AEROGEN INC
Form 10-K
April 15, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

Commission File Number 0-31913

Aerogen, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**33-0488580**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
2071 Stierlin Court, Suite 100, Mountain View, CA	**94043**
(Address of Principal Executive Offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.001

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 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 x No o

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

The aggregate market value of the common stock held by non-affiliates of the registrant based upon the closing price on the Nasdaq SmallCap Market reported on June 30, 2004 was $12,619,359. Shares of common stock held by each executive officer, director and each person who is known by the Registrant to own 5% or more of the Registrant s outstanding common stock have been excluded in that such persons may be deemed to be affiliates; share ownership information of certain persons known by the Registrant to own greater than 5% of the outstanding common stock for purposes of the preceding calculation is based solely on information on Schedule 13Gs filed with the Commission and is as of June 30, 2004. This determination of affiliate status is not a conclusive determination for other purposes.

The number of shares of common stock outstanding as of March 31, 2005 was 7,298,834.

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statement incorporated by reference in Part III of this

form 10-K or any amendment to this form 10-K. o

AEROGEN, INC.
FORM 10-K ANNUAL REPORT
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

TABLE OF CONTENTS

PART I

Item 1. BUSINESS

Notice Concerning Forward-Looking Statements

This Annual Report on Form 10-K (Form 10-K) of Aerogen, Inc. contains 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. These forward-looking statements are not historical facts, but rather are based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. Words such as anticipate, expect, intend, plan, believe, seek, estimate and variations of these words, and similar expressions, are intend identify forward-looking statements. These statements are not guarantees of our future performance and are subject to risks, uncertainties and other factors, some of which are beyond our control, are difficult to predict and could cause actual results to differ materially from those expressed, implied or forecast in the forward-looking statements. In addition, the forward-looking events discussed in this Form 10-K might not occur. These risks and uncertainties include, among others, those described in Risk Factors and elsewhere in this Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect our management s view only as of the date of this Form 10-K. Except as required by law, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Introduction

Aerogen, Inc. (Aerogen or the Company) is 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 for marketing by, pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs through the lungs to the bloodstream.

Our current products address many of the limitations presented by use of traditional nebulizers for pulmonary drug delivery. We believe that our drug products in development for pulmonary drug delivery using our proprietary technology could have a major impact on the treatment of respiratory disorders in the critical care setting.

Our goal is to become the leading provider of aerosol-based pulmonary drug delivery products in the acute care setting, particularly for patients on ventilators. We have identified a multi-billion dollar market opportunity where our OnQ technology, coupled with drugs already commercialized but not previously delivered by the pulmonary route and/or drugs novel to inhalation, addresses an unfulfilled market need.

We launched our first nebulizer, the Aeroneb® Portable Nebulizer System, in June 2001 and our second nebulizer, the Aeroneb® Professional Nebulizer System (Aeroneb Pro, Aeroneb Pro System), in June 2002. Our third nebulizer, the Aeroneb® Go Nebulizer (Aeroneb Go) was commercialized in January 2004.

Our lead therapeutic product, in a Phase 2 clinical trial, is an aerosolized antibiotic comprising a formulation of amikacin delivered via Aerogen s Pulmonary Drug Delivery System (PDDS) (previously referred to as a next generation or optimized Aeroneb Professional Nebulizer System) for the treatment of patients on ventilators with ventilator-associated pneumonia (VAP). This Phase 2 clinical trial was initiated on December 28, 2004, and 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 a majority of our sites open, and 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. Until all sites are open and we observe steady enrollment, we will be unable to reliably project the completion date of the trial. In light of the fact that we currently have no patients enrolled in this study, we are uncertain at this time when the study will be completed, if at all.

Our business plan also includes the development, in collaboration with pharmaceutical and biotechnology company partners, of respiratory products that will combine our technology with the partners proprietary compounds. The partner companies generally will commercialize these products, which may utilize a version of our PDDS, one of our Aeroneb nebulizers or an Aerodose® inhaler.

In addition to our respiratory therapy activities, we have the capability to develop novel pulmonary drug products for systemic drug input in collaboration with pharmaceutical and biotechnology companies and other partners. Systemic drug delivery of biotechnology products via the lungs provides significant market opportunities. We have developed an Aerodose inhaler for the delivery of insulin via the pulmonary route to Type 1 and Type 2 diabetic patients, and have successfully taken the product through Phase 2a testing and design verification testing of the commercial version of the inhaler. Product development activities have been placed on hold, pending an agreement with an appropriate partner willing to commit the financial resources required to complete the development, registration and commercialization of the product.

Aerogen was incorporated in the state of California in November 1991 under the name Fluid Propulsion Technologies, Inc. Our name was changed to AeroGen, Inc. in April 1997 and then to Aerogen, Inc. in May 2002. In March 1998, we changed our domicile to the state of Delaware. Our principal executive offices are located at 2071 Stierlin Court, Suite 100, Mountain View, California 94043; our telephone number is (650) 864-7300. Our business comprises one industry segment the development, manufacture and commercialization of pulmonary drug delivery products.

In May 2000, we acquired Cerus Limited, which is now our wholly owned subsidiary, Aerogen (Ireland) Limited. Cerus was a development stage company engaged in the development of pulmonary inhalation devices, utilizing our OnQ Aerosol Generator. Aerogen (Ireland) Limited developed our Aeroneb Professional Nebulizer System, and manages its assembly and distribution, incorporating OnQs produced in our Mountain View facility. Aerogen (Ireland) Limited also manufactures and distributes the Aeroneb Go for markets outside the U.S.

As of December 31, 2004, Aerogen had cash and cash equivalents of approximately $16.9 million. We believe this cash balance is sufficient to sustain operations into the first quarter of 2006; however, if we do not receive funds from certain expected product sales and/or royalties, our cash balance may not sustain planned operations beyond the middle of the fourth quarter of 2005. In order to continue operations beyond that time, we will need to raise additional capital, either through strategic transactions, collaborative relationships, the sale of assets, licensing of technologies and/or products, public or private financings, or other arrangements.

Aerogen®, Aerodose®, Aeroneb®, OnQ® and the associated brand marks are our trademarks. This Form 10-K also includes references to registered service marks and trademarks of other companies, which are indicated when used in this Form 10-K.

Pulmonary Drug Delivery

Pulmonary drug delivery is widely used to treat respiratory diseases. In addition, we believe it is a viable means to deliver drugs to the bloodstream via the lungs. The size of the inhaled droplets generally influences where the drug will be deposited in the lungs. Large droplets, greater than three microns in diameter, typically are deposited in the conducting airways of the lung, where they may be useful in treating diseases such as asthma, chronic obstructive pulmonary disease (COPD) and cystic fibrosis.

Small droplets, at three microns or less in diameter, are more likely to pass through the conducting airways into the deep lung, where they may be absorbed into the bloodstream to treat diseases such as diabetes. Our technology permits drug delivery to the lungs in a liquid aerosol of a defined droplet size within a range of one to five microns MMAD (Mass Median Aerodynamic Diameter).

Acute Care Market Respiratory Disorders

Respiratory disorders are associated with impaired quality of life, reduced life expectancy and significant treatment costs. Approximately 1.2 million patients are treated in the intensive care units (ICUs) of United States hospitals each year for respiratory disorders including pneumonia, COPD, asthma and respiratory distress syndrome (RDS). The cost of drugs for treatment of these patients totals approximately $3.5 billion per year, averaging approximately $500 per day in the ICU. There are also less prevalent diseases, such as neonatal pulmonary hypertension and infant respiratory distress syndrome (IRDS), which have few but costly treatments available. Other than for treatment of airways diseases, virtually all drug therapy for treatment of respiratory disorders in the ICU is given systemically by injection or infusion. This reflects, in part, the historical lack of sufficiently reproducible and efficient pulmonary drug delivery technologies.

We are currently focusing on the evaluation of products for marketing in the U.S. by Aerogen, for treatment of respiratory disorders in the acute care setting, including respiratory infections in ventilated patients, neonatal pulmonary hypertension and acute exacerbations of COPD. We are also focusing on improving pulmonary drug delivery generally for patients using nebulizers and those receiving therapy via externally-assisted breathing devices.

Approximately 1.5 million patients are placed on ventilators in United States hospitals each year. The presence of a breathing (endotracheal) tube promotes introduction of bacteria into the lungs and is a significant risk factor for the development of pneumonia (ventilator-associated pneumonia, or VAP). Approximately 10% to 30% of mechanically ventilated patients develop VAP; the risk increases with increasing duration of mechanical ventilation. Despite aggressive therapy with intravenous antibiotics, VAP is associated with a very high mortality rate (20% to 50%). Current therapy relies almost exclusively upon intravenous antibiotics. Treatment with the required high doses of intravenous antibiotics can be associated with severe side effects. Historically, aerosol therapy has not been utilized due to the low efficiency and reproducibility of available devices in delivering drugs to the lungs.

We estimate neonatal pulmonary hypertension affects more than 40,000 neonates annually in the United States. The only approved treatment for infants of greater than 34 weeks gestational age is inhaled nitric oxide (NO), which is expensive and has significant side effects. In addition, 30% to 50% of neonates treated with NO do not respond. There is no currently approved treatment for pulmonary hypertension in infants of less than 34 weeks gestational age.

We estimate approximately 150,000 patients per year in the U.S. require mechanical ventilation for an acute exacerbation of COPD (AECOPD), a rapid worsening of lung function, commonly triggered by a bacterial or viral infection. Intensive care unit (ICU) admission for AECOPD is associated with a 10-day average hospital stay and greater than 20% mortality within the following year. Current therapy is largely supportive, including mechanical ventilation, standard bronchodilators and antibiotics as clinically indicated.

Systemic Drug Delivery

In addition to our focus on pulmonary drug delivery in the acute care setting, we pursue systemic drug input via the pulmonary route on an opportunistic basis. The physiology of the lungs makes pulmonary delivery an attractive method for delivery of drugs to the bloodstream. The absorptive surface area of the deep lung in the adult approximates 70 square meters, and is only one to two cells in thickness. This large

surface area is available for the free exchange of oxygen, carbon dioxide and other molecules between the air and the bloodstream. This permits drugs deposited in the deep lung to be transported rapidly into the bloodstream.

Pulmonary drug delivery is being evaluated for non-invasive delivery of drugs to the bloodstream to treat non-respiratory diseases. There is increasing interest in pulmonary drug delivery as a result of the inability of currently available, non-injectable dosage forms to deliver molecules such as proteins and peptides to the bloodstream effectively. For these large molecules, oral delivery is ineffective due to rapid breakdown of the molecules following ingestion. Dosage forms such as intravenous or intramuscular injections and implants, while effective for delivering proteins and peptides, have many drawbacks, including pain, inconvenience, expense, risk of infection and poor compliance. Alternatives like transdermal and nasal dosage forms do not generally allow reproducible delivery of large molecules. We believe that systemic drug delivery of biotechnology products via the lungs may provide significant market opportunities**.** For example, pulmonary delivery is being considered for drugs such as insulin, which require rapid input to the bloodstream for optimal therapy.

Methods for Pulmonary Drug Delivery and Their Limitations

Three basic classifications of devices are currently being used for pulmonary drug delivery: metered dose inhalers (MDIs), dry powder inhalers (DPIs), and nebulizers. These devices were developed originally for local treatment of respiratory diseases, including asthma and COPD, and have inherent limitations in delivering drugs to the lungs. Metered dose inhalers consist of a portable canister containing the drug as a suspension or solution mixed with a volatile propellant, traditionally a chlorofluorocarbon. In order to administer the drug, the patient must activate the inhaler by pressing down on the canister while simultaneously inhaling slowly and evenly. Even with repeat training, many patients using MDIs have difficulty coordinating activation of the device with their breathing. Once the inhaler is activated, particles are released at an initial velocity of at least 30 miles per hour. Metered dose inhalers typically deliver only 10% to 20% of the drug to the lungs. Newer hydrofluoralkane (HFA) versions deliver a higher percentage of the dose, but are available for a few drug formulations. Most of the remainder of the drug is deposited in the mouth and swallowed. To overcome these limitations, patients are sometimes prescribed holding chambers, or spacers, to use with their MDIs. These spacers increase the complexity of use and reduce the portability of MDIs. In the acute care setting, for patients on ventilators, MDIs are used by opening the ventilator circuit and spraying medication into the tubing via a spacer. It takes several actuations for a metered-dose inhaler, over several minutes, timed with inhalation, to deliver the dose levels typically prescribed for a patient in the ICU. This requires significant time and the associated expense of an attendant respiratory therapist. Available formulations are limited mainly to bronchodilators and steroids.

Traditional DPIs were introduced to overcome some of the problems inherent with the use of MDIs. Dry powder inhalers deliver dry powdered aerosols without using a compressed propellant. Dry powder inhalers are breath activated and thus eliminate the need for the press and breath coordination associated with use of MDIs; however, traditional DPIs have meaningful limitations that may prevent their broad use in pulmonary drug delivery. Dry powder inhalers usually require a strong, deep inhalation to create the air velocity that generates the aerosol and delivers the drug. Children, the elderly and patients with breathing difficulties often cannot achieve the strong inhalation necessary to generate the required dose. In addition, these devices do not allow the patient to inhale the desired drug in multiple breaths, and moisture entering into the dry powder inhaler from the environment, or a patient s own breath, can result in dose-to-dose variation. Because there is no mechanism in ventilator circuits for actuating DPIs, they are not used to administer drugs to the lungs of patients on ventilators in clinical practice.

Traditional nebulizers create a continuous liquid aerosol that can be inhaled by patients through a mask or mouthpiece. With the use of a nebulizer, patients can breathe normally, thereby requiring less

patient coordination and cooperation than use of MDIs or DPIs. Traditional jet nebulizers typically require an external source of compressed air or oxygen and are therefore bulky and noisy. Nebulizer treatments are time-consuming and inefficient, with less than 20% of the drug typically reaching the lungs in ambulatory patients. The remainder of the drug is either aerosolized during the patient s exhalation and released into the surrounding air, or it is left behind in the nebulizer. Because of these limitations, traditional nebulizers are only appropriate for relatively inexpensive, small-molecule drugs that can be formulated and stored as liquids. In the acute care setting, jet nebulizers are used to introduce aerosol into the ventilator circuit for inhalation by the patient.

The use of jet nebulizers results in introduction of additional air into a ventilator circuit, disturbing the precise control of air pressures used to ventilate patients and to monitor their pulmonary function. Perhaps most significantly, these delivery devices are inefficient, resulting in only a very small amount of the drug dose (1% to 3%) ever reaching the patient s lungs. Ultrasonic nebulizers (which rely on droplets breaking free from standing waves at the surface of the drug solution) are more efficient than jet nebulizers, but are expensive, heat the administered drug and are unable to nebulize suspensions.

To date there has been little emphasis on improving the efficiency of pulmonary drug delivery in the hospital setting. Of the $3.5 billion in annual drug sales for respiratory indications in the ICU, the overwhelming majority represents use of intravenous formulations. Few drugs, other than generic bronchodilators, are given via the pulmonary route due to the inefficiency and lack of reproducibility of currently available devices in delivering drugs to the lungs.

Our Core Technology and Marketed Products

OnQ Aerosol Generator

The OnQ Aerosol Generator technology produces liquid aerosol via a mechanism called an electronic micropump, comprising a domed aperture plate that contains over 1,000 tapered apertures, or holes, of a discrete shape and size. The aperture plate is produced through an electroforming process using a metal alloy. The aperture plate is surrounded by a vibrational element that, when energy is applied to this element, causes the aperture plate to vibrate over 100,000 times per second. This creates a micro-pumping action that draws drug solutions or suspensions in contact with the concave surface of the plate through the apertures to form a low velocity, fine droplet aerosol. The aerosol droplet size formed is determined by the size of the holes in the aperture plate, and the flow rate is controlled by the voltage and frequency applied to the vibrational element. A controllable manufacturing process is used to produce aperture plates with selected hole sizes that result in aerosol droplets of a predetermined size. When the OnQ Aerosol Generator is incorporated into one of our nebulizers or inhalers, it is capable of producing consistently sized, high-quality respirable aerosols, which can be optimized for a specific indication.

We have demonstrated the ability to aerosolize solutions and suspensions of drugs of both small and large molecular weight. Results to date indicate that the OnQ technology does not affect the integrity of proteins or peptides.

Benefits of Our Technology

- *Optimization and Customization of Aerosol Droplet Size.* The OnQ Aerosol Generator delivers a low-velocity liquid aerosol of precisely defined average droplet size. It enables us to provide aerosols with droplets ranging from one to three microns MMAD in diameter for deposition in the deep lung for systemic drug delivery or three to five microns MMAD in diameter for respiratory therapy.

- *Ease of Formulation.* Drugs can be aerosolized in solution or suspension. The OnQ Aerosol Generator uses no propellants or pressure, and generates negligible heat. We have evaluated the

OnQ Aerosol Generator with a wide range of drugs, proteins and peptides and have thus far not observed any degradation or any other adverse impact on drug integrity. In many cases, we can use existing drug formulations, eliminating the need to demonstrate the stability of new formulations.

- *Flexibility of Dosing.* The OnQ Aerosol Generator can be used for the administration of drugs as a single dose, or as a unit dose from a multi-dose canister. For example, our Aerodose insulin inhaler contains a titration mechanism, developed with Ypsomed (formerly Disetronic Medical Systems), which allows a diabetic patient to deliver a specific dose of insulin from a glass cartridge designed to hold up to two weeks of inhaleable insulin for the average Type 2 diabetic patient.

- *Breath-Activation.* We have developed a breath-activation feature that triggers aerosol formation and is designed to enable a broad range of patients to obtain consistent dosing over one or more breaths. This feature is designed so that drug will be aerosolized only when the patient s inhalation flow rate has reached a predetermined threshold, which can be pre-programmed for a particular target patient population. If a patient exhales or coughs, the aerosolization will stop and will only resume when the patient begins inhaling again. Our electronic controls are designed to allow us to customize products for both relaxed and controlled breathing.

- *Dosage Guidance.* We can incorporate electronic features to provide information to the patient or respiratory attendant. Lights can indicate when a dose is ready for inhalation and when the total dose has been inhaled. Audible/vibratory signals can be used to indicate other system modes. Additional features may include indicators of patient compliance with the prescribed regimen and lockout features to prevent abuse or overdose.

- *Convenience.* Our products are designed to be lightweight and easy for patients and care-providers to use. Aerodose inhalers fit in the palm of the hand and can be carried in a shirt pocket or small purse. We believe our products will require minimal patient or clinician training, are easy to assemble and use and offer the potential to improve clinical outcomes and to increase compliance with prescribed treatment regimens. The Aeroneb Go Nebulizer is designed to be faster, easier to use and more efficient than currently commercialized nebulizers. The Aeroneb Professional Nebulizer System is lightweight and provides efficient generation of aerosol close to the lung.

Our OnQ Aerosol Generator has been incorporated into our nebulizers and inhalers. Since 2002, much of our effort has been directed to streamlining and improving the manufacturing processes for our OnQ technology. We also undertook development of a lower cost OnQ using components similar to those used in our commercially available nebulizers, but with a changed configuration. This new OnQ Aerosol Generator is incorporated into the Aeroneb Go and the Aeroneb Pro.

Our Nebulizer Products

Aeroneb Go Nebulizer. Our newest commercial product, the Aeroneb Go Nebulizer, was CE marked in July 2003 and received 510(k) clearance from the FDA in November 2003. This product replaces the Aeroneb Portable Nebulizer System in the home market.

The Aeroneb Go is a fast, efficient, simple-to-use nebulizer developed for the millions of patients worldwide who require respiratory therapy in and away from home. The product was designed to eliminate many of the problems associated with current methods of medication delivery when using nebulizers. Unlike many compressor, ultrasonic, or mesh-based nebulizers, the Aeroneb Go allows patients to complete their treatments quickly, and delivers a high-quality respirable aerosol.

In June 2003, we made initial commercial shipments of the product to Norway via our distributor Normed, as part of a test market. In September 2003, we entered into an agreement with Evo Medical Solutions (Evo), formerly Medical Industries America Inc. for marketing and manufacturing of the Aeroneb Go, under which Evo has exclusive rights to manufacture and market the product in the United

States and certain countries worldwide. In connection with our agreement with Evo, we received upfront payments from Evo totaling $2.5 million in 2003; in addition, Aerogen is supplying its OnQ Aerosol Generators to Evo under a transfer pricing arrangement, and Evo will pay us royalties on its gross sales of the Aeroneb Go and on Evo s sales of accessories. First commercial shipments occurred in the United States in January 2004.

Aeroneb Professional Nebulizer System. The Aeroneb Professional Nebulizer System was introduced worldwide in June 2002. The product is CE marked in Europe and received 510(k) clearance in the United States as a nebulizer intended to aerosolize physician-prescribed solutions for inhalation approved for general-purpose nebulization. The product is the first significant advance in more than 20 years in respiratory drug therapy specifically for patients on ventilators in the hospital, and is designed to improve the efficiency of drug delivery and reduce personnel and drug costs associated with inpatient care, particularly for patients on ventilators. Use of the Aeroneb Pro System on the ventilator increases the efficiency of drug deposition in the lungs of patients when compared *in vitro* with use of small volume jet nebulizers. The Aeroneb Pro is flexible because it can be used not only on the ventilator, but also in the hospital or in an ambulance, and it can also be used with both adult and children s masks. The device is autoclaveable, so it is suitable for multi-patient use, and its low residual volume allows efficient drug delivery to the lungs. The Aeroneb Pro System is small and lightweight, allowing it to be positioned close to the patient s airway and is designed to allow the addition of medication to the nebulizer without opening the ventilator tubing, thereby potentially reducing a major source of infection. The drug is aerosolized without the use of compressed air and therefore avoids the introduction of additional air and pressure into the ventilator circuit.

We have worldwide agreements with ventilator manufacturers, including Puritan Bennett (PB), Maquet, and Respironics, under which they sell the Aeroneb Pro System with certain of their ventilators. We also have an agreement with Cardinal Health under which Cardinal s Respiratory Care Products Group sales force is marketing the product to ICUs in the United States. These ICUs represent an installed base of approximately 100,000 ventilators from several manufacturers. In Europe, we have agreements with additional distributors on a country-by-country basis, who are targeting the installed base of ventilators in those countries.

Aerogen has entered into a worldwide, non-exclusive supply agreement with Datex-Ohmeda, Inc., a division of Instrumentarium, which was acquired by GE Healthcare in October 2003. Under the agreement, Aerogen is supplying GE Healthcare with a customized version of the Aeroneb Pro for integration into future products designed for critical care. GE Healthcare launched their first two critical care products incorporating Aerogen technology in the fourth quarter of 2004.

Aerogen s sales of the Aeroneb Pro System were approximately $3.5 million, $3.0 million and $1.6 million in 2004, 2003 and 2002, respectively. The product was launched in June 2002, and is now available in over 30 countries.

