition of any shares of capital stock of the Company (except with respect to the repurchase of shares of Common stock held by employees, officers or directors of the

Company, which has been approved by the Company s Board of Directors); (7) consummate an acquisition or enter into an agreement with respect to an acquisition; (8) materially change the nature or scope of the business of the Company to a business other than the manufacturing or formulation of devices or drugs for aerosol delivery; (9) consummate or agree to make any sale, transfer, assignment, pledge, lease, license or similar transaction by which the Company grants on an exclusive basis any rights to any of the Company s intellectual property other than intellectual property relating to the Company s insulin program or the licensing of any of the Company s intellectual property to a ventilator manufacturer for incorporation into such manufacturer s ventilator technology; (10) create, incur, assume or suffer to exist, any lien, charge or other encumbrance on any of its properties or assets, other than liens of carriers, warehousemen, artisans, bailees, mechanics and materialmen incurred in the ordinary course of business securing sums not overdue; or (11) agree to do any of the foregoing.

Note 2 - RECENT ACCOUNTING PRONOUNCEMENTS

None.

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

In addition to historical information, this report contains predictions, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results could differ materially from any future performance suggested in this report as a result of many factors, including those referred to in Factors That May Affect Future Operating Results, at the end of this Item 2. The following discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes included elsewhere in this report and the information included in the Company s Annual Report on Form 10-K for the year ended December 31, 2003, filed with the Securities and Exchange Commission 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.

Restatement

On March 9, 2005, we issued a press release and filed a Current Report on Form 8-K announcing that an error had been identified relating to the classification of the warrants issued in connection with our Series A-1 Convertible Preferred Stock (the A-1 Preferred) financing (the A-1 Financing) (see NOTE 3). The Company has identified errors related to the initial valuation, classification, and subsequent accounting of the warrants issued in conjunction with the A-1 Financing, and we have determined that the prior accounting for this transaction should be revised. Accordingly, we have reclassified the warrant from equity and preferred stock, where they were originally recorded, to a liability at fair value. The liability is adjusted to its current fair value at the end of each reporting period. This fair value adjustment resulted in $361,000 and $1,421,000 increases in net loss for the three and six month periods ended June 30, 2004, respectively.

Originally, the proceeds from the A-1 Financings that closed on March 23, 2004 and May 12, 2004 were allocated on a pro rata basis using the estimated fair market value of the warrants and A-1 Preferred. Under our revised accounting, however, proceeds are first allocated to the warrant liability based on its fair market value, and then residual proceeds are allocated to the A-1 Preferred. This change in allocation has the result of substantially reducing the proceeds allocated to the A-1 Preferred. A beneficial conversion feature ("BCF") is recorded as a dividend to the preferred stockholders based on the difference between the proceeds allocated to the preferred stock and the transaction date fair market value of the common stock issuable upon conversion in an amount not to exceed the proceeds allocated to the preferred stock in the transaction. As a result of the change in proceeds allocated to the preferred, the deemed dividend increased by $748,000 for the three months ended June 30,

2004 and decreased by $724,000 for the six months ended June 30, 2004.

Consequently, the condensed consolidated financial statements for the second quarter of 2004 are restated in this Form 10-Q/A. These restated condensed consolidated financial statements reflect adjustments relating to the classification and valuation of the warrants.

For the three and six months ended June 30, 2004, net loss increased to $4.2 million from $3.8 million and to $9.6 million from $8.1 million, respectively, and net loss attributable to common stockholders increased to $9.8 million from $8.7 million and $21.7 million from $21.0 million, respectively, (basic and diluted loss per share increased to $2.05 from $1.81 and to $4.69 from $4.54, respectively), each as compared to the amounts previously reported on our Form 10-Q filed on August 16, 2004.

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 June 30, 2004, we had two nebulizer products on the market. We have an accumulated deficit of approximately $119.0 million as of June 30, 2004. In 2002, we generated significant revenues from our planned principal operations and thus exited the development stage. We will, however, continue to devote substantial efforts to the development of current and future products. We expect to incur significant additional operating losses over the next several years and expect cumulative losses to increase, primarily due to the costs associated with the manufacturing and marketing of our products, the expansion of our research and development activities and the general expansion of our business activities. We anticipate that our quarterly results will fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods. Our sources of working capital have primarily been equity financings, convertible debentures, product revenues, research and

development revenues, license fees, royalties, and interest earned on investments.

