AEROGEN INC
Form 10-K
April 14, 2004

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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, 2003

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, 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 ý 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 ý

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, 2003 was $7,357,041. 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, 2003. This determination of affiliate status is not a conclusive determination for other purposes.

The number of shares of common stock outstanding as of March 26, 2004 was 4,780,195.

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, 2003

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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. 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 intended to 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 focusing on respiratory therapy in the acute care setting. Based on our proprietary OnQ Aerosol Generator ("OnQ") for aerosolizing liquids, we have developed and commercially introduced nebulizers that optimize aerosol production for use in both the home and hospital. We are developing, and intend to commercialize, drug products that specifically target treatment of respiratory disorders in the acute care setting. In addition, we are developing pulmonary drug delivery products in collaboration with partner companies for respiratory therapy and systemic drug input.

Our current products address many of the limitations presented by use of traditional nebulizers for pulmonary drug delivery. We believe our drug products in development for pulmonary drug delivery using our proprietary technology could have a major impact on treatment of respiratory disorders in the acute 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 development 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"). 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 intend 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 2 diabetic patients, and have successfully taken the product through Phase 2a testing. We have completed 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, 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.

As of December 31, 2003, Aerogen had cash and cash equivalents of approximately $0.8 million, which was subsequently augmented on January 26, 2004 by $0.5 million in proceeds from the issuance of a secured convertible debenture to the Carpenter Family Trust, the trustees of which are Aerogen's Chairman and Chief Executive Officer, Dr. Jane Shaw and her husband Peter Carpenter. On March 23, 2004, a first closing of a $32.7 million equity financing provided gross proceeds of $15.0 million, with an additional $17.7 million to be provided in a second closing conditional upon approval by Aerogen's stockholders, currently anticipated to take place within a few days of the Company's Annual Meeting, which is scheduled for May 10, 2004.

"Aerogen®," "Aerodose®," "Aeroneb®" 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 upper 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, less than three microns in diameter, are more likely to pass through the upper 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. 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 United States 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 ventilators.

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 therefore a strong risk factor for the development of pneumonia (ventilator-associated pneumonia, or "VAP"). Approximately 10-30% 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%-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 United States require mechanical ventilation for an acute exacerbation of COPD ("AECOPD"), a rapid worsening of lung function, commonly triggered by a bacterial or viral infection. 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 only 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 intensive care unit. 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 (1-3%) 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 that is strong, corrosion resistant and durable. 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 efficient and lightweight, allowing it to be placed close to the ventilated patient's windpipe, providing 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.

Our Nebulizer Products

Aeroneb Portable Nebulizer System. This product is no longer being manufactured or actively marketed by Aerogen.

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, with minimal wasted medication, 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 Medical Industries America Inc. ("MIA") for marketing and manufacturing of the Aeroneb Go, under which MIA has exclusive rights to manufacture and market the product in the United States and certain countries worldwide, including the major markets of Europe and Japan. In connection with our agreement with MIA, we received upfront payments from MIA totaling $2.5 million in 2003; in addition, Aerogen is supplying its OnQ Aerosol Generators to MIA under a transfer pricing

arrangement, and MIA will pay us royalties on its gross sales of the Aeroneb Go and MIA's sales of accessories. First commercial shipments occurred in the United States in January 2004.

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 general-purpose nebulizer intended to aerosolize physician-prescribed solutions for inhalation. 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 a worldwide agreement with Puritan Bennett ("PB") under which PB sells the Aeroneb Pro System with certain of its 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. These distributors are supported in the United States by our small group of contract clinical specialists. 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 Medical Systems in October 2003. Under the agreement, Aerogen will supply Datex-Ohmeda with a customized version of the Aeroneb Pro for integration into future products designed for critical care.

Aerogen's sales of the Aeroneb Pro System were approximately $3.0 million and $1.6 million in 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 animal testing laboratories, marketed as the Aeroneb® Lab (Aeroneb Lab).

Sales of our Aeroneb products accounted for 77% of our total revenues in 2003 and 75% of our total revenues in 2002.

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 incorporating our Pulmonary Drug Delivery System ("PDDS") that will deliver drug-containing aerosols to patients in the acute care setting.

Our activities for therapeutic products to be marketed by Aerogen will be focused on product development, clinical testing, and 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 the ventilator and aerosolizing the drug during a predetermined portion of the ventilator cycle. 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, where it was used 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 delivery of drug products in the acute care setting.

Aerosolized Antibiotics. Our lead drug product is a combination of 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 during 2003. In this study, we compared drug deposition in the lungs of 12 ventilated patients when the drug was administered by a first generation clinical version of the PDDS, the commercially available Aeroneb Pro System and the commercially available Airlife Misty Neb nebulizer. We used a sulfite-free solution of amikacin approved for intravenous administration that is commercially available in France. This particular formulation has been associated with off-label use administered by aerosol for treatment of infections in children with cystic fibrosis. The study confirmed the higher efficiency of the PDDS vs. the two comparator devices. We intend to initiate a Phase 2 dose-ranging study under a United States investigational new drug application ("IND") during the second half of 2004 to select the doses to carry forward into pivotal trials.

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 an Aerogen drug/device combination product 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). We have several drug products in the preclinical stage of evaluation.

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. A Phase 1b study has been completed by Discovery Labs with the goal of evaluating aerosolized surfactant delivered using Aerogen technology for treatment of asthma in the emergency room setting.

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.

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 are ongoing.

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.

In addition to insulin, we are continuing to evaluate the market opportunities for other drugs that we believe can be delivered to the bloodstream using our Aerodose inhaler. We intend to collaborate with pharmaceutical and biotechnology companies for the development, clinical testing and commercialization of other Aerodose inhaler products.

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 will receive 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. We have been advised that launches in additional countries are planned for 2004. We will continue to explore out-licensing opportunities for our technologies

outside the field of pulmonary drug delivery.

Research and Development Spending

During 2003, 2002 and 2001 we spent approximately $11.5 million, $17.4 million and $19.7 million, respectively, on our own research and development activities, and approximately $0.2 million, $0.4 million and $2.0 million in 2003, 2002 and 2001, 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 for the major worldwide markets by MIA.

We outsource production of many components of our products to manufacturers in the United States and elsewhere. Generally, there is more than one potential supplier for these components, but some are manufactured to our specifications and an interruption in supply could adversely affect our ability to manufacture and supply our products. The brazing process used in assembly of our OnQ Aerosol Generators is conducted at a third party's facilities. Loss of the use of those facilities would result in several months' delay in our supply of components while we establish an alternative brazing site. Palladium, which we use in our OnQ aperture plate, is expensive and is subject to price volatility. The palladium plating bath chemicals we use to manufacture our OnQ Aerosol Generators are formulated by a single supplier.

Sales and Marketing

The Aeroneb Go Nebulizer is sold by MIA in the United States to home medical equipment dealers and pharmacies. MIA intends to commercialize the Aeroneb Go outside of the United States. Aerogen also sells the Aeroneb Go in Norway through its distributor Normed. The Aeroneb Pro is sold to United States hospitals by Cardinal Health and Puritan Bennett, supported by Aerogen's contract

clinical specialists. Outside the United States, we have agreements with independent distributors on a country-by-country basis, and also with Puritan Bennett. 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.

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, 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.

The pulmonary drug delivery market, in particular, is intensely competitive. Several companies, including Alkermes, Inc., Aradigm Corporation, Battelle Pharma, PARI 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. 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 compete on the basis of not only efficacy, but also 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, 2003, we held 22 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 employed 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 and amended them to 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 he 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 regional court in Munich, Germany alleging that Aerogen's Aeroneb Pro product infringes a patent licensed to PARI GmbH. While the suit has not yet been formally initiated by the German regional court, we believe that it is without merit and intend to vigorously defend against all allegations in the suit. In May 2003, we filed an action in the German patent office requesting that the patent in question be rendered null and void.

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 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 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. 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 66 employees as of December 31, 2003. Approximately 15 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 155 employees at the beginning of 2002. We reduced our workforce twice during 2002 by a total of

48 employees, and again 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.	65	Chief Executive Officer and Chairman of the Board of Directors
Yehuda Ivri	52	Chief Technical Officer, Director and Founder
Robert S. Breuil	42	Chief Financial Officer, Vice President, Corporate Development
Robert S. Fishman, M.D.	42	Vice President, Scientific Affairs
Nancy Isaac	42	Vice President, Regulatory Affairs and Quality
John S. Power	44	Managing Director Aerogen (Ireland) Limited and Senior Vice President, Sales

Jane E. Shaw, Ph.D. has served as Chairman of our Board of Directors and as our Chief Executive Officer since 1998. Dr. Shaw was the founder of The Stable Network, a consulting company focusing on improving the productivity and profitability of biopharmaceutical companies, from 1994 to 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 Boise Cascade Corporation, an office, wood and paper products company, Intel Corporation, a semiconductor manufacturer, and McKesson Corporation, a healthcare supply management company.

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 spent eight years at ALZA Corporation, 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 served as Worldwide Vice President, Regulatory and Quality for BD Biosciences, a business segment of Becton, Dickinson & Company. Ms. Isaac has also held senior 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 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.

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. 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.

In April 2004, we adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer and controller or persons performing similar functions. Our code of ethics will be posted on our Web site at *www.aerogen.com* during the second quarter of 2004. In addition, we intend to promptly disclose on our Web site in the future (1) the nature of any

amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer and controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver.

Certain Financial Information

As of December 31, 2003, 2002 and 2001, 88%, 73% and 70%, respectively, of our long-lived assets were maintained in the United States. For the years ended December 31, 2003, 2002 and 2001, 22%, 29% and 97%, respectively, of our consolidated revenues were generated in the United States.