Finally, we have developed a version of the Aeroneb Pro specifically for use in pre-clinical research and inhalation studies, marketed as the Aeroneb® Lab (Aeroneb Lab).

Sales of our OnQ and Aeroneb products accounted for 71%, 77% and 75% of our total revenues in 2004, 2003, and 2002, respectively.

Our Drug Product Pipeline

We intend to incorporate our versatile and flexible OnQ technology into a portfolio of devices and drug products, some to be developed for commercialization by us, and some to be developed with partners who will market the product themselves. We also intend to continue to out-license our technology for applications outside of the field of pulmonary drug delivery.

Aerogen Products Under Development for Treatment of Respiratory Disorders

We intend to create and market in the United States a respiratory product portfolio consisting of pharmaceutical products that incorporate our Pulmonary Drug Delivery System (PDDS) for delivery of drug-containing aerosols to patients in the acute care setting.

Our activities for therapeutic products to be marketed by Aerogen is focused on product development, clinical testing, regulatory approval and commercialization within the United States. The rights to these products outside the United States will most likely be licensed to partners who will undertake the studies and other activities necessary to obtain regulatory approvals in their territories.

We are developing Aerogen s PDDS as a proprietary platform for the high-efficiency delivery of aerosolized drugs to the lungs of patients on ventilators in the acute-care setting. The PDDS comprises a unique software-driven controller, which is capable of sensing the performance of a ventilator and aerosolizing the drug during a predetermined portion of the ventilator cycle, alternatively, it can be breath-activated for use in extubated patients. In addition, the PDDS incorporates an OnQ Aerosol Generator with a particle size that has been customized for the individual therapeutic application. Initial *in vitro* studies document lung deposition of drug that is typically greater than 60% of the administered dose. This product has been CE marked in Europe, for use in our Phase 2 clinical trial to deliver amikacin. We do not intend to market the PDDS as a stand-alone device, as we intend to use it exclusively for our drug/device combination products in the acute care setting.

Aerosolized Antibiotics. Our lead combination product is our PDDS with the aminoglycoside amikacin, under development to address the large unmet need for more effective treatment of VAP. Aminoglycosides, as a class of antibiotics, are effective in treating pulmonary infections associated with gram-negative organisms, such as *Pseudomonas aeruginosa,* when administered systemically. However, they penetrate poorly from the blood to the lung relative to other classes of antibiotics, and often cause unwanted systemic toxicities (including damage to kidneys and hearing). The potential to administer aerosolized amikacin allows for the possibility of more effectively treating VAP while minimizing the toxicity associated with systemically administered aminoglycosides.

Our aerosolized amikacin PDDS completed its first Phase 2 study in France in 2003. In this study, we compared drug deposition in the lungs of 12 ventilated patients in which a preservative-free solution of amikacin was administered by three different devices: a first generation clinical version of the PDDS, the commercially available Aeroneb Pro System and the commercially available Airlife Misty-Neb nebulizer. This particular formulation has been associated with off-label use administered by aerosol for treatment of pulmonary infections in children with cystic fibrosis. The study confirmed the higher efficiency of the PDDS versus the two comparator devices.

The second Phase 2 clinical trial with this product was initiated on December 28, 2004, and 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 a majority of our sites open, and 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. Until all sites are open and we observe steady enrollment, we will be unable to reliably project the completion date of the trial. In light of the fact that we currently have no patients enrolled in this study, we are uncertain at this time when the study will be completed, if at all.

Other Product Development Opportunities

We are evaluating various drugs, including generically available drugs and proprietary drugs in-licensed or available for in-licensing from third parties, for development as Aerogen drug/device

combination products with our PDDS. Drug development opportunities in the acute care setting include treatment of neonatal pulmonary hypertension (with prostacyclins), asthma (with bronchodilators and anti-inflammatory agents), COPD (with protease inhibitors, phosphodiesterase inhibitors, mucoactive agents) and ARDS (protease inhibitors, anti-coagulative agents, inhibitors of fibrosis).

Our Product Development Process

Feasibility is the first stage of development for our drug products. In the feasibility stage, we determine the solubility of the drug, the type of solution or suspension we would likely need in order to use the drug in our inhalers or nebulizers, our ability to aerosolize the drug and the likely stability of the drug when used with our nebulizers or inhalers. In this stage, we conduct laboratory studies primarily focused on the drug itself, and its compatibility with the OnQ Aerosol Generator.

During the preclinical development stage, we focus on the customization of our nebulizer or inhaler for use with a particular drug. We determine the appropriate container to hold the drug in the nebulizer or inhaler, the method of delivery of the drug to be aerosolized, the type of breath-activation mechanism or ventilator sensing algorithm that is likely to be needed and the configuration of the aperture plate for the product. Preclinical development is conducted primarily in the laboratory and is targeted toward development and the initial production of the nebulizer or inhaler to be used in the clinical studies.

After feasibility testing and preclinical development, the products are tested in human subjects. Our products are combinations of discrete devices and drugs, and therefore the regulatory pathway, and the clinical programs that will be required for product approvals are complex due to the presence of both drug and device elements in our products. As the regulatory requirements are discussed in detail with the United States Food and Drug Administration (FDA) and clarified, it is possible that certain products will be less attractive commercial targets for Aerogen marketing than others. For example, in 2001 and 2002, we were developing products to deliver albuterol and ipratropium via our hand-held Aerodose respiratory inhaler for home use. Based on regulatory feedback that such products would most likely require a New Drug Application (NDA), we have put these products on hold due to the likely need for costly clinical programs and the extended time to regulatory approval for generic drug products delivered from a new device. In December of 2002, the FDA established the Office of Combination Products to streamline the regulatory life cycle of combination products, however, the jurisdictional questions and regulatory approaches are still to be defined. The Aerodose respiratory inhaler developed for these programs has proven of interest for partnered activities where partners have proprietary drugs for treatment of either a respiratory problem or for systemic drug input that will require an NDA.

Partnered Drug Development Activities

We are collaborating, and intend to continue to collaborate, with pharmaceutical and biotechnology companies to develop novel pulmonary drug delivery products for respiratory therapy and for systemic drug input via the pulmonary route. Such collaborations can take one of two approaches: either a company contacts us with a proprietary drug to be delivered to the lungs, or we proactively identify product opportunities and approach potential partners after obtaining preclinical data, if possible.

Respiratory Therapy

The flexibility of our technology to facilitate improved respiratory therapy has attracted potential development partners. We currently have feasibility activities underway with potential partners with undisclosed compounds for respiratory therapy and systemic drug input. A feasibility study can be paid for by us or by the partner company. Generally, development agreements and the associated activities can be canceled at any time by the company funding the work. In the drug delivery area, it is common for pharmaceutical and biotechnology companies to conduct feasibility studies with multiple partners. Once feasibility of a particular drug has been established, the pharmaceutical and biotechnology companies

typically fund additional development work. Following collaborative development of a product, the partner will typically commercialize the product and pay us a royalty on the partner s sales.

We signed a collaborative agreement in July 2002 with Discovery Laboratories, Inc. (Discovery Labs) to explore pulmonary delivery of aerosolized human surfactant in the hospital setting. Aerosolized surfactant has the potential for treatment of many respiratory conditions. The preclinical data developed as a result of our agreement with Discovery Labs has indicated that our technology can effectively aerosolize surfactant while maintaining the integrity of the formulation.

In 2002, we signed a Cooperative Research and Development Agreement with the United States Army for pulmonary delivery of novel vaccines (subsequently amended to include antiviral applications). Initial preclinical work was done by the United States Army Medical Research Institute for Infectious Diseases (USAMRIID). In addition, grant proposals for aerosol research on both vaccines and antiviral agents were submitted to USAMRIID. Both were favorably reviewed, but funding for the proposals is not currently available.

In March 2005, we signed an agreement with Biota Holdings Ltd. for the development of CS-8958, one of the new LANI (long-acting neuraminidase inhibitor) compounds being developed by Biota and Sankyo, suitable for use with Aerogen s proprietary Aeroneb Go.

Our Aerodose inhalers and our Aeroneb nebulizers are all customizable for use with partner drugs in programs funded by the partners, and these devices can be, and have been, made available for different preclinical and clinical programs.

Systemic Drug Delivery

In addition to our respiratory therapy activities, our strategy includes collaborating with pharmaceutical and biotechnology companies to develop novel pulmonary drug delivery products for systemic therapy.

We have developed an Aerodose inhaler for delivery of insulin to diabetic patients. The Aerodose insulin inhaler is designed to utilize a patient-adjustable titration cartridge for pulmonary delivery of insulin, allowing patients to precisely adjust their insulin dose based on anticipated carbohydrate intake and other factors. The titration mechanism was developed in conjunction with Ypsomed.

Phase 1 clinical studies using prototype Aerodose inhalers delivering insulin were conducted in the United Kingdom and Germany and were completed in 2000. The studies compared insulin inhalation to subcutaneous injection, focusing on both the absorption of insulin into the bloodstream and its glucose-lowering effects. Subjects used Aerodose inhalers configured for slow, deep inhalations and production of a small-droplet aerosol appropriate for systemic drug delivery. Results from the first study indicated that the absorption and glucose-lowering effects of inhaled insulin, relative to injected insulin, were consistent with the effects reported in the published literature for other inhaled insulin dosage forms. In the second study, optimal aerosolization parameters were defined, resulting in the selection of a final design for our commercial version of the inhaler.

Phase 2 trials were initiated in Europe and the United States in 2000, and completed in 2001. These studies were designed to provide additional evidence of Aerodose inhaler performance, inter- and intra-subject variability and dose proportionality of circulating levels of insulin following inhalation in Type 2 (non-insulin dependent) diabetic patients. The results indicated that delivery of insulin into the bloodstream by inhalation was no more variable within a patient than when insulin was delivered subcutaneously to the same patient, and that inhaled insulin performed consistently, across a broad dose-range, relative to injected insulin. In the four studies we have completed, there were no serious adverse events or clinically significant differences in lung function between the inhaled and subcutaneous treatments.

We have an agreement with Diosynth B.V., a business unit of Akzo Nobel, for the supply of clinical and commercial quantities of recombinant human insulin for use in the product. We successfully completed our design verification testing for the Aerodose insulin inhaler during 2002. In December 2003, Aerogen s high-concentration insulin formulation met stability requirements through twelve months of testing. Stability studies have been completed.

We believe that the nature of the diabetes market requires a major pharmaceutical company partner with a diabetes franchise to effectively market the product. In late 2002, it became apparent that we would be unable to partner our inhaled insulin product under appropriate financial terms hence we halted development of the product. We may revisit that decision once clarity as to the overall safety of inhaled insulin is provided by the companies who are developing the leading inhaled insulin product.

Technology Out-licensing

Our aerosol generator technology has proven to be of value to industries focused outside the field of pulmonary drug delivery. In 1999, we entered into an exclusive license agreement with a worldwide consumer company permitting it to use a modified version of the aerosol generator in the fields of air fresheners and insect repellants. Under the license agreement, we receive minimum annual payments and, in the third quarter of 2004, began to earn royalties based on net sales of units and refills above a certain threshold. The license also gives us access to any improvements in the technology made by the consumer company during the conduct of its development and manufacturing activities. The first product covered by the agreement was launched outside the United States in January 2003, which triggered an increase in the minimum royalty payments to Aerogen, and additional countries were launched in 2004, increasing our royalty receipts. We will continue to explore out-licensing opportunities for our technologies outside the field of pulmonary drug delivery.

Research and Development Spending

During 2004, 2003 and 2002 we spent approximately $11.2 million, $11.5 million and $17.4 million, respectively, on our own research and development activities, and approximately none, $0.2 million and $0.4 million in 2004, 2003 and 2002, respectively, for customer-sponsored research and development activities.

Manufacturing

We plan to manufacture our OnQ Aerosol Generators and outsource the manufacture of the other components used in our products. We manufacture the aperture plates and assemble the OnQs at our Mountain View, California facility. We design the remaining components of our products, such as molded parts and electronic circuitry, and outsource the manufacture and/or assembly of these parts to qualified vendors. The manufacture of cartridges and sterile drug filling will also be outsourced, minimizing the need for capital investment in specialized drug filling facilities. The Aeroneb Pro is assembled for us by outside vendors in Ireland. The Aeroneb Go is manufactured and assembled by Evo for markets in North America and Japan.

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.

Sales and Marketing

The Aeroneb Pro is sold to United States hospitals by Cardinal Health, and by major ventilator Original Equipment Manufacturers (OEMs) including Maquet**,** Respironics, GE Healthcare and Puritan Bennett. Outside the United States, we have agreements with independent distributors on a country-by-country basis, and also with ventilator OEMs mentioned above. We generally intend to maintain the marketing rights for our acute care respiratory drug products in the United States and to commercialize the products in other countries through marketing partners or distributors. Products developed in collaboration with partner companies will generally be commercialized by the partners.

The Aeroneb Go Nebulizer is sold by Evo in the United States to home medical equipment dealers and pharmacies. Evo currently markets the Aeroneb Go outside of the United States, in Canada, France and Japan. Aerogen also sells the Aeroneb Go through its independent distributors in Norway, Sweden, Greece, Ireland and Switzerland.

Competition

There is intense competition in our target markets. 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, which is currently dominated by injectable dosage forms, our competition includes companies providing oral, buccal, intranasal, transdermal and colonic absorption delivery technologies. 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.

The pulmonary drug delivery market, in particular, is intensely competitive. Several companies, including Alkermes, Inc., Aradigm Corporation, Battelle Pharma, PARI, Microdose, Respironics, Mannkind and Nektar Therapeutics, are developing competing pulmonary drug delivery dosage forms. These competing dosage forms typically are designed to treat respiratory disorders or to deliver drugs systemically. We also face competition from existing pulmonary drug delivery dosage forms such as MDIs, DPIs and nebulizers, which have been used effectively to treat respiratory diseases in certain patient populations for years. There can be no assurance that competitors will not develop and introduce products or technologies that are competitive with, or superior to, ours.

Some of our products are expected to be more expensive than MDIs and currently available DPIs, as the products are expected to provide significant advantages over currently marketed devices, and are packaged in different dosage forms. It is difficult to predict whether, and to what extent, our products will be reimbursed by insurance companies, health maintenance organizations or government healthcare providers. In addition, although we believe that physicians are likely to recommend our products to their patients, it is impossible to predict to what extent or how quickly this may occur.

Most competitors have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do. Accordingly, they may succeed in developing competing products and technologies, obtaining regulatory approval for products or gaining market acceptance more rapidly than we can. We believe that our products will not only compete on the basis of efficacy, but also on patient convenience, efficiency, dose reproducibility, safety and cost.

Intellectual Property and Proprietary Rights

Our ability to compete effectively depends in part on developing and maintaining the proprietary aspects of our aerosolization technology. As of December 31, 2004, we held 26 issued United States patents and 11 issued international patents. In addition, we had 19 pending United States patent applications and 35 pending international patent applications as of that date. None of the issued patents expire earlier than 2011. Our patents are directed at, among other things, the following: (i) apparatus and methods for generating aerosols, including vibrating dome technology in which liquid is drawn through tiny tapered holes in the dome to be emitted as a mist of controlled droplet size and speed; (ii) particular aspects of aperture plate dome construction and use; and (iii) particular embodiments of our aerosolization devices, including pressure assisting breathing systems for use in the hospital. The pending patent applications include coverage for numerous improvements on the fundamental aspects of our aerosolization technology.

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. In 1999, we prevailed in a United States Patent and Trademark Office (the USPTO) patent interference involving United States Patent No. 5,261,601, assigned to Bespak, plc. The USPTO granted all but one of the independent claims of Bespak s 5,261,601 patent to Aerogen which issued in Aerogen s United States patent 6,629,646. A settlement between Aerogen and Bespak provided a cross-license arrangement from which Aerogen has a license to 5,261,601 s equivalent patents in foreign countries and Bespak received a license to the same patent in the United States. The scope of the granted license was limited to products employing technology that was disclosed by Bespak in United States Patent No. 5,261,601. The license does not extend to any of our technology that was not disclosed in this patent. 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 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.

At the time of commencement of employment, our international employees generally sign offer letters specifying basic terms and conditions of employment. In general, our United States employees are not subject to written employment agreements. Each of our employees has, however, entered into a standard confidential information and invention assignment agreement that provides that the employee will not disclose any of our confidential information received during the course of their employment and that, with some limited exceptions, the employee will assign to us any and all inventions conceived or developed during the course of employment.

Government Regulation

Our products are subject to extensive regulation by numerous governmental authorities, principally the FDA in the United States, as well as numerous state and foreign regulatory agencies. We need to obtain clearance of our device products by the FDA before we can begin marketing our products in the United States. Similar requirements or approvals generally are required in other countries before our products can be marketed in those countries.

Product development and approval within this regulatory framework is uncertain, can be unpredictable with respect to review times and requires substantial resources. The nature and extent of the governmental premarket review process or requirements for our products will vary depending on the regulatory categorization of particular products. Because our products may be characterized as devices, drugs or biologics, the regulatory approval path will not be the same for all of our device products.

Those of our products that are regulated as medical devices will be classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. The class for any particular product, as follows, will determine the regulatory route:

- *Class I:* General controls, e.g., labeling, premarket notification, if not exempted, and adherence to the quality system regulation (QSR);
- *Class II:* General controls and special controls, (e.g., performance standards and postmarket surveillance); and
- *Class III:* Premarket approval.

Device Regulatory Premarket Requirements in the United States. Before a new device can be marketed, its manufacturer must obtain marketing clearance through either a premarket notification under Section 510(k) of the United States Federal Food, Drug and Cosmetic Act or approval of a premarket approval application.

510(k) clearance. A 510(k) clearance typically will be granted if a company establishes that its device is substantially equivalent to a legally marketed Class I or II medical device, or to a Class III device that was on the market prior to 1976 for which the FDA has not required the submission of a premarket approval application. A 510(k) clearance must contain information to support the claim of substantial equivalence, which may include laboratory test results or the results of other studies. Commercial distribution of a device subject to the 510(k) requirement may begin only after the FDA issues an order finding the device to be substantially equivalent to a predicate device. It generally takes from three to twelve months from the date of submission to obtain clearance of a 510(k) submission, but it may take longer. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, that additional information is needed before a substantial equivalence determination may be made, or that the product must be approved through the premarket approval process. An FDA determination of not substantially equivalent, a request for additional information, or the requirement that a premarket approval application be filed could delay market introduction of products that fall into this category. Furthermore, for any devices cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, require new 510(k) submissions. We received 510(k) clearance for the Aeroneb® Portable Nebulizer System, the Aeroneb Professional Nebulizer System and the Aeroneb Go Nebulizer, and we expect that future similar nebulizer products will also proceed through the 510(k) clearance route.

Premarket approval. If a device does not qualify for the 510(k) premarket notification procedure, a company must file a premarket approval application. The premarket approval application requires more extensive pre-filing testing than required for a 510(k) premarket notification, and usually involves a

significantly longer review process. A premarket approval application must be supported by valid scientific evidence that typically includes extensive data, including preclinical and clinical trial data, to demonstrate the safety and efficacy of the device. If clinical trials are required, and the device presents a significant risk, an investigational device exemption (IDE) application must be filed with the FDA and must be approved before a clinical trial begins. The IDE must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin if the FDA and the appropriate institutional review boards both approve the IDE. Trials must be conducted in conformance with FDA regulations and the institutional review boards requirements. The sponsor or the FDA may suspend the trials at any time if it is believed that they pose unacceptable health risks, or if the FDA finds deficiencies in the way that they are being conducted. Data from clinical trials are often subject to varying interpretations that could delay, limit or prevent FDA approval. If the device presents a nonsignificant risk to trial subjects, clinical trials may begin on the basis of appropriate institutional review board approval.

A premarket approval application may be denied if applicable regulatory criteria are not satisfied, or the FDA may impose certain conditions upon the applicant, such as postmarket testing and surveillance. The premarket approval application process can be expensive, uncertain and lengthy, and approvals may not be granted. A number of third parties devices for which premarket approval has been sought have never been approved for marketing. After approval, a new application or a supplement is required if certain modifications are made to the device, its labeling or its manufacture.

New Drug Application and Biologics License Application (BLA). New chemical entities or biologics will be regulated as such and premarket approval will be required. If a specific inhaler or nebulizer is designed to be used in combination with the new chemical entity or biologic, it will need to be included in the application. The combination of an already-approved drug or biologic with an already-approved device may be treated in the same regulatory manner. If clinical studies of such drugs or drug-device combinations used in humans are required by the FDA, then an IND will be required before those studies can be initiated in the United States. Approval of an NDA, or a BLA, will be required before the product can be marketed. In addition to reports of the preclinical and clinical trials conducted under an effective IND application, the NDA or BLA would include information pertaining to the preparation of the drug substance, the manufacture of the inhaler or nebulizer, analytical methods, details on the manufacture of finished products and proposed packaging and labeling. Submission of an NDA or BLA does not assure FDA approval for marketing. The application process generally takes several years to complete. The process may take substantially longer if, among other things, the FDA has questions or concerns about the safety or efficacy of a product. In general, the FDA requires at least two properly conducted, prospective, randomized double-blinded and well-controlled clinical studies demonstrating efficacy with sufficient levels of statistical assurance. The process for approval of products regulated as drugs and biologics outside the United States is similar to the NDA/BLA process within the United States. For partner products that incorporate drugs or biologics, we anticipate that an NDA or BLA will be required in addition to, or separate from, any 510(k) clearance that we may be required to obtain.

There can be no assurance that approval for any of our products will be granted on a timely basis, or at all. Notwithstanding the submission of safety and efficacy data, the FDA ultimately may decide that the application does not satisfy all of its regulatory criteria for approval. The FDA also may require additional clinical tests (i.e., Phase 4 clinical trials) following the NDA or BLA approval to confirm safety and efficacy. These studies can often extend for years after a product s launch. Upon approval, a product may only be marketed for the approved indications.

In addition, the FDA may in some circumstances impose restrictions on the use of a product that may be difficult and expensive. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. The FDA also requires reporting of certain safety and other information that becomes known to a manufacturer of an approved product.

European Union Clearance of Devices. Commercialization of medical devices in the European Union is regulated under a system which presently requires that all medical devices sold in the European Union bear the CE mark, an international symbol of adherence to quality assurance standards, demonstrated fulfillment of the essential requirement and clinical effectiveness. Medical devices are classified in accordance with Annex IX of the Medical Device Directive (MDD). The classification determines which conformity assessment procedure the manufacturer must follow in order to affix the CE mark on its products. In 2001, we obtained the CE mark for the Aeroneb Pro, and in 2002 we received the CE mark for our clinical PDDS, which we used in our Amikacin clinical study in France. In July 2003 the Aeroneb Go Nebulizer was CE marked. We cannot be certain that we will obtain a CE mark, or that we will not have delays in obtaining a CE mark, for any other product.

