AEROGEN INC
Form 10-Q
May 13, 2005

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 2005**

**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**<br>(State or other jurisdiction of incorporation or organization) | **33-0488580**<br>(I.R.S. Employer Identification No.) |
| **2071 Stierlin Court, Suite 100, Mountain View, CA**<br>(Address of principal executive offices) | **94043**<br>(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 May 9, 2005, there were 7,367,441 shares of the Registrant s Common Stock, par value $0.001, outstanding.

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Aerogen, Inc.

Form 10-Q

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**Part I.** **Financial Information**

**Item 1.** **Condensed Consolidated Financial Statements**

**Aerogen, Inc.**

**Condensed Consolidated Balance Sheets**

(unaudited; in thousands, except per share data)

| | March 31, 2005 | December 31, 2004 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 13,571 | $ 16,883 |
| Accounts receivable | 734 | 1,225 |
| Inventories, net | 803 | 775 |
| Prepaid expenses and other current assets | 756 | 942 |
| Total current assets | 15,864 | 19,825 |
| | | |
| Property and equipment, net | 2,977 | 2,964 |
| Goodwill | 1,827 | 1,951 |
| Intangible assets | 159 | 147 |
| Other assets | 539 | 868 |
| Total assets | $ 21,366 | $ 25,755 |
| | | |
| **LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,077 | $ 1,043 |
| Deferred revenue, current | 375 | 500 |
| Dividend payable | 429 | 1,094 |
| Accrued liabilities | 1,773 | 1,873 |
| Total current liabilities | 3,654 | 4,510 |
| | | |
| Deferred rent | 264 | 234 |
| Deferred revenue, non-current | 1,901 | 1,848 |
| Warrant liability | 6,333 | 10,296 |
| Other long-term liabilities | 253 | 267 |
| Total liabilities | 12,405 | 17,155 |
| | | |
| Redeemable convertible preferred stock | | |
| Redeemable convertible preferred stock, par value $0.001: | | |
| Authorized: 5,000 shares; issued and outstanding: | | |
| 952 and 1,194 shares at March 31, 2005 and December 31, 2004, respectively | 13,722 | 15,749 |
| | | |
| Stockholders deficit: | | |
| Common stock, par value $0.001: | | |
| Authorized: 95,000 shares; issued and outstanding: | | |
| 7,299 and 5,318 shares at March 31, 2005 and December 31, 2004, respectively | 7 | 6 |

| | | | | |
|---|---|---|---|---|
| Additional paid-in capital | | 114,388 | | 111,691 |
| Notes receivable from stockholders | | (279) | | (292) |
| Accumulated other comprehensive income | | 1,001 | | 991 |
| Accumulated deficit | | (119,878) | | (119,545) |
| Total stockholders deficit | | (4,761) | | (7,149) |
| Total liabilities, redeemable convertible preferred stock and stockholders deficit | $ | 21,366 | $ | 25,755 |

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 March 31, | |
|---|---|---|
| | **2005** | **2004** |
| Revenues: | | |
| Product sales | $ 1,074 | $ 849 |
| Research and development | 32 | |
| Royalty and other | 531 | 250 |
| Total revenues | 1,637 | 1,099 |
| Costs and expenses: | | |
| Cost of products sold | 977 | 737 |
| Research and development | 3,107 | 1,933 |
| Selling, general and administrative | 1,726 | 2,005 |
| Total costs and expenses | 5,810 | 4,675 |
| Loss from operations | (4,173) | (3,576) |
| Interest income (expense), net | 86 | (560) |
| Decrease (increase) in warrant liability | 3,963 | (1,060) |
| Other expense, net | (208) | (219) |
| Net loss | (332) | (5,415) |
| Dividends related to convertible preferred stock | (429) | (6,460) |
| Net loss attributable to common stockholders | $ (761) | $ (11,875) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.13) | $ (2.66) |
| Weighted - average shares used in computing net loss per share attributable to common stockholders, basic and diluted | 5,872 | 4,456 |

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

**Aerogen, Inc.**

**Condensed Consolidated Statements of Cash Flows**

(unaudited; in thousands, except per share data)

| | Three Months Ended March 31 | |
|---|---|---|
| | **2005** | **2004** |
| **Cash flows from operating activities:** | | |
| Net income loss | $ (332) | $ (5,415) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Increase (decrease) in warrant liability | (3,963) | 1,060 |
| Depreciation and amortization | 304 | 291 |
| Changes in inventory reserves | 81 | |
| Accrued interest on notes receivable from stockholders | (4) | (3) |
| Amortization of deferred stock-based compensation | 6 | 117 |
| Amortization of discount on convertible notes | | 522 |
| Unrealized foreign exchange loss | 201 | |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 442 | 72 |
| Inventories | (142) | 19 |
| Prepaid expenses and other current assets | 159 | 128 |
| Accounts payable | 60 | (443) |
| Accrued liabilities | (85) | 1,921 |
| Deferred rent | 30 | (1,513) |
| Deferred revenue | (72) | 53 |
| Other | 26 | (102) |
| Net cash used in operating activities | (3,289) | (3,293) |
| | | |
| **Cash flows from investing activities:** | | |
| Acquisition of property and equipment | (45) | (59) |
| Net cash provided by (used in) investing activities | (45) | (59) |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of preferred stock and warrants, net | | 14,644 |
| Proceeds from issuance of convertible debenture | | 505 |
| Proceeds from issuance of debenture | | 300 |
| Repayment of shareholder notes | 18 | |
| Repayment of debenture | | (300) |
| Net cash provided by financing activities | 18 | 15,149 |
| | | |
| Effect of exchange rate changes on cash | 4 | 76 |
| | | |
| Net increase (decrease) in cash and cash equivalents | (3,312) | 11,873 |
| | | |
| Cash and cash equivalents at beginning of period | 16,883 | 762 |
| | | |
| Cash and cash equivalents at end of period | $ 13,571 | $ 12,635 |
| | | |
| **Supplemental disclosure of noncash investing and financing activities:** | | |
| Preferred stock converted to common stock | $ 2,027 | $ |

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

**Aerogen, Inc.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

**NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Organization and Business of the Company**

Aerogen, Inc. ( Aerogen, the Company or we ) was incorporated in November 1991. We are a specialty pharmaceutical company developing novel drug/device combination aerosol products for treatment of respiratory disorders in the critical care setting. Based on our proprietary OnQ® Aerosol Generator ( OnQ ), we are developing respiratory products for marketing by us, and products in collaboration with, and 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 its ability to obtain adequate funding and eventually establish profitable operations. As of March 31, 2005, Aerogen had cash and cash equivalents of approximately $13.6 million. Based on its current expectations of sales and royalty levels and operating costs, existing capital resources will not enable the Company to maintain current and planned operations beyond the first quarter of 2006; however, if it does not achieve expected product sales and royalties, Aerogen s cash balance may not sustain planned operations beyond the middle of the fourth quarter of 2005. Aerogen is pursuing a number of alternatives to maximize stockholder value, including strategic transactions, collaborative partnerships and the licensing or sale of certain intellectual property. If these efforts are not successful, the Company will need to raise additional capital before the end of 2005 to continue normal operations. Licensing or collaborative arrangements, if necessary to raise additional funds, may require the Company to relinquish rights to either certain of their products or technologies or desirable marketing territories, or all of these.