Item 2. PROPERTIES

Our United States operations are currently located in a single 66,096 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 month to month basis. 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

In April 2003, we received notice that a German patent infringement suit had been filed by PARI GmbH in the regional court in Munich, Germany alleging that Aerogen's Aeroneb Pro product infringes a patent licensed to PARI GmbH. While the suit has not yet been formally initiated by the German regional court, we believe that it is without merit and intend to vigorously defend against all allegations in the suit. In May 2003, we filed an action in the German patent office requesting that the patent in question be rendered null and void.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On October 30, 2003, Aerogen held a special meeting of its stockholders to: (i) approve the second closing of a convertible debt financing with SF Capital Partners, Ltd., including the issuance of a convertible debenture and warrant to purchase Common Stock; (ii) amend the Company's Amended and Restated Certificate of Incorporation to effect a reverse stock split of our common stock pursuant to which any whole number of outstanding shares between and including four and eight would be combined into one share of our common stock and to authorize our

Board of Directors to select and file one such amendment; (iii) conduct the annual election of directors prescribed by the Company's Amended and Restated Certificate of Incorporation by electing three Class III directors to hold office for a term ending in 2006 and until their successors are elected and have qualified; and (iv) ratify the selection of PricewaterhouseCoopers LLP as the Company's independent auditors for the fiscal year

ending December 31, 2003. See Aerogen's Definitive Proxy Statement filed on Form 14A on October 9, 2003.

The results of the 2003 stockholder vote appear in the table below:

Proposal	For	Against	Abstain	Broker Non-Vote
Proposal 1: To approve the issuance of a convertible debenture and warrant to purchase Common Stock pursuant to a convertible debt financing with SF Capital Partners, Ltd.	8,088,928	276,112	39,972	7,085,420
Proposal 2: To amend the Company's Amended and Restated Certificate of Incorporation to effect a reverse stock split.	15,151,209	331,923	7,300	0

Proposal 3: Election of Directors

Name	For	Withheld
Jean-Jacques Bienaimé	15,424,962	65,470
Yehuda Ivri	14,900,315	590,117
Bernard Collins	15,439,537	50,895

Proposal	For	Against	Abstain	Broker Non-Vote
Proposal 4: Ratification of appointment of PricewaterhouseCoopers LLP as independent auditors for the fiscal year ending December 31, 2003.	15,434,352	38,680	17,400	0

As indicated in the table above, Jean-Jacques Bienaimé, Yehuda Ivri and Bernard Collins were elected as Class III directors. The directors whose terms continued after the stockholders' meeting were Phyllis I. Gardner, M.D., Philip M. Young, Thomas R. Baruch and Jane E. Shaw, Ph.D.

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 2002 and 2003 adjusted for the October 31, 2003 one-for-five reverse stock split are as follows:

	High	Low
Q1 '02	$ 18.00	$ 7.50
Q2 '02	$ 10.75	$ 3.95

	High	Low
Q3 '02	$ 5.50	$ 2.00
Q4 '02	$ 3.60	$ 1.70
Q1 '03	$ 2.50	$ 0.25
Q2 '03	$ 5.00	$ 0.75
Q3 '03	$ 6.40	$ 1.55
Q4 '03	$ 5.30	$ 1.65

As of March 26, 2004, there were approximately 164 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.

Since December 26, 2002, our common stock has been listed on the Nasdaq SmallCap Market. Prior to that time, our common stock had been listed on the Nasdaq National Market since November 10, 2000. On October 30, 2003, our stockholders approved a one-for-five reverse stock split that became effective at 5:00 pm PST on October 31, 2003.

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, 2003.

Plan Category	Number of securities to be issued upon exercise of outstanding options and rights	Weighted average exercise price of outstanding options and rights	Number of securities available for future issuance
Equity compensation plans approved by security holders (1)(2)(3)	477,180	$ 13.27	562,334
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 2003, the Board of Directors decided not to increase the number of shares available for grant under the 2000 Equity Incentive Plan pursuant to this provision.

(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 2003, the Board of Directors decided not to increase the number of shares available for grant under the 2000 Employee Stock Purchase Plan pursuant to this provision.

Sales of Unregistered Securities

On October 24, 2003, we issued 60,000 shares of our common stock to our landlord, EOP-Shoreline Technology Park, L.L.C. ("EOP"), in connection with an agreement to defer a portion of the base rent due under the lease relating to our offices in Mountain View, California (the "Lease") for the 24-month period ending on June 30, 2005. We issued an additional 50,000 shares of our common stock to EOP in connection with a further amendment of the Lease on March 9, 2004 to, among other things, reduce our rented space, reduce the rental rate per square foot and reduce the term of the Lease.

On September 10, 2003, the Company entered into a loan and securities purchase agreement with SF Capital, and the Company closed the first round of a two-round convertible debt financing. In the first closing, SF Capital purchased a secured convertible debenture with a face value of approximately $950,000 that subsequently converted in its entirety, along with accrued interest, into an aggregate of 564,224 shares of our common stock. The debenture, as amended, was due June 1, 2004, bore interest at a rate of 10% per annum and had a conversion price of $1.75 per share. SF Capital also received a warrant to purchase up to approximately 271,428 shares of common stock at an exercise price of $1.75 per share, which expires in September 2007. This warrant may not be exercised to the extent that such exercise would result in SF Capital and its affiliates owning in excess of 9.999% of the Company's outstanding common stock.

The second closing of the SF Capital transaction occurred on November 3, 2003 after approval by Aerogen's stockholders at a special meeting on October 30, 2003. In the second closing, SF Capital purchased a secured convertible debenture (the "Second Debenture") with a face amount of $1,000,000. The Second Debenture bears interest at a rate of 10% per annum and, as amended, is due June 1, 2004, and is currently convertible into common stock at a conversion price of $3.044 per share, as adjusted. If fully converted, the principal amount of the Second Debenture would result in the issuance of 328,515 shares of our common stock. SF Capital also received a warrant to purchase up to 164,257 shares of our common stock at an exercise price of $3.044 per share, as adjusted, which expires in November 2007. The terms of the debentures and warrants preclude SF Capital from converting or exercising such securities if such conversion or exercise would result in SF Capital and its affiliates owning in excess of 9.999% of the Company's outstanding stock.

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

On March 11, 2004, we signed definitive documents for a $32.7 million equity financing (the "Financing") with Xmark Fund, L.P. and Xmark Fund, Ltd. ("Xmark") and other accredited investors. The Financing entails the sale and issuance, in two closings, of an aggregate of approximately 1,142,067 shares of Series A-1 Preferred Stock initially convertible into approximately 11,420,670 shares of the

Company's common stock, and warrants to purchase approximately 11,249,210 shares of common stock at an exercise price of $3.25 per share.

On March 23, 2004, the Company completed the first closing of the Financing, resulting in the sale and issuance of 499,981 shares of Series A-1 Convertible Preferred Stock and warrants to purchase 4,999,810 shares of the Company's common stock, in exchange for gross proceeds of $14,999,430. If the second closing of the Financing is approved at Aerogen's annual meeting of stockholders scheduled for May 10, 2004, Aerogen will issue an additional 642,086 shares of Series A-1 Convertible Preferred Stock and warrants to purchase 5,898,810 shares of common stock for anticipated gross proceeds of approximately $17.7 million. Under the terms of the Financing, the Company terminated the Rights Agreement between it and Mellon Investor Services LLC as Rights Agent, dated as of June 5, 2001, as amended February 24, 2003, pursuant to Amendment No. 2 to Rights Agreement dated as of March 19, 2004.

As part of the Financing, SF Capital and the Carpenter Trust have agreed to exchange the outstanding secured convertible debentures previously issued to them for an aggregate of approximately 52,205 shares of Series A-1 Preferred Stock, assuming an exchange date of May 10, 2004. The exchange is scheduled to occur at the earliest of (i) the second closing of the Financing, (ii) the termination of the definitive documents relating to the Financing or (iii) May 17, 2004. SF Capital also will receive warrants to acquire approximately 350,590 shares of common stock in connection with its debt exchange, assuming an exchange date of May 10, 2004.

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

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,				
	2003	2002	2001	2000	1999
Consolidated Statement of Operations Data:					
Total revenues	$ 4,171	$ 2,532	$ 2,469	$ 5,832	$ 468
Costs and expenses:					
Cost of products sold	2,296	1,786	285		
Research and development	11,744	17,772	21,698	16,219	7,910
Selling, general and administrative	6,507	8,382	8,138	4,143	2,076
Purchased in-process research and development				3,500	
Litigation settlement			2,000		
Total costs and expenses	20,547	27,940	32,121	23,862	9,986
Loss from operations	(16,376)	(25,408)	(29,652)	(18,030)	(9,518)
Interest and other income (expense), net	(1,043)	497	2,250	1,160	550
Net loss	(17,419)	(24,911)	(27,402)	(16,870)	(8,968)
Dividend related to beneficial conversion feature of preferred stock				(16,517)	
Net loss available to common stockholders	$ (17,419)	$ (24,911)	$ (27,402)	$ (33,387)	$ (8,968)
Net loss per common share, basic and diluted	$ (4.22)	$ (6.17)	$ (6.96)	$ (36.49)	$ (24.77)
Shares used in computing net loss per common share, basic and diluted	4,126	4,036	3,936	915	362

	December 31,				
	2003	2002	2001	2000	1999
Consolidated Balance Sheet Data:					
Cash, cash equivalents and available-for-sale securities	$ 762	$ 8,887	$ 36,077	$ 60,976	$ 7,809
Working capital	(2,181)	8,679	33,457	60,639	7,408
Total assets	9,576	19,194	43,468	66,712	9,674
Long-term obligations, less current portion	246	205	212	184	100
Convertible preferred stock					31,476
Accumulated deficit	(109,471)	(92,052)	(67,141)	(39,739)	(22,869)
Total stockholders equity (deficit)	1,680	15,744	38,531	64,228	(23,013)

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 focusing on respiratory therapy in the acute care setting. Based upon our proprietary and commercially-proven OnQ aerosol generator, we are developing respiratory products for marketing by us, and products in collaboration with, and for marketing by, pharmaceutical and biotechnology companies for both respiratory therapy and for the delivery of drugs through the lungs to the bloodstream.

