

AEROGEN INC  
Form 10-K  
March 31, 2003

[QuickLinks](#) -- Click here to rapidly navigate through this document

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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, 2002

Commission File Number 0-31913

---

**Aerogen, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**33-0488580**

(IRS Employer  
Identification No.)

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

(Address of Principal Executive Offices)

**94043**

(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**

(Title of Class)

---

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  No

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

The aggregate market value of the common stock held by non-affiliates of the registrant based upon the closing price on the Nasdaq National Market reported on June 28, 2002 was \$17,839,000.

The number of shares of common stock outstanding as of March 26, 2003 was 20,403,747.

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.

---

**Aerogen, Inc.**  
**FORM 10-K ANNUAL REPORT**  
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>Part I.</b>	
Item 1. Business	1
Item 2. Properties	26
Item 3. Legal Proceedings	27
Item 4. Submission of Matters to a Vote of Security Holders	27
<b>Part II.</b>	
Item 5. Market for Registrant's Common Equity and Related Stockholder Matters	27
Item 6. Selected Consolidated Financial Data	28
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	29
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	37
Item 8. Consolidated Financial Statements and Supplementary Data	38
Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosures	63
<b>Part III.</b>	
Item 10. Directors and Executive Officers of the Registrant	64
Item 11. Executive Compensation	68
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	70
Item 13. Certain Relationships and Related Transactions	73
Item 14. Controls and Procedures	74
<b>Part IV.</b>	
Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K	74
Exhibit Index	77
Signatures	79
Certifications	81

**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" and "estimate," 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 technology 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 should have a major impact on treatment of respiratory diseases 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 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 product, the Aeroneb® Portable Nebulizer System, in June 2001, and our second product, the Aeroneb® Professional Nebulizer System (the "Aeroneb Pro" nebulizer), in June 2002. We have next generation versions of both products in development.

Our lead therapeutic product in development is an aerosolized antibiotic product in which a formulation of amikacin is delivered via a next generation Aeroneb Pro nebulizer for the treatment of patients on ventilators with respiratory infections. 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 the products developed in the collaborations. These products may utilize one of our Aeroneb Pro nebulizers or one of our nebulizers or inhalers for the home market.

1

---

In addition to our respiratory therapy activities, we intend to develop novel pulmonary drug delivery 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 pulmonary delivery of insulin 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 clinical studies and commercialize 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; telephone number (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 Aerogen (Ireland) Limited and our wholly-owned subsidiary. Cerus was a development stage company engaged in the development of pulmonary inhalation products utilizing our core aerosol generator technology. Aerogen (Ireland) developed our Aeroneb Pro nebulizer, and is responsible for its assembly, utilizing aerosol generators produced in our Mountain View facilities.

As of December 31, 2002, we had \$8.9 million in cash, cash equivalents and available-for-sale securities. During 2003, our expenditures have been approximately \$1.6 million per month. We will need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next 30 to 60 days in order to continue as a going concern. We cannot be certain that such additional 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.

"Aerogen," "Aerodose," "Aeroneb" and the Aerogen logo 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**

## Edgar Filing: AEROGEN INC - Form 10-K

Pulmonary drug delivery is widely used to treat respiratory diseases and is also believed to be 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 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 average droplet size.

### *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 U.S. hospitals each year for respiratory disorders, including pneumonia, chronic obstructive pulmonary disease, asthma and respiratory distress syndrome. The cost of drugs for treatment of these

2

---

patients totals approximately \$3.5 billion per year, averaging approximately \$500 per day. There are also less prevalent diseases, such as neonatal pulmonary hypertension and infant respiratory distress syndrome (IRDS) that 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 lack of sufficiently reproducible and efficient pulmonary drug delivery technology.

We are currently focusing on development of our own products for treating two respiratory disorders in the acute care setting: respiratory infections in ventilated patients and pulmonary hypertension. 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 U.S. hospitals each year. We estimate that as many as one third of the patients develop tracheobronchitis, which is an infection of the upper airways. If not treated, tracheobronchitis can develop into ventilator associated pneumonia (VAP). Despite aggressive intravenous therapy, a very high mortality rate (20-50%) is associated with VAP. 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 of available devices in delivering drugs to the lungs. Approximately 150,000 patients in the U.S. are diagnosed with VAP annually.

Pulmonary hypertension affects approximately 50,000-60,000 neonates annually in the United States. The approved treatment for infants of greater than 34 weeks gestation age is inhaled nitric oxide. Treatment is expensive and side effects are significant. There is no currently approved treatment for pulmonary hypertension in infants of less than 34 weeks gestational age.

### *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 thwarted due to rapid breakdown of the molecules following ingestion. Dosage forms such as intravenous or intramuscular injections and implants, while effective for delivering proteins, have many drawbacks, including pain, inconvenience, expense, risk of infection and poor compliance. Alternatives like transdermal and nasal dosage forms do not 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.

### *Traditional and New Methods of Pulmonary Drug Delivery and Their Limitations*

Three basic classifications of devices are currently being used for pulmonary drug delivery: metered dose inhalers, dry powder inhalers and nebulizers. These devices were developed originally for local treatment of respiratory diseases, including asthma and chronic obstructive pulmonary disease, 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 metered dose inhalers 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 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 metered dose inhalers. These spacers increase the complexity of use and reduce the portability of metered dose inhalers. In the acute care setting, for patients on ventilators, MDIs are used by opening the ventilator circuit and spraying into the tubing via a spacer. This interruption of assisted breathing poses significant inherent risks, including the introduction of infectious agents to a patient with already compromised pulmonary function. In addition, it takes several actuations for a metered-dose inhaler, spaced over several minutes, to deliver the dose levels typically prescribed in an intensive care unit. This requires the significant time and the associated expense of an attendant respiratory therapist.

Traditional dry powder inhalers were introduced to overcome some of the problems inherent with the use of metered dose inhalers. 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 metered dose inhalers; however, traditional dry powder inhalers 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 dry powder inhalers, they are not generally 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. Nebulizers allow patients to breathe normally, thereby requiring less patient coordination and cooperation than metered dose inhalers or dry powder inhalers. Traditional jet nebulizers typically require an external source of compressed air or oxygen and are therefore bulky and generally 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, released into the surrounding air or 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, compressor nebulizers are used to introduce aerosol into the ventilator circuit for inhalation by the patient.

Use of compressor nebulizers can introduce additional air into the ventilator circuit, disturbing the precise balance 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 compressor nebulizers, but are expensive, heat the administered drug and are unable to nebulize suspensions.

Several companies are developing technologies to improve the efficiency and accuracy of pulmonary drug delivery in the home setting. Because systemic drug delivery requires the ability to create and deliver small particles to the deep lung, research has centered on developing devices capable

---

of consistently delivering fine particle aerosols. One technique involves the processing and stabilizing of drugs in dry powder form. Another uses mechanical pressure to aerosolize custom formulations of drugs in solution. Both of these technologies will require an extensive investment in new formulations, new packaging, new materials and customized manufacturing, as well as an extensive validation effort for Good Manufacturing Practices. The dry powder technology will also face the challenge of consistently creating a cloud of uniform fine particles in varying environmental conditions that can include both high humidity and electrostatic charge.

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 treatment of patients with respiratory infections in the ICU, virtually all are given intravenously, due to the inefficiency of currently available devices in delivering drugs to the lungs.

*Our Core Technology and Marketed Products*

*Aerosol Generator*

Our proprietary aerosol generator contains a domed aperture plate that contains hundreds of apertures, or holes, of a discrete shape and size. The aperture plate is produced through an electroforming process using a metal alloy which is strong, corrosion resistant and durable. The plate is placed within a vibrational element that, when energy is applied to this element, causes the aperture plate to vibrate. 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 fine droplet aerosol. The aerosol droplet size formed is determined by the size of the holes in the aperture plate. A controllable manufacturing process is used to produce aperture plates with selected hole sizes that result in aerosol droplets of the same sizes. The micro-pumping action creates a low velocity aerosol, the flow rate of which is controlled by the voltage and frequency applied to the vibrational element. When the aerosol generator is incorporated into one of our nebulizers or inhalers, it is capable of producing aerosols of consistent droplet size in a low velocity aerosol, 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 aerosol generator does not affect the integrity of proteins or peptides.

*Benefits of Our Technology*

*Optimization and Customization of Aerosol Droplet Size.* Our aerosol generator delivers a low-velocity liquid aerosol of precisely defined average droplet size. The aerosol generator enables us to provide either an aerosol with droplets averaging three to five microns in diameter for respiratory therapy, or an aerosol with droplets averaging one to three microns in diameter for deposition in the deep lung for systemic drug delivery.

*Ease of Formulation.* Drugs can be aerosolized in solution or suspension. The aerosol generator uses no propellants or pressure, and generates negligible heat, so it is not likely to degrade drug molecules. In many cases, we can use existing drug formulations, eliminating the need to demonstrate the stability of new formulations.

*Flexibility of Dosing.* Our technology can be used to administer 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 Disetronic Medical Systems, which allows the diabetic patient to deliver a specific dose of insulin from a glass cartridge designed to hold 1-2 weeks of inhaleable insulin.

*Breath-Activation.* We have developed a breath-activation feature which triggers aerosol formation and is designed to enable a broad range of patients to obtain consistent dosing over

5

---

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 lock-out features to prevent abuse or overdose.

*Convenience.* Our products are designed to be lightweight and easy to use for patients and care-providers. 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 training, will be easy to use for the very young and the elderly and will have the potential to increase compliance with prescribed treatment regimens. The Aeronex® Portable Nebulizer System is quieter and more compact than currently commercialized nebulizers. The Aeronex Pro nebulizer is lightweight, allowing it to be placed close to the ventilated

## Edgar Filing: AEROGEN INC - Form 10-K

patient's windpipe, providing efficient generation of aerosol close to the lung. The next generation of products will also be lightweight and compact.

Our core aerosol generator technology is being incorporated into our nebulizers and inhalers. In 2002, much of our effort was directed to streamlining and improving the manufacturing processes for our aerosol generator as we moved into our new laboratories and manufacturing facilities, including a Class 10,000 clean room, in our Mountain View, California headquarters. We also undertook development of a lower cost aerosol generator using components similar to those used in our commercially available nebulizers, but with a changed configuration. We completed the design verification testing of the commercial form of our Aerodose insulin inhaler, and produced clinical quantities of our Aerodose respiratory inhaler.

### *Our Nebulizer Products*

We have two nebulizer products currently on the market, the Aeroneb® Portable Nebulizer System and the Aeroneb® Professional Nebulizer System.