The Company has incurred net losses since inception and is expected to incur substantial losses for the next several years. The auditor s report on the Company s consolidated financial statements as of December 31, 2004 included in the Form 10-K/A, filed on April 19, 2005, contains an explanatory paragraph, which refers to the recurring operating losses and negative cash flows from operations and notes that these matters raise substantial doubt about the Company s ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis which contemplates continuity of operations, realization of assets and liquidation of liabilities in the ordinary course of business and do not reflect adjustments that might result if it was not to continue as a going concern.

**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 statement 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/A for the year ended December 31, 2004, filed with the Securities and Exchange Commission on April 19, 2005.

The results of operations for the three months ended March 31, 2005 are not necessarily indicative of the operating results that may be reported for the fiscal year ending December 31, 2005, or for any other future period.

**Inventories**

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

| | March 31, 2005 | December 31, 2004 |
|---|---|---|
| Raw materials | $ 393 | $ 499 |
| Work-in-process | 388 | 228 |
| Finished goods | 22 | 48 |
| Net inventories | $ 803 | $ 775 |

**Accrued Liabilities**

Accrued liabilities are summarized as follows:

| | March 31, 2005 | December 31, 2004 |
|---|---|---|
| Compensation and benefits | $ 580 | $ 580 |
| Warranty accrual | 251 | 251 |
| Other accrued liabilities | 942 | 1,042 |
| | $ 1,773 | $ 1,873 |

**Warranty**

The Company offers a warranty of certain products and records a liability for the estimated future costs associated with warranty claims, which is based on historical experience and the Company s estimated level of future costs. Warranty costs are reflected in the statement of operations as a cost of products sold. A reconciliation of the changes in the Company s warranty liability for the three months ending March 31, 2005 is as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Warranty accrual at the beginning of the period | $ 251 | $ 138 |
| Accruals for warranties issued during the period | 52 | 30 |
| Settlements made in kind during the period | (52) | (36) |
| Ending warranty accrual | $ 251 | $ 132 |

**Other Comprehensive Loss**

Other comprehensive loss 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 loss that are excluded from the Company s net loss. Total comprehensive loss during the three months ended March 31, 2005 and 2004 consisted of:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Net loss | $ (332) | $ (5,415) |
| Foreign currency translation adjustments | 10 | 117 |
| Comprehensive loss | $ (322) | $ (5,298) |

**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 issued and issuable 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 is as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Net loss | $ (332) | $ (5,415) |
| Deemed dividend on preferred stock | | (6,440) |
| Accrued dividend on preferred stock | (429) | (20) |
| Net loss attributable to common stockholders | $ (761) | $ (11,875) |
| Weighted-average shares used in computing basic and diulted net loss per common share attributable to common stockholders | 5,872 | 4,456 |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.13) | $ (2.66) |

The following outstanding options, warrants, convertible debentures, convertible preferred stock (on an as-converted basis), and shares issuable through the Company s Employee Stock Purchase Plan (ESPP) were excluded from the computation of diluted net loss per share as they all had an anti-dilutive effect:

| | March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Options to purchase common stock | 4,168 | 453 |
| Shares issuable through ESPP | 63 | |
| Warrants | 11,767 | 5,522 |
| Convertible debentures | | 493 |
| Convertible preferred stock | 9,520 | 5,000 |

**Accounting for Stock-based Compensation**

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| Net loss - as reported | $ (332) | $ (5,415) |
| Add: employee stock based compensation included in reported net loss | | 116 |
| Deduct: total employee stock based compensation determined under fair value based method for all awards | (614) | (175) |
| Net loss - pro forma | $ (946) | $ (5,474) |
| Net loss per share attributable to common stockholders, as reported | $ (0.13) | $ (2.66) |
| Net loss per share attributable to common stockholders, pro forma | $ (0.23) | $ (2.68) |

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 for Aerogen s corporate headquarters located in Mountain View, CA. Under the terms of the amended lease, Aerogen now occupies roughly 32,000 square feet, which is about one half of the building area that the Company had previously occupied. The terms of the lease required Aerogen to make additional payments during 2004 totaling $1,625,000 comprising $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 then-outstanding standby letter of credit. The Company was also required to fund $140,000 in building access improvements. 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 maintenance commitments for the reduced term of the lease are:

| | | |
|---|---|---|
| 2005 | $ | 742 |
| 2006 | | 1,028 |
| 2007 | | 1,102 |
| 2008 | | 1,152 |
| 2009 | | 193 |
| Total minimum payments | $ | 4,217 |

**NOTE 2 FINANCING EVENTS**

In January 2004, the Company entered into a loan and securities purchase agreement pursuant to which a convertible debenture (the Carpenter Debenture ) and a warrant (the Carpenter Warrant ) were issued to the Carpenter 1983 Family Trust UA ( the Carpenter Trust ), the trustees of which are Aerogen s Chairman and Chief Executive Officer, Dr. Jane Shaw and her husband Peter Carpenter. The Company received approximately $505,000 in gross proceeds in exchange for the Carpenter Debenture and the Carpenter Warrant. The Carpenter Debenture, as amended, was convertible into 164,258 shares of common stock at a conversion price of $3.044 per share, but is no longer outstanding. The Carpenter Warrant is exercisable for 82,129 shares of common stock at an exercise price of $3.044 per share. The difference between the conversion price and the fair market value of the common stock on the commitment date (transaction date) resulted in a beneficial conversion feature recorded on the Carpenter 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 on the transaction date. The discount on the Carpenter Debenture for the beneficial conversion feature and the allocation discount on the 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. Total interest expense recognized relating to the beneficial conversion feature of the Carpenter Debenture and the Carpenter Warrant allocation discount was $417,991 for the three month period ended March 31, 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 were 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 were initially convertible into an aggregate of 11,420,940 shares of common stock of the Company, as well as the issuance of warrants to purchase 11,249,390 shares of common stock at an exercise price of $3.25 per share. Under the terms of the A-1 Financing, the Company terminated its Rights Agreement with Mellon Investor Services, LLC on March 19, 2004.

In the first closing, the Company issued 499,981 shares of 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 approximately $14,999,000. The aggregate fair value of the warrants on the date of issuance was approximately $8,200,000 and was recorded as a liability, with the remaining net proceeds of approximately $6,440,000 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 approximately $6,440,000, which was treated as a deemed dividend.

On May 12, 2004, the Company completed a 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 approximately $17,696,000. The aggregate fair value of the warrants on the date of issuance was $7,937,000 and was recorded as a liability, with the remaining net proceeds of $9,397,000 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 $5,249,000, which was treated as a deemed dividend.

The fair value of the warrants and 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 months ended March 31, 2004 and decreased during the three months ended March 31, 2005, which resulted in the Company recording a loss of $1.1 million and gain of $4.0 million**,** respectively. The fair value of the warrant is determined at each reporting period using a valuation model that takes into consideration a variety of assumptions, including stock price, stock volatility and 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 in May 2004. Under the terms of the A-1 Financing SF Capital retained both of its warrants originally issued in connection with its 2003 debentures, and also received a new warrant to purchase 350,770 shares of common stock at an exercise price of $3.25 per share in connection with its debenture exchange into A-1 Preferred. The Carpenter Trust retained its warrant originally issued in connection with the Carpenter Debenture, but did not receive a new warrant in connection with the exchange of the Carpenter Debenture into A-1 Preferred.