Post-Approval Requirements. Regulatory approval, if granted, may entail limitations on the indicated uses for which a product may be marketed, and product approvals, once granted, may be withdrawn if problems occur after initial marketing. Manufacturers of FDA-regulated products are subject to pervasive and continuing governmental regulation, including extensive recordkeeping requirements and reporting of adverse experiences associated with product use. Compliance with these requirements is costly, and failure to comply properly can result in withdrawal of a product approval.

Good Manufacturing Practices. We will be required to adhere to applicable FDA cGMP as set forth in the QSR, which include testing, controls and documentation requirements. Other countries have similar requirements. Failure to comply with these and other applicable regulatory requirements may result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to review pending marketing clearances or approval applications, withdrawal of marketing clearances or approvals and criminal prosecution.

Hazardous materials. Our operations involve use of hazardous and toxic materials and generate hazardous, toxic and other wastes. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for using, handling, storing and disposing of such materials comply with these standards required by state and federal laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials.

Employees

We had approximately 74 employees as of December 31, 2004. Approximately 19 of those employees are located at our Irish facility. Our employees are not represented by a collective bargaining agreement. All employees are eligible to participate in an employee stock option plan and generally receive options vesting over a four-year period at the time they join the Company, and subsequent options that generally vest over three to four years. We had approximately 88 employees at the beginning of 2003. We reduced our workforce on January 3, 2003 by 22 employees in connection with a restructuring. In January 2004, we announced a furlough of nine employees, seven of which were subsequently terminated in March 2004. We believe our relations with our employees are good.

Executive Officers

Name	Age	Position
Jane E. Shaw, Ph.D.	66	Chief Executive Officer and Chairman of the Board of Directors
Yehuda Ivri	53	Chief Technical Officer, Director and Founder
Robert S. Breuil	43	Chief Financial Officer, Vice President, Corporate Development
Robert S. Fishman, M.D.	43	Vice President, Scientific Affairs
Nancy Isaac	43	Vice President, Regulatory Affairs and Quality
John S. Power	45	Managing Director Aerogen (Ireland) Limited and Senior Vice President, Sales
Angela Strand	36	Vice President, Marketing
Mauro Folena	45	Vice President, Operations

Jane E. Shaw, Ph.D., has served as Chairman of our Board of Directors and as our Chief Executive Officer since 1998. Dr. Shaw held various scientific and management positions with ALZA Corporation, a pharmaceutical company, from 1970 to 1994, most recently as President and Chief Operating Officer from 1987 to 1994. Dr. Shaw received a B.Sc. and Ph.D. in Physiology from Birmingham University in England. Dr. Shaw serves as a director of OfficeMax Corporation, Intel Corporation, and McKesson Corporation.

Yehuda Ivri, founded Aerogen in 1991 and has served as a member of our Board of Directors since its inception. Mr. Ivri has served as our Chief Technical Officer since 1996 and previously was our Chief Scientist and Vice President. Mr. Ivri received an M.S. in Mechanical Engineering from the Technion-Israel Institute of Technology.

Robert S. Breuil, Chief Financial Officer, Vice President Corporate Development, joined Aerogen in April 2002 as Vice President, Corporate Development. In July 2002 Mr. Breuil was appointed Chief Financial Officer. Prior to joining Aerogen, Mr. Breuil was employed by ALZA Corporation from 1994 to 2002, where he served in numerous leadership positions including Controller of ALZA Pharmaceuticals and Director of Corporate Planning and Analysis. Prior to joining ALZA, Mr. Breuil served for eight years as a Naval Officer and Aviator. Mr. Breuil received a B.S. in Electrical Engineering at the United States Naval Academy and an M.B.A. from the Stanford Graduate School of Business.

Robert S. Fishman, M.D. F.C.C.P., Vice President, Scientific Affairs, joined Aerogen in June 1998 as Director of Clinical Operations and was promoted to Vice President of Clinical Operations in 2001. He assumed the expanded role of Vice President of Scientific Affairs in July 2002. Prior to joining Aerogen, Dr. Fishman was Director of Clinical Affairs at Heartport, Inc. where he led the clinical trials, medical monitoring, and clinical training development functions. Prior to Heartport, he was Assistant Professor of Medicine at Stanford University and was Associate Medical Director of the Stanford Lung and Heart-Lung Transplant Program. He received an A.B. in Biology from Harvard University and an M.D. from Stanford University School of Medicine, and completed his fellowship training in pulmonary and critical care medicine at Massachusetts General Hospital. Dr. Fishman continues to teach respiratory physiology at Stanford. He is a Fellow of the American College of Chest Physicians and a member of the American Thoracic Society.

Nancy Isaac, J.D., M.P.H., Vice President, Regulatory Affairs and Quality, joined Aerogen in July 2002. Prior to joining Aerogen she was with BD Biosciences, a business segment of Becton, Dickenson & Company, from 1989 to 1993 and returned after graduate school from 1997 to 2002 in various regulatory capacities, and finally as Worldwide Vice President, Regulatory and Quality. Ms. Isaac

has also held regulatory positions at Genzyme Corporation and SYVA. Ms. Isaac received a J.D. from Boston University, a Masters in Public Health from Harvard University, and a Bachelor of Science in Cell and Molecular Biology from San Francisco State University. She is also a member of the State Bar of California.

John Power, Managing Director and Senior Vice President, Sales, has served as Senior Vice President, Sales since August 2002 and as Vice President, European Operations and Managing Director, Aerogen (Ireland) Limited since May 2000. Mr. Power was the founder and Managing Director of Cerus Limited (now Aerogen (Ireland) Limited), from 1998 to 2000. Mr. Power was Engineering Manager in Mechanical Development at Nellcor Puritan Bennett from 1993 to 1997, and an engineering consultant to various companies from 1988 to 1992. Registered with I. Eng. status from UK Engineering Council, Mr. Power holds qualifications in both Computer Mechanical and Production Engineering and an MBA from Oxford Brookes University, Oxford, England.

Angela Strand, Vice President, Marketing, joined Aerogen in November 2000. Prior to joining Aerogen, Ms. Strand served from 1999 to 2000 as Vice President of Marketing for Novacept, a women s healthcare company recently acquired by Cytyc, and Vice President of Sales and Marketing for eCliniq, an internet-based healthcare software concern. Following graduate school in 1992 through 1999, she served in leadership positions with Baxter Healthcare and FemRx, a women s healthcare company acquired by Johnson & Johnson. Ms. Strand received a B. S. with high honors in Communications and an M.B.A. in marketing and finance, both from the University of Tennessee.

Mauro J. Folena, Vice President of Operations, joined Aerogen in February 2005. Prior to joining Aerogen, Mr. Folena was Director of Operations for Honeywell International, from 2001 to 2004, where he led a multi-site pressure sensor manufacturing operation. Prior to his years at Honeywell, Mr. Folena was employed by National Semiconductor from 1977 to 1998, where he worked in the field of equipment engineering, and development of high volume manufacturing operations. Mr. Folena received a bachelor s degree in Information Systems Management from the University of San Francisco and is a Certified Instructor in Total Productive Maintenance (T.P.M.) from the Japan Institute of Plant Maintenance.

Corporate Disclosures

Our Web site address is *www.aerogen.com*. We make available free of charge through our Web site, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to these reports as soon as reasonably practicable after filing, by providing a hyperlink directly to our reports. Information contained on our website is not a part of this report. We make available free of charge, on or through out website s investor relations page, our Code of Ethics. You may read and copy materials that Aerogen files with the SEC at the SEC s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site at http://www.sec.gov that contains reports, proxy and information statements, and other information.

Certain Financial Information

As of December 31, 2004, 2003 and 2002, 82%, 88% and 73%, respectively, of our long-lived assets were maintained in the United States. For the years ended December 31, 2004, 2003 and 2002, 40%, 22% and 29%, respectively, of our consolidated revenues were generated in the United States.

Item 2. PROPERTIES

Our United States operations are currently located in a single 32,148 square foot building in Mountain View, CA. We conduct our manufacturing activities in this facility. The lease on this space was amended in November 2003 to defer a significant portion of our rent during a two-year period to be paid during the last six years of the lease in exchange for the issuance of 60,000 shares of common stock to our landlord, and again in March 2004, to, among other things, reduce our occupancy to 32,148 square feet, reduce the term of the lease to five years and to reduce our rental expense in exchange for cash payments, forfeiture of our security deposit and the issuance of 50,000 shares of common stock to our landlord. See Exhibits 10.12.1 and 10.12.2 for a full description of these two amendments.

Aerogen (Ireland) Limited leases a laboratory and office facility of approximately 2,500 square feet in Galway, Ireland on a lease that will expire on December 31, 2006. In early 2002 we entered into a 980-year land lease with the Irish Development Agency for approximately $220,000. We estimate a new facility on the site would cost approximately $1.5 million. We do not have final plans for the building of the facility; when we do, it would likely be financed through a mortgage on the property, guaranteed by us, with the remainder provided by us in the form of a loan to our subsidiary.

Item 3. 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.

PART II

Item 5. MARKET FOR REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Stock Listing, Trading and Dividend Policy

Our common stock traded on the Nasdaq Stock Market® under the symbol AEGN from November 10, 2000 to December 26, 2002, and has been listed on the Nasdaq SmallCap Market since December 26, 2002. The high and low sales price for 2003 and 2004 adjusted for the October 31, 2003 one-for-five reverse stock split are as follows:

	High	Low
Q1 03	$ 2.50	$ 0.25
Q2 03	$ 5.00	$ 0.75
Q3 03	$ 6.40	$ 1.55
Q4 03	$ 5.30	$ 1.65
Q1 04	$ 4.00	$ 2.16
Q2 04	$ 3.80	$ 2.41
Q3 04	$ 3.22	$ 1.79
Q4 04	$ 2.49	$ 1.53

As of March 25, 2004, there were approximately 195 holders of record of our common stock. We have not paid any dividends on our common stock and have no present intention to do so, as we expect to continue investing in our business, and incurring losses, for several years.

Under the terms of our Series A-1 Preferred Stock, holders as of the last day of each calendar quarter are entitled to dividends, payable in cash or common stock at the Company s election. The value of these quarterly dividends has been, and is currently, $0.45 per share of Series A-1 Preferred Stock. If the Company elects to pay these dividends in common stock, the number of common shares currently payable on each share of Series A-1 Preferred Stock is equal to $0.45 divided by the closing price of the common stock on the last trading day of each quarter. The Company has elected to pay this dividend with the Company s common stock for each quarter of 2004, and has issued a total of 613,921 common shares for payment of the 2004 dividends through March 25, 2005.

Equity Compensation Plan Information

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2004.

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights (a)	Weighted average exercise price of outstanding options and rights (b)	Number of securities available for future issuance under equity compensation plans (excluding securities in column (a)
Equity compensation plans approved by security holders(1)(2)(3)	4,083,401	$ 3.60	3,462,898
Equity compensation plans not approved by security holders	0		0

(1) Consists of Aerogen s 2000 Equity Incentive Plan, 2000 Non-Employee Directors Stock Option Plan, 2000 Employee Stock Purchase Plan, 1996 Amended and Restated Stock Plan and 1994 Amended and Restated Stock Plan.

(2) The 2000 Equity Incentive Plan has a provision for increasing the number of shares available for the grant of options on an annual basis by a number of shares equal to the least of (i) 4.5% of the then outstanding shares of common stock on a fully diluted basis, (ii) 400,000 shares, or (iii) a lesser number of shares determined by Aerogen s Board of Directors. In 2004, the Board of Directors increased the number of shares available for grant under the 2000 Equity Incentive Plan by 40,000 shares pursuant to this provision, and, in addition, authorized an additional 4,515,309 shares for issuance under the plan, which was subsequently approved by Aerogen stockholders.

(3) The 2000 Employee Stock Purchase Plan has a provision for increasing the number of shares available for purchase under the plan on an annual basis by a number equal to the least of (i) 1.0% of the then outstanding shares of common stock on a fully diluted basis, (ii) 50,000 shares, or (iii) a lesser number of shares determined by Aerogen s Board of Directors. In 2004, the Board of Directors and the stockholders of Aerogen approved an increase in the number of shares available for grant under the 2000 Employee Stock Purchase Plan by an additional 1,589,752 shares.

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations (Item 7 of this Form 10-K) and the Consolidated Financial Statements and Supplementary Data (Item 8 of this Form 10-K). The consolidated financial data for periods prior to the periods covered by the consolidated financial statements included in Item 8 of this Form 10-K are derived from audited consolidated financial statements not included in this document.

	For the years ended, December 31,				
	2004	2003	2002	2001	2000
Consolidated Statement of Operations Data:					
Total revenues	$ 6,248	$ 4,171	$ 2,532	$ 2,469	$ 5,832
Costs and expenses:					
Cost of products sold	4,051	2,296	1,786	285	
Research and development	11,185	11,744	17,772	21,698	16,219
Selling, general and administrative	6,789	6,507	8,382	8,138	4,143
Purchased in-process research and development					3,500
Litigation settlement				2,000	
Total costs and expenses	22,025	20,547	27,940	32,121	23,862
Loss from operations	(15,777)	(16,376)	(25,408)	(29,652)	(18,030)
Interest and other income (expense), net	5,703	(1,043)	497	2,250	1,160
Net loss	(10,074)	(17,419)	(24,911)	(27,402)	(16,870)
Dividend related to beneficial conversion feature of preferred stock	(13,097)				(16,517)
Net loss attributable to common stockholders	$ (23,171)	$ (17,419)	$ (24,911)	$ (27,402)	$ (33,387)
Net loss per common share attributable to common stockholders, basic and diluted	$ (4.86)	$ (4.22)	$ (6.17)	$ (6.96)	$ (36.49)
Shares used in computing net loss per common share attrubutable to common stockholders, basic and diluted	4,765	4,126	4,036	3,936	915

	December 31,				
	2004	2003	2002	2001	2000
Consolidated Balance Sheet Data:					
Cash, cash equivalents and available-for-sale securities	$ 16,883	$ 762	$ 8,887	$ 36,077	$ 60,976
Working capital	15,315	(2,181)	8,679	33,457	60,639
Total assets	25,755	9,576	19,194	43,468	66,712
Warrant liability	10,296				
Long-term obligations, less current portion	267	246	205	212	184
Redeemable convertible preferred stock	15,749				
Accumulated deficit	(119,545)	(109,471)	(92,052)	(67,141)	(39,739)
Total stockholders equity (deficit)	(7,149)	1,680	15,744	38,531	64,228

Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the related notes included in Item 8 of this Form 10-K. This discussion may contain forward-looking statements that involve risks and uncertainty. We undertake no duty to update these forward-looking statements. Should events occur subsequent to the filing of this Form 10-K that require us to update the forward-looking information contained in this Form 10-K, the updated information will be filed with the SEC in a quarterly report on Form 10-Q or a Form 8-K, or disclosed in a press release. As a result of many factors, including those set forth under Risk Factors and elsewhere in this Form 10-K, our actual results may differ materially from those anticipated in any forward-looking statements.

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 marketing by, pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs through the lungs to the bloodstream.

In 2004, we had two nebulizer products on the market. We have an accumulated deficit of approximately $119.5 million as of December 31, 2004. In 2002, we generated significant revenues from our planned principal operations and 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.

In June 2001 we launched our first commercial product, the Aeroneb Portable Nebulizer System, a simple, compact and silent nebulizer for use in the home setting. In June 2002 we launched the Aeroneb Professional Nebulizer System, developed for use in a hospital setting including the treatment of patients on ventilators. In January 2004, the Aeroneb Go Nebulizer was launched in the United States by our commercial partner Evo. All of our products incorporate a version of our proprietary OnQ aerosol generator. Since the launch of the first Aeroneb product, we have recorded cumulative revenues of $9.7 million associated with sales of the Aeroneb products and component parts as of December 31, 2004. Prior to our agreement with Evo, the Aeroneb Portable Nebulizer System had been promoted in the United States by a small sales force under contract from a division of Cardinal Health, and by several home medical equipment distributors. The Aeroneb Pro is available in over 30 countries worldwide under agreements with ventilator OEMs including Maquet, Respironics, Tyco-Puritan Bennett and GE Healthcare, as well as independent distributors, including Cardinal Health, in the United States and select countries.

In June 2003, we made initial commercial shipments of our Aeroneb Go product to Norway, via our distributor Normed, as part of a test market. In September 2003, we entered into an agreement with Evo for marketing and manufacturing of the Aeroneb Go, under which Evo has exclusive rights to manufacture and market the product in the United States and certain countries worldwide. In connection with our

agreement with Evo, we received upfront payments from Evo totaling $2.5 million in 2003; in addition, Aerogen is supplying its OnQ Aerosol Generators to Evo under a transfer pricing arrangement, and Evo will pay us royalties on its gross sales of the Aeroneb Go and related accessories. First commercial shipments occurred in the United States in January 2004, and in Japan during the third quarter of 2004.

We perform feasibility and initial development work to customize our nebulizers and inhalers to deliver specific drugs, for our own account or under agreement with third parties who compensate us for expenses incurred in performing this work. Once feasibility is demonstrated for a potential product, we may seek to enter into a development agreement with the corporate partner holding the commercial rights to the compound to be used in the product, under which we would expect to receive reimbursement from partners for our fully-burdened development expenses incurred under approved work plans, and royalties on future total product sales similar collaborations, and royalties based on our partner s sales of products, if and when commercialized. We recognize research and development revenues as reimbursable research and development expenses are incurred. We also expect to receive revenue from products that we manufacture and we expect to out-license marketing and/or manufacturing rights to products or territories that do not fit within our area of commercial focus.

The Company s lead pharmaceutical product under development for its own account is a drug/device combination product which delivers the aminoglycoside amikacin to the lungs for treatment of Ventilator-Associated Pneumonia (VAP). The second Phase 2 clinical trial with this product was initiated on December 28, 2004, and 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 a majority of our sites open, and 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. Until all sites are open and we observe steady enrollment, we will be unable to reliably project the completion date of the trial. In light of the fact that we currently have no patients enrolled in this study, we are uncertain at this time when the study will be completed, if at all.

We have incurred stock-based compensation expenses of $0.3 million, $1.0 million and $1.4 million, for the years ended December 31, 2004, 2003 and 2002, respectively. Stock-based compensation included in research and development expenses was $0.1 million, $0.3 million and $0.5 million for the years ended December 31, 2004, 2003 and 2002, respectively. Stock-based compensation included in selling, general and administrative expenses was $0.2 million, $0.7 million and $0.9 million, respectively, for the years ended December 31, 2004, 2002 and 2001. As of December 31, 2004, there was no remaining deferred stock-based compensation. We anticipate incurring additional stock-based compensation expense in the future as a result of fluctuations in the market value of our common stock, which will continue to have a direct impact on the value of common stock options held by non-employees.

We had federal and state net operating loss carry forwards of approximately $82.4 million and $35.4 million, respectively, as of December 31, 2004. We also had aggregate federal and state research and development tax credit carryforwards of approximately $2.2 million and $2.3 million, respectively, as of December 31, 2004. The net operating loss and credit carryforwards will expire, if not utilized, in various amounts beginning in 2009 for federal purposes and 2005 for state purposes. Due to the uncertainty regarding the ultimate utilization of the net operating loss and credit carryforwards, we have not recorded any benefit for losses, and a valuation allowance has been recorded for the entire amount of the net deferred tax asset. Utilization of net operating losses and credits may be substantially limited by the change in ownership provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before they can be used.

During 2002, we had two reductions in force, one in January and one in June, involving the termination of a total of 48 employees. The prospective annualized payroll related savings resulting from

the reductions in force was $3.9 million, the majority of which was in research and development. Severance-related costs were $0.3 million, all of which was expensed and paid during 2002. In December 2002, we began a restructuring, which included the suspension of further development of our Aerodose insulin inhaler, followed by an additional reduction in force in January 2003 terminating 22 employees with an annualized payroll related savings of $2.3 million. Severance-related costs were $0.2 million, all of which was expensed and paid during the quarter ending March 31, 2003. In January 2004, we announced a furlough of nine employees, seven of which were subsequently terminated on March 22, 2004. Severance-related costs were $0.2 million.

Critical Accounting Policies and Estimates

Aerogen s discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including inventories, bad debts, intangible assets (including goodwill), warranty obligations, contingencies and litigation. We base our estimates on assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We have an Irish subsidiary, which accounted for approximately 7% of our net loss for the year ended December 31, 2004 and 21% of our assets and 16% of our total liabilities as of December 31, 2004. In preparing our consolidated financial statements, we are required to translate the financial statements of the foreign subsidiary from the currency in which it keeps its accounting records into United States dollars. Under the relevant accounting guidance, the treatment of these gains or losses is dependent upon our determination of the functional currency. The determination of the functional currency is based on our judgment and involves consideration of all relevant economic facts and circumstance affecting the subsidiary. Based on our assessment, we consider our Irish subsidiary s local currency, the Euro, to be the functional currency.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

- We write down our inventory for estimated obsolescence or unmarketable inventory in an amount equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required.

- We provide for the estimated cost of product warranty at the time revenue is recognized. While we engage in product quality programs and processes, including actively monitoring and evaluating the quality of our component suppliers, our warranty obligation is affected by product failure rates, material usage and delivery costs incurred in correcting any product failure. Should actual product failure rates or material usage differ from our estimates, revisions to the estimated warranty liability would be required.

- We record revenues from product sales at the time of product shipment, provided an enforceable claim exists, any significant rights to return product have expired and collection of the receivable is probable. To date, we have made minor discounts to revenue for one customer program or incentive offering, which was done at the time of the sale to this customer. If we determined to take additional actions to initiate such incentive offerings, such action might result in a reduction of revenue at the time the incentive is offered. Our assessment of the facts at a given time may result

in revenues being recorded in a period other than what they would have been, based on actual subsequent events.

- We record revenue from royalties arrangements when we are able to estimate the amounts due, which generally is when they are reported to us. Prior to that time, we may not have the ability to accurately estimate the royalties due to us. As a result, we may record the revenue in a period subsequent to when the related sales have occurred.

- We review the need for an allowance for doubtful accounts for estimated losses resulting from the failure of our customers to make required payments. If conditions change, additional allowances may be required.

- Currently, we have established a full valuation allowance with respect to all of our deferred tax assets. Changes in our estimates of future taxable income may cause us to reverse the valuation allowance. Subsequently, we would report income tax expenses in amounts approximating the statutory rates.

- We recognize royalties on our sales to Evo based on their sales of the Aeroneb Go. In addition, we received up-front payments totaling $2.5 million, which we are amortizing as royalty revenue on a straight-line basis over the 5-year term of the agreement.

- The value of our warrant liability resulting from the A-1 Financing is adjusted to its then-estimated fair value at the end of each reporting period based on a valuation model. Increases or decreases are reflected as non-operating expense or income, respectively, on the statement of operations. Changes in the assumptions used to estimate the value could cause the recorded liability of the warrants to change. Increases in our stock price could cause the recorded value of the warrants to increase significantly, which would result in us recording a non-operating expense in the period of the change. Such changes in the future are likely to be material.