On March 23, 2004, we completed a first closing of a $32.7 million financing for gross proceeds of $15.0 million. The second and final closing for gross proceeds of $17.7 million was completed on May 12, 2004. As of June 30, 2004, we had $24.8 million in cash and cash equivalents.

Results of Operations

Revenues

Total revenues for the three months ended June 30, 2004 were $1.7 million, compared with $1.1 million for the same period of 2003. Total revenues for the six months ended June 30, 2004 were $2.8 million, compared with $2.7 million for the same period of 2003. Total revenues include revenues from product sales, research and development activities for unrelated third parties, royalties on gross sales of licensed products, and royalties associated with the licensing of our technology for use outside the medical field.

Product sales for the three months ended June 30, 2004 were $1.3 million, compared with $1.0 million for the same period of 2003. Product sales for the six months ended June 30, 2004 were $2.1 million compared with $2.3 million for the same period of 2003. The increase in product sales for the three month period year over year was due to the sales of our OnQ Aerosol Generators to Medical Industries America Inc. (MIA). The decrease in sales for the six months ended June 30, 2004 over the same period of 2003 was due to lower Aeroneb Pro sales partially offset by the sales of our OnQ Aerosol Generators to MIA.

There were no research and development revenues for the three months ended June 30, 2004 or 2003. Research and development revenues for the six months ended June 30, 2004 were none compared with $165,000 for the same period of 2003. Research and development revenues can be expected to vary from period to period based on the activities requested by partner companies in any particular period, and therefore are not predictable. Based on agreements we currently have in place, we expect research and development revenues for 2004 to be lower than those for 2003.

Royalty revenues were $444,000 and $125,000, for the three months ended June 30, 2004 and 2003, respectively. Royalty revenues for the six months ended June 30, 2004 were $694,000 compared with $250,000 for the same period of 2003. The increase over the three months and six months ended June 30, 3003 was due to up-front payments associated with the September 2003 commercial agreement with MIA, which resulted in the quarterly amortization of $125,000 relating to the $2.5 million upfront payment which is being amortized ratably over the five year term of the agreement. Additionally, royalties from the first commercial shipments were recognized in the three months ended June 30, 2004 on shipments of the Aeroneb® Go by MIA, which will pay royalties on its gross product and accessories sales. No royalty revenues from the Aeroneb® Go were recognized during the same periods of 2003. Other royalties represent a minimum royalty obligation associated with licensing our aerosol generator technology to a consumer product company for use in the fields of air fresheners and insect repellants.

Cost of Products Sold

Cost of products sold for the three months ended June 30, 2004 was $1.3 million, compared with $0.6 million for the same period in 2003. Cost of products sold for the six months ended June 30, 2004 was $2.0 million, compared with $1.4 million for the same period in 2003. Cost of products sold increased as a percent of product sales for the three months and six months ended June 30, 2004 as compared to the same periods in 2003, primarily due to the commencement of sales in January 2004 of a lower-margin product component under a contract supply agreement. Additionally, an increased amount of costs related to the manufacturing scale-up of this new component were recognized early in the quarter ended June 30, 2004.

Research and Development Expenses

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

Research and development expenses for the three months ended June 30, 2004 were $2.9 million, compared with $3.0 million for the same period of 2003. The decrease in research and development expenses of $0.1 million for the three months ended June 30, 2004, as compared with the same period of 2003, was primarily due to reduced payroll and related expenses of $0.6 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, partially offset by the increased $0.4 million of spending on pre-clinical expenses related to preparations for a Phase 2 human clinical trial for our amikacin product, and other program spending increases of $0.1 million.