**Series A-1 Preferred Stock Preferences**

**Liquidation Rights**

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

**Dividends**

Each holder of A-1 Preferred is entitled to receive cumulative dividends in preference to any dividend on the common stock at the rate of 6% of the Series A-1 Stated Value per share, paid quarterly in arrears on the first day of January, April, July and October in each year (the Preferred Dividends ). The Preferred Dividends will be paid, at the Company s election, out of legally available funds or through the issuance of shares of common stock. For the three months ended March 31, 2005, cumulative dividends of $429,000 have been accrued on the A-1 Preferred, and are in the process of being paid through the issuance of an aggregate of 319,805 shares of the Company s 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 A-1 Preferred shall have the right, at the holder s option at any time, to convert any such shares of A-1 Preferred into such number of fully paid and nonassessable shares of common stock as is obtained by: (i) multiplying the number of shares of A-1 Preferred to be converted by the A-1 Stated Value and adding to such product the amount of any accrued but unpaid dividends with respect to such shares of A-1 Preferred to be converted; and (ii) dividing the result obtained pursuant to clause (i) above by the Series A-1 Conversion Price then in effect. 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 Company in existence on March 23, 2004, so long as the issuance of such stock or options is approved by a majority of the independent members of the Board or a majority of the members of a committee of independent directors established for such purpose; (iii) issuances of securities as consideration for a merger or consolidation with, or purchase of assets from, a non-affiliated third party or in connection with any strategic partnership or joint venture with a non-affiliated third party with which the Company will enter into technology agreements (the primary purpose of any such action is not to raise equity capital); (iv) shares of common stock issuable upon conversion of A-1 Preferred or as payment-in-kind dividends on the A-1 Preferred; (v) shares of common stock issued or issuable as a result of any stock split, combination, dividend, distribution, reclassification, exchange or substitution for which an equitable adjustment is provided for; and (vi) shares of common stock issued (or issuable upon exercise, exchange or conversion of rights, options or warrants outstanding from time to time) which the Requisite Holders expressly elect in writing to treat as an Excluded Issuance.

The conversion of A-1 Preferred into common stock is limited so that no share may be converted that would cause the holder of such share (or such stockholder s affiliates) to beneficially own more than 4.99% of the Company s then-outstanding common stock, provided that such stockholder may waive the provision upon 61 days written notice to the Company. On November 3, 2004, the Xmark Funds delivered to Aerogen a written waiver of this limitation, thereby permitting the conversion of any or all of their A-1 Preferred into common stock at any time on or after January 3, 2005.

During the three months ended March 31, 2005, 146,700 shares of A-1 Preferred were converted into 1,467,000 shares of common stock.

**Voting Rights**

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

As long as at least 200,000 shares of A-1 Preferred are outstanding, the consent of the Requisite Holders shall be required to take or agree to any of the following actions: (1) amend, alter or repeal any of the provisions of the Company s Amended and Restated Certificate of Incorporation, Bylaws or the Certificate of Designations, or in any way change the preferences, privileges, rights or powers with respect to the A-1 Preferred or reclassify any class of stock, including, without limitation, by way of merger or consolidation; (2) authorize, create, designate, issue or sell any (A) class or series of capital stock (including shares of treasury stock), (B) rights, options, warrants or other securities convertible into or exercisable or exchangeable for capital stock or (C) any debt security which by its terms is convertible into or exchangeable for any capital stock or has any other equity feature or any security that is a combination of debt and equity, which capital stock, in each case, is senior to or pari passu with the A-1 Preferred; (3) increase the number of authorized shares of A-1 Preferred or authorize the issuance of or issue any shares of A-1 Preferred (other than in connection with the payment of Preferred Dividends); (4) increase or decrease the number of authorized shares of any class of capital stock of the Company; (5) agree to any restriction on the Company s ability to satisfy its obligations hereunder to holders of A-1 Preferred or the Company s ability to honor the exercise of any rights of the holders of A-1 Preferred; (6) declare or pay any dividend or make any distribution on shares of capital stock of the Company (except with respect to shares of A-1 Preferred), or redeem, purchase or otherwise acquire for value, or set apart money or other property for any mandatory purchase or analogous fund for the redemption, purchase or acquisition of any shares of capital stock of the Company (except with respect to the repurchase of shares of common stock held by employees, officers or directors of the Company, which has been approved by the Company s Board of Directors); (7) consummate an acquisition or enter into an agreement with respect to an acquisition; (8) materially change the nature or scope of the business of the Company to a business other than the manufacturing or formulation of devices or drugs for aerosol delivery; (9) consummate or agree to make any sale, transfer, assignment, pledge, lease, license or similar transaction by which the Company grants on an exclusive basis any rights to any of the Company s intellectual property other than intellectual property relating to the Company s insulin program or the licensing of any of the Company s intellectual property

to a ventilator manufacturer for incorporation into such manufacturer s ventilator technology; (10) create, incur, assume or suffer to exist, any lien, charge or other encumbrance on any of its properties or assets, other than liens of carriers, warehousemen, artisans, bailees, mechanics and materialmen incurred in the ordinary course of business securing sums not overdue; or (11) agree to do any of the foregoing.

**NOTE 3 - RECENT ACCOUNTING PRONOUNCEMENTS**

In December 2004, the Financial Accounting Standards Board ( FASB ) issued FASB Statement No. 123R (revised 2004) Share-Based Payment, which is a revision of FASB Statement No. 123 Accounting for Stock-Based Compensation. Statement 123R supersedes APB Opinion No. 25 Accounting for Stock Issued to Employees, and amends FASB Statement No. 95 Statement of Cash Flows. Generally, the approach in Statement 123R is similar to the approach described in Statement 123. However, Statement 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. The new standard will be effective for the Company in the quarter ending September 30, 2005. The Company is in the process of assessing the impact of adopting this new standard.

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 151 Inventory Costs ( SFAS 151 ), which adopts wording from the International Accounting Standards Board s IAS 2 Inventories in an effort to improve the comparability of international financial reporting. The new standard indicates that abnormal freight, handling costs, and wasted materials (spoilage) are required to be treated as current period changes rather than as a portion of inventory cost. Additionally, the standard clarifies that fixed production overhead should be allocated based on the normal capacity of a production facility. The provisions of SFAS 151 are effective for fiscal years beginning after June 15, 2005. Adoption of SFAS 151 is not expected to have a material impact on the Company s financial position or results of operations.

# 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/A for the year ended December 31, 2004, filed with the Securities and Exchange Commission on April 19, 2005 ( Form 10-K/A ).*

**Critical Accounting Policies and Estimates**

Our critical accounting policies and estimates are described in Item 7 of the Form 10-K/A for the year ended December 31, 2004, and have not changed materially since that date.

**Overview**

Aerogen, Inc. ( Aerogen, the Company or we ) was incorporated in November 1991. We are a specialty pharmaceutical company developing novel drug/device combination aerosol products for treatment of respiratory disorders in the critical care setting. Based upon our proprietary OnQ® Aerosol Generator, we are developing respiratory products for marketing by us, and products in collaboration with, and for marketing by, pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs through the lungs to the bloodstream.

In the period ended March 31, 2005, we had two nebulizer products on the market. We have an accumulated deficit of approximately $119.9 million as of March 31, 2005. In 2002, we generated significant revenues from our planned principal operations and thus exited the development stage. However, we will continue to devote substantial efforts to the development of current and future products. We expect to incur significant additional operating losses over the next several years and expect cumulative losses to increase, primarily due to the costs associated with the manufacturing and marketing of our products, the expansion of our research and development activities and the general expansion of our business activities. We anticipate that our quarterly results will fluctuate for the foreseeable future. Therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods. Our sources of working capital have primarily been equity financings, convertible debentures, product revenues, research and development revenues, license fees, royalties, and interest earned on investments.