*Aeroneb® Portable Nebulizer Systems.* Our first commercial product, the Aeroneb® Portable Nebulizer System, was launched in June 2001, and is marketed in the United States to home medical equipment dealers, pharmacies and directly to patients over the Internet. We distribute the product through Cardinal Health, CareFore Medical, Inc. and other regional distributors. Recently, the product has been featured on the top shelf of "The Asthma and Allergy Place," a display featured at more than 200 pharmacies which contains devices and supportive products necessary for asthma patients to treat their condition. Total sales of this product in 2002 and 2001 were approximately \$0.3 million and \$0.2 million, respectively.

We are developing a smaller, less expensive version of the Aeroneb® Portable Nebulizer System, which is targeted for launch in the third quarter of 2003, upon CE marking in Europe and 510(k) clearance in the U.S. The product will use a lower-cost aerosol generator and will be offered with both an AC wall controller and a battery pack to allow for portability.

*Aeroneb® Professional Nebulizer Systems.* Our second commercial product, the Aeroneb® Professional Nebulizer System (Aeroneb Pro nebulizer) 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-

6

---

purpose nebulizer intended to aerosolize physician-prescribed solutions for inhalation. This nebulizer, which produces a continuous flow of aerosol, is targeted to improve pulmonary delivery of drugs to patients on or off ventilators. The nebulizer is small and lightweight, allowing it to be positioned close to the patient's airway. It 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 a compressor and avoids the introduction of additional air into the ventilator tubing. This nebulizer provides the first significant innovation in aerosolized drug therapy in 20 years specifically designed for patients on ventilators in the ICU.

The Aeroneb Pro nebulizer is flexible because it can be used not only on the ventilator, but also on the hospital floor or in the ambulance. It can interfit with both adults' and children's masks. The device is autoclaveable and therefore available for multi-patient use. Its low residual volume allows efficient drug delivery to the lungs. Using the Aeroneb Pro nebulizer on the ventilator, efficiency of drug deposition in the lungs of patients, when compared *in vitro* with use of small volume jet nebulizers, is improved more than four fold, to the 10-15% range.

We have a worldwide agreement with Puritan Bennett ("PB") under which PB sells the Aeroneb Pro nebulizer with its newer ventilators in the United States, and with both its 840 series and the installed base of ventilators outside the United States. We also have an agreement with Cardinal Health under which Cardinal's Respiratory Care Products Group sales force is targeting the Aeroneb Pro nebulizer to the installed base of ventilators in the United States (approximately 100,000 ventilators from several manufacturers). These distributors are supported 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's sales of the Aeroneb Pro nebulizer were approximately \$1.6 million in 2002 (the product was introduced in June 2002), and the product is now available in more than 20 countries.

We are developing a phasic version of the Aeroneb® Pro general-purpose nebulizer, which we plan to launch in Europe in late 2003, after CE marking. Phasic nebulizers, which are commonly used in Europe with ventilators, release the drug only during the inhalation phase of the ventilator cycle, rather than continuously. We have also developed an optimized phasic version of the Aeroneb Pro nebulizer, which is capable

## Edgar Filing: AEROGEN INC - Form 10-K

of sensing the performance of the ventilator and aerosolizing the drug during a predetermined fraction of the inhalation phase of the ventilator cycle. *In vitro* deposition of drug in the lung is typically greater than 60% of the starting dose with this optimized nebulizer. This product has been CE marked in Europe, where it is currently in use in our Phase 2 clinical trial delivering amikacin. We do not intend to market the optimized phasic nebulizer as a stand-alone device, but rather for use exclusively with drug products.

Finally, we have developed a version of the Aeroneb® Pro specifically for use in animal testing laboratories, called the Aeroneb® Lab. In 2002, we sold approximately 100 units of the product to a company that packages and sells it with the company's testing equipment systems for use in animal testing. We also plan to sell the product in 2003 on a stand-alone basis directly to contract research organizations for use in animal testing.

Sales of our Aeroneb® products accounted for 75% of our total revenues in 2002.

### ***Our Drug Product Pipeline***

We intend to incorporate our versatile and flexible technology into a portfolio of devices and drug products, some to be developed for commercialization by us and some to be developed with partners for 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.

7

---

### *Aerogen Products Under Development for Treatment of Respiratory Diseases*

We intend to create and market a respiratory disease product portfolio consisting of products delivering drug-containing aerosols in the acute care setting.

Our activities for therapeutic products to be marketed by Aerogen will be focused on development, clinical testing, U.S. regulatory approval and market introduction. The rights to the 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.

*Amikacin.* Our lead drug product is the aminoglycoside amikacin, under development to address the large unmet need for more effective treatment of respiratory infections in patients requiring mechanical ventilation. We are targeting the product to treat early infection (tracheobronchitis) and 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, which often leads to unwanted systemic toxicities (including damage to kidneys and hearing). The potential to administer nebulized amikacin allows for the possibility of treating tracheobronchitis either via aerosol alone or in concert with antibiotics less toxic than systemically administered aminoglycosides. There is also the potential that the treatment of tracheobronchitis using this product will be clinically demonstrated to prevent the progression of the pulmonary infection into VAP.

Our first Phase 2 study in 12 patients is underway in France. In this study, we are comparing drug deposition in the lungs of ventilated patients when the drug is administered by the Aeroneb Pro nebulizer, the optimized phasic version of the Aeroneb Pro nebulizer and the commercially available Airlife Misty Neb nebulizer. We are using a preservative-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. We anticipate that we will conduct a second Phase 2 study and then seek a development and commercialization partner to sponsor pivotal clinical studies and worldwide registration for this product. In any such partnering arrangement, we intend to negotiate to receive royalties on product sales.

*Pulmonary Vasodilators.* Neonatal pulmonary hypertension affects approximately 50,000-60,000 neonates in the United States each year. The most common treatment is inhaled nitric oxide, which is expensive and can result in serious side effects. Pulmonary vasodilators are currently approved for the intravenous treatment of pulmonary hypertension in adults. To date, use of aerosolized pulmonary vasodilators has been very limited due to the inefficiency of the available aerosol delivery devices. Our product is in pre-clinical development. We plan to develop the drug product for aerosolized delivery using the optimized phasic version of the Aeroneb Pro nebulizer, so that the aerosol particle size and the aerosolization time during the inspiratory phase of the ventilator will be preset to optimize deposition of drug in the lung.

*Aerosolized Humanized Surfactant.* We signed an agreement in July 2002 with Discovery Laboratories, Inc. (Discovery Labs) to explore pulmonary delivery of aerosolized human surfactant in the hospital setting. Discovery Labs has a synthetic surfactant consisting of phospholipids and a protein that mimics endogenous surfactant B protein. Discovery Labs currently has two Phase 3 trials in infants and one



Phase 2 trial in ventilated adults underway for treatment of respiratory conditions. In these studies, the liquid surfactant is administered in a bolus either through an endotracheal tube (a tube inserted into the mouth and down the trachea) or by a lavage technique through a bronchoscope. 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 the surfactant while maintaining the integrity of the formulation.

#### *Other Product Development Opportunities*

Additional drug development opportunities in the acute care setting include treatment of asthma (with bronchodilators and anti-inflammatory agents), COPD (with anti-inflammatory agents, phosphodiesterase inhibitors, mucoactive agents), pulmonary hypertension (vasodilators) and ARDS (protease inhibitors, anti-coagulative agents, inhibitors of fibrosis). We have several drugs in the preclinical stage of evaluation.

We plan to explore additional drugs in 2003 and beyond, including available drugs and drugs in-licensed or available for in-license from third parties, starting with feasibility, preclinical and initial clinical activities. We also plan to explore the potential for commercializing appropriate drug combinations for delivery via our nebulizers and inhalers.

#### *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 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 differ from dry powder inhalers and metered dose inhalers, in that 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 the regulatory climate in 2002, 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. 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 a full New Drug Application (NDA). Feasibility activities are underway for products using this inhaler to deliver partner drugs.

#### *Partnered 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.

## Edgar Filing: AEROGEN INC - Form 10-K

The flexibility of our technology to facilitate improved respiratory therapy has attracted potential development partners. We currently have feasibility activities with potential partners with undisclosed compounds for respiratory therapy and systemic drug input underway. A feasibility study can be paid for by us or by the other 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 commercialize the product and pay us a royalty on sales.

In March 2002, we signed a Cooperative Research and Development Agreement (CRADA) with the United States Army for pulmonary delivery of novel vaccines. The initial work was done by the United States Army Medical Research Institute for Infectious Diseases (USAMRIID), and a grant proposal has been submitted to fund the next stage of the activities at Aerogen. The CRADA was expanded in June 2002 to also cover antiviral applications.

Our Aerodose respiratory inhaler is available for use with partner drugs in programs funded by the partners, and that inhaler can be, and has been, customized for different 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 cartridge for pulmonary delivery of insulin, allowing patients to precisely adjust their insulin dose based on anticipated caloric intake and other factors. The titration mechanism was developed with Disetronic Medical Systems.

Phase 1 clinical studies using prototype Aerodose inhalers delivering insulin have been completed in the United Kingdom and Germany. 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 published literature. In the second study, optimal aerosolization parameters were evaluated.

Phase 2 trials were initiated in Europe and the United States at the end of 2000. 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. 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 the fourth quarter of 2002.

We had planned to enter into an agreement with a marketing partner for the Aerodose insulin inhaler for the further development, clinical testing and commercialization of the product before the end of 2002. We believe that the nature of the diabetes market requires a major pharmaceutical company partner with a diabetes franchise to market the product. We were unable to enter into such an agreement in 2002 under favorable financial conditions; therefore further activities for the product were placed on hold until and unless we enter into an agreement with a commercialization partner.

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 with our Aerodose inhaler. We intend to collaborate with pharmaceutical and biotechnology companies for development, clinical testing and commercialization of other Aerodose inhaler products. We currently have an undisclosed feasibility agreement with a pharmaceutical company targeting a protein for systemic therapy.

### *Technology Out-licensing*

## Edgar Filing: AEROGEN INC - Form 10-K

Our aerosol generator technology has proven to be of value to industries focusing outside the field of pulmonary drug delivery. In October 1999, we entered into an exclusive license agreement with a consumer company permitting it to use the aerosol generator in the fields of air fresheners and insect repellants worldwide. 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. We have the right to terminate the agreement with respect to either the air freshener products or insect repellent products if products are not introduced within specific time limits. The first product covered by the agreement was launched outside the U.S. 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 2002, 2001 and 2000 we spent approximately \$17.4 million, \$19.7 million and \$10.4 million, respectively, on our own research and development activities, and approximately \$0.4 million, \$2.0 million and \$5.8 million in 2002, 2001 and 2000, respectively, for customer sponsored research and development activities.

### ***Manufacturing***

We plan to manufacture our aerosol generators and outsource the manufacture of the other components used in our products. We manufacture the aperture plates and assemble the aerosol generators at our Mountain View, California facility. We design the remaining components of the 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. We assemble the Aeroneb® Portable Nebulizer System in our California facilities, and the Aeroneb Pro nebulizer is assembled for us in Ireland.