Research and development expenses for the six months ended June 30, 2004 were $4.8 million compared with $6.2 million for the same six months ended 2003. The decrease in research and development expenses of $1.4 million for the three months ended June 30, 2004, as compared with the same period of 2003, was primarily due to reduced payroll and related expenses of $0.8 million associated with reductions in force in 2003, reduced facility related expenses of $0.6 million, as well as reductions in other programs of $0.4 million, partially offset by the increased $0.4 million of spending on pre-clinical expenses related to preparations for a Phase 2 human clinical trial for our amikacin product.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended June 30, 2004 were $1.3 million, compared with $1.5 million for the same period of 2003. The decrease of $0.2 million for the three months ended June 30, 2004 compared with the same period of 2003 was primarily due to reductions in selling and marketing expenses associated with our product of $0.1 million, lower spending of $0.1 million on legal fees, and reductions in stock based compensation of $0.1 million, partially offset by increased salaries of $0.1 million.

Selling, general and administrative expenses for the six months ended June 30, 2004 were $3.3 million, compared with $3.4 million for the same period of 2003. The decrease of $0.1 million for the six months ended June 30, 2004 compared with the same period of 2003 was primarily due to reductions in selling and marketing expenses associated with our product of $0.3 million, decreases in payroll and related expenses of $0.1 million associated with reductions in force in 2003, decreases in deferred stock based compensation of $0.1 million, partially offset by an increase in outside legal expenses of $0.2 million, and an increase in facility related expenses of $0.1 million.

Interest and Other Income (Expense), Net

Net interest income for the three months ended June 30, 2004 was $25,000 compared with $14,000 for the same period in 2003. Interest income was higher due to the higher balances in interest earning accounts in 2004 compared to the same period in 2003.

Net interest expense for the six months ending June 30, 2004 was $0.5 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 during the second half of 2003 and to the Carpenter Family Trust in the first quarter of 2004, all of which totaled $0.5 million in the first quarter of 2004.

Other income and expense for the three months ended June 30, 2004 consisted solely of an expense of $74,000, compared with income of $326,000, for the same period of 2003. Other income and expense for the six months ended June 30, 2004 consisted solely of an expense of $293,000, compared with income of $366,000, for the same period of 2003. The change in other income and expense for both the three and six month periods are solely due to change in the currency exchange rate between the Eurodollar and the United States dollar, and the resulting impact on intercompany balances.

Increase in Warrant Liability (restated)

The first closing of the A-1 Financing on March 23, 2004 included the issuance of warrants to purchase 4,999,810 shares of common stock, and the second closing on May 12, 2004 included the issuance of warrants to purchase 6,249,580 shares of common stock. The aggregate fair value of the warrants of $16.1 million is recorded as a liability with subsequent changes to the fair value of the warrants recorded as a non-operating item through the statement of operations. For the three months ended June 30, 2004, the fair value of the warrants increased, resulting in non-operating losses of $361,000 and $1,421,000, respectively, for the three and six month periods ended June 30, 2004.

Dividend Related to Beneficial Conversion Feature of Preferred Stock (restated)

A beneficial conversion feature ("BCF") is recorded as a dividend to the preferred stockholders based on the difference between the proceeds allocated to the preferred stock and the transaction date fair market value of the common stock issuable upon conversion, in an amount not to exceed the proceeds allocated to the preferred stock in the transaction. The first closing of the Series A-1 Convertible Preferred Stock offering on March 23, 2004, resulted in a beneficial conversion feature of $6,440,000 which was treated as a deemed dividend in the three months ended March 31, 2004. The second closing of the A-1 Financing on May 12, 2004, resulted in a beneficial conversion feature of $5,249,000 which was also treated as a deemed dividend. For the six months ending June 30, 2004 the total beneficial conversion feature was $11,689,000 and was treated as deemed dividends.

In addition to the deemed dividends, during the six months ending June 30, 2004 stock dividends to holders of the A-1 Preferred were declared with a market value of $399,000. The combined value of the deemed dividends and the stock dividends

appears on the Statement of Operations as dividends of $12,088,000 related to convertible preferred stock.