As of March 31, 2005, we had $13.6 million in cash and cash equivalents. We are pursuing a number of alternatives to maximize stockholder value, including strategic transactions, collaborative partnerships, and the licensing or sale of certain intellectual property. If these efforts are not successful, we will need to raise additional capital before the end of 2005 to continue operations. Licensing or collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to certain of our products or technologies or desirable marketing territories, or all of these.

**Results of Operations**

**Revenues**

Total revenues for the three months ended March 31, 2005 were $1.6 million, compared with $1.1 million for the same period of 2004. Total revenues include revenues from product sales, research and development activities for unrelated third parties, royalties associated with the licensing of our technology for use outside of the medical field and other revenues.

Product sales for the three months ended March 31, 2005 were $1.1 million, compared with $0.8 million for the same period of 2004. Product sales were higher for the three months ending in March 31, 2005 due to increased sales of the Aeroneb® Professional Nebulizer System ( Aeroneb Pro ), as compared to the same period in 2004, when product shipments were curtailed during the quarter in an effort to conserve working capital, resulting in a backlog of approximately $492,000 at March 31, 2004. The increase in Aeroneb Pro sales was slightly offset by a decrease in the sales of our OnQ Aerosol Generators to Evo Medical Solutions ( Evo formerly Medical Industries America) in the three months ended March 31, 2005, as compared to the same period in 2004. There were no shipments to Evo during January or February 2005, but shipments resumed in March 2005, after design and manufacturing changes were implemented to address the durability issues which had led to a suspension of shipments throughout the last half of 2004.

Research and development revenues for the three months ended March 31, 2005 were approximately $32,000, compared with none for the same period of 2004. The revenues for the three months ended March 31, 2005 resulted from product development activities performed under a partner agreement signed in late 2004. Research and development revenues can be expected to vary from period to period based on the activities requested by partner companies in any particular period, and therefore are not predictable.

Royalty and other revenues were $0.5 million and $0.3 million, for the three month periods ended March 31, 2005 and 2004, respectively. The increase in royalty and other revenue was due to the increased royalty revenue associated with licensing our aerosol generator technology to a consumer product company for use in the fields of air fresheners and insect repellants.

**Cost of Products Sold**

Cost of products sold for the three months ended March 31, 2005 and 2004 were $1.0 million and $0.7 million, respectively. Cost of products sold, as a percentage of product sales revenue, increased in the first three months ended March 31, 2005 as compared to the same period of 2004, primarily as a result of reserves recorded on excess inventories created by a new product design. As the manufacturing processes mature, and as we see volumes increase, we anticipate improvements in the cost of products sold as a percentage of product sales revenue.

**Research and Development Expenses**

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

Research and development expenses for the three months ended March 31, 2005 were $3.1 million, compared with $1.9 million for the same period of 2004. The increase in research and development expenses of $1.2 million for the three months ended March 31, 2005, as compared with the same period of 2004, was primarily due to spending related to the Phase 2 clinical trial for our aerosolized antibiotic product.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses for the three months ended March 31, 2005 were $1.7 million, compared with $2.0 million for the same period of 2004. The decrease for the three months ended March 31, 2005 of $0.3 million compared with the

same period of 2004 was primarily due to decreased legal expenses of $0.5 million related to the lease restructuring and financing activities during the first quarter of 2004, partially offset by increases in market research spending of $0.1 million related to our aerosolized antibiotic product, and $0.1 million related to recruiting expense incurred due to the initiation of our search for a new CEO.

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

Net interest expense for the three months ending March 31, 2005 was zero compared with $0.6 million in the same period of 2004. The decrease in net interest expense is primarily due to imputed interest in 2004 resulting from the beneficial conversion feature of the convertible debentures, and the imputed value associated with the warrants that were issued to SF Capital in 2003 and to the Carpenter Family Trust in 2004, all of which totaled $0.5 million in the period ended March 31, 2004, offset by an increase in interest income of $0.1 million in the period three month ended March 31, 2005, as compared to the same period in 2004..

**Changes in Warrant Liability**

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 issued on the date of the first and second closing of $16.1 million was 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 month period ended March 31, 2005, the fair value of the warrants decreased from $10.3 million at December 31, 2004 to $6.3 million at March 31, 2005, resulting in a gain of $4 million for the three month period ended March 31, 2005. The fair value of the warrants increased from $8.2 million at the date of the first closing to $9.3 million at March 31, 2004 resulting in a loss of $1.1 million for the three month period ended March 31, 2004.

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

The issuance of the A-1 Preferred during the three months ended March 31, 2004 resulted in the recognition of a beneficial conversion feature of approximately $6,440,000. A beneficial conversion feature ( BCF ) is recorded as a dividend to the preferred stockholders, and is calculated as the difference between the value of proceeds allocated to the preferred stock and the fair market value on the transaction date of the common stock issuable upon conversion. The amount of the BCF cannot exceed the proceeds allocated to the preferred stock in the transaction.

**Liquidity and Capital Resources**

The Company has incurred net losses since inception and is expected to incur substantial losses for the next several years. The auditor s report on our condensed consolidated financial statements as of December 31, 2004 contains an explanatory paragraph, which refers to our recurring operating losses and negative cash flows from operations and notes that these matters raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis which contemplates continuity of operations, realization of assets, and liquidation of liabilities in the ordinary course of business, and do not reflect adjustments that might result if we were not to continue as a going concern.

To date, 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 products will continue to require significant research and development, clinical trials and regulatory approvals. These activities, together with selling, general and administrative expenses, are expected to result in substantial operating losses for the next several years. As of March 31, 2005, Aerogen had cash and cash equivalents of approximately $13.6 million. Based on current expectations of sales and royalty levels and operating costs, existing capital resources will not enable the Company to maintain current and planned operations beyond the first quarter of 2006; however, if we do not receive certain expected product sales and/or royalties, our cash balance may not sustain planned operations beyond the middle of the fourth quarter of 2005. We are pursuing a number of alternatives to maximize stockholder value, including strategic transactions, collaborative partnerships and the licensing or sale of certain of our intellectual property. If these efforts are not successful, we will need to raise additional capital before the end of 2005 in order to continue operations. Licensing or collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to certain of our products or technologies, or desirable marketing territories, or all of these.

Net cash used in operating activities during the three months ended March 31, 2005 was $3.3 million, resulting primarily from the net loss for the period of $0.3 million, increased by the $4.0 million non-cash gain resulting from the decrease in warrant liability, and offset by net collections on receivables of $0.4 million. Net cash used in operating activities during the three months ended March 31, 2004 was $3.3 million resulting primarily from the net loss for the period of $5.4 million and a net decrease in

accounts payable of $0.4 million. These uses were partially offset by non-cash related charges of approximately $1.1 million in warrant liability increases, $0.5 million in amortization of discounts on convertible notes, and $0.1 million in amortization of deferred stock-based compensation, offset by $0.3 million in depreciation and amortization. Additionally, accrued liabilities increased by $1.9 million primarily due to the payment obligations associated with the restructuring of our lease, partially offset by a related decrease in deferred rent of $1.5 million.