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 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 aerosol generator, is expensive and is subject to price volatility. The

11

---

palladium plating bath chemicals we use to manufacture our aerosol generator are formulated by a single supplier. It would be difficult to replace this supplier, if it were necessary to do so.

### ***Sales and Marketing***

The Aeroneb® Portable Nebulizer System has been marketed in the United States to home medical equipment dealers and pharmacies, and directly to patients over the Internet. We distribute the product through a division of Cardinal Health and other regional distributors throughout the United States. The product has recently been featured on the top shelf of "The Asthma And Allergy Place," a pharmacy program exclusively offered by Cardinal Consumer Health that features devices and supportive products necessary for asthma patients to treat their condition. The Aeroneb Pro nebulizer is sold to U.S. hospitals by Aerogen's contract clinical specialists, Cardinal Health, and Puritan Bennett. 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.

At December 31, 2002, we had a backlog of orders for the Aeroneb Pro nebulizers of approximately \$1.0 million; the orders were filled during the first quarter of 2003.

### ***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 and Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), 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 metered dose inhalers, dry powder inhalers 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 metered dose inhalers and currently available dry powder inhalers, 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

12

---

acceptance more rapidly than we can. We believe that our products will compete on the basis of 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, 2002, we held ten issued U.S. patents and eleven issued international patents. In addition, we had 37 pending U.S. patent applications and 39 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 the aerosolization devices. The pending patent applications include coverage for numerous improvements on the fundamental aspects of the aerosolization technology.

We cannot assure that the patents which we have obtained, or any patents that we may obtain as a result of our U.S. or international patent applications, will provide any competitive advantages for our products or that they will not be successfully challenged, invalidated or circumvented in the future. In addition, we cannot assure that competitors, many of whom have substantial resources and have made substantial investments in competing technologies, have not applied for and will not 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.

A number of other companies, universities and research institutions have filed patent applications or have issued patents relating to vibratory aerosolization technology. In addition, we have become aware of, and may become aware of in the future, patent applications and issued patents that relate to our products. We do not believe that our current products infringe any valid and enforceable claims of the issued patents that we have reviewed. However, if third party patents (or patent applications that may issue as patents) contain valid and enforceable claims held by a court to be infringed by our products, we cannot assure that we would be able to obtain licenses to those patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. The inability to do either would have a material, adverse effect on our business, financial condition, results of operations and future growth prospects. We cannot assure that we will not have to defend ourselves in court against allegations of infringement of third-party patents.

In addition to patents, we rely on trade secrets and proprietary know-how, which we make every effort we can 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. These agreements generally provide that all confidential information developed or made known to the individual by us during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties. These agreements are also assignments to Aerogen, exclusively, of inventions conceived by the individual in the course of rendering services to Aerogen, and any patent rights arising therefrom, all such material being Aerogen's exclusive property.

However, we cannot assure that employees and consultants will not breach the 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.

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. We cannot assure that we will not become subject to patent infringement claims or litigation or interference proceedings declared by

the United States Patent and Trademark Office to determine the priority of inventions. In 1999, we settled a patent interference involving U.S. Patent No. 5,261,601, assigned to Bepak plc concerning methods and apparatus for dispensing atomized sprays by vibrating a membrane to atomize the liquid in contact with the membrane through flared holes in the membrane. The settlement provided for a cross-license between Aerogen and Bepak, as a result of which Bepak has a license to certain of our technology. The scope of the granted license was limited to products employing technology which was disclosed by Bepak in U.S. Patent No. 5,261,601. The license would not extend to any of our technology which was not disclosed in this patent.

Our patent position involves complex legal and factual questions and is generally uncertain. The field of aerosolized drug delivery is crowded, and a substantial number of patents have been issued to others. We are aware of several issued U.S. and international patents that cover certain aspects of vibratory aerosolization technology. Legal standards relating to the validity and scope of patent claims in the biotechnology and pharmaceutical field are evolving. Therefore, the degree of protection which our patents will afford is uncertain. Patents, if issued, may be challenged, invalidated or designed around. Thus, any patents that we own or license may not provide any, or significant, protection against competitors. Our pending patent applications or those which we may file in the future may not result in patents being issued. Also, patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed.

The defense and prosecution of intellectual property litigation, United States Patent and Trademark Office interference proceedings and related legal and administrative proceedings are both costly and time-consuming. If others violate our proprietary rights, litigation may be necessary to enforce our patents, to protect trade secrets or know-how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings will be costly and cause significant diversion of effort by our technical and management personnel. An adverse determination, or litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. Furthermore, we cannot be sure that we could obtain necessary licenses on satisfactory terms, if at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

At the time of commencement of employment, our 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 entered into a standard form 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 United States Food & Drug Administration (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

## Edgar Filing: AEROGEN INC - Form 10-K

regulatory approval path will not be the same for all of our products.

Those of our products which 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 Good Manufacturing Practices (GMP) and 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 four 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 and the Aeroneb® Professional Nebulizer System, 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 becomes effective prior to initiating clinical trials. An IDE application generally 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.

## Edgar Filing: AEROGEN INC - Form 10-K

*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 Investigational New Drug Application (IND) will be required before those studies can be initiated in the United States. Approval of a New Drug Application (NDA), or a Biologics License Application (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, adequate 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 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 October 2001, we obtained the CE mark for the Aeroneb Pro nebulizer, and in December 2002 we received the CE mark for our optimized phasic Aeroneb Pro, which we are using in a clinical study in France. 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 current Good Manufacturing Practices as set forth in the Quality System Regulation, 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**

## Edgar Filing: AEROGEN INC - Form 10-K

We had approximately 80 employees on March 1, 2003. Approximately 20 of those employees are located at our Irish facility. Our employees are not represented by a collective bargaining agreement. All employees 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 once more on January 3, 2003 by 22 employees in connection with a restructuring, which reduced our number of employees to the current number. We believe our relations with our employees are good.

### ***Certain Financial Information***

As of December 31, 2002, 2001 and 2000, 73%, 70% and 48%, respectively, of our long-lived assets were maintained in the United States. For the years ended December 31, 2002, 2001 and 2000, 29%, 97% and 99%, respectively, of our consolidated revenues were generated in the United States.

### ***Risk Factors***

Our business and the value of our stock are subject to a number of risks, many of which are set out below. 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.

17

---

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

We have never been profitable. Through December 31, 2002, we have incurred a cumulative deficit of approximately \$92.1 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 assure that we will generate sufficient product revenues, royalties or research and development revenues to become profitable or to sustain profitability.

### **We need additional capital. If we cannot secure additional funding on acceptable terms within the next 30 to 60 days, we may not be able to continue as a going concern.**

As of December 31, 2002, we had cash, cash equivalents and available-for-sale securities of approximately \$8.9 million. During 2003, our expenditures have been approximately \$1.6 million per month. We will need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next 30 to 60 days in order to continue as a going concern. We cannot be certain that such additional 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. Even if we are successful at raising 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.

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



## Edgar Filing: AEROGEN INC - Form 10-K

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:

- the availability of additional funding and the terms of any such funding;
- the success of any restructuring actions we have taken or may take in the future;
- changes in domestic and international economic, business, industry and political conditions;
- 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; and
- allocation of our resources, particularly when they are limited.

### **Our 2002 reductions in force and our January 2003 restructuring may not be sufficient to accomplish our goals.**

In January and June 2002, we engaged in reductions in force in order to reduce our operating expenses. In December 2002, we began a restructuring that included the suspension of development of our Aerodose insulin inhaler product, and a workforce reduction in January 2003. While these changes

18

---

were designed to reduce spending, align resources with long-term growth opportunities and preserve cash, there can be no assurances that we will realize any of these expected benefits to the extent needed. Further, we cannot predict whether we will need to engage in additional restructuring actions, which may impact our operating results.

### **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;

## Edgar Filing: AEROGEN INC - Form 10-K

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; or

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.

### **Our common stock may be delisted from The Nasdaq SmallCap Market, which may adversely affect the market liquidity and market price of our common stock.**

Our common stock is currently listed on the Nasdaq SmallCap Market and has since July 1, 2002, had, a closing bid price of less than \$1.00 per share on all but three days. Nasdaq rules do not permit listed companies to maintain closing bid prices below \$1.00 per share for more than 30 consecutive trading days. Nasdaq has granted us a grace period until August 4, 2003 to regain compliance with this requirement.

If we fail to meet the minimum bid price requirement by that date, or fail to meet any of the other requirements of the Nasdaq SmallCap Market, our stock may be delisted and the trading of our common stock is likely to be conducted on the OTC Bulletin Board or in the over-the-counter market in what is commonly referred to as the "pink sheets," which may have an adverse affect on the market price of our common stock and on the ability of stockholders and investors to buy and sell the common stock. If delisting occurs, stockholders may lose some or all of their liquidity and/or value.

19

---

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

Other than the Aeroneb® Portable Nebulizer System, which was introduced in 2001, and the Aeroneb® Professional Nebulizer System, which was introduced in 2002, our products are in the research or development stages. Before we can begin to sell our other products commercially, we will need to invest in substantial additional development 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 predictable 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.**

## Edgar Filing: AEROGEN INC - Form 10-K

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 predictable 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 Aerodose inhalers or Aeronex nebulizers may not be commercialized.**

Before either we or our partners can file for regulatory approval for the commercial sale of products using our Aerodose inhalers or our Aeronex 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 Aerodose inhalers and Aeronex 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.

20

---

**We have limited manufacturing experience and may not be able to manufacture our products in commercially sustainable quantities. We will 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 two products, and limited clinical supplies of other products. We currently plan to produce all of our aerosol generators for our products, partnered or not. We plan to use contract manufacturers to produce certain other key components and subassemblies of our products. We may assemble some or all of our products ourselves, or we may use contract manufacturers for the final assembly of some or 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, 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.

**During 2002, our inhaled insulin product was our most mature product in development for systemic drug delivery; however, we have suspended development of that product.**

We have only completed four small clinical trials (two Phase 1 and two Phase 2) 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. During 2002, we did not sign 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 stopped our work on that product, and do not expect to re-start the program until we have an acceptable partner or sufficient funding 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.

**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 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 program, we will not be able to sustainably commercialize our products.**

We currently have a very limited sales and marketing staff, and many of our competitors have substantial sales and marketing infrastructure. We rely on third party distributors to sell our products. Our success in commercializing our respiratory products in the United States will depend on our ability to develop and execute a successful sales and marketing program. There can be no assurance that our first two products, the Aeroneb® Portable Nebulizer System and the Aeroneb® Professional Nebulizer System, will be successful, and, 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 expenditures necessary to launch and grow the products. Successful worldwide commercialization will depend upon finding effective marketing partners for our products outside the United States.