Liquidity and Capital Resources (restated)

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

As of June 30, 2004, we had cash and cash equivalents of approximately $24.8 million. Net cash used in operating activities during the six months ended June 30, 2004 was $7.3 million, resulting primarily from the net loss for the period of $9.6 million. We had additional uses of cash resulting from increases in accounts receivable of $0.4 million due to sales appearing late in the quarter and remaining uncollected at quarter end, increases of $0.2 million in inventory balances of OnQ Aerosol Generators, and payments totaling $1.5 million made to the landlord for changes in the lease, comprising past due rent, security deposit and rent reduction fees, during the quarter ended June 30, 2004. These uses were partially offset by $0.2 million in deferred revenue, $0.9 million in prepaid expense, and non-cash related charges related to the increase of warrant liability of $1.4 million, depreciation of $0.6 million, amortization of note discounts of $0.5 million, amortization of deferred stock compensation of $0.2 million, and disposal of property of $0.8 million due to the consolidation into the first floor of our Mountain View facility and the subsequent write-off of the leasehold improvements that had been made to the second floor.

Net cash used in operating activities during the six months ended June 30, 2003 was $6.5 million, resulting primarily from the net loss for the period of $7.9 million. Additional uses were seen in increases in accounts receivable of $0.3 million, increases in inventories of $0.1 million, and net decreased accounts payable and accrued liabilities of $0.4 million. These uses were partially offset by non-cash related charges of approximately $0.6 million in depreciation and amortization, and $0.5 million in amortization of deferred stock-based compensation.

For the six months ended June 30, 2004, net cash used in investing activities was $0.1 million, consisting primarily of property and equipment acquisitions associated with process improvements. For the three months ended June, 2003, net cash provided by investing activities was $5.4 million consisting primarily of proceeds from maturing available-for-sale securities of $5.6 million, partially offset by $0.2 million of property and equipment acquisitions associated with process improvements.

Net cash provided by financing activities was $31.4 million for the six months ended June 30, 2004, consisting of $30.9 million in net proceeds from issuance of A-1 Preferred and associated common stock warrants, and $0.8 million in net proceeds from the issuance of debentures and convertible debentures, partially offset by the repayment of a $0.3 million debenture. Net cash provided by financing activities for the six months ending June 30, 2003 was $0.1 million, consisting of repayment of a note receivable from a stockholder, and the issuance of common stock through the employee stock purchase program.

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 second and final closing for gross proceeds of $17.7 million was approved by stockholders at our annual meeting held on May 10, 2004 and was completed on May 12, 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.

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 stockholders.

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

Twelve investors in our Series A-1 Preferred Convertible Stock own equity securities that, if such securities were all converted into common stock, would represent ownership of approximately 86% of the outstanding common shares of the Company. While each of these investors is contractually prohibited from owning more than 4.99% of the Company s common stock at any one time, any investor can waive this limitation as to the shares it holds upon 61 days written notice to the Company. Additionally as few as eleven of these investors, or investors to whom the A-1 securities are resold, could acquire in excess of 50% of the voting securities of the Company without exceeding this limitation. 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.

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

If the Series A-1 Convertible Preferred stockholders were to exercise all of the common stock warrants they hold and convert all of the shares of Series A-1 Convertible Preferred stock they own as of July 23, 2004, they would own approximately 22,670,330 shares of our common stock, in addition to any other shares such stockholders may own now or in the future. If the Series A-1 Convertible Preferred stockholders exercise the warrants or convert our preferred stock into shares of common stock and sell the shares into the market, such sales could have a negative effect on the market price of our common stock and will dilute the holdings of our existing common stockholders. The Company may choose to pay the cumulative quarterly dividend on the Series A-1 Convertible Preferred Stock in shares of Common Stock instead of cash, in which case more dilution will result. Dilution or the potential for dilution also could materially impair our ability to raise capital through the future sale of equity securities. As a result of the issuance of the Series A-1 Convertible Preferred Stock and warrants, the Company recorded a charge in the first and

second quarters of 2004 related to the beneficial conversion feature of the preferred stock in the amount of $7.9 million and $4.5 million respectively. If the Company were to issue additional equity securities in a future financing transaction at a per share price lower than the current conversion price of the Series A-1 Convertible Preferred Stock, then the conversion price of the Series A-1 Convertible Preferred Stock would automatically adjust downward to be equal to the common stock equivalent price of the newly-issued securities, and an additional deemed dividend charge would be recorded. Any such charge would reduce stockholder s equity and the amount of net income available to common stockholders. While the Company currently has no plans to issue securities in a manner that would trigger these anti-dilution provisions, it may elect to do so in the future. The full details of these anti-dilution provisions are contained in the Series A-1 Convertible Preferred Stock Certificate of Designation, which was filed on the Company s Form 8-K on March 23, 2004 and is incorporated by reference herein.