Net cash used in investing activities was approximately $45,000 for the three months ended March 31, 2005, consisting primarily of property and equipment acquisitions associated with clinical research. Net cash used in investing activities was approximately $59,000 for the three months ended March 31, 2004 consisting primarily of property and equipment acquisitions associated with process improvements.

Net cash provided by financing activities was approximately $18,000 for the three months ended March 31, 2005, consisting of repayment on a stockholder note receivable. Net cash provided by financing activities was $15.1 million for the three months ended March 31, 2004, consisting of $14.6 million in net proceeds from issuance of Series A-1 Convertible Preferred Stock and common stock warrants and $0.8 million in net proceeds from the issuance of debentures and convertible debentures, partially offset by repayment of debentures of $0.3 million.

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.

**Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Board ( FASB ) issued FASB Statement No. 123R (revised 2004), Share-Based Payment, which is a revision of FASB Statement No. 123 Accounting for Stock-Based Compensation. Statement 123R supersedes APB Opinion No. 25 Accounting for Stock Issued to Employees, and amends FASB Statement No. 95 Statement of Cash Flows. Generally, the approach in Statement 123R is similar to the approach described in Statement 123. However, Statement 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forms disclosure is no longer an alternative. The new standard will be effective for the Company in the quarter ending September 30, 2005. The Company is in the process of assessing the impact of adopting this new standard.

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 151 Inventory Costs ( SFAS 151 ), which adopts wording from the International Accounting Standards Board s IAS 2 Inventories in an effort to improve the comparability of international financial reporting. The new standard indicates that abnormal freight, handling costs, and wasted materials (spoilage) are required to be treated as current period charges rather than as a portion of inventory cost. Additionally, the standard clarifies that fixed production overhead should be allocated based on the normal capacity of a production facility. The provisions of SFAS 151 are effective for fiscal years beginning after June 15, 2005. Adoption of SFAS 151 is not expected to have a material impact on the Company s financial position or results of operations.

**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 to continue as a going concern, we will need capital in excess of our current cash resources.**

**We expect our current cash and cash equivalents will allow us to continue planned operations until approximately the first quarter of 2006; however, if we do not receive expected product revenues and/or royalties, our cash balance may be insufficient to sustain operations beyond the middle of the fourth quarter of 2005. Our current cash resources will be insufficient to complete Phase 3 clinical trials for any of our products, and may be insufficient to complete our current Phase 2 clinical trial. Sufficient cash to complete our Phase 2 and Phase 3 trials may be provided from strategic transactions or collaborative partnerships, such as from out-licensing and partnering one or more of our pharmaceutical products, or from product sales or royalties 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, royalty revenues or operating expenses 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.**

**We recently received a delisting letter from Nasdaq, and our common stock may become delisted from the Nasdaq SmallCap Stock Market, which may adversely impact the liquidity of our common stock and significantly depress its value.**

On April 19, 2005, we received a notice from the staff of the Nasdaq Stock Market stating that Aerogen is not in compliance with the minimum stockholders equity requirement of Marketplace Rule 4310(c)(2)(B) and the staff is reviewing our eligibility for continued listing on the Nasdaq SmallCap Market. The staff had requested that we provide, on or before May 4, 2005, a specific plan to achieve and sustain compliance with Nasdaq SmallCap listing requirements, including a timeframe for completion of the plan. On May 3, 2005, we requested and were granted an extension to submit our plan by May 13, 2005

On May 13, 2005, we submitted a plan to Nasdaq that would bring us back in compliance with Marketplace Rule 4310(c)(2)(B). As part of our plan, we are in discussions with the holders of the A-1 Preferred to make certain changes to the underlying agreements that may allow us to eliminate the warrant liability and reclassify the warrants into stockholders equity. However, due to continued losses, this change by itself will not be sufficient to bring us back into compliance with Nasdaq s continued listing requirements.

While the Company intends to continue to pursue its plan to achieve and sustain compliance as requested by Nasdaq, there can be no guarantee that the Nasdaq staff will find the Company s plan acceptable, that we will be successful in implementing our plan as intended, or that our common stock will not be delisted by Nasdaq. If our common stock is delisted, the only public market for our common stock is likely to be the OTC Bulletin Board. Being delisted may adversely impact the liquidity of our common stock and significantly depress its value.

**The Company s Phase 2 clinical trial of its lead product under development, aerosolized amikacin, has experienced delays, and we are uncertain at this time when the study will be completed, if at all. Timelines for the Company s clinical trials are subject to uncertainties beyond the Company s control, including the potential for slower than expected opening of clinical study sites and enrollment of patients, or an inability to enroll patients at all.**

The Company s lead pharmaceutical product under development is a drug/device combination product for treatment of Ventilator-Associated Pneumonia ( VAP ). The second Phase 2 clinical trial with this product was initiated on December 28, 2004. This trial involves the enrollment of 108 patients at approximately 31 study sites, with each patient to be studied for 28 consecutive days. Based upon estimates provided by our study sites, we anticipated we would have the first patients enrolled during the first quarter of 2005. As of March 31, 2005, however, we had only 8 sites open due to administrative delays at the sites, 33 patients with suspected VAP screened for entry into the trial, and no patients enrolled. As of May 12, 2005, although we have more sites open and screening patients, we have only recently enrolled the first patient. Until all sites are open and we observe steady enrollment, we will be unable to reliably project the completion date of the trial and we are uncertain when the study will be completed, if at all.

**The lead investor in our preferred stock financing has voting rights that may prevent us from raising additional capital, selling an exclusive license to our intellectual property, selling our assets or merging with or otherwise being acquired by another entity.**

As stated in the Certificate of Designations of our Series A-1 Convertible Preferred Stock (the A-1 Preferred ), Xmark Fund, L.P. and Xmark Fund, Ltd. (the Xmark Funds ) currently have the right to prevent us from, among other things, issuing securities with rights that are senior or equal to the A-1 Preferred, increasing the authorized number of shares of our common stock, or providing any security interest in our assets outside of the ordinary course of business. The Xmark Funds have recently stated in letters to us, which they have publicly filed, that they will not approve any capital raising transaction presented to them unless we comply with certain conditions. Although there are ways in which we could raise capital that would not require the approval of the Xmark Funds, the position of the Xmark Funds may make it more difficult for us to raise capital on favorable terms, in sufficient amounts to meet our business objectives, or at all.

**Our largest stockholders may exert significant influence on us.**

Based upon our records, and upon the public filings made by holders of our A-1 Preferred reporting their securities sales and purchases, three holders of our A-1 Preferred, including the Xmark Funds, appear to own 50.4% of the A-1 Preferred outstanding as of March 31, 2005. Those same records and filings also indicate that, as of March 31, 2005, the holders of our A-1 Preferred also owned

an aggregate of up to 1.97 million common shares. If all of the A-1 Preferred outstanding as of March 31, 2005 were to convert into common, and the holders of the A-1 Preferred were to still own 1.97 million additional common shares, then (i) as few as seven of the A-1 Preferred holders, including the Xmark Funds, would own 52.9% of the then-outstanding common shares of the company and (ii) all of the A-1 Preferred holders, as a group, would own at least 68.3% of the Company s then-outstanding common stock before accounting for common stock that may have been acquired by them in the open market and/or via unreported acquisitions.