In 2003, we had two nebulizer products on the market. We have an accumulated deficit of approximately $109.5 million as of December 31, 2003. 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 December 2003, we announced FDA marketing clearance for the Aeroneb Go Nebulizer, which began shipping in January 2004. All of our products incorporate our OnQ aerosol generator. Since the launch of the first Aeroneb product, we have recorded cumulative revenues of $5.3 million associated with sales of the Aeroneb products and component parts as of December 31, 2003. The Aeroneb Portable Nebulizer System has been promoted in the United States by a small contract sales force under contract from a division of Cardinal Health, and by several home medical equipment distributors. The Aeroneb Pro is available in the United States where it is sold by Puritan Bennett as an accessory to ventilators and through Cardinal Health. The Aeroneb Pro is available in over 30 countries worldwide under agreements with Puritan Bennett and independent distributors in 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 Medical Industries America Inc. ("MIA") for marketing and manufacturing of the Aeroneb Go, under which MIA has exclusive rights to manufacture and market the product in the United States and

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

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. We expect to receive payments from partners for the development of products under contract for reimbursement of development expenses incurred under an approved work plan, and royalties on future total product sales similar collaborations, and royalties based on partner 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 the manufacturing of products 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.

We have incurred stock-based compensation expenses of $1.0 million, $1.4 million and $1.3 million, for the years ended December 31, 2003, 2002 and 2001, respectively. Stock-based compensation included in research and development expenses was $0.3 million, $0.5 million and $0.9 million for the years ended December 31, 2003, 2002 and 2001, respectively. Stock-based compensation included in selling, general and administrative expenses was $0.7 million, $0.9 million and $0.4 million, respectively, for the years ended December 31, 2003, 2002 and 2001. As of December 31, 2003, there was approximately $0.3 million of remaining deferred stock-based compensation, which will continue to be amortized to expense on a straight line basis through 2004. 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 $85.7 million and $27.5 million, respectively, as of December 31, 2003. We also had aggregate federal and state research and development tax credit carryforwards of approximately $2.0 million each as of December 31, 2003. The net operating loss and credit carryforwards will expire in various amounts beginning in 2009 for federal purposes and 2004 for state purposes, if not utilized. 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, terminating the employment 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.

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 11% of our net loss for the year ended December 31, 2003 and 12% of our assets and 10% of our total liabilities as of December 31, 2003. 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. Accordingly we had cumulative translation gains (losses) of approximately $700,000, $217,000 and ($80,000), which were in accumulated other comprehensive income (loss) on our balance sheets at December 31, 2003, 2002 and 2001, respectively. During 2003, 2002 and 2001, respectively, translation adjustments of $483,000, $297,000 and ($100,000), respectively, were recorded as components of other comprehensive loss. Had we determined that the functional currency of our subsidiary was the United States dollar, these gains (losses) would have affected our net losses for each of the years presented. The magnitude of these gains or losses is dependent upon movements in the exchange rates of the foreign currencies in which we transact business against the United States dollar. Any future translation gains or losses could be significantly different from those noted in each of these years.

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 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.

Results of Operations

Comparison of years ended December 31, 2003, 2002 and 2001

Product sales. Product sales were $3.2 million in 2003, $1.9 million in 2002 and $0.2 million in 2001. We launched our first commercial product, the Aeroneb Portable Nebulizer System, in June 2001 and our second commercial product, the Aeroneb Pro in June 2002. The increase in product sales for the year ended 2002 over 2001 was due to the launch of 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.

Research and development revenues. Research and development revenues were $0.3 million in 2003, $0.4 million in 2002 and $2.0 million in 2001. The revenue decrease in 2003 compared with 2002 resulted from the ending of the Puritan Bennett contract in 2002. The revenue decrease in 2002 as compared to 2001 resulted from decreased development activities for Chiron of $1.8 million, partially offset by development activities for other partners of $0.2 million. Research and development revenues can be expected to vary from period to 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 $0.6 million in 2003, $0.3 million in 2002 and $0.3 million in 2001. The increase in royalty and other revenue in 2003 over 2002 was partially due to up front payments associated with the October 2003 commercial agreement with MIA, which resulted in the amortization of $0.1 million of a $2.5 million upfront payment which is being amortized ratably over the five year term of the agreement. Additionally, in 2003, a consumer company that has licensed our aerosol generator technology for use in the field of air fresheners and insect repellants introduced the first product outside the United States, which caused the minimum royalty payment to increase to $0.5 million from $0.2 million in 2002 and 2001.

Cost of products sold. Cost of products sold was $2.3 million in 2003, $1.8 million in 2002 and $0.3 million in 2001. In 2003 the average cost of sales was 72%, down from 95% in 2002, and negative gross margins in 2001. 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 $11.7 million in 2003, $17.8 million in 2002 and $21.7 million in 2001. 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 to 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 Amikacin clinical trials of $0.2 million. The decrease in research and

development expenses in 2002 compared with 2001 was primarily due to a $2.2 million decrease in expenses associated with finalizing the commercial version of the Aerodose insulin inhaler and the completion of Phase 2a clinical trials for the insulin program. In addition, in 2002, there was a reduction of $1.9 million in payroll-related expenses associated with the reductions in force, reductions in expense with the finalizing the development of an Aerodose respiratory inhaler of $1.3 million and other spending reductions of $0.9 million, partially offset by increased facility and information technology related expenses of $2.6 million.

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 $6.5 million in 2003, $8.4 million in 2002 and $8.1 million in 2001. 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 trades 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. The increase in selling, general and administrative expenses for 2002 as compared to 2001 was primarily due to the increased facility expenses associated with the new Mountain View facility of $0.6 million, an incremental $0.3 million increase associated with the outside sales force, and an incremental $0.5 million of stock compensation expense amortized in 2002. Partially offsetting the increases were reductions in payroll related expenses of $0.2 million associated with the reduction in force, reductions in advertising expenses of $0.2 million, and reductions in consulting expenses of $0.3 million. In addition, the amortization of goodwill was discontinued in 2002 in accordance with SFAS 142 resulting in a $0.4 million reduction of expenses.

Litigation settlement. In October of 2001, we settled a lawsuit brought by us against BD. Under the settlement agreement, we paid BD a total of $2.0 million, in two equal installments, in October 2001 and February 2002. As a result of the settlement, we own all of the intellectual property developed by either party under the now terminated agreement, and BD has a non-exclusive license to certain technology developed by BD under the agreement for use outside the field of inhaled insulin. 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.

Interest and other income, net. Net interest expense was $1.0 million in 2003, compared with $0.5 million of net interest income in 2002 and $2.3 million of net interest income in 2001. The growth in interest expense 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 totaling $1.0 million. There was no interest expense for 2002 or 2001. Interest income in 2003 was $0.1 million compared with $0.5 million in 2002 and $2.3 million in 2001. 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. The decrease in interest income in 2002, as compared to 2001,

was primarily due to lower average cash and investment balances, and to a lesser extent, lower interest rates.

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

Since inception, we have financed our operations primarily through equity and convertible debt financings, product revenues, research and development revenues, licensing fees, royalties, and the interest earned on related proceeds. We have received approximately $98.5 million aggregate net proceeds from sales of our common and preferred stock through December 31, 2003, including approximately $44.5 million of net proceeds from our initial public offering in November 2000. In the year ended December 31, 2003, $2.0 million was raised through the issuance of convertible notes.

As of December 31, 2003, Aerogen had cash and cash equivalents of approximately $0.8 million, which was subsequently augmented on January 26, 2004, by $0.5 million from the issuance of a secured convertible debenture to the Carpenter Family trust, the trustees of which are Aerogen's Chairman and Chief Executive Officer, Dr. Jane Shaw and her husband Peter Carpenter. On March 23, 2004, Aerogen completed the first closing of a $32.7 million equity financing that provided gross proceeds of approximately $15.0 million. The second closing is expected to provide an additional $17.7 million of gross proceeds and is conditioned upon approval of Aerogen's stockholders.

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 in operating activities for the year ended December 31, 2001 was $23.7 million, primarily due to the operating loss of $27.4 million, partially offset by an increase in accrued liabilities of $1.9 million, primarily due to the $1 million accrual for litigation settlement, depreciation expense of $1.2 million, and amortization of stock based compensation of $1.3 million.

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. For the year ended December 31, 2001, cash used by investing activities was $9.9 million, and resulted primarily from the addition of leasehold improvements, which amounted to $0.9 million, acquisition of property and equipment, which was $1.0 million, and the net purchase of available-for-sale securities of $8.0 million.

Net cash provided by financing activities was $2.1 million, $0.5 million, and $0.5 million, for the years ended December 31, 2003, 2002 and 2001, respectively. 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. In 2001, approximately $0.5 million was provided 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 and 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 products, costs involved in obtaining and maintaining patents, and our ability to enter into and maintain collaborative agreements.

The Company will need additional capital in the future. The first closing of our recent equity financing on March 23, 2004 provided us with funds to continue operations through approximately April 2005. Should our stockholders fail to approve the second closing, we will need to raise additional funds through public or private financings to continue our operations on a longer-term basis.

We currently have no material commitment for capital expenditures. We have a five-year lease for our Mountain View facility that was originally signed in October of 2001 and amended in November of 2003 and in March of 2004. Under the original lease agreement, our total lease obligation through 2012 was approximately $22.7 million, plus approximately $3.1 million of common area maintenance fees. Under the amended lease agreement, our total lease obligation through 2009 is approximately $4.1 million, plus approximately $1.0 million of common area maintenance fees, and the Company was required to relinquish to our landlord the remaining $900,000 balance of its standby letter of credit, and make additional cash payments to our landlord in the first half of 2004 totaling $650,000.

In addition, we have a commitment of approximately $0.2 million to Irish investors under a tax advantaged business expansion scheme 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, 2003, we had contractual obligations and commercial commitments of approximately $27.4 million as shown in the table below, $25.8 million of which related to the operating lease of our facility in Mountain View, CA, and which excludes obligations related to accounts payable and accrued liabilities incurred in the ordinary course of business.