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

We have never been profitable. Through June 30, 2004, we have incurred an accumulated deficit of approximately $119.0 million. We expect to continue to incur substantial losses over at least the next several years as we:

expand our research and development efforts;

expand our preclinical and clinical testing activities;

expand our manufacturing efforts, including our commercial production capability; and

build our sales and marketing capabilities and launch our products currently being developed.

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

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

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

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

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

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

allocation of our resources, particularly when they are limited;

the costs and expenses relating to any litigation;

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

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

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

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

Our stock price may continue to be volatile.

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

market conditions relating to the life sciences industry;

investor perception of us as a company;

securities analysts recommendations;

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

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

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

developments or disputes concerning patent or intellectual property rights;

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

public concern as to the safety of drugs and drug delivery technologies, including those of our competitors;

period-to-period fluctuations in financial results; and

economic and other external factors.

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

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

Many of our products are in the research or development stages. Before we can begin to commercialize our new products, we will need to invest in substantial additional activities, generally including the conduct of clinical trials. To further develop our products, we will need to obtain additional funds and address engineering and design issues, including ensuring that our products deliver a consistent and reproducible amount of drug to the lung and that they can be manufactured successfully. We cannot assure that:

our research and development efforts will be successful;

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

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

We have built our own manufacturing capabilities to produce key components of our products. We have manufactured only limited quantities of our first 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.

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

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

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

Our products are subject to extensive regulation by the FDA, state and local government agencies, and by international regulatory authorities. These agencies regulate the development, testing, manufacture, labeling, storage, approval, advertising, promotion, sale and distribution of medical devices, drugs and biologics. If we, or our partners, fail to obtain regulatory clearances or approval to develop or to market our products, our business will be harmed and we, or our collaborative partners, will not be able to market and sell our products. Even if granted, regulatory approvals may include significant limitations on the uses for which products may be tested or marketed. Once obtained, required approvals may be withdrawn, or we may not remain in compliance with regulatory requirements. The process for obtaining necessary regulatory approvals for drugs and biologics is generally lengthy, expensive and uncertain. Obtaining and maintaining foreign regulatory approvals in multiple countries is expensive, and we cannot be certain that we will receive approvals in any foreign country in which we or our partners plan to market our products. If we or our

partners fail to obtain regulatory approval in the United States or in any foreign country in which we plan to market our products, our revenues will be lower. A longer than expected regulatory process, additional or significant changes in regulatory requirements, or more expensive clinical studies than we anticipate, may cause us to stop development of particular products.

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

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

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

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

- safety;
- efficacy;
- the benefits associated with pulmonary delivery;
- ease of use; and
- price.

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

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

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

As of May 2004, the Galway, Ireland, and Mountain View, California, facilities 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 Bespak s 5,261,601 patent, we entered into a cross-license agreement with Bespak, as a result of which Bespak has a license to certain of our technology, including the right to sublicense. The scope of the granted license was limited to products employing technology which was disclosed by Bespak in United States Patent No. 5,261,601. Additionally, in April 2003, we received notice that a German patent infringement suit had been filed by PARI GmbH in the regional court in Munich, Germany alleging that Aerogen s Aeroneb Pro product infringes a patent licensed to PARI GmbH. While the suit has not yet been formally initiated by the German regional court, we believe that it is without merit and intend to vigorously defend against all allegations in the suit. In May 2003, we filed an action in the German patent office requesting that the patent in question be rendered null and void. In July 2004, the Federal Patent Court in Munich, Germany ruled in favor of Aerogen by nullifying all contested claims of this patent, which is owned by The Technology Partnership plc (TTP) of Hertfordshire, England, and is licensed to PARI, GmbH of Munich, Germany. The Court ordered TTP to pay Aerogen s legal expenses related to this nullity action to the maximum extent allowed under German law. As TTP has the right to appeal this decision, there can be no guarantee that an appeals court will not reverse the nullity ruling and again provide PARI with the legal standing to reassert their infringement suit.