- We record a deemed dividend related to the beneficial conversion feature of convertible securities when there is a difference between the conversion price and the fair market value, if any, of the convertible securities on the commitment date (transaction date). The convertible securities include provisions which could cause the conversion rate to change in the event of future equity issuances of the Company. If this occurs, the Company would record additional deemed dividends on the convertible securities.

- In accordance with Statement of Financial Accounting Standards (SFAS) No. 142 Goodwill and Other Intangible Assets (SFAS 142), we perform an annual assessment for impairment of our goodwill by applying a fair-value-based test. Future events could lead us to conclude that the recorded value of our goodwill has been impaired.

Results of Operations

Comparison of years ended December 31, 2004, 2003 and 2002

Product sales. Product sales were $4.4 million in 2004, $3.2 million in 2003 and $1.9 million in 2002. We launched the Aeroneb Pro in June 2002. The increase in product sales in 2003 over 2002 was due to a full year of sales for the Aeroneb Pro in 2003. The increase in product sales in 2004 over 2003 was due to continued increases in our sales of the Aeroneb Pro, as well as sales of our OnQ Aerosol Generators to Evo Medical Solutions (Evo formerly Medical Industries America) during the first two quarters of 2004.

Research and development revenues. There were no research and development revenues for the year ended December 31, 2004. Research and development revenues were $0.3 million in 2003 and $0.4 million in 2002. The revenue decrease in 2003 compared with 2002 resulted from the ending of the Puritan Bennett contract in 2002. Research and development revenues can be expected to vary from period to

26

period based on the activities requested by partners in any particular period, and therefore are not predictable.

Royalty and other revenues. Royalty and other revenues were $1.8 million in 2004, $0.6 million in 2003 and $0.3 million in 2002. The increase in royalty and other revenue in 2004 over 2003 was partially due to up-front payments associated with the September 2003 agreement with Evo, which resulted in amortization of $0.5 million during the year ended 2004, compared to $0.1 million in 2003. During the first two quarters of 2004, royalties of $0.3 million were recognized on Evo s first commercial shipments of the Aeroneb®, which pays royalties on its gross product and accessory sales. In addition, royalty revenue from a consumer company that has licensed our aerosol technology for use in the field of air fresheners and insect repellants, has increased to $1.0 million in 2004, compared to $0.5 million in 2003, and $0.2 million in 2002, and is expected to increase substantially again in 2005. An additional increase in royalty and other revenue in 2003 over 2002 was due to up front payments associated with the September 2003 commercial agreement with Evo, which resulted in $0.1 million of amortization in 2003, related to the $2.5 million in upfront payments which are being amortized ratably over the five year term of the agreement.

Cost of products sold. Cost of products sold was $4.1 million in 2004, $2.3 million in 2003 and $1.8 million in 2002. In 2004 the average cost of sales was 91%, compared to 72% in 2003 and 95% in 2002. In 2004, the average cost of sales was higher than in 2003, due to the low yields related to the start of commercial manufacturing of the OnQ Aerosol Generator for sale to Evo. In addition, we recognized a reserve of $100,000 against cost of goods sold for potential costs related to Aerogen s support of the Evo risk mitigation plan, implemented in response to the FDA s Class II, firm-initiated recall of Evo s Aeroneb Go product. In 2003, the average cost of sales was lower than in 2002 due to the change in product mix, and to improvements in our manufacturing processes. In 2002, the cost of products sold was high as a percentage of product sales due primarily to low yields early in the year associated with the start-up of the commercial manufacturing processes and the move to the new facility in Mountain View, California. During the second half of 2002, we saw improved margins as volumes increased and as we completed our move into our new facility, which incorporates more automated manufacturing processes and improved environmental controls. We anticipate that costs per unit will decrease over time as volumes increase, and as we refine our manufacturing processes and focus on cost reductions.

Research and development expenses. Research and development expenses were $11.2 million in 2004, $11.7 million in 2003 and $17.8 million in 2002. The decrease in research and development expenses of $0.5 million in 2004 was primarily due to a reduction of $1.0 million in facilities related expenses, reduced payroll and related expenses of $0.4 million associated with reductions in force in 2003, a decrease of $0.2 million related to decreased stock compensation expense, and a decrease of $1.3 million in research and development spending related to absorbed manufacturing costs as we began commercial operations and increased our sales. These reductions were partially offset by increased spending of $2.4 million related to preparations for a Phase 2 clinical trial for our aerosolized antibiotic product. The decrease in research and development expenses of $6.1 million in 2003 compared with 2002 was primarily due to a reduction of $3.4 million in payroll-related expenses and $0.2 million in stock compensation expenses associated with the reductions in force, a reduction of $1.4 million in expenses associated with a halt of the development of the commercial version of the Aerodose insulin inhaler, reductions of $0.3 million in expense associated with the completion of the development of an Aerodose respiratory inhaler, reductions in facility related expenses of $0.2 million, and other spending reductions of $0.7 million, partially offset by increased spending in clinical trials of our aerosolized antibiotic product of $0.2 million. During the quarter ended March 31, 2003, we reduced our headcount in research and development by seventeen. Costs associated with terminating these individuals were $0.1 million based on a severance package calculated on length of service. We expect spending for research and development in 2005 to increase as we complete our Phase 2 clinical trial of our aerosolized antibiotic product, and prepare for a Phase 3 clinical trial.

Research and development expenses relate to our own research and development projects, as well as the costs related to development activities for our partners. Development expenses for partner activities approximate 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, in each case including related overhead. We expect research and development spending to increase over the next several years as we increase clinical activities and expand our research and development activities in support of our products and those which we develop in partner collaborations. The increase in research and development expenditures cannot be predicted reliably, as it depends in part upon our success in entering into new partnering agreements and the timing of development and clinical activities that are largely controlled by our partners.

Selling, general and administrative expenses. Selling, general and administrative expenses were $6.8 million in 2004, $6.5 million in 2003 and $8.4 million in 2002. The increase of $0.3 million in selling, general and administrative expenses was primarily due to an increase in outside legal expenses of $0.6 million, and an increase in audit and tax service fees of $0.1 million, partially offset by a decrease in stock compensation expense of $0.5 million. The decrease in selling, general and administrative expense for 2003 as compared to 2002 was primarily due to reductions in payroll related expenses of $1.1 million and $0.2 million in stock compensation expenses associated with the reduction in force, reductions in trade shows and advertising expenses of $0.1 million, and reductions in outside services of $0.8 million, partially offset by a $0.6 million increase in legal expenses and a $0.2 million increase in insurance expense. During the quarter ended March 31, 2003, we reduced our headcount in selling, general and administration by five. Costs associated with terminating these individuals were approximately $39,000 based on a severance package calculated on length of service. We expect spending for selling, general and administration in 2005 to be comparable to 2004.

Interest and other income, net. Net interest expense was $0.4 million in 2004, compared with $1.0 million of net interest expense in 2003 and $0.5 million of net interest income in 2002. Interest expense in 2004 was primarily related to imputed interest, totaling $0.4 million, resulting from the beneficial conversion feature of the convertible debenture and the value associated with the warrant issued to the Carpenter Family Trust in 2004, as well as interest paid on all debentures of $0.1 million. Interest expense, totaling $1.0 million, in 2003 is primarily due to imputed interest resulting from the beneficial conversion feature of the convertible debenture and the value associated with the warrants issued to SF Capital in 2003. There was no interest expense in 2002. Interest income in 2004 was $0.2 million compared with $0.1 million in 2002 and $0.5 million in 2002. The increase in interest income in 2004 compared to 2003 is primarily due to higher average cash and investment balances, and to a lesser extent, higher interest rates. The decrease in interest income in 2003 compared to 2002 is primarily due to lower average cash and investment balances, and to a lesser extent, lower interest rates.

Decrease in warrant liability. The issuance in the first closing of Series A-1 Convertible Preferred Stock on March 23, 2004 included warrants to purchase 4,999,810 shares of common stock, and the second closing on May 12, 2004 included warrants to purchase 6,249,580 shares of common stock. The aggregate fair value of the warrants on their issuance dates totaled $16.1 million, and 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 year ended December 31, 2004, the aggregate fair value of the warrants decreased to $10.3 million, resulting in a gain of $5.8 million.

Dividends related to Convertible Preferred Stock. We record a deemed dividend related to the beneficial conversion feature of convertible securities when there is a difference between the proceeds allocated to the preferred stock and the transaction date fair value of the common stock issuable upon conversion, in an amount not to exceed the proceeds allocated to the preferred stock in the transaction. For the year ended December 31, 2004, a total deemed dividend of $11.7 million was reflected in our net

loss attributable to common stockholders. 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 twelve months ended December 31, 2004 cumulative dividends of $1.4 million had been accrued on the A-1 Preferred, and these dividends have all been paid through the issuance of an aggregate of 613,921 shares of the Company s common stock.

We report segments in accordance with SFAS No. 131, Disclosures About Segments of an Enterprise and Related Information. SFAS 131 requires the use of a management approach in identifying segments of an enterprise. The Company consists of one operating segment.

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 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 December 31, 2004, Aerogen had cash and cash equivalents of approximately $16.9 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 on 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 to continue operations. Licensing or collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to either certain of our products or technologies or desirable marketing territories, or all of these.

Net cash used in operating activities for the year ended December 31, 2004 was $14.5 million, primarily due to the operating loss of $10.1 million, payments to our landlord totaling $1.6 million in connection with the restructuring of our Mountain View, CA facility lease, comprising past due rent, security deposit and rent reduction fees, and non-cash operating expenses of $2.7 million. Net cash used in operating activities for the year ended December 31, 2003, was $9.9 million, primarily due to the operating loss of $17.4 million, partially offset by an increase in deferred revenue of $2.2 million, depreciation expense of $1.3 million, amortization of stock based compensation of $1.0 million, amortization of discounts on notes of $1.0 million and deferred rent of $0.8 million. Net cash used in operating activities for the year ended December 31, 2002, was $24.0 million, primarily due to the net operating loss of $24.9 million and the payment of accrued liabilities of $1.9 million, partially offset by the amortization of stock based compensation of $1.4 million, and depreciation of $1.2 million.

Net cash used by investing activities for the year ended December 31, 2004 was $0.8 million and was due to the acquisition of property and equipment related to manufacturing process improvements. Net cash provided by investing activities for the year ended December 31, 2003 was $5.2 million and was due to the maturity of available-for-sale securities of $5.6 million, partially offset by $0.4 million for acquisition of property and equipment. Net cash provided by investing activities for the year ended December 31, 2002 was $11.0 million and was due to the maturity of available-for-sale securities of $22.8 million, partially offset by $8.1 million for the purchase of available-for-sale securities and $3.7 million for acquisition of property and equipment.

Net cash provided by financing activities was $31.4 million, $2.1 million, and $0.5 million, for the years ended December 31, 2004, 2003 and 2002, respectively. In 2004, $30.9 million was provided from the issuance of preferred stock and warrants related to the sale of Series A-1 Convertible Preferred Stock and associated common stock warrants, and $0.8 million in net proceeds from the issuance of debentures and convertible debentures, partially offset by the repayment of a $0.3 million debenture. In 2003, $2.0 million was provided by the sale of two separate convertible debentures, and a minimal amount was provided by purchases of common stock under our employee stock purchase plan. In 2002, approximately $0.5 million was provided almost equally by repayment of earlier loans to stockholder/executives, and by purchases of common stock under our employee stock purchase plan.

The development of our technology and future products requires a commitment of substantial funds to conduct the costly and time-consuming research, development and clinical trials required to develop and refine our technology and future products and to bring those 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, manufacturing and marketing costs associated with commercialization of our products, costs involved in obtaining and maintaining patents, and our ability to enter into and maintain collaborative agreements.

We currently have no material commitment for capital expenditures. We lease our Mountain View, CA facility under a non-cancelable operating lease, expiring in February 2009. Future minimum payments due under this lease are as follows:

	Total (in thousands)	One Year And Less	One to Three Years	Three to Five Years	More than Five Years
Operating Lease	$ 4,587	$ 990	$ 3,404	$ 193	$

These minimum payments include a reasonable estimate of future common area maintenance charges.

In addition, we have a commitment of approximately $267,000 to Irish investors under a tax advantaged Business Expansion Scheme (as that term is defined under Irish tax law) that must be repaid out of the operating profits, if any, of our Irish subsidiary.

Our long-term liquidity also depends upon our ability to attract and maintain collaborative relationships, to increase revenues from the sale of our products, to develop and market new products and ultimately, to achieve profitability.

As of December 31, 2004, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE 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. Our cash and cash equivalents are invested in money market funds and are generally of a short-term nature. Due to the short term nature of these investments, 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 exchange rates. The revenues and expenses of our subsidiary, Aerogen (Ireland) Limited, are denominated in its local currency. The Irish subsidiary s functional currency is the Euro (previously the Irish punt). At the end of each period, the revenues and expenses of our subsidiary are translated into United States dollars using the average currency 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. 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 purposes.

If 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 may adjust our policies to allow for financial hedging techniques to minimize exchange rate risk.

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 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 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.

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 have owned 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 indeed 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 seeking, negotiating, or making their investment in the Company, and consider themselves to be independent investors. Due to the termination of our rights plan, there can be no assurance that further concentration of ownership will not occur, or that these securities will not be resold to different investors who may or may not act as a group.

The conversion of our 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 will substantially dilute the ownership interests of existing common stockholders.

If the A-1 Preferred stockholders were to exercise all of the common stock warrants they hold and convert all of the shares of A-1 Preferred they owned as of 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 will 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 December 31, 2004, we have incurred an accumulated deficit of approximately $119.5 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. 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 as of December 31, 2004, 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. However, as of December 31, 2004, management has 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;

35

- public concern as to the safety of drugs and drug delivery technologies, including those of our competitors;
- period-to-period fluctuations in financial results; and
- economic and other external factors.

Our common stock is currently trading at a market price significantly below the initial public offering price. There can be no assurance that the price will increase in the future or will recover to the initial public offering price. Furthermore, 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/or other additional clinical trials will prove the safety and effectiveness of our product. We have not secured an agreement with a marketing partner to fund the additional development and clinical trials necessary to obtain regulatory approval and to commercialize the product; therefore we have not yet resumed our work on that product, and do not expect to re-start the program until we have an acceptable partner to pay for additional clinical trials. We cannot assure that we will ever be able to enter into a satisfactory agreement with a marketing partner, and we currently do not have sufficient funds to conduct the necessary development and clinical programs ourselves.

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

Our ability to become a successful specialty pharmaceutical company depends upon our ability to commercialize our own combination drug/device products, the majority of which will incorporate our Pulmonary Drug Delivery System (PDDS). Although our PDDS leverages the basic technology platform of the Aeroneb Pro, 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.

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, 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 which delivers the aminoglycoside amikacin to the lungs 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 a majority of our sites open, and 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. Until all sites are open and we observe steady enrollment, we will be unable to reliably project the completion date of the trial. In light of the fact that we currently have no patients enrolled in this study, we are uncertain at this time when the study will be completed, 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 has indicated a desire to retire.

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. 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 Medical Solutions, Inc. (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 with ten observations, and which was followed by a warning letter concerning the Aeroneb Go. In response to the warning letter, Evo voluntarily suspended shipments of the Aeroneb Go 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 goods 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. 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. The Aeroneb Pro is not currently reimbursed by insurance or government entities, which may limit its market penetration. 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 granted additional extensions through February, 2005. PARI assumed control over the nullity case from TTP on December 14, 2004. The decision on the mullity 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 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

AEROGEN, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Aerogen, Inc.

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Aerogen, Inc. and its subsidiary (the Company) at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

PricewaterhouseCoopers LLP
San Jose, California
March 31, 2005

AEROGEN, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2004	2003
	(In thousands, except per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,883	$ 762
Accounts receivable	1,225	445
Inventories, net	775	301
Prepaid expenses and other current assets	942	428
Total current assets	19,825	1,936
Property and equipment, net	2,964	3,901
Goodwill	1,951	1,796
Intangible assets	147	135
Restricted cash		1,200
Other assets	868	608
Total assets	$ 25,755	$ 9,576
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,043	$ 937
Deferred revenue, current	500	500
Dividends payable	1,094	
Convertible debentures, net		1,486
Accrued liabilities	1,873	1,194
Total current liabilities	4,510	4,117
Deferred rent	234	1,658
Deferred revenue, non-current	1,848	1,875
Warrant liability	10,296	
Other long-term liabilities	267	246
Total liabilities	17,155	7,896
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock, par value $0.001		
Authorized: 5,000 shares; issued and outstanding:		
1,099 and no shares at December 31, 2004 and 2003		
(Liquidation preference: $32,963 at December 31, 2004)	15,749	
Stockholders equity (deficit):		
Common stock, par value $0.001:		
Authorized: 95,000 shares; issued and outstanding:		
5,318 and 4,396 shares at December 31, 2004 and 2003, respectively	6	4
Additional paid-in capital	111,691	110,991
Notes receivable from stockholders	(292)	(280)
Deferred stock-based compensation, net		(264)
Accumulated other comprehensive income (loss)	991	700
Accumulated deficit	(119,545)	(109,471)
Total stockholders equity (deficit)	(7,149)	1,680
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 25,755	$ 9,576

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

AEROGEN, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2004	**2003**	**2002**
	(In thousands, except per share amounts)		
Revenues:			
Product sales	$ 4,428	$ 3,198	$ 1,896
Research and development		348	386
Royalty and other	1,820	625	250
Total revenues	6,248	4,171	2,532
Costs and expenses:			
Cost of products sold	4,051	2,296	1,786
Research and development(1)	11,185	11,744	17,772
Selling, general and administrative(2)	6,789	6,507	8,382
Total costs and expenses	22,025	20,547	27,940
Loss from operations	(15,777)	(16,376)	(25,408)
Interest income (expense), net	(372)	(996)	487
Decrease in warrant liability	5,840		
Other income (expense), net	235	(47)	10
Net loss	(10,074)	(17,419)	(24,911)
Dividends related to redeemable convertible preferred stock (Note 7)	(13,097)		
Net loss attributable to common stockholders (Note 7)	$ (23,171)	$ (17,419)	$ (24,911)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.86)	$ (4.22)	$ (6.17)
Shares used in computing net loss per share attributable to common stockholders, basic and diluted	4,765	4,126	4,036

(1) Including stock-based compensation expense of $103,000, $304,000 and $514,000 in 2004, 2003 and 2002, respectively.

(2) Including stock-based compensation expense of $169,000, $702,000 and $841,000 in 2004, 2003 and 2002, respectively.

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

AEROGEN, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

	Common Stock Shares (in thousands)	Amount	Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balances, December 31, 2001	4,029	$ 4	$ 110,444	$ (693)	$ (4,069)	$ (14)	$ (67,141)	$ 38,531
Repayment of notes receivable from stockholders				285				285
Issuance of common stock pursuant to employee stock purchase plan for cash	50		260					260
Issuance of common stock upon exercise of stock options for cash	4		10					10
Repurchase of common stock	(2)		(7)					(7)
Deferred stock-based compensation			(1,194)		1,194			
Stock-based compensation					1,355			1,355
Accrued interest on notes receivable from stockholders				(26)				(26)
Changes in unrealized loss on available-for-sale securities						(50)		(50)
Foreign currency translation						297		297
Net loss							(24,911)	(24,911)
Balances, December 31, 2002	4,081	$ 4	$ 109,513	$ (434)	$ (1,520)	$ 233	$ (92,052)	$ 15,744

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

AEROGEN, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

	Common Stock Shares (in thousands)	Amount	Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balances, December 31, 2002	4,081	4	109,513	(434)	(1,520)	233	(92,052)	15,744
Issuance of warrants			529					529
Beneficial conversion feature related to issuance of convertible debentures			593					593
Issuance of common stock upon conversion of convertible debentures	230		402					402
Issuance of common stock to landlord	60		180					180
Repayment of notes receivable from stockholders				167				167
Issuance of common stock pursuant to employee stock purchase plan for cash	25		22					22
Issuance of common stock upon exercise of stock options for cash			2					2
Repurchase of common stock								
Deferred stock-based compensation			(250)		250			
Stock-based compensation					1,006			1,006
Accrued interest on notes receivable from stockholders				(13)				(13)
Changes in unrealized loss on available-for-sale securities						(16)		(16)
Foreign currency translation						483		483
Net loss							(17,419)	(17,419)
Balances, December 31, 2003	4,396	$ 4	$ 110,991	$ (280)	$ (264)	$ 700	$ (109,471)	$ 1,680

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

AEROGEN, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

	Common Stock Shares (in thousands)	Amount	Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity (Deficit)
Balances, December 31, 2003	4,396	4	110,991	(280)	(264)	700	(109,471)	1,680
Issuance of common stock upon exercise of stock options for cash	5		8					8
Stock-based compensation			8		264			272
Issuance of common stock for A-1 Preferred dividends	100		314					314
Issuance of common stock upon conversion of convertible debentures	334	1	585					586
Issuance of common stock upon conversion of convertible preferred stock	433	1	601					602
Issuance of common stock to landlord	50		165					165
Beneficial conversion feature related to issuance of convertible debenture			422					422
Issuance of warrants			5					5
Accrued dividend on convertible preferred stock			(1,408)					(1,408)
Accrued interest on notes receivable from stockholders				(12)				(12)
Foreign currency translation						291		291
Net loss							(10,074)	(10,074)
Balances, December 31, 2004	5,318	$ 6	$ 111,691	$ (292)	$	$ 991	$ (119,545)	$ (7,149)

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

AEROGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2004	**2003**	**2002**
	(In thousands)		
Cash flows from operating activities:			
Net loss	$ (10,074)	$ (17,419)	$ (24,911)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,209	1,251	1,209
Decrease in warrant liability	(5,840)		
Changes in inventory reserves	283	11	15
Loss on disposal of property and equipment	804	4	180
Accrued interest on notes receivable from stockholders	(13)	(13)	(26)
Amortization of notes discount (premium)		6	9
Amortization of deferred stock-based compensation	272	1,006	1,355
Non cash interest expense on convertible debentures	584	1,018	
Changes in operating assets and liabilities:			
Accounts receivable	(690)	558	(666)
Inventories	(705)	95	110
Restricted cash	1,200		
Prepaid expenses and other current assets	(470)	708	267
Accounts payable	62	(102)	(243)
Accrued liabilities	662	(37)	(1,893)
Deferred rent	(1,424)	832	603
Deferred revenue	(27)	2,167	8
Other	(289)	2	30
Net cash used in operating activities	(14,456)	(9,913)	(23,953)
Cash flows from investing activities:			
Acquisition of property and equipment	(842)	(376)	(3,728)
Purchases of available-for-sale securities			(8,134)
Proceeds from maturities of available-for-sale securities		5,599	22,817
Net cash provided by (used in) investing activities	(842)	5,223	10,955
Cash flows from financing activities:			
Proceeds from issuance of common stock	8	24	270
Repurchase of common stock			(7)
Proceeds from issuance of preferred stock and warrants, net	30,921		
Proceeds from issuance of convertible notes, net	505	1,950	
Repayment of note receivable from stockholder		167	285
Net cash provided by financing activities	31,434	2,141	548
Effect of exchange rate changes on cash and cash equivalents	(15)	45	2
Net increase (decrease) in cash and cash equivalents	16,121	(2,504)	(12,448)
Cash and cash equivalents at beginning of year	762	3,266	15,714
Cash and cash equivalents at end of year	$ 16,883	$ 762	$ 3,266
Supplemental disclosure of noncash investing and financing activities:			
Deferred stock-based compensation, net of cancellations	$	$ (250)	$ (1,194)
Issuance of common stock upon conversion of debt	$ 586	$ 402	$
Issuance of warrants	$	$ 529	$
Issuance of commont stock for dividends	$ 314	$	$
Issuance of common stock for future services	$ 165	$ 180	$
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 1	$ 1	$ 1

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

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Tabular amounts in thousands, except share and per share amounts)

NOTE 1 FORMATION AND BUSINESS OF THE COMPANY:

Aerogen, Inc., or the Company, was incorporated in the state of California on November 18, 1991 to develop products using its proprietary OnQ aerosol generator to aerosolize liquids. The Company was reincorporated in the state of Delaware in 1998. The Company has commenced planned principal operations and during 2002 generated significant revenues therefrom. Accordingly, the Company exited the development stage in December 2002.