Contractual Obligations

Payments Due by Period as of December 31, 2003

	Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
			(in thousands)		
Operating Lease	$ 25,784	$ 2,784	$ 5,645	$ 6,785	$ 10,570
Convertible Debentures	1,569	1,569			
Total	$ 27,353	$ 4,353	$ 5,645	$ 6,785	$ 10,570

Under the terms of our March 2004 lease amendment, our revised operating lease obligations are as follows:

Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
$5,046	$704	$1,895	$2,254	$193

We have no relationship with unconsolidated entities or financial partnerships. We have two debt arrangements with restrictive covenants, which limit our ability to assume additional indebtedness, dispose of assets, pay dividends, create or incur liens, or make guaranties without the prior written consent of the debenture holders.

As of December 31, 2003, 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 January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of FIN 46 did not have a material impact on the Company's consolidated financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how companies classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires companies to classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS No. 150 was effective for financial instruments entered into or modified after May 31, 2003, and otherwise was effective at the beginning of the first interim period after June 15,2003. The adoption of SFAS No. 150 did not have a material impact on the Company's consolidated financial statements.

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, cash equivalents and short term investments are invested in government notes and 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. Effective January 1, 2002 the Irish subsidiary's functional currency became 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.

Risk Factors

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.

We will need additional capital in the future.

As of December 31, 2003, we had $0.8 million in cash and cash equivalents. On January 26, 2004, the Company issued a certain debenture and warrant in exchange for approximately $505,000 in gross proceeds. On March 11, 2004, we entered into an agreement to sell certain equity securities for a total of $32.7 million in gross proceeds. On March 23, 2004, we completed a first closing of that financing for gross proceeds of $15 million. The net proceeds from this first closing provided us with funds to continue operations through approximately April 2005. A second closing for gross proceeds of $17.7 million is conditioned on stockholder approval at our annual meeting of stockholders, which is scheduled for May 10, 2004. Should our stockholders fail to approve this second closing, we will need to raise additional funds through public or private financings, sale of certain of our assets, collaborative relationships or other arrangements in order to continue our operations on a longer-term basis. We cannot be certain that alternative funding will be available on terms attractive to us, or at all. Furthermore, additional equity or debt financing may involve substantial dilution to our existing stockholders, restrictive covenants or high interest rates. 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. We may also explore other potential options, such as a merger or sale. If the stockholders reject the second closing, and our efforts to secure alternative funding are unsuccessful, we will have to significantly curtail our operations. Even if

the stockholders approve the second closing, or we are successful at raising alternative funds to continue our operations, our cash requirements may increase in the future because of our research and development efforts, including clinical trials, capital expenditures and the manufacture and marketing of our products.

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

Even if our stockholders approve the second closing of the $32.7 million equity financing, our cash resources will most likely be insufficient to complete Phase 3 clinical trials for any of our products, and may be insufficient to complete all of our anticipated Phase 2 clinical trials. Sufficient cash to complete our Phase 2 and 3 clinical trials may be provided from strategic partnerships, such as from out-licensing and partnering of our insulin product, and product sales in excess of our expectations. There can be no guarantee, however, that these capital resources will materialize in sufficient magnitude or at all, or that product sales will meet our expectations. In the alternative, the Company will have to raise significant capital through the sale of convertible debt, convertible securities, and/or common stock, and there can be no guarantee that such capital will be available on favorable terms, if at all, and could result in significant dilution to our current shareholders.

Our March 2004 equity financing has resulted in a concentration of ownership, which will only intensify if our stockholders approve the second closing of that financing.

Following the first closing of the $32.7 million Series A-1 Preferred equity financing, twelve Series A-1 investors own equity securities that, if all such securities were converted into common stock, would represent ownership of approximately two-thirds of the then-outstanding common shares of the Company. While each of these investors is contractually prohibited from owning more than 4.99% of the Company's common stock at any one time, as few as eleven of these investors, or investors to whom the A-1 securities are resold, could acquire in excess of 50% of the voting securities of the Company without exceeding this limitation. To our knowledge, the Series A-1 investors have not acted as a group in seeking, negotiating, or making their investment in the Company, have not acted as a group since making their investment, and consider themselves to be independent investors. Following the second closing, if approved by our stockholders, the Series A-1 investors will own equity securities that, if all such securities were converted into common stock, would represent ownership of approximately 86% of the then-outstanding common shares of the Company. Due to the termination of our rights plan, there can be no assurance that further concentration of ownership will not occur, or that these securities will not be resold to different investors who may or may not act as a group.

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

We have never been profitable. Through December 31, 2003, we have incurred an accumulated deficit of approximately $109.5 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 operating results may fluctuate significantly and may fail to meet the expectations of investors.

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

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

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

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

allocation of our resources, particularly when they are limited; and

the costs and expenses relating to any litigation.

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

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

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

Due to our extremely limited cash resources at the end of 2003 and during the first quarter of 2004, we were at times unable to procure critical components and/or manufacturing services necessary to satisfy customer demand for our products, most of whom were unable to provide cash payments in a timeframe that resolved our procurement issues. Compounding this limitation, orders in the same time period exceeded our expectations. As a result, we currently have a backlog of orders that we believe will not be completely filled until late in the second quarter of 2004, assuming that new orders in the second quarter of 2004 do not materially exceed our revised expectations. As of April 13, 2004, the current value of this backlog is approximately $524 thousand.

Our stock price may continue to be volatile.

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

market conditions relating to the life sciences industry;

investor perception of us as a company;

securities analysts' recommendations;

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

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

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

developments or disputes concerning patent or intellectual property rights;

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

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

period-to-period fluctuations in financial results; and

economic and other external factors.

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

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

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

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

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

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

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

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

If clinical trials of our drug products are not successful, drug products using our inhalers or nebulizers may not be commercialized.

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

pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials.

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

We have built our own manufacturing capabilities to produce key components of our products. We have manufactured only limited quantities of our first three products, and limited clinical supplies of other products. We currently produce all of our aerosol generators for our products, partnered or not, in a single facility. We plan to continue using contract manufacturers to produce certain other key components and subassemblies of our products, many of which are produced in unique facilities and/or with unique tooling. We may assemble some of our products ourselves, or we may use contract manufacturers for the final assembly of all of our products. We do not have long-term supply contracts with most of our key suppliers or contract manufacturers. In addition, most of them are currently our sole source of supply. We may not be able to enter into, or maintain, satisfactory contracts or arrangements. In addition, manufacturing of our products could be delayed by supply problems at our suppliers or contract manufacturers. If we need to qualify a new supplier or redesign the product, there could be significant delay, and a regulatory filing could be required before we could use the new supplier to provide material for our products. There can be no assurance that we, or our contract manufacturers, can successfully manufacture in high volumes in a timely manner, at an acceptable cost, or at all. We cannot assure that:

- the design of our products will permit their manufacture on a commercially sustainable scale;
- manufacturing and quality control problems will not arise as we attempt to scale-up production; or
- any scale-up of production can be achieved in a timely manner or at a commercially reasonable cost.

Failure to address these issues adequately could delay or prevent clinical testing and commercialization of our products.

Our Aerodose inhaled insulin product is our most mature product in development for systemic drug delivery; however, we have suspended development of that product.

We have completed four small clinical trials (two Phase 1 and two Phase 2a) of our Aerodose insulin inhaler product. Early studies generally focus on the safety of a product rather than its effectiveness in treating the disease. We cannot be sure that the results of these and/or other additional clinical trials will prove the safety and effectiveness of our product. We have not secured an agreement with a marketing partner to fund the additional development and clinical trials necessary to obtain regulatory approval and to commercialize the product; therefore we have not yet resumed our work on that product, and do not expect to re-start the program until we have an acceptable partner to pay for additional clinical trials. We cannot assure that we will ever be able to enter into a satisfactory agreement with a marketing partner, and we currently do not have sufficient funds to conduct the necessary development and clinical programs ourselves.

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

Our products are subject to extensive regulation by the FDA, state and local government agencies, and by international regulatory authorities. These agencies regulate the development, testing, manufacture, labeling, storage, approval, advertising, promotion, sale and distribution of medical

devices, drugs and biologics. If we, or our partners, fail to obtain regulatory clearances or approval to develop or to market our products, our business will be harmed and we, or our collaborative partners, will not be able to market and sell our products. Even if granted, regulatory approvals may include significant limitations on the uses for which products may be tested or marketed. Once obtained, required approvals may be withdrawn, or we may not remain in compliance with regulatory requirements. The process for obtaining necessary regulatory approvals for drugs and biologics is generally lengthy, expensive and uncertain. Obtaining and maintaining foreign regulatory approvals in multiple countries is expensive, and we cannot be certain that we will receive approvals in any foreign country in which we or our partners plan to market our products. If we or our partners fail to obtain regulatory approval in the United States or in any foreign country in which we plan to market our products, our revenues will be lower. A longer than expected regulatory process, additional or significant changes in regulatory requirements, or more expensive clinical studies than we anticipate, may cause us to stop development of particular products.

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

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

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

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

safety;

efficacy;

the benefits associated with pulmonary delivery;

ease of use; and

price.

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

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

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

and sales expenditures necessary to launch and grow the products. Our distribution and marketing partners have significant discretion in allocating and applying their selling and marketing efforts, so we have limited ability to predict or manage the end-user acceptance of our products, and there can be no guarantee that we can meet demand that rises sharply as a result of our partners' selling and/or marketing efforts.

Our corporate partners may not commercialize our products or may develop products that compete against our products.

Our business model includes collaborations with pharmaceutical and biotechnology companies. There can be no assurance that we will be able to enter into arrangements that result in successful commercial products. Even if we do enter into such arrangements, we will depend on corporate partners to commercialize the products developed in collaboration with us. If any of our existing or future corporate partners do not complete the development and commercialization of products to which they have obtained rights from us, our business could be impaired. In the drug delivery industry, it is common for corporate partners to conduct feasibility studies with multiple partners. There can be no assurance that our existing or future corporate partners will continue to choose our technology over their own technology or that of our competitors.

Collaboration agreements generally provide that the partner can terminate the agreement at any time.

If we are unable to attract and retain the highly skilled personnel necessary for our business, we may not be able to develop our products successfully.