While each of these A-1 Preferred holders, except the Xmark Funds, 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. On November 3, 2004, the Xmark Funds delivered to us a written waiver of this limitation, thereby permitting the conversion of any or all of their A-1 Preferred into common stock at any time on or after January 3, 2005. Based upon the number of the Company s common shares outstanding as of March 31, 2005, and upon the public filings of Xmark, if the Xmark Funds were to convert all of their A-1 Preferred, and no other holder of A-1 Preferred were to convert, then the total number of shares of outstanding Aerogen common stock would increase to at least 8,432,164 shares, of which the Xmark Funds would own at least 1,255,635 shares, or 14.89%, based upon our records of common stock already received by Xmark pursuant to common stock dividends, less the sales of common stock publicly reported by Xmark. To our knowledge, the A-1 Preferred investors have not acted as a group in negotiating or making their investment in the Company, and consider themselves to be independent investors. Due to the termination of our rights plan, there can be no assurance that further concentration of ownership will not occur, or that these securities will not be resold to different investors who may or may not act as a group.

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

If the A-1 Preferred stockholders were to exercise all of the common stock warrants they hold and convert all of the shares of A-1 Preferred they owned as of March 31, 2005, they would own approximately 19,103,340 shares of our common stock, in addition to any other shares such stockholders may now or in the future own. Furthermore, as of March 31, 2005, a total of 613,921 shares of Aerogen common stock had been issued, or were in the process of being issued, to the A-1 Preferred stockholders in satisfaction of Aerogen s quarterly dividend obligation to them for the quarters ended March 31, June 30, September 30, and December 31, 2004. If the A-1 Preferred stockholders exercise the warrants or convert our preferred stock into shares of common stock and sell the shares into the market, such sales could have a negative effect on the market price of our common stock and would dilute the holdings of our existing common stockholders. Dilution or the potential for dilution also could materially impair our ability to raise capital through the future sale of equity securities. If the Company were to issue additional equity securities in a future financing transaction at a per share price lower than the current conversion price of the A-1 Preferred, then the conversion price of the A-1 Preferred would automatically adjust downward to be equal to the common stock equivalent price of the newly-issued securities. In such a circumstance, the exercise of the warrants issued with the Series A-1 Preferred Stock would also be reduced to that lower price. 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 26, 2004 and incorporated by reference herein.

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

We have never been profitable. Through March 31, 2005, we have an accumulated deficit of approximately $119.9 million. We expect to continue to incur substantial losses over at least the next several years as we:

- expand our research and development efforts;
- expand our preclinical and clinical testing activities;
- expand our manufacturing efforts, including our commercial production capability; and
- build our sales and marketing capabilities and launch our 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 internal controls may not be sufficient to ensure timely and reliable financial information.**

We have recently restated our financial results for the quarters ended March 31, June 30 and September 30, 2004 to reflect adjustments to our previously reported financial information. The restatements arose, in part, due to errors related to the initial valuation, classification and subsequent accounting of the warrants issued in conjunction with the A-1 Financing. During the period covered by this report, and in connection with the treatment of our financial results for the year ended December 31, 2004, management has evaluated the effectiveness of our

disclosure controls and procedures and, as a result, has determined that for any future issuance of complex equity or derivative instruments, 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. As of March 31, 2005, management has determined that our disclosure controls and procedures were effective, however, as of December 31, 2004, management determined that our disclosure controls and procedures were not effective because these enhanced procedures were not in place.

**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 may experience in the future 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. As a result, we accumulated a backlog of orders that were not completely filled by the end of the second quarter of 2004, but which were filled in the third quarter of 2004. In the future, 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.

The A-1 Preferred is not traded in the public market and has many rights and privileges that are superior to our common stock, including certain redemption rights. As of March 31, 2005, the holders of the currently outstanding A-1 Preferred collectively own at least 68% of the Company s outstanding equity on an as-converted basis. The limited amount of our total equity that publicly trades as common stock could, therefore, be subject to additional volatility pressures.

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

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

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

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

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

- drugs may be safely and effectively delivered using our technologies;
- our inhalers, nebulizers and pulmonary drug delivery systems are safe across a range of drugs and formulations;
- our products consistently deliver accurate and reproducible amounts of drug over time; and
- drug formulations are stable in our products.

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

**If clinical trials of our drug/device combination products are not successful, drug products using our technology or inhalers may not be commercialized.**

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

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

We have built our own manufacturing capabilities to produce key components of our products. We have manufactured only limited quantities of our first three products, and limited clinical supplies of other products. We currently produce all of the OnQ Aerosol Generators for our products, partnered or not, in a single facility. We plan to continue using contract manufacturers to produce certain other key components and subassemblies of our products, many of which are produced in unique facilities and/or with unique tooling. We may assemble some of our products ourselves, or we may use contract manufacturers for the final assembly of all of our products. We do not have long-term supply contracts with most of our key suppliers or contract manufacturers. In addition, some 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 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 resumed our work on that product, and do not expect to re-start the program unless and 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, it 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; a second Phase 2 clinical trial for this product is ongoing. In addition to the satisfactory completion of this trial, the development of this product will require, at a minimum, a Phase 3 clinical trial in order to support a New Drug Application ( NDA ), which must be filed with the FDA to obtain approval prior to marketing the product in the United States. If these clinical trials fail to meet their objectives, or are halted for safety reasons, we may be required to suspend further development of this product, conduct additional clinical trials, or return to an earlier stage of research and development. Any or all of these possible outcomes could materially impair our ability to raise additional capital on attractive economic terms, if at all.

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

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

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

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

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

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

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

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

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

We currently have a small sales and marketing staff and modest marketing budget, and many of our competitors have substantial sales and marketing infrastructures and significant marketing budgets. We rely on third party distributors to sell our products, some of which have limited experience in the markets that we are trying to access. Our success in commercializing our respiratory products in the United States and worldwide will depend on our and our partners ability to develop and execute a successful sales and marketing effort. There can be no assurance that our current products, which include the Aeroneb Pro and the Aeroneb Go will be successful. In any event, these products are not expected to generate revenues sufficient enough to solely support the Company s operations in the foreseeable future. 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. Our Chairman and Chief Executive Officer is retiring by June 30, 2005.**

Because of the specialized nature of our business, we depend upon qualified scientific, engineering, technical and managerial personnel. In particular, our business and prospects currently depend in large part upon the continued employment of Dr. Jane E. Shaw, our Chairman and Chief Executive Officer. In late 2004, Dr. Shaw indicated a desire to retire by the middle of 2005, and has since informed the Company that she intends to retire no later than June 30, 2005. As a result, our Board of Directors has initiated a search for a new Chief Executive Officer, which is ongoing. There is intense competition for qualified personnel in our business and 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, including a Chief Executive Officer to replace Dr. Shaw. The loss of the services of existing personnel without timely and

effective replacement, as well as the failure to recruit additional key scientific, technical, engineering and managerial personnel in a timely manner, would harm our research and development programs and our business.

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

Our manufacturing facilities, and those of our subcontractors and manufacturing licensee Evo, are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with Quality System Regulation ( QSR ). Evo was the subject of an FDA inspection that was completed in early July 2004, and pursuant to which Evo received a Form-483, and which was followed by a warning letter concerning the Aeroneb Go. In response to the warning letter, Evo voluntarily suspended shipments of the Aeroneb Go for a 3-week period until a risk mitigation plan could be developed and presented to the FDA. Similarly, Aerogen voluntarily suspended shipments of OnQ Aerosol Generators to Evo, which resulted in no revenues from OnQ Aerosol Generator sales to Evo during the last six months of 2004. Evo implemented a risk mitigation plan that was reviewed by the FDA, which included enhanced patient education as to the importance of cleaning the device in accordance with the manufacturer s directions for use and the importance of having spare batteries and a backup device available if the user-patient is treating a life-threatening disease, the stocking of replacement handsets at distributors and customer support for rapid-turnaround of reported failures, as well as the provision of a back-up handset to certain identified, high-risk patients. Evo s implementation of the risk mitigation plan was structured according to the FDA s regulations for a Class II, firm-initiated recall, and updates are being forwarded to the FDA.