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 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, the Company has financed its 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 December 31, 2004, Aerogen had cash and cash equivalents of approximately $16.9 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. In 2005, the company will seek to raise such capital from various possible sources, such as strategic transactions, collaborative partnerships, the sale of assets, licensing of technologies and/or products, the public equity markets, private financings, and debt, or some combination thereof. If revenues are less than expected, or costs exceed expectations, the Company may need to obtain additional capital sooner than expected. Such efforts may not be successful. Collaborative arrangements, if necessary to raise additional funds, may require the Company to relinquish rights to either certain of our products or technologies or desirable marketing territories, or all of these.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Basis of consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Aerogen (Ireland) Limited. All intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents include money market and deposit accounts.

Inventories

Inventories are stated at the lower of cost (on a first in, first out basis) or market value. Reserves for potentially excess and obsolete inventory are made based upon management s analysis of inventory levels and future sales forecasts.

Depreciation and amortization

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, generally three to five years. Amortization of leasehold improvements is provided on a straight-line basis over the life of the related asset or the lease term, if shorter. Upon sale or retirement of assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations.

Goodwill and other intangible assets

Goodwill and other intangible assets primarily consist of goodwill and acquired workforce related to the acquisition of the Company s subsidiary, and were amortized on a straight-line basis to operations over six and two years, respectively, through December 31, 2001. In accordance with Statement of Financial Accounting Standards (SFAS) No. 142 Goodwill and Other Intangible Assets (SFAS 142), goodwill and other intangible assets are no longer systematically amortized, but, rather, the Company performs an annual assessment for impairment by applying a fair-value-based test. No impairment charges have been recorded to date.

In accordance with SFAS 142, the Company discontinued the amortization of goodwill effective January 1, 2002. In addition, the Company re-characterized any unamortized acquired assembled workforce as goodwill because it is no longer defined as an acquired intangible asset under SFAS No. 141, Business Combinations. Accordingly, no goodwill or acquired workforce amortization was recognized during the years ended December 31, 2004, 2003 and 2002. The provisions of SFAS 142 also required the completion of a transitional impairment test within 12 months of adoption, with any impairment treated as a cumulative effect of change in accounting principle. The Company has completed annual impairment tests in 2004 and 2003, which did not result in impairment of recorded goodwill.

Impairment of long-lived assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs, management determines whether there has been an impairment by comparing the anticipated

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

undiscounted future net cash flows to the related asset s carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset.

Warranty accrual

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 years ending December 31, 2004 and 2003 is as follows:

Warranty accrual at January 1, 2003	$ 101
Accruals for warranties issued during the year	73
Settlements made in kind during the year	(36)
Balance at December 31, 2003	138
Accruals for warranties issued during the year	226
Settlements made in kind during the year	(113)
Balance at December 31, 2004	$ 251

Concentration of credit risk and other risks and uncertainties

The Company maintains its cash and cash equivalents in accounts with two financial institutions in the United States and one financial institution in Ireland. Deposits in these institutions may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents to date.

Carrying amounts of certain of the Company s financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

Each product developed by the Company generally will require clearance or the approval of the FDA and/or international regulatory agencies prior to the first commercial sale of the product. The Company cannot be assured that its products will receive or maintain the necessary clearance or approval. If the Company is denied approval, or if approval is delayed, suspended, or rescinded, this may have a material adverse impact on the Company.

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, product liability and the need to obtain additional financing.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

The following table summarizes customers with net sales greater than 10% of the Company s total net sales for the years ended December 31, 2004, 2003, and 2002:

	Years Ended December 31,		
	2004	2003	2002
Customer A	35 %	52 %	55 %
Customer B	7 %	12 %	0 %
Customer C	18 %	14 %	0 %
Customer D	21 %	3 %	0 %
Customer E	0 %	0 %	24 %

The following table summarizes customers with outstanding accounts receivable balance greater than 10% of the Company s total outstanding accounts receivable as of December 31, 2004, and 2003.

	As of December 31,	
	2004	2003
Customer A	40 %	56 %
Customer C	10 %	28 %
Customer D	20 %	0 %

Revenue recognition

The Company utilizes distributors to market its products, and recognize revenue at the time of product shipment, provided an enforceable claim exists, title has transferred, any significant rights to return product have expired and collection of the receivable is reasonably assured. The Company s customers are not granted rights of return, except in the instance of defective product. The price is fixed at the date of sale, the buyer takes title upon shipment from the Company s facilities, and their obligation to pay is not contingent upon resale of the product. The Company has no obligation for future performance to bring about resale of the product by the buyer.

The Company recognizes royalty revenue related to up front payments associated with an October 2003 commercial licensing and distribution agreement, which are being amortized ratably over the five year term of the agreement. These amounts are recorded as deferred revenue until recognized as royalty revenue. Related to this agreement, the Company also earns royalty revenues on its licensee s sales of the related product. Under a separate license agreement, minimum royalty revenues are recognized as earned, and the remaining amounts are recognized during the periods that the amounts become known and payments have been received, which have been, and are expected to be, one quarter after they have been earned.

Research and development revenues, which are earned under agreements with third parties for contract research and development activities, are recorded as the related expenses are incurred. Charges to the third parties are based upon negotiated rates for full time equivalent employees of the Company and actual out-of-pocket costs. Rates for full time equivalent employees are intended to approximate the Company s anticipated costs, including overhead. Payments received that are related to future performance are recorded as deferred revenue, and are recognized as revenues as they are earned. None of the revenues recognized to date are refundable if the relevant research effort is not successful.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

Research and development costs

Research and development costs are charged to operations as incurred. Any expenditure associated with products not yet approved by regulatory authorities is expensed. For research and development projects that are funded under agreements with third parties, the costs related to these activities are included in research and development expense. Legal expenses related to patent development are expensed to research and development as incurred.

Foreign currency translation

The Company s Irish subsidiary uses the Euro as its functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date and revenue and expense accounts at average exchange rates during the period. Resulting translation adjustments are recorded directly to a separate component of stockholders equity.

Advertising Costs

Advertising costs are expensed as incurred and were $102,000 in 2004, $80,000 in 2003, and $109,000 in 2002.

Income taxes

The Company accounts for income taxes under the provisions of SFAS No. 109, Accounting for Income Taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Segments

The Company operates in one segment, using one measurement of profitability to manage its business. Revenues recorded by geographic region for the years ended December 31, 2004, 2003, and 2002 were as follows:

	Years Ended December 31,		
	2004	**2003**	**2002**
Total revenues	$ 6,248	$ 4,171	$ 2,532
United States	40 %	22 %	29 %
Ireland	60 %	78 %	71 %

Long term assets by geographic region based on physical location of the assets were as follows:

	As of December 31,	
	2004	**2003**
United States	82 %	88 %
Ireland	18 %	12 %

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

Revenues by geographic region, based on shipping location of the external customer were as follows:

	Years Ended December 31,		
	2004	2003	2002
Total revenues	$ 6,248	$ 4,171	$ 2,532
United States	63 %	51 %	51 %
Japan	11 %	19 %	26 %
United Kingdom	1 %	0 %	17 %
Switzerland	4 %	17 %	0 %
Other	21 %	13 %	6 %

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 Issues to Employees, and related interpretations, SFAS No. 123 Accounting for Stock-Based Compensation, and complies with the disclosure provisions of 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 shares as if the Company had applied the fair value recognition provisions of SFAS No. 123 to all employee awards:

	Years Ended December 31,		
	2004	2003	2002
Net loss as reported	$ (10,074)	$ (17,419)	$ (24,911)
Add: stock-based employee compensation included in reported net loss	264	990	1,335
Deduct: total stock-based employee compensation determined under fair value based method for all awards	(1,623)	(2,054)	(3,933)
Net loss pro forma	$ (11,433)	$ (18,483)	$ (27,509)
As reported	$ (4.86)	$ (4.22)	$ (6.17)
Pro forma	$ (5.15)	$ (4.48)	$ (6.82)

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.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

The fair value of options granted was estimated on the date of grant using the Black-Scholes option pricing model, using the following assumptions:

	Stock option plans Years Ended December 31,		
	2004	2003	2002
Risk-free interest rate	3.96 %		3.54 %
Expected life (in years)	6		4
Dividend yield			
Expected volatility	100 %		148 %
Weighted average fair values			
Exercise price less than market price	$	$	$
Exercise price equal to market price	$ 2.25	$	$ 3.25
Exercise price greater than market price	$	$	$

	Employee Stock Purchase Plan (ESPP) Years Ended December 31,		
	2004	2003	2002
Risk-free interest rate	3.50 %	2.13 %	2.31 %
Expected life (in years)	2	2	2
Dividend yield			
Expected volatility	100 %	154 %	148 %
Weighted average fair values			
Exercise price less than market price	$ 1.07	$ 0.90	$ 4.50
Exercise price equal to market price	$	$	$
Exercise price greater than market price	$	$	$

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

Comprehensive income (loss)

Comprehensive income (loss) generally represents all changes in stockholders equity (deficit) except those resulting from investments or contributions by stockholders. The Company s unrealized gains and losses on foreign currency translation gains and losses represent the only components of comprehensive income (loss) that are excluded from the Company s net loss for the years ended December 31, 2004, 2003 and 2002.

Net loss per common share

Basic net loss per share is computed by dividing the net loss by the weighted average number of vested common shares outstanding for the period. Diluted net loss per share is computed giving effect to all potential dilutive common shares, including convertible securities, options and warrants. For the periods

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

reported below, these potentially dilutive securities were not included in the diluted net loss per share calculations because the effect would be antidilutive.

In periods of positive earnings, net income per share is computed using the two-class method as required by Emerging Issues Task Force Statement No. 03-06 Participating Securities and the Two Class Method Under FASB Statement No. 128, Earnings Per Share. In computing basic and diluted net income per share, net income is allocated first to the preferred stockholders based on both their dividend rights and their rights to participate in the earnings for the period as if all of the earnings for the period had been distributed. The residual earnings are then allocated to the common stockholders in determining basic and diluted net income per share.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share attributable to common stockholders follows:

	Years Ended December 31,		
	2004	2003	2002
Net loss attributable to common stockholders	$ (23,171)	$ (17,419)	$ (24,911)
Weighted average shares outstanding	4,765	4,127	4,050
Less: Weighted average shares subject to repurchase		(1)	(14)
Weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders	4,765	4,126	4,036

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

	Years Ended December 31,		
	2004	2003	2002
Options to purchase common stock	4,083	477	665
Shares issuable through ESPP	16		115
Common stock subject to repurchase		1	1
Warrants	11,767	428	4
Convertible debentures		630	
Preferred stock	1,099		

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.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

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.

NOTE 3 LITIGATION SETTLEMENT:

In October 2001, the Company settled a lawsuit brought by the Company against Becton Dickinson (BD). As a result of the settlement, the Company owns all of the intellectual property developed by either party under the now terminated agreement, and BD has a nonexclusive license to certain technology developed by BD under the agreement for use outside the field of inhaled insulin. Under the settlement agreement, the Company paid BD a total of $2 million, in two equal installments in October 2001 and February 2002. The litigation settlement was immediately expensed to operations, as the technology acquired will be used in conjunction with a product that had not yet been approved for sale by regulatory authorities.

NOTE 4 BALANCE SHEET COMPONENTS:

Inventories are summarized as follows:

	December 31,	
	2004	**2003**
Raw materials	$ 499	$ 228
Work-in-process	228	30
Finished goods	48	43
Net inventories	$ 775	$ 301

Property and equipment consists of the following:

	December 31,	
	2004	**2003**
Laboratory, computer and office equipment	$ 4,269	$ 3,964
Furniture	484	482
Land	286	263
Leasehold improvements	1,644	3,577
Construction-in-progress		119
	6,683	8,405
Less: Accumulated depreciation and amortization	(3,719)	(4,504)
Net property and equipment	$ 2,964	$ 3,901

On September 30, 2003, the Company entered into an agreement with Evo for manufacturing and marketing of the Aeroneb Go Nebulizer. During October 2003, Aerogen received upfront payments

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except share and per share amounts)

totaling $2.5 million for distribution rights and for the sale of certain equipment. Per the terms of the Company s agreement with Evo, this equipment became repurchasable by the Company for one dollar. The equipment remains on the Company s premises and, for accounting purposes, has been reclassified to other assets at December 31, 2004 and 2003 and continues to be amortized. The net book value of these assets at December 31, 2004 and 2003 was $299,000 and $571,000, respectively.

In connection with the Cerus Limited acquisition in May 2000, the Company recorded goodwill and other intangible assets. Goodwill and other intangible assets consist of the following:

	December 31, 2004	2003
Goodwill, net	$ 1,951	$ 1,796
Other intangible assets	$ 147	$ 135

Goodwill related to the Company s Irish subsidiary is impacted by changes in the U.S. dollar-to-Euro exchange rate.

Accrued liabilities consists of the following:

	December 31, 2004	2003
Payroll and related expense	$ 580	$ 499
Accrued warranty	251	138
Other accrued liabilities	1,042	557
Accrued liabilities	$ 1,873	$ 1,194

NOTE 5 OTHER LONG-TERM LIABILITIES:

In April 1999, Cerus Limited established an Irish Revenue approved Business Expansion Scheme (BES) under which it raised approximately 196,000 Euro. The BES is an Irish Revenue approved Business Expansion Scheme that grants investors tax breaks on the amounts invested. The maximum amount that the BES investors are entitled to receive from Aerogen (Ireland) Limited was $267,000, when translated as of December 31, 2004. The BES investors have certain dividend and liquidation preferences in our Irish subsidiary. The obligation has been classified as other long-term liabilities.

NOTE 6 COMMITMENTS AND CONTINGENCIES:

Facility leases

The Company leases its facilities in Ireland under an operating lease that expires in December 2006. In April of 2002, the Company entered into a 980-year lease with the Irish Development Agency for a 0.8-acre plot of land for a one-time payment of approximately $220,000. At this time the Company has not determined if and/or when it will build on the land.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

The Company leases its facilities in Mountain View, California under an operating lease that, under its original terms, expired in February 2012. Under the terms of the original lease, the Company was required to provide security to the landlord in the form of a $1,200,000 letter of credit to remain in effect for the entire term of the lease. The letter of credit was secured by a certificate of deposit for $1,200,000, which was classified as restricted cash at December 31, 2003.

In March 2004, the Company negotiated a lease amendment with its landlord. Under the terms of the amended lease, Aerogen relocated to the first floor of its two-story building in Mountain View, CA, and now occupies roughly 32,000 square feet, which is about one half of the building area that the Company had occupied. Under the terms of the amended lease, Aerogen made aggregate payments during the quarter ended June 30, 2004 totaling $1,625,000 which was comprised of $75,000 for a new security deposit, $414,000 in past due rent, and $1,136,000 in rent reduction fees, of which $900,000 was funded by relinquishment to the landlord of cash underlying the Company s standby letter of credit. The Company was required to fund up to $140,000 in building access improvements, which were completed in November 2004. The Company paid the landlord $140,000 as payment in full of the Company s share of those improvements, and has paid an additional $43,000 for modifications to the building s electrical systems. As part of the lease restructuring, the Company issued 50,000 shares of common stock to the landlord. The excess of the value paid to the landlord, including cash, building improvements and stock, over the amounts due, will be amortized as rent expense over the remaining term of the lease. The lease now terminates in February 2009.

Rent expense for the years ending December 31, 2004, 2003 and 2002 was approximately $1,304,000, $3,119,000 and $2,828,000, respectively.

Future aggregate minimum rental and maintenance commitments under non-cancelable operating leases, including common area maintenance fees in effect at December 31, 2004 are:

	Years Ending December 31, (in thousands)
2005	990
2006	1,150
2007	1,102
2008	1,152
2009	193
Total minimum payments	$ 4,587

Executive Severance Benefit Plan

In September 2000, the Board of Directors adopted the Executive Severance Benefit Plan (Severance Plan), which provides the Company s officers with severance benefits upon the involuntary termination of their employment in certain circumstances following an acquisition of the Company. Benefits under the Severance Plan include salary continuation, health benefits and option acceleration.

Contingencies

The Company is a party to a lawsuit brought by PARI GmbH alleging patent infringement in Germany. In May 2003, the Company filed an action in the German patent office requesting that the

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

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.

From time to time, the Company may become involved in litigation relating to additional claims arising from the ordinary course of business. Management is not currently aware of any such matters that will have a material adverse affect on the financial position, results of operations or cash flows of the Company.

NOTE 7 CONVERTIBLE DEBT:

In September 2003, the Company entered into a loan and securities purchase agreement pursuant to which two convertible debentures and two warrants were issued to SF Capital.

The first debenture was issued on September 11, 2003, in the principal amount of $950,000, bore interest at the rate of 10% per year, had an original maturity of December 31, 2003, and the principal amount of which was convertible into 542,857 shares of the Company s common stock at a conversion price of $1.75 per share. This debenture was subsequently amended in January 2004 to extend its maturity to June 1, 2004. The warrant associated with this first debenture is exercisable for 271,428 shares of common stock at an exercise price of $1.75 per share. SF Capital converted the entirety of this first debenture, along with all accrued interest, into an aggregate of 564,224 common shares, in the fourth quarter of 2003 and the first quarter of 2004.

The second SF Capital debenture was issued on November 3, 2003, in the principal amount of $1,000,000, bore interest at the rate of 10% per year, had an original maturity of March 1, 2004, and the principal amount of which was initially convertible into 304,878 shares of the Company s common stock at an original conversion price of $3.28 per share. This debenture was amended in January 2004 to extend its maturity to June 1, 2004. SF Capital exchanged this debenture and all accrued interest for shares of the Company s A-1 Preferred Stock, and associated warrants in May 2004.

The second warrant is exercisable for 164,257 shares of common stock at an adjusted exercise price of $3.044 per share, as adjusted. Total interest expense recognized relating to the second warrant discount was $36,000 and $68,000 during 2004 and 2003, respectively.

The terms of the warrants preclude SF Capital from converting or exercising if such exercise would result in SF Capital and its affiliates owning in excess of 9.999% of the Company s outstanding stock.

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)

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

were issued to the Carpenter 1983 Family Trust UA (the Carpenter Trust), the trustees of which are Aerogen s Chairman and Chief Executive Officer, Dr. Jane Shaw and her husband Peter Carpenter. The Company received approximately $505,000 in gross proceeds in exchange for the Carpenter Debenture and the Carpenter Warrant. The Carpenter Debenture was convertible into 164,258 shares of common stock at a conversion price of $3.044 per share. The Carpenter Warrant is exercisable for 82,129 shares of common stock at an exercise price of $3.044 per share, and expires in January 2008. The difference between the conversion price and the fair market value of the common stock on the commitment date (transaction date) resulted in a beneficial conversion feature recorded on the 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. The discount on the Carpenter Debenture for the beneficial conversion feature and Carpenter Warrant were amortized, using the effective interest method, to interest expense over the original term of the Carpenter Debenture, which had been scheduled to mature on March 1, 2004.

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

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

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

NOTE 8 REDEEMABLE CONVERTIBLE PREFERRED STOCK:

As of December 31, 2004, the Company has authorized 5,000,000 shares of redeemable convertible preferred stock, $0.001 par value, of which 1,098,761 shares were issued and outstanding, compared to none outstanding at December 31, 2003.

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 a total of 1,142,094 shares of Series A-1 redeemable convertible preferred stock (the A-1 Preferred) of the Company that are initially convertible into an aggregate of 11,420,940 shares of common stock of the Company, as well as the issuance of warrants to purchase up to 11,249,390 shares of common stock at an exercise price of $3.25 per share.

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 at an exercise price of $3.25, for gross cash proceeds to the Company of $14,999,430.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

On May 12, 2004, the Company completed the second and final closing of the A-1 Financing. In the second closing, the Company issued 642,113 shares of A-1 Preferred convertible into 6,421,130 shares of common stock, and issued warrants to purchase 6,249,580 shares of common stock at an exercise price of $3.25, for gross proceeds to the Company of $19,263,000, including the exchange of $1,567,000 in previously-issued debentures and accrued interest thereon. Gross cash proceeds from the second closing were $17,696,000.

Issuance costs related to the A-1 Financing were $1,775,000. Net cash proceeds to the Company were $30,921,000.

As a result of certain rights provided to the investors in the Series A-1 financing, the warrants to purchase common stock are accounted for as a liability and marked to market at each period-end date. The aggregate fair value of the warrants of $8,200,000 and $7,937,000, for the first and second closings, respectively, was recorded as a liability, with the remaining net proceeds of $6,439,760 and $9,397,000, for the first and second closings, respectively, recorded as preferred stock. The difference between the accounting conversion price of the preferred stock and the fair market value of the underlying common stock on the commitment date (transaction date), limited to the allocated proceeds of the preferred stock, is recorded as a beneficial conversion feature which is treated as a deemed dividend. The total beneficial conversion feature for the year ended December 31, 2004 was $11,690,000.

The fair value of the warrants and the corresponding liability is re-measured at each reporting period with any change in the fair value being recorded as a non-operating item in the statement of operations. The aggregate fair value of the warrants decreased from $16.1 million to $10.3 million during the year ended December 31, 2004, which resulted in the Company recording a non-operating gain of $5.8 million on the statement of operations. The fair value of the warrant is determined at each reporting period using a valuation model which takes into consideration a variety of assumptions, including stock price, stock volatility and the risk free rate.