Our patent position involves complex legal and factual questions and is generally uncertain. Legal standards relating to the validity and scope of patent claims in the biotechnology and pharmaceutical field are evolving. Defending and prosecuting intellectual property suits, USPTO interference proceedings and related legal and administrative proceedings are costly and time-consuming. Further litigation may be necessary to enforce our patents, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings will be costly and will result in significant diversion of effort by technical and management personnel. An adverse determination in any of the litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties, require us to license disputed rights from third parties or require us to cease using such technology, which would have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, which could include ongoing royalties. We cannot assure that we can obtain the necessary licenses on satisfactory terms, if at all.

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

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

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

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

Exchange rate risk

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

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

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

Item 4. Controls and Procedures (restated)

We have restated our financial results for the quarter ended June 30, 2004 to reflect adjustments to our previously reported financial information. The restatement arose due to an error related to the initial valuation, classification, and subsequent account of the warrants issued in connection with the issuances of our Series A-1 Convertible Preferred Stock on March 23, 2004 and May 12, 2004.

In connection with the restatement of our financial results for the three and six months ended June 30, 2004, we have identified material weaknesses in our internal controls and procedures. As of the end of the period covered by this report, we carried out an evaluation, under the supervision and participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. We have determined that the disclosure controls and procedures were not effective because they failed to identify the errors which led to the restatement. In response, in March 2005, we implemented a policy that requires for any future issuance of complex equity and derivative instruments or complex transactions, an outside expert with experience concerning the related accounting issues will be consulted, or additional internal staff will be trained or hired. In addition, enhanced review and documentation procedures have been implemented in our accounting process in order to ensure accuracy of all accounting entries. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. 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 during the quarter ended June 30, 2004, 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

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

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 and bearing interest at a rate of 10% per annum with a conversion price of $3.044. The Carpenter Trust also purchased a warrant, exercisable on or after July 26, 2004, for up to approximately 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 2004 Financing) with Xmark Fund, L.P. and Xmark Fund, Ltd. (Xmark) and other accredited investors. The 2004 Financing entailed the sale and issuance, in two closings, of an aggregate 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, we completed the first closing of the A-1 Financing, resulting in the sale and issuance of 499,981 shares of A-1 Preferred and warrants to purchase 4,999,810 shares of the Company s common stock, in exchange for gross proceeds of $14,999,430. On May 12, 2004, Aerogen completed the second and final closing of the A-1 Financing, and issued an additional 642,113 shares of A-1 Preferred and warrants to purchase 6,249,580 shares of common stock for gross proceeds of $17.7 million. Under the terms of the A-1 Financing, the Company terminated the Rights Agreement between it and Mellon Investor Services LLC on March 19, 2004.

As part of the A-1 Financing, SF Capital and the Carpenter Trust exchanged the outstanding secured convertible debentures previously issued to them for an aggregate of 52,232 shares of A-1 Preferred. The exchange occurred on May 12, 2004. Upon exchange, SF Capital also received a warrant to acquire 350,770 shares of common stock at an exercise price of $3.25 in connection with its debt exchange. The Carpenter Trust did not receive a new warrant in connection with the exchange of its debenture.

The issuances of the A-1 Preferred, 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.

Item 3. Defaults Upon Senior Securities.

None.

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

Our 2004 Annual Meeting of Stockholders was held on May 10, 2004 at 2:00 pm local time at our headquarters at 2071 Stierlin Court, Suite 100, Mountain View, California. A summary of the votes cast at our 2004 Annual Meeting of Stockholders appears below. As of April 15, 2004, the record date for the Annual meeting, there were 4,783,695 shares of Common Stock and 499,981 shares of A-1 Preferred issued and outstanding. 3,559,254 (74.40%) shares of Common Stock and 490,579 (98.12%) shares of A-1 Preferred entitled to vote were represented either in person or by proxy at the Annual Meeting. The matters voted on at the meeting and the votes cast are as follows:

The proposal to approve the issuance of A-1 Preferred and warrants to purchase Common Stock pursuant to a Preferred Stock financing received the following votes:

	Votes	Percentage of Shares Voted on this Issue:
For:	1,253,626	98.70%
Against:	16,308	1.28%
Abstain:	220	0.02%
Broker non-votes:	2,289,100	

The foregoing proposal was approved.