Because of the specialized nature of our business, we depend upon qualified scientific, engineering, technical and managerial personnel. In particular, our business and prospects depend in large part upon the continued employment of Dr. Jane E. Shaw, our Chairman and Chief Executive Officer. We do not have an employment agreement with Dr. Shaw. Even with the recent downturn in the global economy, there is intense competition for qualified personnel in our business. In addition, our location in northern California makes recruiting qualified personnel from outside the San Francisco Bay area more difficult due to the very high cost of housing. Therefore, we may not be able to attract and retain the qualified personnel necessary to grow our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical, engineering and managerial personnel in a timely manner, would harm our research and development programs and our business.

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

Our manufacturing facilities, and those of our subcontractors and manufacturing licensee MIA, are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with QSR. We moved into a new facility in Mountain View, California during the second quarter of 2002. Prior to transferring product manufacturing to this facility, we underwent a successful inspection by the FDA, which was completed in May 2002. We received our registration in August 2002. We registered with the FDA an additional manufacturing site in Galway, Ireland, in April 2003. In September 2003, the site in Galway underwent an inspection by the FDA. Two observations were noted. One addressed the manner in which Aerogen records documented in-process acceptance test results and the other addressed the calibration standard operating procedure ("SOP") and equipment that was no longer in use, but had exceeded its calibration period. We submitted a timely response to the FDA, which was accepted and the 483 was closed.

All medical devices marketed in the European Union are required to bear the CE Mark. Aerogen, MIA and certain Aerogen subcontractors are required to comply with the MDD and comply with ISO, the International Organization for Standards, to meet the quality standards. ISO is a worldwide

network of national standards institutes. ISO has developed ISO 13485 in order to assist companies in implementing and operating quality management systems to meet the MDD.

In May of 2003, the Mountain View facility successfully obtained certification to ISO 13485:1996. If Aerogen, MIA or Aerogen's subcontractors fail to maintain compliance with QSRs, ISO 13485 or other international regulatory requirements, we may be required to among other things recall product or cease all or part of our operations until we comply with the regulations. We cannot be certain that our facilities, or those of MIA and/or our subcontractors, will be found to comply on an ongoing basis with the QSRs, ISO or other international regulatory requirements.

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

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

We outsource production of many components of our products to manufacturers in the United States and elsewhere. Generally, there is more than one potential supplier for these components, but some are manufactured to our specifications and an interruption in supply could adversely affect our ability to manufacture and supply our products. The brazing process used in assembly of our OnQ Aerosol Generators is conducted at a third party's facilities. Loss of the use of those facilities would result in several months' delay in our supply of components while we establish an alternative brazing site. Palladium, which we use in our OnQ aperture plate, is expensive and is subject to price volatility. The palladium plating bath chemicals we use to manufacture our OnQ Aerosol Generators are formulated by a single supplier.

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

In both domestic and foreign markets, sales of our potential products will depend, in part, on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. There is significant uncertainty about the reimbursement status of newly approved healthcare products. We cannot assure that any of our products will be reimbursed by third-party payors. In addition, we cannot assure that our products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of health care products may change before our products are approved for marketing, and any such changes could further limit reimbursement. One of our first commercial products, the Aeroneb Pro, is not currently reimbursed by insurance or government entities, which may limit its market penetration.

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

We currently compete with device and medical equipment companies for sales of our nebulizer products; as we introduce our drug products, we will compete with pharmaceutical and biotechnology

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

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

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

Our ability to compete effectively depends in part on developing and maintaining the proprietary aspects of our aerosolization technology. We cannot be sure that the patents we have obtained, or any patents we may obtain as a result of our pending United States or international patent applications and, in particular, our vibratory aerosolization technology, which is technology that aerosolizes liquids by vibrating a metal plate that contains holes, will provide any competitive advantages for our products. We also cannot assure that those patents will not be successfully challenged, invalidated or circumvented in the future. In addition, we cannot assure that competitors, many of which have substantial resources and have made substantial investments in competing technologies, have not already applied for, or obtained, or will not seek to apply for and obtain, patents that will prevent, limit or interfere with our ability to make, use and sell our products either in the United States or in international markets. Patent applications are maintained in secrecy for a period after filing. We may not be aware of all of the patents and patent applications potentially adverse to our interests.

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

In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. We require our employees and key consultants to execute confidentiality agreements upon the commencement of employment or a consulting relationship with us. We cannot assure that employees or consultants will

not breach these agreements, that we would have adequate remedies for any breach or that our trade secrets will not otherwise become known to or be independently developed by competitors.

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

The pharmaceutical and medical device industries have been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in these industries have used intellectual property litigation to gain a competitive advantage. We cannot assure that we will not become subject to, whether within or outside of the United States, patent infringement claims or litigation or interference proceedings declared by the United States Patent and Trademark Office, ("USPTO"), to determine the priority of inventions. Although we prevailed in a 1999 interference proceeding before the USPTO, that granted to Aerogen all but one of the independent claims of Bespak's 5,261,601 patent, we entered into a cross-license agreement with Bespak, as a result of which Bespak has a license to certain of our technology, including the right to sublicense. The scope of the granted license was limited to products employing technology which was disclosed by Bespak in United States Patent No. 5,261,601. Additionally, in April 2003, we received notice that a German patent infringement suit had been filed by PARI GmbH in the regional court in Munich, Germany alleging that Aerogen's Aeroneb Pro product infringes a patent licensed to PARI GmbH. While the suit has not yet been formally initiated by the German regional court, we believe that it is without merit and intend to vigorously defend against all allegations in the suit. In May 2003, we filed an action in the German patent office requesting that the patent in question be rendered null and void.

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.

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REPORT OF INDEPENDENT AUDITORS

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, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 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 auditing standards generally accepted in the United States of America, which 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.

As discussed in Note 2 to the consolidated financial statements, in 2002 the Company changed its method of accounting for goodwill and other intangible assets.

PricewaterhouseCoopers LLP

San Jose, California
April 13, 2004

AEROGEN, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2003	2002
	(in thousands, except per share amounts)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 762	$ 3,266
Available-for-sale securities		5,621
Accounts receivable	445	903
Inventories, net	301	374
Prepaid expenses and other current assets	428	934
Total current assets	1,936	11,098
Property and equipment, net	3,901	5,251
Goodwill and other intangible assets, net	1,931	1,612
Restricted cash	1,200	1,200
Other assets	608	33
Total assets	$ 9,576	$ 19,194
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 937	$ 973
Deferred revenue, current	500	208
Convertible debentures, net	1,486	
Accrued liabilities	1,194	1,238
Total current liabilities	4,117	2,419
Deferred rent	1,658	826
Deferred revenue, non-current	1,875	
Other long-term liabilities	246	205
Total liabilities	7,896	3,450
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Convertible preferred stock, par value $0.001 Authorized: 5,000 shares; issued and outstanding: no shares at December 31, 2003 and 2002		
Common stock, par value $0.001:		
Authorized: 95,000 shares; issued and outstanding:		
4,396 and 4,081 shares at December 31, 2003 and 2002, respectively	4	4
Additional paid-in capital	110,991	109,513
Notes receivable from stockholders	(280)	(434)
Deferred stock-based compensation, net	(264)	(1,520)
Accumulated other comprehensive income (loss)	700	233
Accumulated deficit	(109,471)	(92,052)

	December 31,	
Total stockholders' equity	1,680	15,744
Total liabilities and stockholders' equity	$ 9,576	$ 19,194

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

AEROGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2003	**2002**	**2001**
	(in thousands, except per share amounts and footnotes)		
Revenues:			
Product sales	$ 3,198	$ 1,896	$ 185
Research and development	348	386	2,034
Royalty and other	625	250	250
Total revenues	4,171	2,532	2,469
Costs and expenses:			
Cost of products sold	2,296	1,786	285
Research and development(1)	11,744	17,772	21,698
Selling, general and administrative(2)	6,507	8,382	8,138
Litigation settlement			2,000
Total costs and expenses	20,547	27,940	32,121
Loss from operations	(16,376)	(25,408)	(29,652)
Interest income (expense)	(996)	487	2,252
Other income (expense)	(47)	10	(2)
Net loss	$ (17,419)	$ (24,911)	$ (27,402)
Net loss per share, basic and diluted	$ (4.22)	$ (6.17)	$ (6.96)
Shares used in computing net loss per share, basic and diluted	4,126	4,036	3,936

(1) Including stock-based compensation expense of $304,000, $514,000 and $902,000 in 2003, 2002 and 2001, respectively.

(2) Including stock-based compensation expense of $702,000, $841,000 and $364,000 in 2003, 2002 and 2001, respectively.

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

AEROGEN, INC.

CONSOLIDATED STATAEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock							
	Shares	Amount	Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
					(in thousands)			
Balances, December 31, 2000	3,983	4	110,708	(665)	(6,095)	15	(39,739)	64,228
Issuance of common stock pursuant to employee purchase plan for cash	38		448					448
Issuance of common stock upon exercise of stock options for cash	11		56					56
Repurchase of common stock	(3)		(8)					(8)
Deferred stock-based compensation, net of cancellations			(760)		760			
Amortization of deferred stock-based compensation					1,266			1,266
Accrued interest on notes receivable from stockholders				(28)				(28)
Components of comprehensive loss:								
Changes in unrealized loss on available-for-sale securities						71		71
Foreign currency translation						(100)		(100)
Net loss							(27,402)	(27,402)
Total comprehensive loss								(27,431)
Balances, December 31, 2001	4,029	4	110,444	(693)	(4,069)	(14)	(67,141)	38,531

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

	Common Stock							
	Shares	Amount	Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)

	Common Stock			Notes Receivable From Stockholders	(in thousands)	Accumulated Other Comprehensive Income (Loss)		
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			
Amortization of deferred stock-based compensation					1,355			1,355
Accrued interest on notes receivable from stockholders				(26)				(26)
Components of comprehensive loss:								
Changes in unrealized loss on available-for-sale securities						(50)		(50)
Foreign currency translation						297		297
Net loss							(24,911)	(24,911)
Total comprehensive loss								(24,664)
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.