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

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

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

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 valued as of the respective fiscal quarter period. For the twelve months ended December 31, 2004, cumulative dividends of $1,408,000 had been accrued on the A-1 Preferred, of these dividends, $314,000 had been paid as of December 31, 2004, and $1,094,000 was paid in 2005 through the issuance of an aggregate of 613,921 shares of the Company s common stock.

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

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.

Currently, each share of A-1 Preferred is convertible into ten (10) shares of common stock; this conversion ratio is only adjusted in the event that the Company issues or sells certain equity instruments at a price per common share equivalent that is less than $3.00 (the current Series A-1 Conversion Price).

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

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

rights, options or warrants outstanding from time to time) which the Requisite Holders expressly elect in writing to treat as an Excluded Issuance.

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

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

NOTE 9 STOCKHOLDERS EQUITY:

Common Stock

On October 30, 2003, a five-for-one reverse split of the Company s stock was approved by the shareholders. The reverse split was effective on October 31, 2003. All references to common shares, warrants and options to purchase common shares, per share amounts, common share prices and exercise/conversion prices have been retroactively adjusted to reflect the stock split.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No dividends on the Company s common stock have been declared or paid as of December 31, 2004.

The Company issued shares of its common stock to certain employees under stock purchase and other agreements, some of which contain repurchase provisions in the event of termination of service with the Company. The shares are generally released from repurchase provisions ratably over two to four years. Included in common stock as of December 31, 2004, 2003 and 2002 are no shares, no shares and 13,890 shares subject to repurchase, respectively.

The lease on our Mountain View facility was amended in November 2003 to defer a significant portion of our rent during a two-year period to be paid during the last six years of the lease in exchange for the issuance of 60,000 shares of common stock to our landlord. In March 2004, the lease was amended again (see Note 7), and as part of the arrangement, the Company issued an additional 50,000 shares of common stock to the landlord.

Stock Option Plans

The Company has reserved shares of common stock for issuance under the 2000 Equity Incentive Plan, the Amended and Restated 1996 Stock Option Plan, and the Amended and Restated 1994 Stock Option Plan (the Stock Plans). Under the Stock Plans, the Board of Directors may issue incentive stock options to employees and nonstatutory stock options to employees, consultants or nonemployee directors of the Company, and stock purchase rights to employees, nonemployee directors, or consultants. The Board of Directors has the authority to determine to whom options will be granted, the number of shares, the term and exercise price (which cannot be less than fair market value at date of grant for incentive stock options or 85% of fair market value for nonstatutory stock options). If an employee owns stock representing more than 10% of the outstanding shares, the price of each share must be at least 110% of fair market value, as determined by the Board of Directors. Options generally vest over four years and expire ten years from date of grant. All options granted prior to December 4, 2000, are immediately exercisable; if options are immediately exercised, the shares are subject to a right of repurchase by the Company that lapses over time. Unvested shares obtained by early exercise are subject to repurchase by the Company upon termination of the holder s service to the Company. As of December 31, 2004, there were no longer any shares of common stock subject to the Company s repurchase rights. At December 31, 2003 and 2002, 646 and 1,282 shares of common stock, respectively, were subject to the Company s repurchase rights.

On an annual basis, on the date of the annual stockholders meeting, the authorized shares available for issuance under the Company s 2000 Equity Incentive Plan will automatically be increased by a number of shares equal to the lesser of 4.5% of the then outstanding shares of common stock on a fully-diluted basis, 400,000 shares, or a lesser number of shares determined by the Board of Directors. In May 2004, the number of authorized shares available for issuance under this plan was increased by 4,915,309, including the annual increase of 400,000 as set forth in the plan document.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

In 2000, the Company adopted the 2000 Non-Employee Directors Stock Option Plan (2000 Non-Employee Plan) under which 50,000 shares of common stock were originally reserved for issuance. The Company terminated this plan on April 2, 2004. Under the terms of the 2000 Non-Employee Plan, each new non-employee director elected was granted an option to purchase 15,000 shares of common stock, which vested over a three-year period. In addition, on an annual basis, the Plan provided that on the date of the annual stockholder meeting, each non-employee director was granted an option to purchase 5,000 shares of common stock which vested over a three-year period. The exercise price of such options will be the fair market value of the common stock on the date of grant and the term was 10 years. During 2003, the Company did not grant any stock options as it was subject to California blue sky laws which prohibit, among other things, the issuance of stock options unless the issuer has completed a successful review of its stock option plans with the state which was not the case in 2003.

Activity under the Stock Plans has been as follows:

	Available Options	Number of Options Outstanding	Weighted-Average Exercise Price
Balances, December 31, 2001	141	693	$ 19.39
Reservation of shares	187		
Options granted	(189)	189	3.44
Options exercised		(4)	7.96
Options canceled	213	(213)	20.19
Shares repurchased	2		
Balances, December 31, 2002	354	665	14.70
Options exercised			
Options canceled	188	(188)	18.47
Balances, December 31, 2003	542	477	13.22
Reservation of shares	4,915		
Plan shares expired	(43)		
Options granted	(3,845)	3,845	2.63
Options exercised		(5)	1.85
Options canceled	234	(234)	7.52
Balances, December 31, 2004	1,803	4,083	$ 3.60

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

The options outstanding and currently exercisable at December 31, 2004, by exercise price, are as follows:

	Options Outstanding			Options Vested and Exerercisable	
Range of Exercise Prices	Number of Options Outstanding	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.20 - $2.42	283	9.18	$ 2.00	57	$ 1.85
$2.65	3,315	9.49	2.65		
$2.69 - $2.83	138	9.57	2.76		
$2.96 - $8.10	111	7.49	4.76	62	5.43
$15.00 - $15.05	156	6.15	15.03	141	15.02
$18.75	2	5.55	18.75	2	18.75
$21.80	10	6.70	21.80	10	21.80
$22.50	5	5.67	22.50	5	22.50
$22.70	7	6.33	22.70	7	22.70
$25.00	43	6.15	25.00	43	25.00
$30.95	1	6.52	30.95	1	30.95
$33.75	4	5.75	33.75	4	33.75
$37.50	8	5.81	37.50	8	37.50
	4,083	9.23	$ 3.60	340	$ 13.60

Employee Stock Purchase Plan

In November 2000, the stockholders approved the 2000 Employee Stock Purchase Plan (the Purchase Plan) authorizing the issuance of 50,000 shares of common stock pursuant to purchase rights granted to employees in the United States.

On an annual basis, on the date of the annual stockholders meeting for a period of 20 years, the share reserve will automatically be increased by a number of shares equal to the lesser of 1.0% of the then outstanding shares of common stock on a fully diluted basis, 50,000 shares, or a lesser number of shares determined by the Board of Directors. In May 2004, the number of authorized shares available for issuance under this plan was increased by 1,639,752.

The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. As of December 31, 2004, 112,438 shares of common stock have been purchased under the Purchase Plan and 1,659,971 shares remain available for purchase.

The Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined offering periods. The price at which stock is purchased under the purchase plan is equal to 85% of the fair market value of the common stock on the first day of the offering period or 85% of the fair market value on the subsequent designated purchase dates, whichever is lower.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

Deferred stock-based compensation

During 2000 and 1999, the Company issued options to certain employees under the Company s equity compensation plans with exercise prices below the deemed fair market value of the Company s common stock at the date of grant. In accordance with the requirements of APB 25, the Company has recorded deferred stock-based compensation for the difference between the exercise price of the stock options and the deemed fair market value of the Company s stock at the date of grant. This deferred stock-based compensation is amortized to expense on a straight line basis, over the period during which the Company s right to repurchase the stock lapses or the options become vested, generally four years. As of December 31, 2004, the Company had recorded cumulative deferred stock-based compensation related to these options in the amounts of $4,377,000, net of cancellations, of which $264,000, $990,000 and $1,335,000 had been amortized to expense during 2004, 2003 and 2002, respectively.

Stock-based compensation expense related to stock options granted to non-employees is recognized on a straight-line basis as the stock options are earned. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The fair value of the stock options granted to non-employees is calculated at each reporting date using the Black-Scholes option-pricing model as prescribed by SFAS No. 123 using the following assumptions:

	Years Ended December 31,		
	2004	2003	2002
Risk-free interest rate	3.54 %	4.45 %	4.59 %
Expected life (in years)	9.64	10	10
Dividend yield			
Expected volatility	100 %	100 %	100 %

The stock-based compensation expense will fluctuate as the fair market value of the common stock fluctuates. In connection with the grant of stock options to non-employees, the Company amortized to expense stock-based compensation in the amounts of $8,000, $16,000 and $20,000 in 2004, 2003 and 2002, respectively.

Warrants

In connection with financing arrangements entered into by the Company in July 1995 and October 1997, the Company issued warrants to purchase 2,136 shares of common stock and warrants to purchase 65,000 shares of Series C convertible preferred stock at exercise prices of $11.70 and $1.00, respectively. Due to the automatic conversion of the convertible preferred stock in connection with the Company s initial public offering, the warrants for Series C convertible preferred stock became exercisable for 4,333 shares of common stock at $15.00 per share. The warrants issued in July of 1995 expired unexercised on June 30, 2002, and the October 1997 warrants expired unexercised on October 14, 2004.

In connection with the issuance of convertible debentures to SF Capital in September and November 2003, the Company issued warrants to purchase 271,428 and 152,439 shares of common stock at original exercise prices of $1.75 and $3.28, respectively (see Note 7).

In connection with the issuance of the Carpenter Debenture (see Note 7) in January 2004, the Company issued a warrant to purchase 82,129 shares of common stock at a price of $3.044 per share.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

In connection with the issuance of the Series A-1 Convertible Preferred Stock, the Company issued warrants to purchase a total of 11,249,390 shares of common stock at an exercise price of $3.25 per share (see Note 8).

Notes receivable

In May 1994, the Company loaned $69,009 to a stockholder employee. The note bore interest at 6.43% per annum, became due May 2003, and has been fully repaid. In August 1996, the Company loaned an additional $200,000 to the same individual. The note was non-interest bearing, was originally due in 2001 and is partially collateralized by 33,333 shares of common stock. The note was amended in 2002 to extend the due date until December 31, 2006 and to bear interest at 4.38% per annum. In July 2000, the Company loaned the same employee an additional $50,000. This loan bears interest at 6.62% per annum, is due in July 2005 and is collateralized by the same 33,333 shares of common stock. At December 31, 2004, 2003 and 2002, $292,000, $279,000 and $371,000 of principal and accrued interest were outstanding under these notes, respectively. The Company has arranged with this stockholder/employee that the Company will receive a portion of the proceeds from certain sales of the employee s non-collateralized Company stock until the employee s notes to the Company have been paid in full.

NOTE 10 INCOME TAXES:

At December 31, 2004, the Company has a net operating loss carryforward of approximately $82,355,000 for federal and $35,394,000 for state tax purposes. If not utilized, these carryforwards will begin to expire in 2009 for federal and in 2004 for state purposes.

The tax effects of temporary differences and carryforwards that give rise to significant portions of the net deferred tax assets as of December 31, 2004 and 2003 are as follows:

	December 31, 2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$ 31,282	$ 31,715
Federal and state tax credit carryforwards	3,852	3,352
Research and development capitalization	8,782	2,499
Depreciation and amortization	1,110	1,075
Accrued liabilities and reserves	396	93
Other	1,068	1,617
	46,490	40,351
Less: Valuation allowance	(46,490)	(40,351)
Net deferred tax assets	$	$

Based on the available objective evidence, management believes it is likely that the net deferred tax assets are not fully realizable. Accordingly, the Company has established a full valuation allowance against its net deferred tax assets as of December 31, 2004. The increase in the valuation allowance was $6,139,000, $6,723,000 and $8,689,000 during the years ended December 31, 2004, 2003 and 2002, respectively.

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

The Company has research credit carryforwards of approximately $2,207,000 and $2,323,000 for federal and state income tax purposes, respectively. If not utilized, the federal credits will expire in various amounts beginning in 2013. The state credits can be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. In the event the Company has a change in ownership, utilization of the carryforwards could be restricted.

NOTE 11 EMPLOYEE BENEFIT PLAN:

In August 1996, the Company adopted a retirement plan (the 401(k) Plan), which is qualified under Section 401(k) of the Internal Revenue Code of 1986. Eligible employees may make voluntary contributions to the 401(k) Plan of up to 20% of their annual compensation, not to exceed the statutory limit, and the Company may make matching contributions. During the years ended December 31, 2004, 2003 and 2002, the Company made approximately $23,000, $28,000 and $54,000, respectively, of matching contributions to the 401(k) Plan. Prior to 2001, the Company had not made any such contributions.

NOTE 12 QUARTERLY FINANCIAL DATA (UNAUDITED):

The consolidated financial statements for March 31, 2004, June 30, 2004, and September 30, 2004 have been restated from amounts previously reflected in the Company s Form 10-Q s for those respective periods to reflect a revision in the accounting for the Company s Series A-1 Preferred Stock issuance and related warrants. Previously, the Company had accounted for the warrants as a component of permanent equity. The Company subsequently concluded that the warrants should be recorded as a liability and marked-to-market at the end of each reporting period (See Note 8). This change had the impact of increasing total liabilities, and decreasing redeemable convertible preferred stock and stockholders equity. Also as a result, the Company changed the amount of the beneficial conversion feature recorded in the first and second quarter, and recorded gains and losses in each quarter due to the change in the fair value of the warrant. The change is more fully described in the Company s Form 10-Q/A s filed on April 15, 2005.

The following tables present certain unaudited, consolidated, quarterly financial information for the last eight quarters ended December 31, 2004:

	Fiscal 2004 Quarter Ended			
	March 31, (Restated)	June 30, (Restated)	September 30, (Restated)	December 31,
Total revenues	$ 1,099	$ 1,695	$ 1,213	$ 2,241
Gross margin	112	(6)	74	197
Loss from operations	(3,576)	(3,745)	(4,327)	(4,129)
Net income (loss)	(5,415)	(4,155)	1,652	(2,156)
Net income (loss) attributable to common shareholders	$ (11,875)	$ (9,783)	$ 301	$ (1,814)
Net income (loss) per common share, basic and diluted	$ (2.66)	$ (2.05)	$ 0.06	$ 0.36

AEROGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
(Tabular amounts in thousands, except per share amounts)

	Fiscal 2003 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Total revenues	$ 1,568	$ 1,114	$ 519	$ 970
Gross margin	444	378	144	(64)
Loss from operations	(4,375)	(3,962)	(4,127)	(3,912)
Net loss	$ (4,297)	$ (3,622)	$ (4,355)	$ (5,145)
Net loss per common share, basic and diluted	$ (1.05)	$ (0.88)	$ (1.06)	$ (1.22)

The effect of the restatement adjustments on the previously reported amounts for the year ended December 31, 2004 are set forth in the following table.

	Condensed Consolidated Statement of Operations for the three months ended					
	March 31, 2004		June 30, 2004		September 30, 2004	
	As restated	As Previously reported	As restated	As Previously reported	As restated	As Previously reported
Decrease in warrant liability	$ (1,060)	$	$ (361)	$	$ 5,742	$
Net income (loss)	(5,415)	(4,355)	(4,155)	(3,794)	1,652	(4,090)
Dividends related to convertible preferred stock	(6,460)	(7,932)	(5,628)	(4,881)	(514)	(514)
Net income (loss) attributable to common stockholders	(11,875)	(12,287)	(9,783)	(8,675)	301	(4,604)
Net income (loss) per share, basic and diluted	(2.66)	(2.76)	(2.05)	(1.81)	0.06	(0.96)

	Condensed Consolidated Balance Sheets					
	As restated	As Previously reported	As restated	As Previously reported	As restated	As Previously reported
Warrant liability	$ 9,260	$	$ 17,558	$	$ 11,816	$
Total liabilities	17,120	7,860	22,832	5,274	17,690	5,874
Redeemable convertible preferred stock	6,440	8,072	16,351	12,573	16,351	12,573
Additional paid-in capital	112,167	118,735	111,779	131,694	111,527	131,442
Accumulated deficit	(114,886)	(113,826)	(119,041)	(117,620)	(117,389)	(121,710)
Total stockholders equity (deficit)	(2,327)	5,301	(6,705)	14,631	(5,234)	10,360

Item 9A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (Disclosure Controls) as of the end of the period covered by this Annual Report. The controls evaluation was done under the supervision and with the participation of management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Based on the evaluation as of the end of the period covered by this Annual Report, our CEO and CFO have concluded that Aerogen s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) were sufficiently effective to ensure that the information required to be disclosed by Aerogen in the reports that we file under the Exchange Act is gathered, analyzed and disclosed with adequate timeliness, accuracy and completeness, with the exception of the accounting for complex derivatives described below.

Changes in internal controls. We 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 restatement arose due to errors related to the initial valuation, classification, and subsequent accounting for the warrants issued in connection with the sales of our Series A-1 Redeemable Convertible Preferred Stock on March 23, 2004 and May 12, 2004.

In connection with the restatement of our financial results for the quarters ended March 31, June 30 and September 30, 2004, we have identified material weaknesses in our internal controls and procedures. Also, as of the end of the period covered by this report, we carried out an evaluation, under the supervision and participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. We have determined that the disclosure controls and procedures were not effective because they failed to identify the errors which led to the restatement. In response, in March 2005, we implemented a policy that requires for any future issuance of complex equity and derivative instruments or other complex transactions, an outside expert with experience concerning the related accounting issues will be consulted, or additional internal staff will be trained or hired. In addition, enhanced review and documentation procedures have been implemented in our accounting process in order to ensure accuracy of all accounting entries. There have been no other changes in our internal controls subsequent to the date of the evaluation referred to above. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. It should be noted that the design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

Given the additional measures adopted by the Company in March 2005, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are now effectively designed to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Limitations on the effectiveness of controls. The Company s management, including CEO and CFO, does not expect that our Disclosure Controls or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-

making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Accordingly, our Disclosure Controls and our internal controls over financial reporting are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Name and Positions with Aerogen in Addition to Director	Age	Director Continuously Since
Class I Directors		
Dr. Phyllis I. Gardner	54	2000
Robert Roe(1)	63	2004
Class II Directors		
Dr. Jane E. Shaw (Chairman and Chief Executive Officer)	66	1998
Class III Directors		
Jean-Jacques Bienaime	51	1999
Yehuda Ivri (Chief Technical Officer)	53	1991
Bernard Collins	56	2002

(1) Robert Roe joined the Board on December 16, 2004

Business Experience of Directors

Class I Directors

Phyllis Gardner joined Aerogen s Board of Directors in May 2000. Dr. Gardner is the Senior Associate Dean for Education and Student Affairs and Associate Professor of Molecular Pharmacology and Medicine at Stanford University School of Medicine, and has been with the University since 1984. Between 1996 and 1998, Dr. Gardner was Vice President of Research and Principal Scientist of ALZA Corporation, a pharmaceutical company, and head of the ALZA Technology Institute. Between 1994 and 1996, Dr. Gardner was a consultant to ALZA. Dr. Gardner received a B.S. in Biology from the University of Illinois and an M.D. from Harvard Medical School.

Robert L. Roe, M.D. has served as a director of Aerogen since December 2004. Dr. Roe has over 28 years of management and pharmaceutical experience. He has served as President of Corcept Therapeutics, Inc. since 2001. From 1999 to 2001, he served as President and Chief Executive Officer and a Director of Allergenics, Inc. While at Cytel Corporation between 1996 and 1999, Dr. Roe was Executive Vice President, Chief Operating Officer and a Director. At Chugai Biopharmaceuticals, Inc. from 1995 to 1996, he was Executive Vice President, Chief Operating Officer and a Director. Starting at Syntex Research Division, Syntex Corporation in 1976, Dr. Roe progressed through a series of clinical and development research roles culminating in the position of President, Development Research Division and Senior Vice President of Syntex Corporation between 1992 and 1995. Dr. Roe received his A.B. from Stanford University and his M.D. from the University of California, San Francisco.

Class II Directors

Jane E. Shaw, Ph.D., has served as Chairman of our Board of Directors and as our Chief Executive Officer since 1998. Dr. Shaw held various scientific and management positions with ALZA Corporation, a pharmaceutical company, from 1970 to 1994, most recently as President and Chief Operating Officer from 1987 to 1994. Dr. Shaw received a B.Sc. and Ph.D. in Physiology from Birmingham University in England. Dr. Shaw serves as a director of OfficeMax Corporation, Intel Corporation, and McKesson Corporation.

Class III Directors

Jean-Jacques Bienaimé, has served on Aerogen s Board of Directors since 1999. Since November 2002, Mr. Bienaimé has been President, Chief Executive Officer and Chairman of the Board of Genencor International. Before joining Genencor, Mr. Bienaimé was President, Chief Executive Officer

78

and a director of SangStat Medical Corporation since 1998 and Chairman of its Board of Directors since October 2000. Mr. Bienaimé held various positions at Rhône Poulenc Rorer Inc., from 1992 to 1998, most recently as Senior Vice President of Corporate Marketing and Business Development. Mr. Bienaimé received an M.B.A. from the Wharton School of the University of Pennsylvania and a degree in Economics from Ecole Supérieure de Commerce de Paris in France. Mr. Bienaimé is also on the Board of Directors of NeurogesX, Saegis and Ensemble Corporation.

Bernard Collins, currently is an independent consultant in the areas of business strategy and management. From 1994 to 2000, he was the Vice President, International Operations at the Boston Scientific Corporation. Prior to that time he was a management consultant and held management positions in medical device/healthcare companies. Mr. Collins received a B.A. in Industrial Psychology from the National University of Cork. He serves as a director of several privately held companies.

Audit Committee

The current members of the Audit Committee are Messrs. Collins, Roe and Bienaimé. The Audit Committee is responsible for assisting the Board in its responsibilities of overseeing the Company s financial affairs. In this capacity, the Audit Committee reviews the Company s consolidated financial statements and quarterly earnings with management and with the Company s independent accountants, and consults with the Company s independent accountants concerning their audit plan, the results of their audit, the appropriateness of accounting principles used by the Company, the adequacy of the Company s internal controls and the independence of the accountants. The Board of Directors annually reviews the Nasdaq listing standards definition of independence for Audit Committee members and has determined that all members of the Company s Audit Committee are independent (as independence is currently defined in Rule 4350(d)(2)(A)(i) and (ii) of the Nasdaq listing standards). The Board has determined that Jean-Jacques Bienaimé qualifies as an audit committee financial expert, as defined in applicable SEC rules. The Board made an assessment of Mr. Bienaimé s level of knowledge and experience based on a number of factors, including his formal education and experience as the president and chief executive of a publicly-traded biotechnology company.

Executive Officers

The information related to Executive Officers required by this item is incorporated by reference to item 1 of this Registration Statement.