**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.

**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 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, or more expensive clinical studies than we anticipate, may cause us to stop development of particular products, which we did with our albuterol and ipratropium inhaler products.

**If our manufacturing facilities 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 are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated by the FDA for compliance with QSR (Quality System Regulation). 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 also are required to comply with ISO 9001/EN46001 in order to produce products for sale in the European Union. ISO, the International Organization for Standardization, is a worldwide federation of national standards bodies. ISO has developed the ISO 9000 family of standards to assist companies in implementing and operating quality management systems. ISO 9001/EN46001 provides the requirements for a quality management system that a company must meet in order for our products to satisfy applicable regulatory requirements. We received ISO 9001/EN46001 certification for our Sunnyvale facility in July 2000. In August 2002, we passed the surveillance audit, updating our ISO 9001/EN46001 certification for our Mountain View facility.

If we fail to maintain our compliance with QSR requirements, ISO 9001/EN46001 or other international regulatory requirements, we may be required to cease all or part of our operations until we comply with the regulations. We cannot be certain that our facilities will be found to comply on an ongoing basis with QSR, ISO 9001/EN46001 or other international regulatory requirements.

The State of California requires that we maintain a license to manufacture medical devices, 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.

**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® Professional Nebulizer System, 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 compete with pharmaceutical, biotechnology and drug delivery companies, research organizations, individual scientists and nonprofit organizations engaged in the development and commercialization of drug delivery systems and new drug research and testing. We are aware of a number of companies currently seeking to develop pulmonary delivery devices and other non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems and infusion systems. 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 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 may become subject to patent litigation, which would 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 patent infringement claims or litigation or interference proceedings declared by the United States Patent and Trademark Office, the USPTO, to determine the priority of inventions. In 1999, we settled a patent interference with United States Patent No. 5,261,601, assigned to Bepak. The settlement provided for a cross-license between us and Bepak, as a result of which Bepak has a license to certain of our technology, including the right to sublicense. The scope of the granted license was limited to products employing technology which was disclosed by Bepak in United States Patent No. 5,261,601.

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, and 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 or by our partner companies or 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.

**We have implemented anti-takeover measures that could discourage or prevent a takeover, even if an acquisition would be beneficial to stockholders.**

## Edgar Filing: AEROGEN INC - Form 10-K

Provisions of our Amended and Restated Certificate of Incorporation and bylaws, as well as provisions of Delaware law and of our stockholder rights plan (adopted in 2001 and amended in early 2003), could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions also may discourage bids at a premium over the market price of our common stock and may adversely affect both the market price of our common stock and the voting rights of our stockholders.

### **Concentration of ownership among our existing executive officers, directors and entities affiliated with our directors may prevent new investors from influencing significant corporate decisions.**

As of December 31, 2002, our executive officers, directors and entities affiliated with our directors beneficially own, in the aggregate, approximately 28% of the outstanding common stock. As a result, these stockholders may be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change of control of the Company, and will make some transactions difficult or impossible without the support of these stockholders.

## **Item 2. PROPERTIES**

We currently lease a 65,000 square foot facility in Mountain View, California. Our lease expires in 2012. We conduct all of our U.S. operations, including our manufacturing activities, in this facility. The lease and common area costs are approximately \$3.0 million per year. We spent approximately \$3.6 million adapting this facility for our use largely in the manufacturing and laboratory areas.

26

---

Our wholly-owned subsidiary, Aerogen (Ireland) Limited, leases a laboratory and office facility of approximately 5,440 square feet in Galway, Ireland. The lease for this facility expires in November 2003, and we have an option to extend the lease through October 2004. In early 2002, we entered into a 980-year lease with the Irish Development Agency on a 0.8 acre plot of land for a one-time payment of approximately \$220,000. We estimate a new facility on the site would cost approximately \$1.5 million. We do not currently have any final plans for the building of such a facility; however, when we do, we anticipate that the building of a facility would be financed primarily 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**

None.

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

None.

## **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 2001 and 2002 are as follows:

	<u>High</u>	<u>Low</u>
1Q '01	\$ 11.50	\$ 3.88
2Q '01	\$ 8.75	\$ 3.40
3Q '01	\$ 7.20	\$ 3.52



Edgar Filing: AEROGEN INC - Form 10-K

	<u>High</u>	<u>Low</u>
4Q '01	\$ 5.30	\$ 2.01
1Q '02	\$ 3.60	\$ 1.50
2Q '02	\$ 2.15	\$ 0.79
3Q '02	\$ 1.10	\$ 0.40
4Q '02	\$ 0.72	\$ 0.34

As of March 26, 2003, there were approximately 205 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. Our common stock has had, since July 1, 2002, closing bid prices of less than \$1.00 per share on all but three days. Nasdaq rules do not permit listed companies to maintain closing bid prices below \$1.00 per share for more than 30 consecutive trading days. Following the 30th consecutive trading day in which a listed stock closes with a bid price below \$1.00 per share, Nasdaq rules require that the stock's bid price close above \$1.00 for any 10 consecutive trading days during the subsequent 90 calendar days in order to avoid delisting action.

27

In November 2002, we received notice from Nasdaq Stock Market Inc., that our common stock would be delisted from the Nasdaq National Market on November 19, 2002 because the stock had not closed with a bid price of above \$1.00 per share for at least 10 consecutive trading days during the preceding 90 calendar days. In December 2002, the listing of our common stock was transferred to the Nasdaq SmallCap Market. Notwithstanding the transfer, we are still subject to the requirement of a share minimum bid price of \$1.00. Nasdaq has granted us a grace period, until August 4, 2003 to regain compliance.

If we continue to fail to meet all of the listing requirements under The Nasdaq SmallCap Market, the trading of our common stock is likely to be conducted on the OTC Bulletin Board or in the over-the-counter market in what is commonly referred to as the "pink sheets," which may have an adverse affect on the market price of our common stock and on the ability of stockholders and investors to buy and sell the common stock. If delisting occurs, stockholders may lose some or all of their liquidity and/or value.

There were no sales of unregistered securities by the Company in the year ended December 31, 2002.

*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, 2002.

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities available for future issuance</u>
Equity compensation plans approved by security holders (1)(2)(3)	3,326,419	\$ 2.84	1,996,777
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) 2,000,000 shares, or (iii) a lesser number of shares determined by Aerogen's Board of Directors.
- (3)

## Edgar Filing: AEROGEN INC - Form 10-K

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) 250,000 shares, or (iii) a lesser number of shares determined by Aerogen's Board of Directors.

### Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

#### 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

28

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,				
	2002	2001	2000	1999	1998
<b>Consolidated Statement of Operations Data:</b>					
Total revenues	\$ 2,532	\$ 2,469	\$ 5,832	\$ 468	\$ 85
<b>Costs and expenses:</b>					
Cost of products sold	1,786	285			
Research and development	17,772	21,698	16,219	7,910	4,392
Selling, general and administrative	8,382	8,138	4,143	2,076	1,600
Purchased in-process research and development			3,500		
Litigation settlement		2,000			
<b>Total costs and expenses</b>	<b>27,940</b>	<b>32,121</b>	<b>23,862</b>	<b>9,986</b>	<b>5,992</b>
Loss from operations	(25,408)	(29,652)	(18,030)	(9,518)	(5,907)
Interest and other income, net	497	2,250	1,160	550	345
<b>Net loss</b>	<b>(24,911)</b>	<b>(27,402)</b>	<b>(16,870)</b>	<b>(8,968)</b>	<b>(5,562)</b>
Dividend related to beneficial conversion feature of preferred stock			(16,517)		
<b>Net loss available to common stockholders</b>	<b>\$ (24,911)</b>	<b>\$ (27,402)</b>	<b>\$ (33,387)</b>	<b>\$ (8,968)</b>	<b>\$ (5,562)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (1.23)</b>	<b>\$ (1.39)</b>	<b>\$ (7.30)</b>	<b>\$ (4.95)</b>	<b>\$ (3.47)</b>
<b>Shares used in computing net loss per common share, basic and diluted</b>	<b>20,182</b>	<b>19,681</b>	<b>4,576</b>	<b>1,811</b>	<b>1,603</b>
	<b>December 31,</b>				
	<b>2002</b>	<b>2001</b>	<b>2000</b>	<b>1999</b>	<b>1998</b>

#### Consolidated Balance Sheet Data:

# Edgar Filing: AEROGEN INC - Form 10-K

December 31,

Cash, cash equivalents and available-for-sale securities	\$ 8,887	\$ 36,077	\$ 60,976	\$ 7,809	\$ 17,499
Working capital	8,679	33,457	60,639	7,408	16,825
Total assets	19,194	43,468	66,712	9,674	18,608
Long-term obligations, less current portion	205	212	184	100	480
Convertible preferred stock				31,476	31,476
Accumulated deficit	(92,052)	(67,141)	(39,739)	(22,869)	(13,901)
Total stockholders equity (deficit)	15,744	38,531	64,228	(23,013)	(14,140)

## 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

29

"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. Our core technology is based upon our proprietary aerosol generator. Using the technology, 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 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 currently have two nebulizer products on the market. We have an accumulated deficit of approximately \$92.1 million as of December 31, 2002. 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 been equity financings, product revenues, research and development revenues, interest earned on investments and, to a small extent, equipment lease financings.

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 ("Aeroneb Pro nebulizer"), developed for use in a hospital setting including the treatment of patients on ventilators. Both products incorporate our aerosol generator. Since the launch of the first product, we have recorded cumulative revenues of \$2.1 million associated with sales of the Aeroneb products and component parts as of December 31, 2002. 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 nebulizer is available in the United States where it is sold by Puritan Bennett with its newer ventilators and through Cardinal Health. The Aeroneb Pro nebulizer is available in 20 countries worldwide under agreements with Puritan Bennett and independent distributors in select countries.

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. From February 2000 to December 2001, we had such an agreement with PathoGenesis (acquired by Chiron in late 2000) to develop an Aerodose inhaler to deliver TOBI, an inhaled tobramycin therapy for the treatment of cystic fibrosis. Our collaborative agreement with PathoGenesis provided for reimbursement of development expenses incurred under an approved work plan, and royalties on future total product sales. This collaboration was terminated by Chiron in December 2001. We expect to receive similar payments from other partners for the development of products under similar collaborations, and royalties based on partner sales of products, if and when

## Edgar Filing: AEROGEN INC - Form 10-K

commercialized. We also expect to receive revenue from manufacturing of products. We recognize research and development revenues as reimbursable research and development expenses are incurred.

In May 2000, we acquired Cerus Limited, now Aerogen (Ireland) Limited, for 1,725,000 shares of our Series E convertible preferred stock. The total purchase consideration was approximately

30

---

\$6.0 million, including transaction costs of approximately \$150,000. Cerus was developing products under a license from us using our core aerosol generator technology.