	Common Stock		Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			(in thousands)			
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
				167				167

	Common Stock			Notes Receivable From Stockholders		Accumulated Other Comprehensive Income (Loss)		
Repayment of notes receivable from stockholders								
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			
Amortization of deferred stock-based compensation					1,006			1,006
Accrued interest on notes receivable from stockholders				(13)				(13)
Components of comprehensive loss:								
Changes in unrealized loss on available-for-sale securities						(16)		(16)
Foreign currency translation						483		483
Net loss							(17,419)	(17,419)
Total comprehensive loss								(16,952)
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 CASH FLOWS

	Years Ended December 31,		
	2003	2002	2001
	(in thousands)		
Cash flows from operating activities:			
Net loss	$ (17,419)	$ (24,911)	$ (27,402)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,251	1,209	1,198
Changes in inventory reserves	11	15	30
Disposal of property and equipment	4	180	1
Accrued interest on notes receivable from stockholders	(13)	(26)	(28)

	Years Ended December 31,		
Amortization of notes discount (premium)	6	9	(86)
Amortization of deferred stock-based compensation	1,006	1,355	1,266
Non cash interest expense on convertible debentures	1,018		
Changes in operating assets and liabilities:			
Accounts receivable	558	(666)	569
Inventories	95	110	(518)
Prepaid expenses and other current assets	708	267	
Accounts payable	(102)	(243)	266
Accrued liabilities	(37)	(1,893)	1,936
Deferred rent	832	603	223
Deferred revenue	2,167	8	(50)
Other	2	30	(1,124)
Net cash used in operating activities	(9,913)	(23,953)	(23,719)
Cash flows from investing activities:			
Acquisition of property and equipment	(376)	(3,728)	(1,853)
Purchases of available-for-sale securities		(8,134)	(21,340)
Proceeds from maturities of available-for-sale securities	5,599	22,817	13,300
Net cash provided by (used in) investing activities	5,223	10,955	(9,893)
Cash flows from financing activities:			
Proceeds from issuance of common stock	24	270	504
Repurchase of common stock		(7)	(8)
Proceeds from issuance of convertible notes, net	1,950		
Repayment of note receivable from stockholder	167	285	
Net cash provided by financing activities	2,141	548	496
Effect of exchange rate changes on cash	45	2	20
Net decrease in cash and cash equivalents	(2,504)	(12,448)	(33,096)
Cash and cash equivalents at beginning of year	3,266	15,714	48,810
Cash and cash equivalents at end of year	$ 762	$ 3,266	$ 15,714
Supplemental disclosure of noncash investing and financing activities:			
Deferred stock-based compensation, net of cancellations	$ (250)	$ (1,194)	$ (760)
Issuance of common stock upon conversion of debt	$ 402	$	$
Issuance of warrants	$ 529	$	$
Issuance of common stock for future services	$ 180	$	$

	Years Ended December 31,		
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 1	$ 1	$ 2

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

AEROGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. To date, the Company has funded its operations primarily through the sale of convertible debentures, equity securities, product revenues, license fees, royalties, research and development payments from partners and interest income. 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, 2003, Aerogen had cash and cash equivalents of approximately $0.8 million, which was subsequently augmented on January 26, 2004 by $0.5 million in proceeds from the issuance of a secured convertible debenture to the Carpenter Family Trust, the trustees of which are Aerogen's Chairman and Chief Executive Officer, Dr. Jane Shaw and her husband Peter Carpenter. On March 23, 2004, Aerogen completed the first closing of a $32.7 million equity financing that provided gross proceeds of approximately $15.0 million. The second closing is expected to provide an additional $17.7 million and is conditioned upon approval of Aerogen's stockholders. Such approval cannot be assured. In the event the stockholders do not approve the second closing and if additional financing is not obtained, the Company will have to significantly curtail its operations. Management nevertheless believes that the Company has adequate resources available to fund its operations through at least December 31, 2004.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Basis of consolidation

In May 2000, the Company acquired Cerus Limited, which became the Company's wholly-owned subsidiary in Ireland, Aerogen (Ireland) Limited. The consolidated financial statements include the accounts of the Company and its subsidiary. 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 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.

Available-for-sale securities

All investments are classified as available-for-sale and therefore are carried at fair market value. Unrealized gains and losses on such securities are reported as a separate component of stockholders' equity (deficit). Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification cost method.

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 Cerus Limited, 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.

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, 2002 and 2003. 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. During the first quarter of 2002, the Company completed the transitional impairment test, and during the second quarter of 2003, the Company completed its annual impairment test, which did not result in impairment of recorded goodwill.

The following table reconciles the Company's net loss and net loss per share for the three years ended December 31, 2003, 2002 and 2001, adjusted to exclude goodwill and acquired workforce amortization pursuant to SFAS No. 142, to amounts previously reported:

	Years Ended December 31,		
	2003	2002	2001
	(in thousands, except per share amounts)		
Net loss as reported	$ (17,419)	$ (24,911)	$ (27,402)
Add: goodwill amortization			359
Adjusted net loss	$ (17,419)	$ (24,911)	$ (27,043)

	Years Ended December 31,		
Net loss per share, basic and diluted	$ (4.22)	$ (6.17)	$ (6.96)
Add: goodwill amortization			0.09
Adjusted net loss per share, basic and diluted	$ (4.22)	$ (6.17)	$ (6.87)

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 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 year ending December 31, 2003 follows (in thousands):

Warranty accrual at January 1, 2002	$ 6
Accruals for warranties issued during the year	121
Settlements made in kind during the year	(26)
Balance at December 31, 2002	$ 101
Accruals for warranties issued during the year	73
Settlements made in kind during the year	(36)
Balance at December 31, 2003	$ 138

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, available-for-sale securities, 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.

Two customers accounted for 56% and 28% of accounts receivable at December 31, 2003. Three customers accounted for 52%, 14% and 12% of revenues during the year ended December 31, 2003.

One customer accounted for 81% of accounts receivable at December 31, 2002. Two customers accounted for 55% and 24% of revenues during the year ended December 31, 2002.

Four customers accounted for 36%, 31%, 21% and 12% of accounts receivable at December 31, 2001. One of these customers accounted for 76% of revenues during the year ended December 31, 2001. The agreement with this customer terminated in December 2001. Another customer accounted for 13% of revenues during the year ended December 31, 2001.

Revenue recognition

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.

Revenues from product sales are recognized at the time of product shipment, provided an enforceable claim exists, title has transferred, any significant rights to return product have expired and that collection of the receivable is probable.

Royalty revenues are recorded as earned.

Amounts received prior to completion of the earnings process are recorded as deferred revenue and recognized on a straight-line basis over the term of the agreement.

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. Certain research and development projects are funded under agreements with third parties, and the costs related to these activities are included in research and development expense.

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.

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 basis 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. As of December 31, 2003, 2002 and 2001, 88%, 73% and 70%, respectively, of all long-lived assets were maintained in the United States. For the years ended December 31, 2003, 2002 and 2001, 22%, 29% and 97%, respectively, of consolidated revenues were generated in the United States. For the years ended December 2003, 2002 and 2001, 78%, 71% and 3%, respectively, of consolidated revenues were generated in Ireland.

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,		
	2003	2002	2001
	(in thousands, except per share amounts)		
Net loss as reported	$ (17,419)	$ (24,911)	$ (27,402)
Add: employee stock based compensation included in reported net loss	$ 990	$ 1,335	$ 1,168
Deduct: total employee stock based employee compensation determined under fair value based method for all awards	$ (2,054)	$ (3,933)	$ (2,297)
Net loss pro forma	$ (18,483)	$ (27,509)	$ (28,531)
As reported	$ (4.22)	$ (6.17)	$ (6.96)
Pro forma	$ (4.48)	$ (6.82)	$ (7.25)

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

The weighted average grant date fair value, as defined by SFAS 123, of options granted to employees during the years ended December 31, 2002 and 2001, was $3.25 and $17.10, per share, respectively; (there were no employee options granted during 2003).

	Years Ended December 31,		
	2003	2002	2001
Risk-free interest rate		3.54%	4.54%
Expected life (in years)		4	4
Dividend yield			
Expected volatility		148%	100%

The weighted average grant date fair value, as defined by SFAS 123, of purchase awards under the Purchase Plan was $0.90, $4.50 and $6.20, per share, for the years ended December 31, 2003, 2002 and 2001 respectively The fair value of purchase awards are calculated at each purchase date using the Black-Scholes valuation model per the assumptions below:

	Years Ended December 31,		
	2003	2002	2001
Risk-free interest rate	2.13%	2.31%	3.37%
Expected life (in years)	2	2	2
Dividend yield			
Expected volatility	154%	148%	100%

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 available-for-sale securities and 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, 2003, 2002 and 2001.

Net loss per common share

Basic net loss per share is computed by dividing 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. These potentially dilutive securities were not included in the diluted net loss per share calculations because the effect would be antidilutive.

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

	Years Ended December 31,		
	2003	2002	2001
	(in thousands)		
Net loss per share, basic and diluted			
Net loss	$ (17,419)	$ (24,911)	$ (27,402)
Weighted average shares outstanding	4,127	4,050	4,000
Less: Weighted average shares subject to repurchase	(1)	(14)	(64)
Weighted average shares used in computing basic and diluted net loss per share	4,126	4,036	3,936

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,		
	2003	2002	2001
	(in thousands)		
Options to purchase common stock	477	665	693
Common stock subject to repurchase	1	1	27
Warrants	428	4	6
Convertible debentures	630		

Recent accounting pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of FIN 46 did not have a material impact on its consolidated financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." SFAS No. 150 establishes standards for how companies classify and measure certain financial instruments with characteristics of both liabilities and equity. It requires companies to classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. SFAS No. 150 was effective for financial instruments entered into or modified after May 31, 2003, and otherwise was effective at the beginning of the first interim period after June 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the Company's consolidated financial statements.