Yehuda Ivri, founded Aerogen in 1991 and has served as a member of our Board of Directors since its inception. Mr. Ivri has served as our Chief Technical Officer since 1996 and previously was our Chief Scientist and Vice President. Mr. Ivri received an M.S. in Mechanical Engineering from the Technion-Israel Institute of Technology.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires Aerogen s directors and executive officers, and persons who own more than 10% of the Company s Common Stock, to file reports of ownership and changes in ownership of such stock with the Securities and Exchange Commission (SEC). Directors, executive officers and greater than 10% stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such forms filed with the SEC and written representations that no other reports were required to be filed during the fiscal year ended December 31, 2004, our directors, executive officers and greater than 10% stockholders complied with all Section 16(a) filing requirements except as follows:

- Phyllis Gardner failed to timely file one Form 4.

Code of Ethics

We have adopted the Aerogen, Inc. Code of Ethics which applies to all officers, directors, employees, associates and agents of Aerogen and any company that we own or manage. Our Code of Ethics is available in the Corporate Governance section of the Investor Relations section of our web site at *www.aerogen.com*. If we make any substantive changes to our Code of Ethics or grant any waiver from a provision of the Code of Ethics to any executive officer or director we will promptly disclose the nature of the amendment or waver on our web site.

Item 11. EXECUTIVE COMPENSATION

The following table sets forth certain information related to compensation paid or accrued for services in all capacities during the fiscal years indicated with respect to Dr. Jane E. Shaw, the Company s Chairman and Chief Executive Officer and each of the Company s other four most highly compensated executive officers at December 31, 2004 (the Named Executive Officers).

Summary Compensation Table

Name and Principal Positions	Annual Compensation Year	Salary(1)	Bonus	Securities Underlying Options	All Other Compensation
Dr. Jane E. Shaw, Ph.D.	2004	$ 269,984		600,000	
Chairman and Chief Executive Officer	2003	$ 270,000			
	2002	$ 271,188			
Robert S. Fishman, M.D.	2004	$ 239,990		300,000	
Vice President, Scientific Affairs	2003	$ 215,000			
	2002	$ 203,638		9,000	
Robert S. Breuil(2)	2004	$ 239,990		300,000	
Chief Financial Officer Vice President	2003	$ 210,000			
Corporate Development	2002	$ 136,125		36,500	
Nancy Isaac(3)	2004	$ 221,395		250,000	
Vice President, Regulatory Affairs and Quality	2003	$ 205,000			
	2002	$ 83,637		9,000	
Yehuda Ivri	2004	$ 217,984		250,000	
Chief Technical Officer	2003	$ 200,000			
	2002	$ 160,022		45,000	

(1) Amounts shown include compensation earned and received by the Named Executive Officers as well as amounts deferred at the election of such persons under the Company s Tax Deferral Investment Plan.

(2) Mr. Breuil joined the Company in April 2002.

(3) Ms. Isaac joined the Company in August 2002.

The following table sets forth information relating to options granted in 2004 to each Named Executive Officer. In addition, in accordance with rules of the SEC, the table shows hypothetical gains that would exist for such options based on assumed rates of annual compound stock price appreciation of 5% and 10% per year from the date the options were granted over the full option term.

Options Grants in Fiscal Year Ended December 31, 2004

	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(1)(4)	
Name	Number of Securities Underlying Options Granted(2)	Percent of Total Options Granted to Employees in Fiscal Year(3)	Exercise Price Per Share(4)	Expiration Date	5% Per Year	10% Per Year
Jane E. Shaw, Ph.D.	600,000	16.1 %	$ 2.65	6/29/2014	$ 999,942	$ 2,534,051
Robert Fishman, M.D.	300,000	8.1 %	$ 2.65	6/29/2014	$ 499,971	$ 1,267,025
Robert S. Breuil	300,000	8.1 %	$ 2.65	6/29/2014	$ 499,971	$ 1,267,025
Nancy Isaac	250,000	6.7 %	$ 2.65	6/29/2014	$ 416,643	$ 1,055,855
Yehuda Ivri	250,000	6.7 %	$ 2.65	6/29/2014	$ 416,643	$ 1,055,855

(1) The closing price of the Company s Common Stock as reported on the Nasdaq SmallCap Market was $1.96 on December 31, 2004 and $1.36 on March 31, 2005. Actual gains, if any, on stock option exercises are dependent on the future performance of the Company s Common Stock. There can be no assurance that any of the value reflected in the table will be achieved.

(2) Based on options to purchase a total of 3,835,000 shares of Common Stock granted to employees during the fiscal year ended December 31, 2004.

(3) Options were granted at an exercise price equal to the fair market value of Aerogen Common Stock on the date of the grant. Potential realizable value assumes appreciation from the value at the time of the grant. Value at the time of the grant is equal to the exercise price per share times the number of shares covered by the option.

The following table sets forth, with respect to the Named Executive Officers, certain information related to options held by such officers during the fiscal year ended December 31, 2004.

Aggregated Option Exercise in Fiscal Year Ended December 31, 2004

			Number of Securities Underlying Unexercised Options at Year End(l)		Value of Securities Underlying Unexercised Options at Year End(2)	
Executives	Shares Acquired on Exercise	Value Realized	Unexercisable	Exercisable	Unexercisable	Exercisable
Jane E. Shaw, Ph.D.			58,124	24,999	$	$
Robert S. Fishman, M.D.			27,948	303,450	$ 480	$ 240
Nancy Isaac			13,683	258,717	$ 128	$ 64
Robert S. Breuil			26,833	309,667	$ 480	$ 240
Yehuda Ivri			7500	253,000	$ 480	$ 240

(1) Certain of the options granted before 2001 may be exercised under the Company s early exercise program; however, any shares purchased early are subject to repurchase by the Company at the exercise price if the employee s service with the Company terminates prior to the vesting date. The repurchase right lapses over time.

(2) Market value of the Company s Common Stock at fiscal year end based on the closing sales price as reported on the Nasdaq Stock Market on December 30, 200 ($1.96) minus the exercise price of in-the-money options.

Compensation of Directors

Each non-employee director of the Company receives a yearly retainer of $10,000 (plus $1,000 for attending Board meetings, $500 for attending Board calls and $500 for attending Committee meetings and calls). In the fiscal year ended December 31, 2004, the total compensation paid to non-employee directors was $56,500. [The members of the Board of Directors are also eligible for reimbursement for their expenses incurred in attending Board meetings in accordance with Company policy.] During the fiscal year ended December 31, 2004, Jean-Jacques Bienaime received $18,500 for his services on the Board and the Board s Compensation Committee and Audit Committee, Bernard Collins received $21,500 for his services on the Board and the Board s Compensation Committee, Audit Committee and Corporate Governance Committee, and Phyllis Gardner received $16,500 for her services on the Board and the Board s Corporate Governance Committee. No other directors received any compensation for their services on the Board or Board Committees during the fiscal year ended December 31, 2004.

The Company had a 2000 Non-Employee Directors Stock Option Plan, approved by the stockholders in November 2000, that provided for the automatic grant of options to purchase shares of Common Stock to non-employee directors until it was terminated by the Aerogen Board of Directors in April 2004.

Employment, Severance and Change of Control Agreements

The Company does not have employment contracts with any of its executives. The Company has an Executive Severance Benefit Plan which provides severance benefits to eligible executive employees selected by the Board. Benefits are paid only upon involuntary termination of employment without cause, or voluntary termination of employment for good reason, within one month prior to or within 13 months following a change in control of the beneficial ownership of the Company. Upon execution of a release of claims, each eligible executive would receive 12 months of salary continuation payable in monthly installments, continued health benefits for 12 months and option vesting acceleration. The vesting of 100% of the executive s unvested options would accelerate immediately prior to the date of termination such that the options would vest in 12 monthly installments beginning on the date of termination. Dr. Jane E. Shaw, Robert S. Breuil, Robert S. Fishman, Nancy Isaac, Yehuda Ivri, and John S. Power are the current participants in the Executive Severance Benefit Plan.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth the beneficial ownership of the Company s Common Stock as of March 25, 2005, except as otherwise noted, (i) by each person, entity or group of persons or entities known by the Company to be beneficial owners of more than 5% of the Company s Common Stock, (ii) by each director, and each of the Named Executive Officers listed in the Summary Compensation Table, and (iii) by all executive officers and directors as a group. Percentage ownership is based on 6,937,994 shares of Common Stock and 988,145 shares of Series A-1 Preferred outstanding on March 25, 2005, together with options or warrants for that stockholder that are currently exercisable or exercisable within 60 days of March 25, 2005. Except as described below, each person has sole voting and investment power with respect to the Common Stock described in the table. Unless otherwise indicated, the address of each of the individuals named below is: c/o Aerogen, Inc., 2071 Stierlin Court, Suite 100, Mountain View, California 94043.

Beneficial Ownership	Shares of Common Stock Beneficially Owned(1)	Percent of Common Stock Total(2)
5% Holders		
Evan Sturza(3) 156 West 56th Street, 16th Floor New York, NY 10019	991,307	14.3 %
SF Capital Partners, Ltd.(4) c/o Staro Asset Management, LLC 3600 South Lake Drive St. Francis, WI 53235	364,700	4.99 %
Entities Affiliated with Xmark Asset Management, LLC(5) 152 West 57th, 21st Floor New York, NY 10019	1,280,610	7.61 %
Entities Affiliated with OrbiMed Advisors, LLC(6) 767 Third Avenue, 30th Floor New York, NY 10017	364,700	4.99 %
Entities Affiliated with HealthCap(7) c/o HealthCap IV, GP SA 18 Avenue d Ouchy 1006 Lausanne Switzerland	364,700	4.99 %
Perceptive Life Sciences Master Fund, LLC(8) c/o Perspective Advisors, LLC 5437 Connecticut Avenue NW, Suite 100 Washington, DC 20015	364,700	4.99 %
Entities Affiliated with North Sound Capital, LLC(9) 53 Forest Avenue, Suite 202 Old Greenwich, CT 06870	364,700	4.99 %

Bay Star Capital II, L.P.(10) c/o Bay Star Capital Management, LLC 80 E. Sir Francis Drake, Suite 2B Larkspur, CA 94939	364,700	4.99 %
SDS Capital Group SPC, Ltd.(11) c/o SDS Capital Group 53 Forest Avenue, Suite 203 Old Greenwich, CT 06870	364,700	4.99 %
Entities Affiliated with Pequot Capital Management, Inc.(12) 500 Nyala Farm Rd. Westport, CT 06880	364,700	4.99 %
Entities Affiliated with ProMed Management, Inc.(13) 125 Cambridgepark Drive Cambridge, MA 02140	364,700	4.99 %
Entities Affiliated with Ursus Capital(14) 156 West 56th Street, 16th Floor New York, NY 10019	364,700	4.99 %
Porter Partners, LP(15) c/o Porter Capital Management 300 Drakes Landing Rd., Suite 175 Greenbrae, CA 94904	364,700	4.99 %
Entities Affiliated with BVF Partners LP(16) 227 West Monroe Street, Suite 4800 Chicago, Illinois 60606	364,700	4.99 %
Directors and Executive Officers:		
Jane E. Shaw, Ph.D.(17)	364,700	4.99 %
Yehuda lvri(18)	188,333	*
John S. Power(19)	94,217	*
Robert Roe	*	*
Jean-Jacques Bienaimé(20)	7,753	*
Robert S. Breuil(21)	38,118	*
Bernard Collins(22)	6,421	*
Robert S. Fishman(23)	35,103	*
Phyllis I. Gardner, M.D.(24)	5,999	*
Nancy Isaac, J.D.(25)	15,617	*
Angela Strand(26)	20,429	*
Mauro Folena	*	*
All executive officers and directors as a group (12 persons)(27)	869,896	11.78 %

* Percentages are not shown if holdings total less than 1% of total outstanding shares.

(1) Includes outstanding stock options that will be vested on or before March 25, 2005, to purchase shares of the Company s Common Stock, as described in the footnotes below.

(2) The conversion of Series A-1 Preferred Stock (Preferred Stock) into common stock and the exercise of the Warrants covered in this table is limited so that no holder of Preferred Stock or Warrants covered by this table may beneficially own (with such holder s affiliates) more that 4.99% of the Company s then-outstanding common stock (the 4.99% limitation). Each stockholder may waive the 4.99% limitation only upon 61 days written notice to the Company. The shares numbers in this column represent the maximum number of shares of common stock that each selling stockholder subject to the 4.99% limitation could hold upon conversion of its Preferred Stock or exercise of its Warrants, based on 6,937,994 shares of common stock outstanding as of March 25, 2005, and accounting for the shares resulting from the conversion or exercise.

(3) Information is as provided by the holder in his Schedule 13G/A filed with the SEC on August 9, 2004; Evan Sturza is the owner of two separate entities that are exempt from registration under the Investment Advisors Act of 1940 (Ursus Capital Management LLC and Ursus Capital Management Corp.) and provide investment management services to two privately owned entities exempt from registration under the Investment Company Act of 1940 (Ursus Capital, L.P. and Ursus Management LLC). Each of the entities, which have different beneficial owners, hold less than five percent of the common stock of the Company, but the aggregate holdings of the two entities exceed five percent of the common stock of the Company. Ursus Capital, L.P. is managed by Ursus Capital Management LLC. Evan Sturza is the sole member of Ursus Capital Management LLC, and possesses the power to vote and to direct the disposition of all securities held by Ursus Capital, L.P. Ursus Offshore, Ltd. is managed by Ursus Capital Management Corp. Evan Sturza is the investment manager of Ursus Capital Management Corp. and possesses the power to vote and to direct the disposition of all securities held by Ursus Offshore Ltd. For the purposes of Rule 13d-3 of the Securities Exchange Act of 1934, Evan Sturza may be deemed to be the beneficial owner of the common stock of the Issuer held by these two separate entities. Evan Sturza disclaims beneficial ownership of such shares common stock.

(4) Includes (i) 29,707 shares of common stock; (ii) 684,100 shares of common stock issuable upon the conversion of Preferred Stock which are or will be convertible within 60 days of March 25, 2005; (iii) 684,100 shares issuable upon exercise of warrants that are or will be exercisable within 60 days of March 25, 2005; and (iv) 59,203 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by SF Capital Partners, Ltd. for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 1,457,110 shares which would, in aggregate, represent 17.5% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. In addition, no warrant issued to SF Capital can be exercised if it would result in SF Capital and/or its affiliates beneficially owning more than 9.999% of our outstanding common stock. This provision cannot be waived. Michael A. Roth and Brian J. Stark have the power to vote and to direct the disposition of all securities owned by SF Capital Partners Ltd.

(5) Includes (i) 503,370 shares issuable upon the conversion of Preferred Stock held by Xmark Fund, LP; (ii) 629,960 shares issuable upon the conversion of Preferred Stock held by Xmark Fund, Ltd. that are or will be convertible within 60 days of March 25, 2005; (iii) 65,416 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Xmark Fund, LP for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; and (iv) 81,864 shares issued or issuable in lieu of the cash payment and quarterly dividends on the Preferred Stock held by Xmark Fund, Ltd. for the quarters ended March 31, June 30, September 30,

December 31, 2004 and March 31, 2005, for a total of 1,280,610 shares which would, in aggregate, represent 15.9% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding Common Stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. On November 3, 2004, Xmark Fund, LP and Xmark Fund, Ltd., provided a written waiver of this limitation to the Company. Accordingly, as of January 3, 2005, this 4.99% limitation on conversion no longer applies to the shares of Preferred Stock held by these two funds. Xmark Asset Management, LLC (XAM), serves as investment manager for each of Xmark Fund, LP and Xmark Fund, Ltd., as well as various other private investment funds. Mitchell D. Kaye is the Manager of XAM, and as such, Mr. Kay possesses the power to vote and direct the disposition of all securities held by Xmark Fund, LP and Xmark Fund, Ltd.

(6) Includes (i) 21,712 shares of common stock held by Caduceus Capital II LP (ii) 9,337 shares of common stock held by Capital Master Fund Ltd. (iii) 21,712 shares of common stock held by UBS Eucalyptus Fund LLC (iv) 35,611 shares of common stock held by Hare & Co for the A/C Finsbury Worldwide Pharmaceutical Trust (v) 2,606 shares of common stock held by UBS Eucalyptus Fund, Ltd. (vi) 3,257 shares of common stock held by HFC SHC Aggressive (vii) 500,000 shares issuable upon the conversion of Preferred Stock held by Caduceus Capital Master Fund Ltd.; (viii) 215,000 shares issuable upon the conversion of Preferred Stock held by Cadeceus Capital II, LP; (ix) 500,000 shares issuable upon the conversion of Preferred Stock held by UBS Eucalyptus Fund, LLC; (x) 60,000 shares issuable upon the conversion of Preferred Stock held by PW Eucalyptus Fund, Ltd; (xi) 650,000 shares issuable upon the conversion of Preferred Stock held by Finsbury Worldwide Pharmaceutical Trust; (xii) 75,000 shares issuable upon the conversion of Preferred Stock held by HFC SHC Aggressive, that are or will be convertible within 60 days of March 25, 2005; (xiii) 500,000 shares issuable upon the exercise of a warrant held by Caduceus Capital Master Fund Ltd.; (xiv) 215,000 shares issuable upon the exercise of a warrant held by Caduceus Capital II, LP; (xv) 500,000 shares issuable upon the exercise of a warrant held by UBS Eucalyptus Fund, LLC; (xvi) 60,000 shares issuable upon the exercise of a warrant held by PW Eucalyptus Fund, Ltd; (xvii) 650,000 shares issuable upon the exercise of a warrant held by Finsbury Worldwide Pharmaceutical Trust; (xviii) 75,000 shares issuable upon the exercise of a warrant held by HFC SHC Aggressive, that are or will be exercisable within 60 days of March 25, 2005, (xix) 37,642 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Capital Master Fund Ltd. for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (xx) 25,544 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Caduceus Capital II, LP for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (xxi) 44,185 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by UBS Eucalyptus Fund, Ltd. for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (xxii) 5,303 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by PW Eucalyptus Fund, Ltd. for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (xxiii) 57,440 shares issued of issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Finsbury Worldwide Pharmaceutical Trust for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; and (xxiv) 6,629 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by HFC SHC Aggressive for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 4,270,978 shares which would, in aggregate, represent 39.0% of the Company s outstanding common stock. However, the

terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. OrbiMed Advisors LLC and OrbiMed Capital LLC act as investment advisers to certain collective investment funds. Samuel D. Isaly owns a controlling interest in OrbiMed Advisors LLC and OrbiMed Capital LLC. OrbiMed Capital LLC is the investment adviser for Finsbury Worldwide Pharmaceutical Trust and HFC SHC Aggressive. OrbiMed Advisors LLC is the investment adviser for Winchester Global Trust Company. OrbiMed Advisors LLC is also the general partner of Capital II, which is the joint venture partner of UBS Eucalyptus Fund, LLC and of PW Eucalyptus Fund, Ltd. As such, Mr. Isaly has the power to vote and to direct the disposition of all the securities held by Winchester Global Trust Company, UBS Eucalyptus Fund, LLC, PW Eucalyptus Fund, Ltd., Finsbury Worldwide Pharmaceutical Trust and HFC SHC Aggressive.

(7) Includes (i) 50,091 shares of common stock held by HealthCap IV LP; (ii) 36,124 shares of common stock held by HeathCap IV BIS LP; (iii) 3,726 shares of common stock held by HeathCap IV KB; (iv) 1,371 shares of common stock held by OFCO Club IV; (v) 660,650 shares issuable upon the conversion of Preferred Stock held by HealthCap IV Bis, LP; (vi) 914,300 shares issuable upon the conversion of Preferred Stock held by HealthCap IV, LP; (vii) 66,710 shares issuable upon the conversion of Preferred Stock held by HealthCap IV KB; (viii) 25,000 shares issuable upon the conversion of Preferred Stock held by OFCO Club IV that are or will be convertible within 60 days of March 25, 2005; (ix) 660,651 shares issuable upon the exercise of a warrant held by HealthCap IV Bis, LP; (x) 914,300 shares issuable upon the exercise of a warrant held by HealthCap IV, LP; (xi) 66,709 shares issuable upon the exercise of a warrant held by HealthCap IV KB; (xii) and 25,000 shares issuable upon the exercise of a warrant held by OFCO Club IV that are or will be exercisable within 60 days of March 25, 2005; (xiii) 58,312 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by HealthCap IV Bis, LP for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (xiv) 80,796 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by HealthCap IV, LP for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (xv) 5,966 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by HealthCap IV KB for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; and (xvi) 2,211 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by OFCO Club IV for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 3,571,917 shares which would, in aggregate, represent 34.8% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. HealthCap IV GP S.A. is the general partner of HealthCap IV, L.P. and HealthCap IV Bis, L.P. and possesses, through its board of directors, the power to vote and direct the disposition of all securities held by HealthCap IV, L.P. and HealthCap IV Bis, L.P. The board of directors of HealthCap IV GP S.A., consists of Peder Fredrikson, a Swedish citizen and Francois Kaiser, a Swiss citizen. HealthCap IV GP AB is the general partner of HealthCap IV KB and possesses, through its board of directors, the power to vote and direct the disposition of all securities held by HealthCap IV KB. The board of directors of HealthCap IV GP AB consists of Johan Christenson, Anki Forsberg, Staffan Lindstrand, Magnus Persson, Björn Odlander and Per

Samuelsson, each of whom are Swedish citizens. Odlander Fredrikson & Co AB as a member of OFCO Club IV and acting on behalf of the other members of OFCO Club IV has the power to vote and direct the disposition of all securities held by OFCO Club IV. Odlander Fredrikson & Co. AB is in turn controlled by Mr. Fredrikson and Mr. Odlander. Each of HealthCap IV, L.P., HealthCap IV Bis, L.P., HealthCap IV KB and OFCO Club IV are parties to a parallel investment agreement pursuant to which each of them has agreed to invest in parallel. The Odlander, Fredrikson Group acts as investment advisor to each of HealthCap IV, L.P., HealthCap IV Bis, L.P. and HealthCap IV KB.

(8) Includes (i) 55,974 shares of common stock; (ii) 1,183,330 shares issuable upon the conversion of Preferred Stock which are or will be convertible within 60 days of March 25, 2005; (iii) 1,333,330 shares issuable upon the exercise of a warrant that is or will be exercisable within 60 days of March 25, 2005; and (iv) 109,342 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Perceptive Life Sciences Master Fund, Ltd. for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 2,681,976 shares which, in aggregate, would represent 28.4% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. Joseph E. Edelman is the Managing Member of Perceptive Advisors, LLC, the Investment Manager of Perceptive Life Sciences Master Fund, Ltd. (Perceptive). As such, Mr. Edelman has sole dispositive and voting authority for all Perceptive s shares.