The acquisition of Cerus was accounted for using the purchase method of accounting. The purchase price, which for financial accounting purposes was valued at \$6.0 million, was allocated to the assets acquired and the liabilities assumed based on their estimated fair values at the date of acquisition, as determined by management. As a result of this transaction, we recorded expense associated with the purchase of in-process research and development of \$3.5 million, net tangible assets of \$0.4 million, and intangible assets (including goodwill) of \$2.0 million. Through December 31, 2001 goodwill was amortized on a straight line basis, over six years. Beginning in January 2002, in accordance with Statement of Financial Accounting Standards No. 142 "Goodwill and Other Intangible Assets" ("SFAS 142"), goodwill and other intangible assets were no longer systematically amortized; instead we perform an annual assessment for impairment by applying a fair-value-based test.

We have incurred stock-based compensation expenses of \$1.4 million, \$1.3 million, and \$0.8 million, for the years ended December 31, 2002, 2001 and 2000, respectively. Stock-based compensation included in research and development expenses was \$0.5 million, \$0.9 million and \$0.6 million for the years ended December 31, 2002, 2001 and 2000, respectively. Stock-based compensation included in selling, general and administrative expenses was \$0.9 million, \$0.4 million and \$0.2 million, respectively, for the years ended December 31, 2002, 2001 and 2000. As of December 31, 2002, there was approximately \$1.5 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 employees and non-employees.

We had federal and state net operating loss carry forwards of approximately \$74.4 million and \$28.2 million, respectively, as of December 31, 2002. We also had aggregate federal and state research and development tax credit carryforwards of approximately \$2.4 million as of December 31, 2002. The net operating loss and credit carryforwards will expire at various dates through the year 2021, 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 due to 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. We did not incur any expenses in 2002 as a result of the January 2003 restructuring activities.

### *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

31

---

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.

## Edgar Filing: AEROGEN INC - Form 10-K

We have an Irish subsidiary, which accounted for approximately 6% of our net loss for the year ended December 31, 2002 and 19% of our assets and 23% of our total liabilities as of December 31, 2002. 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 \$217,000, (\$80,000) and \$20,000, which were in accumulated other comprehensive income (loss) on our balance sheets at December 31, 2002, 2001 and 2000, respectively. During 2002, 2001 and 2000, respectively, translation adjustments of \$297,000, (\$100,000) and \$20,000, 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, 2002, 2001 and 2000*

*Research and development revenues.* Research and development revenues were \$0.4 million in 2002, \$2.0 million in 2001, and \$5.8 million in 2000. 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. The revenue decrease in 2001 as compared to 2000 resulted from development activities performed for PathoGenesis of \$1.1 million and activities for a biotechnology company of \$2.8 million. Revenues from other customers were not material for these periods. 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. We expect research and development revenues for 2003 to be higher than those for 2002 as several new programs begin to move forward.

*Product sales.* Product sales were \$1.9 million in 2002, \$0.2 million in 2001 and none in 2000. We launched our first commercial product, the Aeroneb® Portable Nebulizer System, in June 2001 and our second commercial product, the Aeroneb Pro nebulizer in June 2002. The increase in product sales for the year ended 2002 is due to the successful launch of the Aeroneb Pro nebulizer in June 2002. We expect sales volume will increase in 2003, with a full year of sales.

## Edgar Filing: AEROGEN INC - Form 10-K

*Royalty revenues.* Royalty revenues were \$0.3 million in 2002, \$0.3 million in 2001 and none in 2000. The 2002 and 2001 revenue represents minimum royalties from a consumer company that licensed our aerosol generator technology for use in the field of air fresheners and insect repellants.

*Cost of products sold.* Cost of products sold were \$1.8 million in 2002, \$0.3 million in 2001, and none in 2000. 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 start-up of the commercial manufacturing processes and the move to the new facility. During the second half of 2002, we saw improved margins as volumes increased and as we completed our move into our new facility in Mountain View, California, 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 \$17.8 million in 2002, \$21.7 million in 2001, and \$16.2 million in 2000. The decrease in research and development expenses in 2002 compared with 2001 was primarily due to reduction 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 of \$2.2 million. 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 completion of 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 increased in 2001 as compared to 2000, which was primarily due to the expansion of product development activities for our respiratory products. Research and development expenses also increased in 2001 over 2000 due to activities for our Aerodose insulin inhaler. The increase was largely attributable to internal salary and related increases of \$2.6 million (excluding Ireland), increased Irish operations of \$1.0 million and machining and tooling costs of \$0.8 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

33

---

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 \$8.4 million in 2002, \$8.1 million in 2001, and \$4.1 million in 2000. 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 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 associated with the reduction in force of \$0.2 million, 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. The increase in selling, general and administrative expenses in 2001 compared with 2000 was due to increases in sales and marketing expenses of \$2.1 million and increases in general and administrative expenses of \$1.9 million. Sales and marketing expenses for 2001 increased as compared to 2000 primarily due to \$1.2 million in expenses relating to the hiring of a contract sales force for the launch of our first commercial product, the Aeroneb® Portable Nebulizer System, in mid 2001, other marketing and sales related personnel costs of \$0.5 million and amortization of deferred stock-based compensation of \$0.1 million. General and administrative expenses for 2001 increased over 2000 primarily due to payroll related increases of \$0.8 million associated with the general and administrative infrastructure including legal, information technology and investor relations. General and administrative expenses for 2001 also increased due to additional costs of \$0.5 million related to being a public company, such as directors and officers liability insurance, NASDAQ fees and the costs associated with filing SEC reports.

*Purchased in-process research and development.* In conjunction with the acquisition of our Irish subsidiary we recorded a \$3.5 million expense during the second quarter of 2000, which was associated with the purchase of in-process research and development. The purchased research and development represents the value of new technologies that were in various stages of development where no alternative future use was identified. The value of purchased in-process research and development was determined by management utilizing various methods, including the income approach.

*Litigation settlement.* In October of 2001, we settled a lawsuit brought by us against Becton, Dickinson and Company (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

## Edgar Filing: AEROGEN INC - Form 10-K

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.* Interest income was \$0.5 million in 2002, \$2.3 million in 2001, and \$1.2 million in 2000. 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. The increase in interest income in 2001 over 2000 was primarily due to higher average cash and investment balances resulting from the completion of equity placements of our common and convertible preferred stock in November, July, May and March of 2000. Sales of common stock include our initial public offering in November 2000, which resulted in approximately \$44.5 million of net proceeds. Interest expense was

34

---

\$1,160 in 2002, \$2,000 in 2001, and \$38,000 in 2000. The decrease in interest expense in 2001, as compared to 2000, was primarily due to repayments of borrowings under an equipment lease financing agreement.

*Dividends related to beneficial conversion feature of preferred stock.* Dividends relating to the beneficial conversion feature of our preferred stock of \$16.5 million were recorded in the year ended December 31, 2000. These dividends arose due to the issuance of 961,539 shares of Series E convertible preferred stock in May 2000 for net proceeds of \$2.5 million (\$202,000 of beneficial conversion) and 7,498,223 shares of Series F convertible preferred stock in July 2000 for net proceeds of \$16.3 million (\$16.3 million of beneficial conversion).

### ***Liquidity and Capital Resources***

Since inception, we have financed our operations primarily through equity financings, product revenues, research and development revenues, 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, 2002, including approximately \$44.5 million of net proceeds from our initial public offering in November 2000.

As of December 31, 2002 we had cash, cash equivalents and available-for-sale securities of approximately \$8.9 million. During 2003, our expenditures have been approximately \$1.6 million per month. We will need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next 30 to 60 days in order to continue as a going concern. We cannot be certain that such additional 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.

Net cash used in operating activities was \$24.0 million, \$23.7 million, and \$11.3 million for the years ended December 31, 2002, 2001 and 2000, respectively, and resulted primarily from operating losses adjusted for non-cash expenses and changes in accrued liabilities, accounts payable, accounts receivable, inventories and other assets.

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. For the years ended December 31, 2001 and 2000, cash used by investing activities was \$9.9 million and \$7.3 million, respectively, and resulted primarily from the addition of leasehold improvements, which amounted to \$0.9 million and \$0.2 million, respectively, acquisition of property and equipment, which was \$1.0 million and \$1.3 million, respectively, and the net purchase of available-for-sale securities.

Net cash provided by financing activities was \$0.5 million, \$0.5 million, and \$65.6 million for the years ended December 31, 2002, 2001, 2000, respectively. In 2002, approximately \$0.5 million was provided almost equally by repayment of earlier loans to stockholder/executives, and 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. We raised \$44.5 million from the sale of our common stock in our initial public offering in November of 2000. We also had proceeds of \$21.3 million in 2000 from the sale of our convertible preferred stock.

The development of our technology and proposed 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 proposed 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.

We currently have no material commitment for capital expenditures. We have a ten-year lease for our Mountain View facility that was signed in October of 2001. Our total lease obligation through 2012 is approximately \$24.6 million, plus approximately \$0.4 million annually of common area maintenance fees, which may escalate in the future. In addition, we have a lease commitment on our facility in Ireland for approximately \$0.1 million, and a commitment for approximately \$0.2 million anticipated to be paid in 2004 to Irish investors under a tax advantaged business expansion scheme.

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.

We have no relationship with unconsolidated entities or financial partnerships. We have no debt arrangements with restrictive covenants.

### ***Recent Accounting Pronouncements***

In April 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 145, "Rescission of FASB Statement No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS No. 145") which eliminates inconsistencies between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. SFAS No. 145 also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of SFAS No. 145 are effective for fiscal years beginning after May 15, 2002 and for transactions occurring after May 15, 2002. We do not expect the adoption of SFAS No. 145 to have a material impact on our consolidated financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Exit or Disposal Activities" ("SFAS No. 146") which addresses the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance that the Emerging Issues Task Force has set forth in EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)". SFAS No. 146 will be effective for exit or disposal activities that are initiated after December 31, 2002. We do not expect the adoption of SFAS No. 146 to have a material impact on our consolidated financial position or results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a reconciliation of changes in the entity's product warranty liabilities. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor's fiscal year-end. The disclosure requirements of FIN 45 are effective for financial statements for interim or annual periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on our consolidated financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure an amendment of FASB Statement No. 123," ("SFAS No. 148") provides

alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires prominent disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation in both annual and interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. The adoption of SFAS No. 148 did not have a material impact on our consolidated financial position or results of operations.



## Edgar Filing: AEROGEN INC - Form 10-K

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. We do not expect the adoption of FIN 46 to have a material impact on our consolidated financial position or results of operations.

### Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

*Interest rate risk.* Interest rate risk represents the risk of loss that may impact our financial position, operating results or cash flows due to changes in interest rates. This exposure is directly related to our normal operating activities. Our cash, 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 U.S. dollars using the average currency rate in effect for that period, and assets and liabilities are translated into U.S. 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 U.S. 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 U.S. 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.