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 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:

Available-for-sale securities at December 31, 2003 and 2002 are summarized as follows:

	December 31,					
	2003			2002		
	Amortized Cost Basis	Unrealized Gain	Fair Market Value	Amortized Cost Basis	Unrealized Gain	Fair Market Value
	(in thousands)					
Government notes	$	$	$	$ 5,605	$ 16	$ 5,621

As of December 31, 2003, we had no available-for-sale securities, and as of December 31, 2002, all available-for-sale securities matured within one year. There were no realized gains or losses on maturities of available-for-sale securities for 2003, 2002 and 2001.

Inventories are summarized as follows:

	December 31,	
	2003	2002
	(in thousands)	
Raw materials	$ 228	$ 333
Work-in-process	30	31
Finished goods	43	10
Net inventories	$ 301	$ 374

Property and equipment consists of the following:

	December 31,	
	2003	2002

	December 31,	
	(in thousands)	
Laboratory, computer and office equipment	$ 3,964	$ 4,604
Furniture	482	483
Land	263	220
Leasehold improvements	3,577	3,577
Construction-in-progress	119	94
	8,405	8,978
Less: Accumulated depreciation and amortization	(4,504)	(3,727)
Net property, plant and equipment	$ 3,901	$ 5,251

On September 30, 2003, the Company entered into an agreement with MIA for manufacturing and marketing of the Aeroneb Go Nebulizer. During October, Aerogen received upfront payments totaling $2.5 million for distribution rights and for the sale of certain equipment. Per the terms of the Company's agreement with MIA, this equipment became repurchasable by the Company for one dollar following the March 23, 2004 first closing of a $32.7 million equity financing (see Note 12). The equipment remains on the Company's premises and, for accounting purposes, has been reclassified to other assets at December 31, 2003 and continues to be amortized. The net book value of these assets at December 31, 2003 was $570,804.

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,	
	2003	2002
	(in thousands)	
Goodwill and other intangible assets	$ 2,724	$ 2,274
Less: Accumulated amortization	(793)	(662)
Net goodwill	$ 1,931	$ 1,612

Accrued liabilities consists of the following:

	December 31,	
	2003	2002
	(in thousands)	
Payroll and related expense	$ 499	$ 669
Other accrued liabilities	695	569
Accrued liabilities	$ 1,194	$ 1,238

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 $216,000. The BES is an Irish Revenue approved Business Expansion Scheme that grants investors tax breaks on the amounts

invested. The maximum amount which the BES investors will receive from Aerogen (Ireland) Limited is $245,540, when translated as of December 31, 2003. The BES investors have certain dividend and liquidation preferences in our Irish subsidiary. Based on the BES investment terms, the investment has been classified as other long-term liabilities, which Aerogen (Ireland) Limited anticipates repaying out of operating profits of the subsidiary, if any, that occur after April 2004.

NOTE 6 COMMITMENTS AND CONTINGENCIES:

Facility leases

The Company leases its facilities in Ireland under an operating lease that under its original terms, expired in November 2003, which the Company is currently extending on a month-to-month basis. 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.

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 Mountain View 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 is classified as restricted cash at December 31, 2003.

On November 6, 2003, the Company and its landlord entered into an amendment to the Mountain View lease under which a significant portion of the base rent due under the lease was deferred for the 24-month period, ending on June 30, 2005, with such deferment to be paid with interest over the last six years of the lease. The Mountain View lease was again amended on March 9, 2004 to, among other things, reduce the rented space, reduce the rental rate per square foot, and reduce the term of the lease.

Rent expense for the years ending December 31, 2003, 2002 and 2001 was approximately $3,119,000, $2,828,000 and $1,148,000, respectively.

Before giving effect to the lease amendment made in March 2004, the aggregate minimum rental and maintenance commitments under non-cancelable operating leases, including common area maintenance fees in effect at December 31, 2003 are:

	Years Ending December 31, (in thousands)
2004	$ 2,784
2005	2,382
2006	3,263
2007	3,349
2008	3,436
Thereafter	10,570
Total minimum payments	$ 25,784

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 aware of a threatened lawsuit by PARI GmbH alleging patent interference. The Company currently believes that such an action would be completely without merit, and has acted upon that belief by requesting that the appropriate patent authority adjudicate the patent upon which the alleged infringement occurs to be null and void. The Company has not established any reserve or contingency for this matter. Aerogen filed a nullity action in the German patent court against the patent in question in May 2003. We are not currently a party to any material legal proceedings.

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. As of December 31, 2003, $1,486,000 of principal and accrued interest, net of discounts, was outstanding under these debentures.

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, a 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 2004 to extend its maturity to June 1, 2004.

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 first debenture of $593,000. The associated warrant is exercisable for 271,428 shares of common stock at an exercise price of $1.75 per share. The first warrant was assigned an initial value of $357,000, estimated using the Black-Scholes valuation model, and has been classified as equity. The first warrant expires four years after issuance. The following assumptions were used to determine the fair value of the first warrant using the Black-Scholes valuation model: term of four years, risk free rate of 3.28%, volatility of 100%, and a dividend yield of zero. The initial values assigned to both the first debenture and the first warrant were allocated based on the relative fair values of the first debenture and the first warrant. The discount on the first debenture for the beneficial conversion feature and the warrant are being amortized to interest expense, using the effective interest method, over the original term of the first debenture, which matured on December 31, 2003. Total interest expense recognized relating to the beneficial conversion feature and the first warrant discount was $950,000 during 2003.

SF Capital has 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, with a 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 2004 to extend its maturity to June 1, 2004. SF Capital has agreed to exchange this debenture for shares of the Company's A-1 Preferred Stock, and associated warrants.

The second warrant is exercisable for 164,257 shares of common stock at an exercise price of $3.044 per share, as adjusted (see Note 12). This warrant was assigned an initial value of $172,000, estimated using the Black-Scholes valuation model, and has been classified as equity. The warrant expires four years from issuance. The following assumptions were used to determine the fair value of this warrant using the Black-Scholes valuation model: term of four years, risk free rate of 3.48%, volatility of 100%, and a dividend yield of zero. The initial values assigned to the second debenture and associated warrant were allocated based on their relative fair values. The discount on the second debenture related to the warrant is being amortized to interest expense, using the effective interest

method, over the original term of the first debenture, which was to mature on March 1, 2004. Total interest expense recognized relating to the second warrant discount was $68,000 during 2003.

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

NOTE 8 STOCKHOLDERS' EQUITY:

Convertible Preferred Stock

As of December 31, 2003, the Company has authorized 5,000,000 shares of convertible preferred stock, $0.001 par value, none of which was issued and outstanding. The Company's Board of Directors is authorized to determine the designation, powers, preferences and rights of preferred stock.

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.

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 have been declared or paid as of December 31, 2003.

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, 2003, 2002 and 2001 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 12).

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. At December 31, 2003, 2002 and 2001, 646, 1,282 and 12,724 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 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. Under the terms of the 2000 Non-Employee Plan, each new non-employee director elected will be granted an option to purchase 15,000 shares of common stock, which will vest over a three-year period. In addition, on an annual basis, the Plan provides that on the date of the annual stockholder meeting, each non-employee director will be granted an option to

purchase 5,000 shares of common stock which will vest 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 will be 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. The Company terminated this plan on April 2, 2004.

Activity under the Stock Plans has been as follows:

	Available Options	Number of Options Outstanding	Exercise Price		Aggregate Price
		(in thousands, except per share amounts)			
Balances, December 31, 2000	390	268	$ 1.20	$50.30	$ 4,286
Reservation of shares	184				
Options granted	(468)	468	$ 15.05	$30.95	9,830
Options exercised		(11)	$ 1.20	$15.00	(56)
Options canceled	32	(32)	$ 1.20	$37.50	(625)
Shares repurchased	3		$	3.00	
Balances, December 31, 2001	141	693	$ 1.20	$50.30	$ 13,435
Reservation of shares	187				
Options granted	(189)	189	$ 1.85	$8.10	651
Options exercised		(4)	$ 4.00	$16.50	(10)
Options canceled	213	(213)	$ 1.85	$50.30	(4,299)
Shares repurchased	2		$ 2.70	$3.00	
Balances, December 31, 2002	354	665	$ 1.20	$50.30	$ 9,777
Options exercised			$	1.85	(2)
Options canceled	188	(188)	$ 1.50	$50.32	(3,445)
Balances, December 31, 2003	542	477	$ 1.20	$50.30	$ 6,330

The options outstanding and currently vested at December 31, 2003, by exercise price, are as follows:

	Options Outstanding		
Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life	Number of Options Vested
	(in thousands)	(in Years)	(in thousands)
$1.85	101	8.95	34
$3.00	17	5.42	9
$3.05	25	8.58	9
$7.00	6	8.37	3
$8.10	34	8.20	19
$15.00	76	6.30	71
$15.05	88	7.95	59
$18.75	2	6.55	2

	Options Outstanding		
$21.80	42	7.70	28
$22.50	11	6.64	9
$22.70	10	7.35	8
$25.00	49	7.15	32
$30.95	4	7.52	3
$33.75	4	6.75	4
$37.50	8	6.81	6
	477		296

At December 31, 2003 and 2002, the weighted average price of all outstanding options were $13.22 and $14.70 per share, respectively. At December 31, 2003, 296,000 outstanding options were vested with a weighted average exercise price of $15.30. At December 31, 2002, 255,000 outstanding options were vested with a weighted average exercise price of $17.80.

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 least 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.

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, 2003, 112,438 shares of common stock have been purchased under the Purchase Plan and 20,219 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.

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, 2003, 2002 and 2001 the Company had recorded cumulative deferred stock-based compensation related to these options in the amounts of $4,377,000, $4,613,000 and $5,755,000, net of cancellations, respectively, of which $990,000, $1,335,000 and $1,168,000 had been amortized to expense during 2003, 2002 and 2001, 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,		
	2003	2002	2001
Risk-free interest rate	4.45%	4.59%	5.02%

	Years Ended December 31,		
Expected life (in years)	10	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 had recorded cumulative deferred stock-based compensation of $506,000, $490,000 and $519,000, as of December 31, 2003, 2002 and 2001, respectively, of which $16,000, $20,000 and $98,000 was amortized to expense in 2003, 2002 and 2001, 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 expire on October 14, 2004. The

fair value of these warrants, determined using the Black-Scholes option-pricing model, was not material.