(9) Includes (i) 7,166 shares of common stock held by North Sound Legacy Fund LLC; (ii) 218,853 shares of common stock held by North Sound Legacy International Fund Ltd.; (iii) 12,816 shares of common stock held by North Sound Legacy Institutional Fund LLC; (iv) 18,000 shares issuable upon the conversion of Preferred Stock held by North Sound Legacy Fund, LLC; (v) 384,000 shares issuable upon the conversion of Preferred Stock held by North Sound Legacy International, Ltd.; (vi) 198,000 shares issuable upon the conversion of Preferred Stock held by North Sound Legacy Institutional Fund, LLC that are or will be convertible within 60 days of March 25, 2005; (vii) 40,000 shares issuable upon the exercise of a warrant held by North Sound Legacy Fund, LLC; (viii) 975,000 shares issuable upon the exercise of a warrant held by North Sound Legacy International, Ltd.; (ix) 485,000 shares issuable upon the exercise of a warrant held by North Sound Legacy Institutional Fund, LLC that are or will be exercisable within 60 days of March 25, 2005(x) 1,910 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by North Sound Legacy Fund, LLC for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (xi) 40,789 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by North Sound Legacy International, Ltd. for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; and (xii) 20,998 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by North Sound Legacy Institutional Fund, LLC for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 2,402,532 shares which, in aggregate, would represent 26.6% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. North Sound Capital LLC is the investment advisor of North Sound Legacy Fund LLC, North Sound Legacy Institutional Fund LLC, and North Sound Legacy International Ltd. Thomas McAuley is the managing member of North

Sound Capital LLC, and is the individual with the power to vote and to direct the disposition of all securities held by North Sound Legacy Fund, LLC, North Sound Legacy International, Ltd. and North Sound Legacy Institutional Fund, LLC.

(10) Includes (i) 50,000 shares of common stock; (ii) 450,000 shares issuable upon the conversion of Preferred Stock which are or will be convertible within 60 days of March 25, 2005; and (iii) 42,505 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by BayStar Capital II, LP for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 542,515 shares which, in aggregate, would represent 7.3% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. BayStar Capital Management, LLC is the General Partner of BayStar Capital II, L.P. Lawrence Goldfarb, Steven M. Lamar, and Bay East, L.P. are the managing members of BayStar Capital Management, LLC. Steve Derby is the General Partner of Bay East, L.P. As such, Lawrence Goldfarb, Steven M. Lamar, and Steve Derby are the individuals with the power to vote and to direct the disposition of all securities owned by BayStar Capital II, LP.

(11) Includes (i) 29,600 shares of common stock; (ii) 450,000 shares issuable upon the conversion of Preferred Stock which are or will be convertible within 60 days of March 25, 2005; (iii) 500,000 shares issuable upon the exercise of a warrant that is or will be exercisable within 60 days of March 25, 2005; and (iv) 42,505 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by SDS Capital Group SPC Ltd. for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 1,022,105 shares which, in aggregate, would represent 13.0% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. SDS Management, LLC is the investment advisor to SDS Capital Group SPC, Ltd. Steve Derby is the sole managing member of SDS Management, LLC, and as such, is the individual with the power to vote and to direct the disposition of all securities owned by SDS Capital Group SPC, Ltd.

(12) Includes (i) 149,840 shares of common stock held by Pequot Scout Fund LP; (ii) 69,170 shares of common stock held by Pequot Navigator Offshore Fund Inc.; (iii) 37,150 shares of common stock held by Pequot Navigator Onshore Fund LP; (iv) 93,980 shares issuable upon the conversion of Preferred Stock held by Pequot Scout Fund, LP; (v) 43,990 shares issuable upon the conversion of Preferred Stock held by Pequot Navigator Offshore Fund, Inc.; (vi) 22,870 shares issuable upon the conversion of Preferred Stock held by Pequot Navigator Onshore Fund, LP that are or will be convertible within 60 days of March 25, 2005; (vii) 390,000 shares issuable upon the exercise of a warrant held by Pequot Scout Fund, LP; (viii) 181,000 shares issuable upon the exercise of a warrant held by Pequot Navigator Offshore Fund, Inc.; (ix) 96,000 shares issuable upon the exercise of a warrant held by Pequot Navigator Onshore Fund, LP that are or will be exercisable within 60 days of March 25, 2005; (x) 21,367 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Pequot Scout Fund for the quarters ended March 31, June 30, September 30, and December 31, 2004; (xi) 9,917 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Pequot Navigator Offshore Fund, Inc. for the quarters ended March 31, June 30, September 30, and December 31, 2004; and (xii) 5,261 shares issued or

issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Pequot Navigator Onshore Fund, LP for the quarters ended March 31, June 30, September 30 and December 31, 2004, for a total of 1,120,545 shares which would, in aggregate, represent 14.4% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. Arthur J. Samberg is the sole owner of Pequot Capital Management, Inc., which is the investment manager/advisor to the Pequot Funds, and as such, possesses the sole power to vote and to direct the disposition of all the securities held by Pequot Scout Fund, LP, Pequot Navigator Offshore Fund, Inc. and Pequot Navigator Onshore Fund, LP. Mr. Samberg disclaims beneficial ownership of any of these securities, except to the extent of his pecuniary interest.

(13) Includes (i) 232,580 shares of common stock ProMed Partners LP; (ii) 42,886 shares of common stock ProMed Partners II LP; (iii) 37,564 shares of common stock held by ProMed Offshore Fund Ltd.; (iv) 80,000 shares issuable upon conversion of Preferred Stock held by David B. Musket; (v) 83,330 shares issuable upon the exercise of warrants held by Paul Scharfer; (vi) 80,000 shares issuable upon the exercise of warrants held by David B. Musket; (vii) 6,808 shares of common stock held by David B. Musket; (viii) 222,900 shares issuable upon the exercise of a warrant held by ProMed Partners LP; (ix) 41,100 shares issuable upon the exercise of a warrant held by ProMed Partners II, LP.; (x) 36,000 shares issuable upon the exercise of a warrant held by ProMed Offshore Fund, Ltd. that are exercisable within 60 days of March 25, 2005; (xi) 12,213 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by ProMed Partners, LP for the quarters ended March 31, June 30, September 30, and December 31, 2004; (xii) 2,254 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by ProMed Partners II, LP for the quarters ended March 31, June 30, September 30, and December 31, 2004; (xiii) 1,973 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by ProMed Offshore Fund, Ltd. for the quarters ended March 31, June 30, September 30, and December 31, 2004; (xiv) 2,653 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Paul Scharfer for the quarters ended March 31, June 30, September 30, 2004; and (xv) 7,071 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by David B. Musket for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 889,332 shares which would, in aggregate, represent 11.9% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. ProMed Partners, L.P., ProMed Partners II, L.P. and ProMed Offshore Fund, Ltd. are managed by ProMed Management, Inc. Barry Kurokawa and David B. Musket are the investment managers of ProMed Management, Inc. and as such, Mr. Kurokawa and Mr. Musket possess the power to vote and to direct the disposition of all securities held by ProMed Partners, L.P., ProMed Partners II, L.P., and ProMed Offshore Fund, Ltd.

(14) Includes (i) 14,548 shares of common stock held by Ursus Capital GSCO (ii) 125,870 shares issuable upon the conversion of Preferred Stock held by Ursus Capital LP; (iii) 168,530 shares issuable upon the conversion of Preferred Stock held by Ursus Offshore, Ltd. that are or will be convertible within 60 days of March 25, 2005; (iv) 180,000 shares issuable upon the exercise of a warrant held by Ursus

Capital, LP; (v) 155,000 shares issuable upon the exercise of a warrant held by Ursus Offshore, Ltd. that are or will be exercisable within 60 days of March 25, 2005; (vi) 15,907 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Ursus Capital LP for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (vii) 13,699 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Ursus Offshore, Ltd. for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 673,554 shares which would, in aggregate, represent 8.9% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. Ursus Capital, L.P. is managed by Ursus Capital Management LLC. Evan Sturza is the sole member of Ursus Capital Management LLC, and possesses the power to vote and to direct the disposition of all securities held by Ursus Capital, L.P. Ursus Offshore, Ltd. is managed by Ursus Capital Management Corp. Evan Sturza is the investment manager of Ursus Capital Management Corp. and possesses the power to vote and to direct the disposition of all securities held by Ursus Offshore Ltd.

(15) Includes (i) 11,580 shares of common stock; (ii) 266,660 shares issuable upon the conversion of Preferred Stock that are convertible within 60 days of March 25, 2005; (iii) 266,660 shares issuable upon the exercise of a warrant that is exercisable within 60 days of March 25, 2005; and (iv) 23,565 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock held by Porter Partners, LP for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005, for a total of 568,465 shares which, in aggregate, would represent 7.6% of the Company s outstanding common stock. However, the terms of such Preferred Stock and Warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or Warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable), provided that such stockholder may waive the provision upon 61 days written notice to the Company. Jeffrey H. Porter has the sole power to vote and to direct the disposition of all securities held by Porter Partners, L.P.

(16) Includes (i) 500,000 shares issuable upon the exercise of a warrant held by Biotechnology Value Fund, L.P.; (ii) 316,663 shares issuable upon the exercise of a warrant held by Biotechnology Value Fund II, L.P.; (iii) 766,664 shares issuable upon the exercise of a warrant held by BVF Investments, L.L.C.; and (iv) 83,333 shares issuable upon the exercise of a warrant held by Investment 10, L.L.C., that are or will be exercisable within 60 days of March 25, 2005, for a total of 1,666,660 shares which would, in aggregate, represent 19.4% of the Company s outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable).

(17) Includes (i) 62,291 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005; (ii) 171,550 shares issuable upon the conversion of Preferred Stock that are convertible within 60 days of March 25, 2005; (iii) 82,129 shares issuable upon the exercise of a warrant that is or will be exercisable within 60 days of March 25, 2005; ((iv) 31,762 shares issued or issuable in lieu of the cash payment of quarterly dividends on the Preferred Stock for the quarters ended March 31, June 30, September 30, December 31, 2004 and March 31, 2005; (v) 12,485 shares of common stock held by the Carpenter Family Trust, in which Dr. Shaw has an economic interest and

(vi) 97,689 shares of common stock owned by Dr. Shaw, for a total of 457,906shares which would, in aggregate, represent 6.39% of the Company s outstanding common stock. However, the terms of such Preferred Stock and warrants preclude the holders thereof from converting or exercising (as applicable) its Preferred Stock or warrants (as applicable) if such conversion or exercise (as applicable) would result in such holder and its affiliates beneficially owning in excess of 4.99% of the Company s outstanding common stock following such conversion or exercise (as applicable).

(18) Includes 8,500 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25 2005 and 146,500 shares held by the Yehuda & Zipora Ivri Revocable Trust, in which Mr. Ivri has an economic interest.

(19) Includes 15,533 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005.

(20) Includes 5,333 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005.

(21) Includes 29,917 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005.

(22) Consists of 4,000 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005.

(23) Includes 29,198 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005.

(24) Includes 5,333 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005.

(25) Consists of 15,617 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005.

(26) Consists of 19,311 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 25, 2005.

(27) Includes shares described in the notes above as applicable to directors and current executive officers.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Compensation Committee Interlocks and Insider Participation

None of Aerogen s executive officers services as a member of the board of directors of compensation committee of any entity that has one or more executive officers services as a member of Aerogen s Board of Directors or Compensation Committee. There are no family relationships among any directors or executive officers.

Certain Transactions

Registration Rights Agreement. The Company entered into an agreement with the holders of its preferred stock, excluding John S. Power, Aerogen s Vice President, European Operations, pursuant to which they have registration rights with respect to the shares of Common Stock into which the preferred stock has converted.

Indemnification Agreements. The Company has indemnification agreements with its directors and officers for the indemnification of and advancement of expenses to these persons to the full extent permitted by Delaware law and the Company s by-laws. The Company intends to execute such agreements with its future directors and officers.

Transactions with Officers and Directors. Yehuda Ivri, Aerogen s Founder and Chief Technical Officer, has three notes payable to the Company. On May 6, 1994, the Company received a promissory note for the principal amount of $69,009. The note bore annual interest of 6.43%, became due in May 2003, and has been fully repaid. On August 15, 1996, the Company received a promissory note from Mr. Ivri for the principal amount of $200,000. The note originally bore no interest and the entire principal balance was due on the earliest of (i) August 14, 2001, (ii) 90 days after Mr. Ivri s Common Stock was no longer subject to a lock-up agreement with the underwriters of the Company s initial public offering, or (iii) the date Mr. Ivri s service with the Company terminates pursuant to Mr. Ivri s resignation or is terminated by the Company for cause. This note was amended effective December 31, 2001 to provide that (i) interest will accrue on the outstanding principal at a rate of 4.38% per annum beginning January 1, 2002, (ii) principal and interest will be due on the earlier of termination of Mr. Ivri s service with the Company or December 31, 2006, and (iii) Mr. Ivri will pay the Company a portion of the proceeds of certain of his sales of Company Common Stock until his notes to the Company have been paid in full. On July 21, 2000, the Company received a promissory note from Mr. Ivri for the principal amount of $50,000. The note bears interest at the rate of 6.62%, and the principal and interest are due on the earlier of (i) July 21, 2005 or (ii) the date at which Mr. Ivri s service with the Company terminates. These latter two notes are secured by 33,333 shares of Mr. Ivri s Common Stock. On December 31, 2004, the principal and accrued interest outstanding on the loans to Mr. Ivri totaled $292,478.

In January 2004, the Company entered into a loan and securities purchase agreement pursuant to which a secured convertible debenture in the aggregate principal amount of $500,000 and a warrant were issued to the Carpenter Family Trust UA (the Carpenter Trust), the trustees of which are Dr. Jane Shaw, Chairman and Chief Executive Officer of the Company, and her husband, Peter Carpenter. The debenture issued to the Carpenter Trust was converted into 164,258 shares of common stock at a conversion price of $3.044 per share. The Carpenter Warrant is exercisable for 82,129 shares of common stock at an exercise price of $3.044 per shares, and expires in January 2008. As part of the A-1 Financing, the Carpenter Trust exchanged the outstanding debentures for an aggregate of 52,232 shares of A-1 Preferred at the second closing.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table presents fees for professional services rendered by PricewaterhouseCoopers, LLP for the audit of the Company s financial statements for fiscal 2004 and 2003 and fees for tax services rendered by PricewaterhouseCoopers. LLP for fiscal 2004 and 2003.

	Fiscal Year Ended	
	2004	2003
	(in thousands)	
Audit Fees(1)	228	160
Tax Fees(2)	8	21
Total Fees	236	181

All fees described above were approved by the Audit Committee.

(1) Audit Fees These are fees for professional services rendered by PricewaterhouseCoopers, LLP for the audit of the Company s annual financial statements and review of the financial statements included in the Company s 10-Q filings, and services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Tax Fees These are fees for professional services performed by PricewaterhouseCoopers, LLP with respect to tax compliance and tax advice.

Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent auditors, PricewaterhouseCoopers LLP. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services, and tax services up to specified amounts. Pre-approval may also e given as part of the Audit Committee s approval of the scope of the engagement of the independent auditor or on an individual explicit case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee s members, but he decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of the services other than audit services by PricewaterhouseCoopers LLP is compatible with maintaining the principal accountant s independence.

The Audit Committee has determined that the rendering of its non-audit services by PricewaterhouseCoopers LLP is compatible with maintaining the accountants independence.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON FINANCIAL STATEMENT SCHEDULE

To the Board of Directors and Stockholders of Aerogen, Inc.:

Our audits of the consolidated financial statements referred to in our report dated March 31, 2005 appearing in this Annual Report on Form 10-K also included an audit of the financial statement schedule listed in Item 15(a)(2) of this Form 10-K. In our opinion, the financial statement schedule presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 31, 2005

Schedule II Schedule of Valuation and Qualifying Accounts (in thousands):

	Balance at beginning of period	Additions	Deductions	Balance at end of period
Provision for Inventories				
Fiscal year ended 2002	$ 30	$ 15	$	$ 45
Fiscal year ended 2003	$ 45	$ 11	$ (53)	$ 3
Fiscal year ended 2004	$ 3	$ 283	$	$ 286
Deferred Tax Valuation Allowance				
Fiscal year ended 2002	$ 25	$ 8	$	$ 33
Fiscal year ended 2003	$ 33	$ 7	$	$ 40
Fiscal year ended 2004	$ 40	$ 6	$	$ 46

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mountain View, State of California, on the 15th day of April 2005.

AEROGEN, INC.

By: /s/ JANE E. SHAW, PH.D.
Jane E. Shaw, Ph.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

POWERS OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jane E. Shaw and Robert S. Breuil, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ JANE E. SHAW Jane E. Shaw	Director and Chief Executive Officer *(Principal Executive Officer)*	April 15, 2005
/s/ PHYLLIS I. GARDNER Phyllis I. Gardner	Director	April 15, 2005
/s/ YEHUDA IVRI Yehuda Ivri	Director	April 15, 2005
/s/ JEAN-JACQUES BIENAIMÉ Jean-Jacques BienaimÉ	Director	April 15, 2005
/s/ ROBERT L. ROE Robert L. Roe	Director	April 15, 2005
/s/ BERNARD COLLINS Bernard Collins	Director	April 15, 2005
/s/ ROBERT S. BREUIL Robert S. Breuil	Chief Financial Officer and Vice President Development *(Principal Financial and Accounting Officer)*	April 15, 2005

No.	Note	Description of Exhibit Document
3.2	(7)	Amended and Restated Certificate of Incorporation of Aerogen, Inc.
3.2.1	(8)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Aerogen, Inc.
3.4	(1)	Amended and Restated Bylaws of Aerogen, Inc.
3.5	(6)	Amendment to Rights Agreement dated as of February 24, 2003, by and between Aerogen, Inc. and Mellon Investor Services, LLC, as Rights Agent
4.1	(1)	Fourth Amended & Restated Information and Registration Rights Agreement dated July 7, 2000 between Aerogen, Inc. and holders of Aerogen, Inc. Series A, Series B, Series C, Series D, Series E, and Series F preferred stock and holders of warrants to purchase Aerogen, Inc. common stock or Series C preferred stock
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	(9)	Loan and Securities Purchase Agreement, dated as of September 9, 2003, by and between the Company and SF Capital Partners, Ltd. (SF Capital).
4.5	(9)	Warrant dated as of September 9, 2003, issued by the Company to SF Capital
4.6	(8)	Debenture dated as of November 3, 2003, issued by the Company to SF Capital
4.7	(8)	Warrant dated as of November 3, 2003, issued by the Company to SF Capital
4.8	(10)	Amendment to Secured Convertible Debenture, dated January 7, 2004, by and between the Company and SF Capital
4.9	(10)	Amendment No. 2 to Secured Convertible Debenture and Consent, dated as of January 20, 2004, by and between the Company and SF Capital
4.10	(10)	Loan and Securities Purchase Agreement, dated as of January 23, 2004, by and between the Company and the Carpenter 1983 Family Trust UA (the Trust)
4.11	(10)	Debenture, dated as of January 23, 2004, issued by the Company in favor of the Trust.
4.12	(10)	Registration Rights Agreement, dated as of January 23, 2004, by and between the Company and the Trust
4.13	(10)	Warrant, dated as of January 23, 2004, issued by the Company in favor of the Trust
4.14	(11)	Purchase Agreement, dated March 11, 2004, by and between the Company, Xmark Fund L.P., Xmark Fund, Ltd. and other investors
4.15	(11)	Certificate of Designations, Preferences and Rights of Series A-1 Preferred Stock of the Company, dated March 19, 2004
4.16	(11)	Form of Warrant
4.17	(11)	Registration Rights Agreement, dated as of March 22, 2004, by and between the Company and the Investors named in the Purchase Agreement
4.18	(11)	Amendment to Purchase Agreement and Waiver, dated as of March 19, 2004, by and between the Company and certain of the Investors named in the Purchase Agreement
4.19	(11)	Amendment No. 2 to Rights Agreement, dated as of March 19, 2004, by and between the Company and Mellon Investor Services LLC as Rights Agent

4.20	(11)	Amendment to Secured Convertible Debentures, dated as of March 1, 2004, by and between the Company and SF Capital
4.21	(11)	Amendment No. 1 to Secured Convertible Debenture and Consent, dated as of March 1, 2004, by and between the Company and the Carpenter Trust
4.22	(11)	Secured Debenture, dated March 12, 2004, issued by the Company to SF Capital
4.23	(11)	Amendment No. 1 to Security Agreement, dated as of March 11, 2004, by and between the Company and SF Capital
4.24	(11)	Amendment No. 1 to IP Security Agreement, dated as of March 11, 2004, by and between the Company and SF Capital
10.1	(1)	Form of Indemnity Agreement
10.2	(3)	Amended and Restated 1994 Stock Option Plan
10.4	(2)	2000 Equity Incentive Plan
10.5	(2)	2000 Non-Employee Directors Stock Option Plan
10.6	(2)	2000 Employee Stock Purchase Plan
10.10	(2)	Amended and Restated 1996 Stock Option Plan
10.11	(4)	Aerogen, Inc. Restated Executive Severance Benefit Plan
10.12	(5)	Form of lease agreement between EOP-Shoreline Technology Park, L.L.C. and Aerogen, Inc. for the premises located at 2071 Stierlin Court, Mountain View, California
10.12.1	(13)	Lease amendment, dated November 6, 2003, between CA-Shoreline Technology Park, LP and Aerogen.
10.12.2	(13)	Lease amendment, dated March 9, 2004, between CA-Shoreline Technology Park, LP and Aerogen.
10.17	(8)*	Distribution and supply agreement, dated as of September 30, 2003, between the Company and Medical Industries America, Inc.
21.1	(12)	Subsidiaries of Aerogen, Inc.
23.1	(12)	Consent of Independent Registered Public Accounting Firm
31.1	(13)	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	(13)	Certification required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	(12)	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to Aerogen s Registration Statement on Form S-1 No. 333-44470 as filed with the Securities and Exchange Commission on August 25, 2000.

(2) Incorporated by reference to Aerogen s Amendment No. 1 to Registration Statement on Form S-1 No. 333-44470 as filed with the Securities and Exchange Commission on October 5, 2000.

(3) Incorporated by reference to Aerogen s Form 10-K for the year ended December 31, 2000 as filed with the Securities and Exchange Commission on March 28, 2001.

(4) Incorporated by reference to Aerogen s Form 10-Q for the quarter ended June 30, 2001 as filed with the Securities and Exchange Commission on August 14, 2001.

(5) Incorporated by reference to Aerogen s Form 10-Q for the quarter ended September 30, 2001 as filed with the Securities and Exchange Commission on November 13, 2001.

(6) Incorporated by reference to Aerogen s Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 25, 2003.

(7) Incorporated by reference to Aerogen s Form 10-Q for the quarter ended June 30, 2002 as filed with the Securities and Exchange Commission on August 13, 2002.

(8) Incorporated by reference to Aerogen s Form 10-Q for the quarter ended September 30, 2003 as filed with the Securities and Exchange Commission on November 14, 2003.

(9) Incorporated by reference to the Company s Current Report on Form 8-K filed on October 7, 2003.

(10) Incorporated by reference to the Company s Current Report on Form 8-K filed on February 5, 2004.

(11) Incorporated by reference to the Company s Current Report on Form 8-K filed on March 26, 2004.

(12) Previously filed with the Company s Form 10-K for the year ended December 31, 2003.

(13) Filed herewith.

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