37

---

### ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

#### AEROGEN, INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<b>Page</b>
Report of Independent Accountants	39
Consolidated Balance Sheets	40
Consolidated Statements of Operations	41
Consolidated Statements of Stockholders' Equity (Deficit)	42
Consolidated Statements of Cash Flows	45
Notes to Consolidated Financial Statements	46

38

---

### REPORT OF INDEPENDENT ACCOUNTANTS

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, 2002 and 2001, and the results of their operations and their cash

## Edgar Filing: AEROGEN INC - Form 10-K

flows for each of the three years in the period ended December 31, 2002 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.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred substantial losses from operations and negative cash flows from operations which, in light of its current liquidity and capital resources, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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  
February 3, 2003

39

### AEROGEN, INC.

#### CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	December 31,	
	2002	2001
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,266	\$ 15,714
Available-for-sale securities	5,621	20,363
Accounts receivable	903	193
Inventories, net	374	488
Prepaid expenses and other current assets	934	1,201
	11,098	37,959
Property and equipment, net	5,251	2,889
Goodwill and other intangible assets, net	1,612	1,362
Restricted cash	1,200	1,200
Other assets	33	58
	\$ 19,194	\$ 43,468
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 973	\$ 1,181

Edgar Filing: AEROGEN INC - Form 10-K

	December 31,	
	2002	2001
Accrued liabilities	1,446	3,321
Total current liabilities	2,419	4,502
Deferred rent	826	223
Other long-term liabilities	205	212
Total liabilities	3,450	4,937
Commitments (Note 6)		
Stockholders' equity:		
Convertible preferred stock, par value \$0.001		
Authorized: 5,000 shares; issued and outstanding: no shares at December 31, 2002 and 2001		
Common stock, par value \$0.001:		
Authorized: 95,000 shares; issued and outstanding: 20,404 and 20,148 shares at December 31, 2002 and 2001, respectively	20	20
Additional paid-in capital	109,497	110,428
Notes receivable from stockholders	(434)	(693)
Deferred stock-based compensation, net	(1,520)	(4,069)
Accumulated other comprehensive income (loss)	233	(14)
Accumulated deficit	(92,052)	(67,141)
Total stockholders' equity	15,744	38,531
Total liabilities and stockholders' equity	\$ 19,194	\$ 43,468

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

40

**AEROGEN, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share amounts and footnotes)

	Years Ended December 31,		
	2002	2001	2000
Revenues:			
Research and development	\$ 386	\$ 2,034	\$ 5,832
Product sales	1,896	185	
Royalty	250	250	
Total revenues	2,532	2,469	5,832
Costs and expenses:			

Edgar Filing: AEROGEN INC - Form 10-K

	Years Ended December 31,		
Cost of products sold	1,786	285	
Research and development(1)	17,772	21,698	16,219
Selling, general and administrative(2)	8,382	8,138	4,143
Purchased in-process research and development			3,500
Litigation settlement		2,000	
<b>Total costs and expenses</b>	<b>27,940</b>	<b>32,121</b>	<b>23,862</b>
Loss from operations	(25,408)	(29,652)	(18,030)
Interest income	487	2,252	1,198
Other income (expense), net	10	(2)	(38)
Net loss	(24,911)	(27,402)	(16,870)
Dividend related to beneficial conversion features of preferred stock			(16,517)
Net loss available to common stockholders	\$ (24,911)	\$ (27,402)	\$ (33,387)
Net loss per common share, basic and diluted	\$ (1.23)	\$ (1.39)	\$ (7.30)
Shares used in computing net loss per common share, basic and diluted	20,182	19,681	4,576

(1) Including stock-based compensation expense of \$514,000, \$902,000, and \$652,000 in 2002, 2001 and 2000, respectively.

(2) Including stock-based compensation expense of \$841,000, \$364,000, and \$177,000 in 2002, 2001 and 2000, respectively.

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

**AEROGEN, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

(in thousands)

	<u>Common Stock</u>		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						
Balances, January 1, 2000	2,310	\$ 2	\$ 955	\$ (510)	\$ (558)	\$ (33)	\$ (22,869)	\$ (23,013)
Beneficial conversion feature related to issuance of Series E and Series F preferred stock			16,517					16,517
Deemed dividend related to beneficial conversion feature of preferred stock			(16,517)					(16,517)

Edgar Filing: AEROGEN INC - Form 10-K

	<u>Common Stock</u>		<u>Notes Receivable From Stockholders</u> <sup>(30)</sup>	<u>Accumulated Other Comprehensive Income (Loss)</u>				
Note receivable from stockholder					(50)			
Repayment of notes receivable from stockholder					25			
Issuance of common stock in conjunction with initial public offering for cash, net of issuance costs of \$1,700	4,140	4	44,498		44,502			
Conversion of convertible preferred stock into common stock	13,003	13	58,533		58,546			
Issuance of common stock pursuant to exercise of stock options for cash and note receivable from stockholders	477	1	348	(106)	243			
Repurchase of common stock	(14)		(8)		(8)			
Deferred stock-based compensation			6,366	(6,366)				
Amortization of deferred stock-based compensation				829	829			
Accrued interest on notes receivable from stockholders				(24)	(24)			
Changes in unrealized loss on available-for-sale securities				28	28			
Foreign currency translation				20	20			
Net loss					(16,870)			
					(16,870)			
Balances, December 31, 2000	19,916	20	110,692	(665)	(6,095)	15	(39,739)	64,228

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

42

AEROGEN, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands)  
(continued)

	<u>Common Stock</u>		<u>Notes Receivable From Stockholders</u>	<u>Deferred Stock-Based Compensation</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficit)</u>	
	<u>Shares</u>	<u>Amount</u>	<u>Capital</u>					
Balances, December 31, 2000	19,916	20	110,692	(665)	(6,095)	15	(39,739)	64,228
Repayment of notes receivable from stockholder								
Issuance of common stock pursuant to employee stock purchase plan for cash	189		448					448
Issuance of common stock upon exercise of stock options for cash	57		56					56
Repurchase of common stock	(14)		(8)					(8)
Cancellations, net of deferred stock-based compensation			(760)	760				
Amortization of deferred stock-based compensation				1,266				1,266
Accrued interest on notes receivable from stockholders				(28)				(28)
Changes in unrealized loss on available-for-sale securities					71			71
Foreign currency translation					(100)			(100)
Net loss							(27,402)	(27,402)

Edgar Filing: AEROGEN INC - Form 10-K

	Common Stock		Notes	Accumulated	Other		
Balances, December 31, 2001	20	110,428	Receivable From Stockholders (693)	(4,069)	(14)	(67,141)	38,531
	20,148				Comprehensive Income (Loss)		

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

43

AEROGEN, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands)  
(continued)

	Common Stock		Additional	Notes	Deferred	Accumulated	Accumulated	Total
	Shares	Amount	Paid-In Capital	Receivable From Stockholders	Stock-Based Compensation	Other Comprehensive Income (Loss)	Deficit	Stockholders' Equity (Deficit)
Balances, December 31, 2001	20,148	20	110,428	(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	250		260					260
Issuance of common stock upon exercise of stock options for cash	17		10					10
Repurchase of common stock	(11)		(7)					(7)
Cancellations, net of 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)
Changes in unrealized loss on available-for-sale securities						(50)		(50)
Foreign currency translation						297		297
Net loss							(24,911)	(24,911)
Balances, December 31, 2002	20,404	\$ 20	\$ 109,497	\$ (434)	\$ (1,520)	\$ 233	\$ (92,052)	\$ 15,744

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

44

AEROGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2002	2001	2000

Edgar Filing: AEROGEN INC - Form 10-K

	Years Ended December 31,		
<b>Cash flows from operating activities:</b>			
Net loss	\$ (24,911)	\$ (27,402)	\$ (16,870)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,209	1,198	895
Changes in inventory reserves	15	30	
Disposal of property and equipment	180	1	
Purchased in-process research and development			3,500
Accrued interest on notes receivable from stockholders	(26)	(28)	(24)
Amortization of available-for-sale securities discount (premium)	9	(86)	
Amortization of deferred stock-based compensation	1,355	1,266	829
Changes in operating assets and liabilities:			
Accounts receivable	(666)	569	(337)
Inventories	110	(518)	
Prepaid expenses and other current assets	267		(811)
Accounts payable	(243)	266	397
Accrued liabilities	(1,893)	1,936	940
Deferred rent	603	223	
Other	38	(1,174)	151
	<u>(23,953)</u>	<u>(23,719)</u>	<u>(11,330)</u>
<b>Cash flows from investing activities:</b>			
Acquisition of property and equipment	(3,728)	(1,853)	(1,547)
Purchases of available-for-sale securities	(8,134)	(21,340)	(14,990)
Proceeds from maturities of available-for-sale securities	22,817	13,300	8,844
Cash acquired, net			392
	<u>10,955</u>	<u>(9,893)</u>	<u>(7,301)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock	270	504	44,746
Repurchase of common stock	(7)	(8)	(8)
Proceeds from issuance of convertible preferred stock, net			21,252
Repayment of note payable			(354)
Issuance of note receivable to stockholder			(50)
Repayment of note receivable from stockholder	285		25
	<u>548</u>	<u>496</u>	<u>65,611</u>
Effect of exchange rate changes on cash	2	20	8
Net increase (decrease) in cash and cash equivalents	(12,448)	(33,096)	46,988
Cash and cash equivalents at beginning of year	15,714	48,810	1,822
	<u>\$ 3,266</u>	<u>\$ 15,714</u>	<u>\$ 48,810</u>
<b>Supplemental disclosure of noncash investing and financing activities:</b>			
Exchange of stockholder note receivable for common stock	\$	\$	\$ 106
Convertible preferred stock issued for acquisition	\$	\$	\$ 5,813

Edgar Filing: AEROGEN INC - Form 10-K

	Years Ended December 31,		
	2003	2002	2001
Deferred stock-based compensation, net of cancellations	\$ (1,194)	\$ (760)	\$ 6,366
Conversion of convertible preferred stock into common stock	\$	\$	\$ 58,796
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid during the year for interest	\$ 1	\$ 2	\$

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

45

**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 a proprietary 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 accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles which contemplate the continued existence of the Company. The Company has incurred net losses since inception and is expected to incur substantial losses for the next several years. The Company's recurring net losses from operations and negative cash flows from operations, in light of the Company's current liquidity and capital resources, raise substantial doubt regarding the Company's ability to continue as a going concern for a reasonable period of time. To date, the Company has funded its operations primarily through the sale of equity securities, product revenues, 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, 2002, the Company had cash, cash equivalents and available-for-sale securities of approximately \$8.9 million. During 2003, the Company's expenditures have been approximately \$1.6 million per month. The Company will need to raise additional funds through public or private financings, collaborative relationships or other arrangements within the next 30 to 60 days in order to continue as a going concern. The Company cannot be certain that such additional funding will be available on terms attractive to the Company, or at all. Furthermore, additional equity or debt financing may involve substantial dilution to the Company's existing stockholders, restrictive covenants or high interest rates. Collaborative arrangements, if necessary to raise additional funds, may require the Company to relinquish rights to either certain of its products or technologies or desirable marketing territories, or all of these.

These consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The continued existence of the Company is dependent on the Company's ability to obtain adequate funding and eventually establish profitable operations. The Company will require additional financing in the near future. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company. The consolidated financial statements do not include any adjustments which may result from this uncertainty.

**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 (see Note 9). 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

46

---

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 year ended December 31, 2002. The provisions of SFAS 142 also required the completion of a transitional impairment test within 12 months of adoption, with any impairment treated as a cumulative effect of change in accounting principle. During the first quarter of 2002, the Company completed the transitional impairment test, which did not result in impairment of recorded goodwill.

47

---

The following table reconciles the Company's net loss and net loss per share for the three years ended December 31, 2002, 2001 and 2000, adjusted to exclude goodwill and acquired workforce amortization pursuant to SFAS No. 142, to amounts previously reported:

Edgar Filing: AEROGEN INC - Form 10-K

	Years Ended December 31,		
	2002	2001	2000
	(in thousands, except per share amount)		
Net loss as reported	(24,911)	(27,402)	(33,387)
Add: goodwill amortization		359	211
Adjusted net loss	\$ (24,911)	\$ (27,043)	\$ (33,176)
Net loss per share, basic and diluted	\$ (1.23)	\$ (1.39)	\$ (7.30)
Add: goodwill amortization		0.02	0.05
Adjusted net loss per share, basic and diluted	\$ (1.23)	\$ (1.37)	\$ (7.25)

**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, 2002 follows (in thousands):

Warranty accrual at the beginning of the year	\$ 6
Accruals for warranties issued during the year	121
Settlements made in kind during the year	(26)
Ending balance at the end of the year	\$ 101

**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 United States Food and Drug Administration ("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.

## Edgar Filing: AEROGEN INC - Form 10-K

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.

Two customers accounted for 50% and 47% of revenues during the year ended December 31, 2000.

### ***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, any significant rights to return product have expired and that collection of the receivable is probable.

Royalty revenues are recorded as earned.

### ***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.

49

---

### ***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, 2002, 2001 and 2000, 73%, 70% and 48%, respectively, of all long-lived assets were maintained in the United States. For the years ended December 31, 2002, 2001, and 2000, 29%, 97%, 99%, respectively, of consolidated revenues were generated in the United States. For the years ended December 2002, 2001 and 2000, 71%, 3% and 1%, respectively, of consolidated revenues were generated in Ireland.

### ***Accounting for stock-based compensation***

During the year ended December 31, 2002, the Company adopted SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure, an Amendment of FASB Statement No. 123." 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 and complies with the disclosure provisions of SFAS No. 123 "Accounting for Stock-Based Compensation." The following provides a reconciliation of net loss and net loss per common share to proforma net loss and proforma net loss per common shares as if the

## Edgar Filing: AEROGEN INC - Form 10-K

Company had applied the fair value recognition provisions of SFAS No. 123 to all employee awards:

	Years Ended December 31,		
	2002	2001	2000
	(in thousands, except per share amounts)		
Net loss as reported	\$ (24,911)	\$ (27,402)	\$ (33,387)
Add: stock based employee compensation included in reported net loss	1,335	1,168	584
Deduct: total stock based employee compensation determined under fair value based method for all awards	(3,933)	(3,465)	(922)
Net loss pro forma	\$ (27,509)	\$ (29,699)	\$ (33,725)
Net loss per share, basic and diluted as reported	\$ (1.23)	\$ (1.39)	\$ (7.30)
Net loss per share, basic and diluted pro forma	\$ (1.36)	\$ (1.51)	\$ (7.37)

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

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

50

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, 2002, 2001 and 2000.

### *Net loss per common share*

Basic net loss per share is computed by dividing net loss attributable to common stockholders 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 options and warrants. Options and warrants 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,		
	2002	2001	2000
	(in thousands)		
Net loss per common share, basic and diluted			
Net loss	\$ (24,911)	\$ (27,402)	\$ (16,870)

Edgar Filing: AEROGEN INC - Form 10-K

	Years Ended December 31,		
Dividend related to beneficial conversion feature of preferred stock			(16,517)
Net loss available to common stockholders	\$ (24,911)	\$ (27,402)	\$ (33,387)
Weighted average common shares outstanding	20,252	20,001	4,983
Less: Weighted average shares subject to repurchase	(70)	(320)	(407)
Weighted average shares used in computing basic and diluted net loss per common share	20,182	19,681	4,576

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

	December 31,		
	2002	2001	2000
	(in thousands)		
Options to purchase common stock	3,326	3,463	1,337
Common stock subject to repurchase	6	133	407
Warrants	22	32	76

51

**Recent accounting pronouncements**

In April 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 145, "Rescission of FASB Statement No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" ("SFAS No. 145") which eliminates inconsistencies between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. SFAS No. 145 also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The provisions of SFAS No. 145 are effective for fiscal years beginning after May 15, 2002 and for transactions occurring after May 15, 2002. The Company does not expect the adoption of SFAS No. 145 to have a material impact on its consolidated financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Exit or Disposal Activities" ("SFAS No. 146") which addresses the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for pursuant to the guidance that the EITF has set forth in EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)". SFAS No. 146 will be effective for exit or disposal activities that are initiated after December 31, 2002. The Company does not expect adoption of SFAS No. 146 to have a material impact on its consolidated financial position or results of operations.

In November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a reconciliation of changes in the entity's product warranty liabilities. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor's fiscal year-end. The disclosure requirements of FIN 45 are effective for financial statements for interim or annual periods ending after December 15, 2002. The adoption of FIN 45 did not have a material impact on the Company's consolidated financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires prominent disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation in both annual and interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. The adoption of SFAS No. 148 did not have a material impact on the Company's consolidated financial position or results of operations.

## Edgar Filing: AEROGEN INC - Form 10-K

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

52

provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company does not expect the adoption of FIN 46 to have a material impact on its consolidated financial position or results of operations.

### NOTE 3 LITIGATION SETTLEMENT:

In October 2001, the Company settled a lawsuit brought by the Company against Becton, Dickinson and Company ("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 \$2,000,000, 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:

	December 31,					
	2002			2001		
	(in thousands)					
	Amortized Cost Basis	Unrealized Gain	Fair Market Value	Amortized Cost Basis	Unrealized Gain	Fair Market Value
Government notes	\$ 5,605	\$ 16	\$ 5,621	\$ 20,297	\$ 66	\$ 20,363

Available-for-sale securities at December 31, 2002 and 2001 are summarized as follows:

As of December 31, 2002, all available-for-sale securities mature within one year. There were no realized gains or losses on maturities of available-for-sale securities for 2002, 2001, and 2000.

Inventories are summarized as follows:

	December 31,	
	2002	2001
	(in thousands)	
Raw materials	\$ 333	\$ 354
Work-in-process	31	99
Finished goods	10	35
Net inventories	\$ 374	\$ 488

53

Edgar Filing: AEROGEN INC - Form 10-K

Property and equipment consists of the following:

	December 31,	
	2002	2001
	(in thousands)	
Laboratory, computer and office equipment	\$ 4,604	\$ 3,550
Furniture	483	604
Land	220	
Leasehold improvements	3,577	685
Construction-in-progress	94	820
	<u>8,978</u>	<u>5,659</u>
Less: Accumulated depreciation and amortization	(3,727)	(2,770)
	<u>\$ 5,251</u>	<u>\$ 2,889</u>
Net property, plant and equipment		

In connection with the Cerus Limited acquisition in May 2000, the Company recorded goodwill and other intangible assets (Note 9). Goodwill and other intangible assets consist of the following:

	December 31,	
	2002	2001
	(in thousands)	
Goodwill and other intangible assets	\$ 2,274	\$ 1,922
Less: Accumulated amortization	(662)	(560)
	<u>\$ 1,612</u>	<u>\$ 1,362</u>
Net goodwill		

Accrued liabilities consists of the following:

	December 31,	
	2002	2001
	(in thousands)	
Payroll and related expense	\$ 669	\$ 843
BD litigation settlement		1,000
Deferred revenue	208	200
Other accrued liabilities	569	1,278
	<u>\$ 1,446</u>	<u>\$ 3,321</u>
Accrued liabilities		

**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 a tax-based scheme which grants investors tax breaks on the amounts invested. The maximum amount which the BES investors will receive from Aerogen (Ireland) Limited is \$205,000, when translated as of December 31, 2002. The BES investors have certain dividend and liquidation preferences. Based on the BES investment terms, the BES has been classified as long-term debt, which Aerogen (Ireland) Limited anticipates repaying in mid 2004.

**NOTE 6 COMMITMENTS:***Facility leases*

The Company leases its facilities in Mountain View, CA under an operating lease that expires in 2012.

The Company leases its facilities in Ireland under an operating lease that expires in November 2003 and the Company has an option to extend the lease through October 2004. 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.

Under the terms of the Mountain View lease, the Company is 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 is secured by investments of \$1,200,000, which are classified as restricted cash at December 31, 2002.

Rent expense for the years ending December 31, 2002, 2001, and 2000 was approximately \$2,828,000, \$1,148,000, and \$776,000 respectively.

Aggregate minimum rental commitments under non-cancelable operating leases in effect at December 31, 2002 are:

	<b>Years Ending December 31,</b>
	<b>(in thousands)</b>
2003	\$ 2,469
2004	2,452
2005	2,531
2006	2,614
2007	2,699
Thereafter	11,958
<b>Total minimum payments</b>	<b>\$ 24,723</b>

*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*

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 matters that will have a material adverse affect on the financial position, results of operations or cash flows of the Company.

**NOTE 7 CONVERTIBLE PREFERRED STOCK:**



## Edgar Filing: AEROGEN INC - Form 10-K

During 2000, the Company issued shares of its Series E convertible preferred stock in conjunction with certain research and development agreements and in conjunction with the acquisition of Cerus Limited (see Note 9). In July 2000, the Company issued 7,498,000 shares of Series F convertible preferred stock at \$2.25 per share for gross proceeds of \$16,871,000. Certain of these issuances resulted in charges associated with the beneficial conversion feature of \$16,517,000, calculated in accordance with EITF No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features." These charges were reflected as preferred stock dividends in the Consolidated Statement of Operations for the year ended December 31, 2000.