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).

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, 2003, 2002 and 2001, $279,494, $370,689 and $364,627 of principal and 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.

In April 2000, the Company received full recourse notes receivable from two then current officers of the Company in exchange for common stock. Each note bore interest at 6.7% and was due in April 2004. Each loan was collateralized by 18,000 shares of common stock. At December 31, 2003, both of the loans had been paid in full. At December 31, 2002, $64,049 of principal and interest were outstanding on these notes.

NOTE 9 INCOME TAXES:

At December 31, 2003, the Company has a net operating loss carryforward of approximately $85,724,000 for federal and $27,477,000 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 are as follows:

	December 31,	
	2003	2002
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 31,715	$ 26,949

	December 31,	
Federal and state tax credit carryforwards	3,352	2,902
Research and development capitalization	2,499	1,941
Depreciation and amortization	1,075	1,111
Accrued liabilities and reserves	93	305
Other	1,617	420
	40,351	33,628
Less: Valuation allowance	(40,351)	(33,628)
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, 2003. The increase in the valuation allowance was $6,723,000, $8,689,000 and $10,406,000 during the years ended December 31, 2003, 2002 and 2001, respectively.

The Company has research credit carryforwards of approximately $1,921,000 and $1,989,000 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 10 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, 2003, 2002 and 2001, the Company made approximately $28,000, $54,000 and $8,000, respectively, of matching contributions to the 401(k) Plan. Prior to 2001, the Company had not made any such contributions.

NOTE 11 QUARTERLY FINANCIAL DATA (UNAUDITED):

The following tables summarize the quarterly financial data for the last two fiscal years (in thousands, except per share data):

	Fiscal 2003 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Total revenues	$ 1,568	$ 1,114	$ 519	$ 970
Gross margin on product sales	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)

	Fiscal 2002 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Total revenues	$ 89	$ 182	$ 704	$ 1,557
Gross margin on product sales	(231)	(123)	(17)	481
Loss from operations	(7,292)	(7,160)	(5,753)	(5,205)
Net loss	$ (7,072)	$ (7,038)	$ (5,667)	$ (5,134)

	Fiscal 2002 Quarter Ended			
Net loss per common share, basic and diluted	$ (1.75)	$ (1.75)	$ (1.40)	$ (1.26)

NOTE 12 SUBSEQUENT EVENTS

In January 2004, the Company entered into a loan and securities purchase agreement pursuant to which a convertible debenture (the "Debenture") and a warrant (the "Warrant") were issued to the Carpenter 1983 Family Trust UA ("the Carpenter Trust"), the trustees of which are Aerogen's

Chairman and Chief Executive Officer, Dr. Jane Shaw and her husband Peter Carpenter. The Company received approximately $505,000 in gross proceeds in exchange for the Debenture and the Warrant. The Debenture, as amended, is convertible into 164,258 shares of common stock on or before May 14, 2004 at a conversion price of $3.044 per share. The Warrant is exercisable for 82,129 shares of common stock at an exercise price of $3.044 per share.

The convertible secured debentures, and related warrants, issued to SF Capital during 2003 are all subject to a conversion price and exercise price adjustment provision that was triggered for the November 3, 2003 debenture and warrant when the Company issued the $0.5 million debenture to the Carpenter Trust with a conversion price less than the initial conversion price of the November 2003 debenture. As a result, the conversion price and exercise price of the November debenture and warrant, respectively, have been 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 23, 2004, the Company completed the first closing of a $32.7 million equity financing (the "Financing"). The Financing entails the sale and issuance of shares of Series A-1 Preferred Stock of the Company initially convertible into an aggregate of approximately 11,420,670 shares of common stock of the Company as well as the issuance of warrants to purchase up to approximately 11,429,210 shares of common stock at an exercise price of $3.25 per share. Under the terms of the Financing, on March 19, 2004, the Company terminated its Rights Agreement with Mellon Investor Services, LLC.

In the first closing, the Company issued shares of Series A-1 Preferred Stock convertible into 4,999,810 shares of common stock, and issued warrants to purchase 4,999,810 shares of common stock, for gross proceeds to the Company of $15,000,000. Aerogen received a waiver from the Nasdaq stockholder approval requirements for the first closing, which was subject to a 10-day stockholder notice requirement. The balance of the Series A-1 Preferred Stock and warrants are expected to be issued in a second closing conditioned upon the approval of Aerogen's stockholders.

As part of the Financing, SF Capital Partners, and the Carpenter Trust have agreed to exchange the outstanding secured convertible debentures previously issued to them for an aggregate of approximately 52,205 shares of Series A-1 Preferred Stock, assuming an exchange date of May 10, 2004. The exchange is scheduled to occur at the earliest of (i) the second closing of the Financing, (ii) the termination of the definitive agreement relating to the Financing or (iii) May 17, 2004. The debentures issued to SF Capital and the Carpenter Trust were amended to extend the maturity of such debentures to June 1, 2004. SF Capital also will receive warrants to acquire approximately 350,590 shares of common stock in connection with its debt exchange, assuming an exchange date of May 10, 2004. Additionally, on March 12, 2003, SF Capital provided a $300,000 secured bridge loan (the "SF Capital Bridge") to support the Company's operations through the first closing. The SF Capital Bridge has been repaid out of the proceeds of the first closing of the Financing.

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

Lease amendment

In March 2004, the Company negotiated a lease amendment with its landlord. Under the terms of the amended lease, Aerogen will relocate to the first floor of the two-story building, and will occupy roughly 32,000 square feet, which is about one half of the building area that the

Company currently occupies. The terms of the lease require Aerogen to make aggregate payments during 2004 totaling $1,625,000 which comprises $75,000 for a new security deposit, $414,000 in past due rent, and $1,136,000 in rent reduction fees, of which $900,000 is to be funded by relinquishment to the landlord of the Company's standby letter of credit. In addition, the Company issued 50,000 shares of common stock to the landlord. The term of the lease has been shortened and now terminates in February 2009 rather than February 2012.

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

	Years Ending December 31,
	(in thousands)
2004	$ 704
2005	867
2006	1,028
2007	1,102
2008	1,152
2009	193
Total minimum payments	$ 5,046

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

There were no changes in and disagreements with accountants on accounting and financial disclosures.

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.

Changes in internal controls. There have been no changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation referred to above, nor were there any significant deficiencies or material weaknesses in Aerogen internal controls. Accordingly, no corrective actions were required or undertaken.

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 error 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, our CEO and CFO have concluded, based on their evaluation, that our Disclosure Controls and our internal controls over financial reporting were sufficiently effective as of December 31, 2003.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Certain information required by this item concerning executive officers is set forth in Part I of this Report in "Business Management" and certain other information required by this item is incorporated by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement related to the Company's Annual Meeting of Stockholders to be held May 10, 2004 to be filed by the Company with the Securities and Exchange Commission within 120 days of the end of the Company's fiscal year pursuant to General Instruction G (3) of Form 10-K (the "Proxy Statement").

Item 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the sections captioned "Executive Compensation" and "Employment, Severance and Change of Control Agreements" contained in the Proxy Statement.

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

The information required by this item is incorporated by reference to the sections captioned "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference to the sections captioned "Compensation Committee Interlocks and Insider Participation" and "Certain Transactions" contained in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required in this section is incorporated by reference to the section captioned "Ratification of Selection of Independent Auditors" contained in the Proxy Statement.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

			Page
(a)	(1)	**Financial Statements**	
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(a)	(2)	**Financial Statement Schedules**	
		Report of Independent Auditors on Financial Statement Schedule.	73
		Schedule II Schedule of Valuation and Qualifying Accounts.	74
		All other schedules have been omitted as they are not required, not applicable, or the required information is otherwise included.	
(a)	(3)	**Exhibits**	

Page

The exhibits in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

(b) **Reports on Form 8-K**

The following reports on Form 8-K were filed during the three month period ended December 31, 2003:

On October 7, 2003, the Company filed a current report on Form 8-K relating to the closing of the first round of a two-part convertible debt financing with SF Capital Partners, Ltd. ("SF Capital"). On November 13, 2003, the Company filed a current report on Form 8-K relating to the issuance of a press release announcing its financial results for the quarter ended September 30, 2003.

REPORT OF INDEPENDENT AUDITORS 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 April 13, 2004 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
April 13, 2004

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

	Balance at beginning of period	Charged to Costs and Expense	Deductions	Balance at end of period
Provision for Inventories				
Fiscal year ended 2001	$	$ 30	$	$ 30
Fiscal year ended 2002	$ 30	$ 15	$	$ 45
Fiscal year ended 2003	$ 45	$ 11	$ (53)	$ 3

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 14th day of April, 2004.

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 14, 2004
/s/ PHYLLIS I. GARDNER Phyllis I. Gardner	Director	April 14, 2004
/s/ THOMAS R. BARUCH Thomas R. Baruch	Director	April 14, 2004
/s/ YEHUDA IVRI Yehuda Ivri	Director	April 14, 2004
/s/ JEAN-JACQUES BIENAIMÉ Jean-Jacques Bienaimé	Director	April 14, 2004
/s/ PHILIP M. YOUNG Philip M. Young	Director	April 14, 2004
/s/ BERNARD COLLINS Bernard Collins	Director	April 14, 2004
/s/ ROBERT S. BREUIL Robert S. Breuil	Chief Financial Officer and Vice President Development *(Principal Financial and Accounting Officer)*	April 14, 2004

Exhibit Index

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, 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

No.	Note	Description of Exhibit Document

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	(11)	Lease amendment, dated November 6, 2003, between CA0-Shoreline Technology Park, LP and Aerogen.
10.12.2	(11)	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		Subsidiaries of Aerogen, Inc.
23.1		Consent of independent accountants
31.1		Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2		Certification required by Rule 13a-14(a) or Rule 15d-14(a)

32.1	Certification 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.

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

AEROGEN, INC. FORM 10-K ANNUAL REPORT FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003
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