The following nominees for election as Directors, to hold office for a term as defined in the proxy statement, and until their successor is duly elected and qualified, received the following number of votes set opposite their name:

Nominee	For	Percent of Voted	Withheld	Percent of Voted
Phyllis I. Gardner, M.D.	8,456,051	99.89%	8,993	0.11%
Philip M. Young	8,459,651	99.94%	5,393	0.06%

The aforesaid nominees were elected as Director for the term set forth above.

The proposal to amend the Company s 2000 Equity Incentive Plan to increase the number of shares of Common Stock authorized for issuance thereunder received the following votes:

	Votes	Percentage of Shares Voted For & Against
For:	5,753,867	93.17%
Against:	421,677	6.83%
Abstain:	400	0.01%
Broker non-votes:	2,289,100	

The foregoing proposal was approved.

The proposal to amend the Company s 2000 Employee Stock Purchase Plan to increase the number of shares of Common Stock

authorized for issuance thereunder received the following votes:

	Votes	Percentage of Shares Voted For & Against
For:	5,770,149	93.43%
Against:	405,395	6.56%
Abstain:	400	0.01%
Broker non-votes:	2,289,100	

The foregoing proposal was approved.

The proposal to ratify the selection of PricewaterhouseCoopers LLP as independent auditors of the company for its fiscal year ending December 31, 2004 received the following votes:

	Votes	Percentage of Shares Voted For & Against
For:	8,454,535	99.88%
Against:	3,350	0.04%
Abstain:	7,159	0.08%
Broker non-votes:	0	

The foregoing proposal was approved.

Item 5. **Other Information.**

None.

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

(a) Exhibits.

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

(b) Reports on Form 8-K.

On May 5, 2004, we filed a current report on Form 8-K relating to our press release announcing our financial results for the quarter ended March 31, 2004. On May 19, 2004, we filed a current report on Form 8-K relating to the shareholder meeting and the approval for the second closing of the $32.7 million Series A-1 Convertible Preferred Stock financing. On August 3, 2004, we filed a current report on Form 8-K relating to our press release announcing our financial results for the quarter ended June 30, 2004.

Signatures

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

Aerogen, Inc.
(Registrant)

Dated: April 15, 2005 By: /s/ JANE E. SHAW
Jane E. Shaw, Ph.D.
Chairman and Chief Executive Officer

Dated: April 15, 2005 By: /s/ ROBERT S. BREUIL
Robert S. Breuil
Chief Financial Officer

Exhibit List

No.	Note	Description of Exhibit Document
10.12.1	(1)	Lease amendment, dated November 6, 2003, between CA-Shoreline Technology Park, LP and Aerogen.
10.12.2	(1)	Lease amendment, dated March 9, 2004, between CA-Shoreline Technology Park, LP and Aerogen.
10.17	(2)*	Distribution and supply agreement, dated as of September 30, 2003, between the Company and Medical Industries America Inc.
10.18	(3)	First Amendment to Distribution, Manufacturing and Supply Agreement, dated as of January 30, 2004, by and between the Company and Medical Industries America Inc.
31.1		Certification required by Rules 13a-15(3) and 15d-15(e)
31.2		Certification required by Rules 13a-15(3) and 15d-15(e)

32.1	Certification required by Section 13a or Section 15(3) 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).

(1) Incorporated by reference to our Form 10-K/A for the year ended December 31, 2003, filed on May 10, 2004.

(2) Incorporated by reference to our Form 10-Q/A for the quarter ended September 30, 2003 filed on August 9, 2003.

(3) Incorporated by reference to our Form 10-Q/A for the quarter ended March 31, 2004, filed on August 9, 2004.

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