Evo resumed Aeroneb Go shipments incorporating their existing inventory of OnQ Aerosol Generators in accordance with their risk mitigation plan. Aerogen has implemented several design and manufacturing changes to enhance the inherent durability of the OnQ Aerosol Generator. Aerogen resumed commercial shipments during the first quarter of 2005. Although these changes were implemented upon successful completion of design verification testing, we cannot be certain that these changes will be successful in enhancing the durability and reliability of the device. During the year ended December 31, 2004, reserves totaling $100,000 against cost of products sold were established for potential costs related to Aerogen s support of the Evo risk mitigation plan, but we cannot assure that this reserve will be adequate to cover all expenses that are or will be related to the recall.

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

As of May 2004, the Galway, Ireland, and Mountain View, California, facilities successfully obtained certification to ISO 13485:2003. On May 3, 2005, Aerogen Mountain View was subject to a surveillance audit in which there were no major non-conformances found. If Aerogen, Evo or Aerogen s subcontractors fail to maintain compliance with QSRs, ISO 13485 or other international regulatory requirements, we may be required to, among other things, recall product or cease all or part of our operations until we comply with the regulations. We cannot be certain that our facilities, or those of Evo and/or our subcontractors, will be found to comply on an ongoing basis with the QSRs, ISO or other international regulatory requirements.

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

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

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

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

In both domestic and foreign markets, sales of our potential products will depend, in part, on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. There is significant uncertainty about the reimbursement status of newly approved healthcare products. We cannot assure that any of our products will be reimbursed by third-party payors. In addition, we cannot assure that our products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize a profit.

Legislation and regulations affecting the pricing of health care products may change before our products are approved for marketing, and any such changes could further limit reimbursement. In addition, changes to Medicare reimbursement policies for nebulizers and/or the drugs used with them, particularly as a result of the Medicare Prescription Drug Improvement and Modernization Act of 2003, may limit the market penetration of the Aeroneb Go in the United States.

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

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

Many of these companies and entities have greater research and development, manufacturing, marketing, financial and managerial resources and experience than we do. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval for products or gaining market acceptance more rapidly than we can. If competitors bring effective products to market before we do, there is a risk that we may not be able to gain significant market share because our competitors may have firmly established their products in the market. It is also possible that a competitor may develop a technology or product that renders our technology or products obsolete.

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

Our ability to compete effectively depends in part on developing and maintaining the proprietary aspects of our aerosolization technology. We cannot be sure that the patents we have obtained, or any patents we may obtain as a result of our pending United States or international patent applications and, in particular, our vibratory aerosolization technology, which is technology that aerosolizes liquids by vibrating a metal plate that contains holes, will provide any competitive advantages for our products.

We also cannot assure that those patents will not be successfully challenged, invalidated or circumvented in the future. In addition, we cannot assure that competitors, many of which have substantial resources and have made substantial investments in competing technologies, have not already applied for, or obtained, or will not seek to apply for and obtain, patents that will prevent, limit or interfere with our ability to make, use and sell our products either in the United States or in international markets. Patent applications are maintained in secrecy for a period after filing. We may not be aware of all of the patents and patent applications potentially adverse to our interests.

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

In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. We require our employees and all consultants to execute confidentiality

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

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

The pharmaceutical and medical device industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in these industries have used intellectual property litigation to gain a competitive advantage. We cannot assure that we will not become subject to, whether within or outside of the United States, patent infringement claims or litigation or interference proceedings declared by the United States Patent and Trademark Office, ( USPTO ), to determine the priority of inventions. Although we prevailed in a 1999 interference proceeding before the USPTO, that granted to Aerogen all but one of the independent claims of Bespak s 5,261,601 patent, we entered into a cross-license agreement with Bespak, as a result of which Bespak has a license to certain of our technology, including the right to sublicense. The scope of the granted license was limited to products employing technology which was disclosed by Bespak in United States Patent No. 5,261,601. Additionally, in April 2003, we received notice that a German patent infringement suit had been filed by PARI GmbH in the District Court in Munich, Germany alleging that Aerogen s Aeroneb Pro product infringes a patent licensed to PARI GmbH. In May 2003, we filed an action in the German patent office requesting that the patent in question be rendered null and void. In July 2004, the Federal Patent Court in Munich, Germany ruled in favor of Aerogen by nullifying all contested claims of this patent, which is owned by The Technology Partnership plc ( TTP ) of Hertfordshire, England, and is licensed to PARI, GmbH of Munich, Germany. The Court ordered TTP to pay Aerogen s legal expenses related to this nullity action to the maximum extent allowed under German law. During October 2004, TTP requested, and was granted, a three-month extension of time to file an appeal of this decision, and was granted additional extensions through February 2005. PARI assumed control over the nullity case from TTP on December 14, 2004. The decision on the nullity action has been appealed to the German Supreme Court, with PARI submitting its arguments in support of the appeal in March 2005. Additionally, during October 2004 TTP formally served Aerogen with the infringement suit that PARI had advised Aerogen in April 2003 had already been filed in Munich, Germany. A preliminary hearing on the infringement case is scheduled for June 2005. We believe that this suit is without merit and intend to vigorously defend against all allegations in the suit. Although the infringement suit claims that Aerogen infringes solely on the patent claims that have since been ruled null and void, there can be no guarantee that the German Supreme Court will not reverse or modify the nullity ruling and again provide PARI with the legal standing to reassert their infringement suit.

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

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

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

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

Our operations involve the use of hazardous and toxic materials and generate hazardous, toxic and other wastes. In particular, we use a special metal alloy to build our aerosol generators, a component of which is regulated as a hazardous material. The risk of accidental contamination or injury from hazardous and toxic materials cannot be completely eliminated. In the event of such an

accident, we could be held liable for any damages that result, and this liability could exceed our resources. Our operations could be shut down by government officials if we were not in compliance with environmental laws.

# Item 3. Quantitative and Qualitative Disclosures About Market Risk

**Interest rate risk**

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

**Exchange rate risk**

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

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

## Item 4. Controls and Procedures

As of March 31, 2005, we carried out an evaluation, under the supervision and the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934). Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective and timely in alerting them to material information required to be included in our periodic Securities and Exchange Commission ( SEC ) reporting.

In response to the restatement of our financial results for the quarters ended March 31, June 30, and September 30, 2004, we implemented a policy during the period covered by this report whereby an outside expert with experience concerning the related accounting issues will be consulted, or additional internal staff will be trained or hired, to ensure accurate reporting for any future issuance of complex equity and derivative instruments or other complex transactions,. In addition, enhanced review and documentation procedures have been implemented in our accounting process in order to ensure accuracy of all accounting entries. Other than these changes, 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**

Aerogen is a party to a lawsuit brought by PARI GmbH alleging patent infringement 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. In July 2004, the Federal Patent Court in Munich, Germany ruled in favor of Aerogen by nullifying all contested claims of this patent, which is owned by The Technology Partnership plc ( TTP ) of Hertfordshire, England, and is licensed to PARI, GmbH of Munich, Germany. The Court ordered TTP to pay Aerogen s legal expenses related to this nullity action to the maximum extent allowed under German law. During October 2004, TTP requested, and was granted, a three-month extension of time to file an appeal of this decision, and granted additional extensions through February 2005. PARI assumed control over the nullity case from TTP on December 14, 2004. The decision on the nullity action has been appealed to the German Supreme Court, with PARI submitting its arguments in support of the

appeal in March 2005. Additionally, during October 2004 TTP formally served Aerogen with the infringement suit that PARI had advised Aerogen in April 2003 had already been filed in Munich, Germany. A preliminary hearing on the infringement case is scheduled for June 2005. We believe that this suit is without merit and intend to vigorously defend against all allegations in the suit.

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

In accordance with the terms of the A-1 Preferred, Aerogen has issued quarterly dividends in the form of Aerogen common stock to the holders of the A-1 Preferred, commencing with the quarter ended March 31, 2004 through the quarter ended March 31, 2005. The total number of common shares issued pursuant to these dividends was 1,043,053 shares, including the dividend payable for the quarter ended March 31, 2005. The issuance of all of these shares was or will be 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.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits**

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

**Signatures**

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

**Aerogen, Inc.**
(Registrant)

| | | |
|---|---|---|
| Dated: May 13, 2005 | By: | /s/ JANE E. SHAW<br>Jane E. Shaw, Ph.D.<br>*Chairman and Chief Executive Officer* |
| Dated: May 13, 2005 | By: | /s/ ROBERT S. BREUIL<br>Robert S. Breuil<br>*Chief Financial Officer* |

Exhibit List

| No. | Note | Description of Exhibit Document |
|---|---|---|
| 3.2 | (4) | Amended and Restated Certificate of Incorporation of Aerogen, Inc. |
| 3.2.1 | (5) | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Aerogen, Inc. |
| 3.4 | (1) | Amended and Restated Bylaws of Aerogen, Inc. |
| 3.5 | (3) | Amendment to Rights Agreement dated as of February 24, 2003, by and between Aerogen, Inc. and Mellon Investor Services, LLC, as Rights Agent |
| 4.2 | (1) | Warrant, dated October 14, 1997, to purchase Series C preferred stock of Aerogen, Inc. issued to Venture Lending & Leasing II, Inc. |
| 4.3 | (1) | Warrant, dated October 14, 1997, to purchase Series C preferred stock of Aerogen, Inc. issued to Venture Lending & Leasing, Inc. |
| 4.4 | (6) | Loan and Securities Purchase, dated as of September 9, 2003, by and between the Company and SF Capital Partners, Ltd. ( SF Capital ). |
| 4.5 | (6) | Warrant dated as of September 9, 2003, issued by the Company to SF Capital |
| 4.6 | (5) | Debenture dated as of November 3, 2003, issued by the Company to SF Capital |
| 4.7 | (5) | Warrant dated as of November 3, 2003, issued by the Company to SF Capital |
| 4.8 | (7) | Amendment to Secured Convertible Debenture, dated January 7, 2004, by and between the Company and SF Capital |
| 4.9 | (7) | Amendment No. 2 to Secured Convertible Debenture and Consent, dated as of January 20, 2004, by and between the Company and SF Capital |
| 4.10 | (7) | Loan and Securities Purchase Agreement, dated as of January 23, 2004, by and between the Company and the Carpenter 1983 Family Trust UA (the Trust ) |
| 4.11 | (7) | Debenture, dated as of January 23, 2004, issued by the Company in favor of the Trust. |
| 4.12 | (7) | Registration Rights Agreement, dated as of January 23, 2004, by and between the Company and the Trust |
| 4.13 | (7) | Warrant, dated as of January 23, 2004, issued by the Company in favor of the Trust |
| 4.14 | (8) | Purchase Agreement, dated March 11, 2004, by and between the Company, Xmark Fund L.P., Xmark Fund, Ltd. and other investors |
| 4.15 | (8) | Certificate of Designations, Preferences and Rights of Series A-1 Preferred Stock of the Company, dated March 19, 2004 |
| 4.16 | (8) | Form of Warrant |
| 4.17 | (8) | Registration Rights Agreement, dated as of March 22, 2004, by and between the Company and the Investors named in the Purchase Agreement |
| 4.18 | (8) | Amendment to Purchase Agreement and Waiver, dated as of March 19, 2004, by and between the Company and certain of the Investors named in the Purchase Agreement |
| 4.19 | (8) | Amendment No. 2 to Rights Agreement, dated as of March 19, 2004, by and between the Company and Mellon Investor Services LLC as Rights Agent |
| 4.20 | (8) | Amendment to Secured Convertible Debentures, dated as of March 1, 2004, by and between the Company and SF Capital |
| 4.21 | (8) | Amendment No. 1 to Secured Convertible Debenture and Consent, dated as of March 1, 2004, by and between the Company and the Carpenter Trust |
| 4.22 | (8) | Secured Debenture, dated March 12, 2004, issued by the Company to SF Capital |
| 4.23 | (8) | Amendment No. 1 to Security Agreement, dated as of March 11, 2004, by and between the Company and SF Capital |
| 4.24 | (8) | Amendment No. 1 to IP Security Agreement, dated as of March 11, 2004, by and between the Company and SF Capital |
| 10.12 | (2) | Form of lease agreement between EOP-Shoreline Technology Park, L.L.C. and Aerogen, Inc. for the premises located at 2071 Stierlin Court, Mountain View, California |
| 10.12.1 | (9) | Lease amendment, dated November 6, 2003, between CA-Shoreline Technology Park, LP and Aerogen. |
| 10.12.2 | (9) | Lease amendment, dated March 9, 2004, between CA-Shoreline Technology Park, LP and Aerogen. |
| 10.17 | (5)* | Distribution and supply agreement, dated as of September 30, 2003, between the Company and Medical Industries America Inc. |
| 10.17.1 | | Amendment to Distribution, Manufacturing and Supply Agreement, dated as of March 18, 2005, between the Company and Medical Industries America, Inc. |

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| 31.1 | Certification required by Rule 13a-14(a or Rule 15d-14(a) |
| 31.2 | Certification required by Rule 13a-14(a) or Rule 15d-14(a) |
| 32.1 | Certification required by Rule 13a-14(b) or Rule 15d-14(b) of the Securities and Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of The United States Code (18 U.S.C. Section 1350). |

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(1) Incorporated by reference to our Registration Statement on Form S-1 No. 333-44470 filed on August 25, 2000.

(2) Incorporated by reference to our Form 10-Q for the quarter ended September 30, 2001 filed on November 13, 2001.

(3) Incorporated by reference to our Current Report on Form 8-K filed on February 25, 2003.

(4) Incorporated by reference to our Form 10-Q for the quarter ended June 30, 2002 filed on August 13, 2002.

(5) Incorporated by reference to our Form 10-Q for the quarter ended September 30, 2003 filed on November 14, 2003.

(6) Incorporated by reference to our Current Report on Form 8-K filed on October 7, 2003.

(7) Incorporated by reference to our Current Report on Form 8-K filed on February 5, 2004.

(8) Incorporated by reference to our Current Report on Form 8-K filed on March 26, 2004.

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

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