Concurrent with the closing of the Company's initial public offering in November 2000, all outstanding shares of preferred stock (39,010,653 shares) were converted into 13,003,514 shares of common stock of the Company.

### **NOTE 8 STOCKHOLDERS' EQUITY:**

#### *Convertible Preferred Stock*

As of December 31, 2002, 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*

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, 2002.

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, 2002 and 2001 are no shares and 69,453 shares subject to repurchase, respectively.

#### *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

56

---

subject to repurchase by the Company upon termination of the holder's service to the Company. At December 31, 2002 and 2001, 6,411 and 63,619 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, 2,000,000 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 250,000 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 vests over a 3 year period. In addition, on an annual basis, 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 vests over a three year period. The exercise price of an option will be the fair market value of the common stock on the date of grant and the term will be 10 years.

## Edgar Filing: AEROGEN INC - Form 10-K

Activity under the Stock Plans has been as follows:

	Options Available for Grant	Number of Options Outstanding	Exercise Price	Aggregate Price	Weighted Average Exercise Price
(in thousands, except per share amounts)					
Balances, January 1, 2000	226	708	\$ 0.24 - \$3.75	\$ 389	\$ 0.55
Reservation of shares	2,817				
Options granted	(1,206)	1,205	\$ 0.60 - \$10.06	4,441	\$ 3.68
Options exercised		(477)	\$ 0.24 - \$3.00	(349)	\$ 0.73
Options canceled	99	(99)	\$ 0.24 - \$7.50	(195)	\$ 1.96
Shares repurchased	14				
Balances, December 31, 2000	1,950	1,337	\$ 0.24 - \$10.06	4,286	\$ 3.21
Reservation of shares	922				
Options granted	(2,342)	2,342	\$ 3.01 - \$6.19	9,830	\$ 4.20
Options exercised		(57)	\$ 0.24 - \$3.00	(56)	\$ 0.98
Options canceled	159	(159)	\$ 0.24 - \$7.50	(625)	\$ 3.95
Shares repurchased	14				
Balances, December 31, 2001	703	3,463	\$ 0.24 - \$10.06	13,435	\$ 3.88
Reservation of shares	937				
Options granted	(945)	945	\$ 0.37 - \$1.62	651	\$ 0.69
Options exercised		(17)	\$ 0.80 - \$3.30	(10)	\$ 0.56
Options canceled	1,065	(1,065)	\$ 0.37 - \$10.06	(4,299)	\$ 4.04
Shares repurchased	11				
Balances, December 31, 2002	1,771	3,326	\$ 0.24 - \$10.06	\$ 9,777	\$ 2.94

57

The options outstanding and currently vested at December 31, 2002, by exercise price, are as follows:

Exercise Price	Options Outstanding		
	Number of Options Outstanding	Weighted Average Remaining Contractual Life	Number of Options Vested
	(in thousands)	(in Years)	(in thousands)
\$ 0.24	2	4.07	2
\$ 0.30	3	5.38	3
\$ 0.37	589	9.95	
\$ 0.60	131	6.55	112
\$ 0.61	127	9.58	
\$ 0.62	7	9.73	
\$ 1.40	42	9.37	6
\$ 1.62	180	9.20	23
\$ 3.00	484	7.31	280
\$ 3.01	657	8.95	366
\$ 3.75	14	7.55	10
\$ 4.36	259	8.70	93

Edgar Filing: AEROGEN INC - Form 10-K

	Options Outstanding		
\$ 4.50	82	7.66	47
\$ 4.54	88	8.35	39
\$ 5.00	501	8.15	216
\$ 6.19	44	8.52	17
\$ 6.75	30	7.75	17
\$ 7.50	70	7.81	36
\$10.06	16	7.95	8
	3,326		1,275

At December 31, 2001, 427,000 outstanding options were vested.

**Employee Stock Purchase Plan**

In November 2000, the stockholders approved the 2000 Employee Stock Purchase Plan (the "Purchase Plan") authorizing the issuance of 250,000 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, 250,000 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, 2002, 437,812 shares of common stock have been purchased under the Purchase Plan and 225,476 shares remain available for purchase.

58

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.

**Pro forma disclosure**

The Company has adopted the disclosure-only provisions of SFAS No. 123. (See Note 2) The fair value of all options granted are calculated using the Black-Scholes option-pricing model.

The weighted average grant date fair value, as defined by SFAS 123, of options granted to employees during the years ended December 31, 2002, 2001, and 2000 was \$0.65, \$3.42, and \$1.66 per share, respectively. The assumptions used are primarily as follows:

Stock option plans:	Years Ended December 31,		
	2002	2001	2000
Risk-free interest rate	3.54%	4.54%	6.45%
Expected life (in years)	4	4	5
Dividend yield			
Expected volatility	148%	100%	70%

The weighted average grant date fair value, as defined by SFAS 123, of purchase awards under the Purchase Plan was \$0.90, \$1.24, and \$0, per share, for the years ended December 31, 2002 and 2001 respectively. No shares were issued under the Purchase Plan during 2000. The fair value of purchase awards are calculated at each purchase date using the Black-Scholes valuation model per the assumptions below:

Edgar Filing: AEROGEN INC - Form 10-K

	Years Ended December 31,		
	2002	2001	2000
<b>Stock purchase plans:</b>			
Risk-free interest rate	2.46%	3.37%	
Expected life (in years)	2	2	
Dividend yield			
Expected volatility	148%	100%	

**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, 2002 and 2001 the Company had recorded cumulative deferred stock-based compensation related to these options in the amounts of \$4,613,000 and \$5,755,000, net of

59

cancellations, respectively, of which \$1,335,000, \$1,168,000, and \$584,000 had been amortized to expense during 2002, 2001, and 2000, 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,		
	2002	2001	2000
Risk-free interest rate	4.59%	5.02%	5.81%
Expected life (in years)	10	10	10
Dividend yield			
Expected volatility	100%	100%	70%

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 \$490,000 and \$519,000, as of December 31, 2002 and 2001, respectively, of which \$20,000, \$98,000 and \$245,000 was amortized to expense in 2002, 2001 and 2000, respectively.

**Warrants**

In connection with financing arrangements entered into by the Company in July 1995 and October 1997, the Company issued warrants to purchase 10,683 shares of common stock and warrants to purchase 65,000 shares of Series C convertible preferred stock at exercise prices of \$2.34 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 21,666 shares of common stock at \$3.00 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.

**Notes receivable**

In May 1994, the Company loaned \$69,009 to a stockholder employee. The note bears interest at 6.43% per annum and is due May 2003. 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

## Edgar Filing: AEROGEN INC - Form 10-K

and is collateralized by 166,666 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 individual an additional \$50,000. This loan bears interest at 6.62% per annum, is due in July 2005 and is collateralized by the same 166,666 shares of common stock. At December 31, 2002 and 2001, \$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 his non-collateralized Company stock until his notes to the Company have been paid in full.

In January and December 1998, the Company received two full recourse notes receivable from then current officers of the Company in exchange for common stock. The notes were interest bearing at 5.93% and 4.51%, and were due in January and December 2002, respectively. At December 31, 2002, all principal and interest had been paid in full. At December 31, 2001, \$210,832 of principal and interest was outstanding on these notes.

60

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 bears interest at 6.7% and is due in April 2004. Each loan is collateralized by 90,000 shares of common stock. At December 31, 2002, one of the loans had been paid in full. At December 31, 2002 and 2001, \$64,049 and \$117,820 of principal and interest were outstanding on these notes, respectively.

### NOTE 9 ACQUISITION:

In May 2000, the Company acquired all the voting stock of Cerus Limited ("Cerus"), now Aerogen (Ireland) Limited, in exchange for 1,725,000 shares of Series E convertible preferred stock valued at \$3.37 per share and transaction costs of approximately \$150,000. Cerus was engaged in the development of pulmonary inhalation products utilizing the Company's core aerosol generator technology, under a license agreement with the Company.

The acquisition of Cerus was accounted for using the purchase method of accounting and, accordingly the results of operations of Cerus were included in the Company's financial statements subsequent to May 25, 2000. The purchase price was allocated to the assets acquired and the liabilities assumed based on their estimated fair values at the date of acquisition as determined by management. The excess of the purchase price over the fair value of the net identifiable assets was allocated to goodwill. The purchase price was allocated as follows:

Cash and cash equivalents	\$	542,174
Grants receivable		105,038
Property and equipment, net		34,772
Other assets		50,895
Assumed liabilities		(287,908)
Acquired workforce		100,000
Acquired in-process research and development		3,500,000
Goodwill		1,917,589
		_____
Total purchase price	\$	5,962,560

Prior to the adoptions of SFAS 142, the acquired workforce and goodwill was amortized over two and six years, respectively, on the straight-line basis. The acquired in-process research and development represents the value of new medical and other technologies that were in various stages of development where no alternative future use was identified. Management is primarily responsible for the valuation of the acquired in-process research and development. The fair value of the in-process research and development was based on the discounted cash flow method. As Cerus was a development stage company, there were no historical pricing and margin assumptions to utilize and therefore estimates used were based on the expectations of management. Management did not expect material net cash in-flows until at least 2005. The present value of these cash flows was calculated with an overall discount rate of 40%. At the date of acquisition, the Company determined the technological feasibility of Cerus' products was not established and, accordingly, wrote off the corresponding amounts to acquired in-process research and development. Approximately \$500,000 in research and development has been spent up to the date of the acquisition in an effort to develop the technologies to produce commercially viable products. At the date of acquisition, the only identifiable intangible assets acquired were the technologies under development and the acquired workforce. Currently the Company knows of no developments, which would lead it to significantly change its original assessment of the expected timing and commercial viability of these projects.

61

## Edgar Filing: AEROGEN INC - Form 10-K

The unaudited pro forma financial information, had the acquisition of Cerus occurred at the beginning of fiscal 2000, giving effect to an acquisition adjustment for the elimination of acquired in-process research and development, is as follows (in thousands, except per share data):

	<b>Year Ended December 31, 2000</b>
Revenues	\$ 5,942
Net loss available to common stockholders	\$ (13,724)
Net loss per common share, basic and diluted	\$ (3.00)

The unaudited pro forma financial information is presented for illustrative purposes only and is not necessarily indicative of the operating results that would have occurred had the transaction been completed at January 1, 2000, nor is it necessarily indicative of future operating results.

### NOTE 10 INCOME TAXES:

At December 31, 2002, the Company has a net operating loss carryforward of approximately \$74,415,000 for federal and \$28,246,000 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:

	<b>December 31,</b>	
	<b>2002</b>	<b>2001</b>
	<b>(in thousands)</b>	
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 26,949	\$ 21,475
Federal and state tax credit carryforwards	2,902	1,731
Research and development capitalization	1,941	1,203
Depreciation and amortization	1,111	240
Stock-based compensation		75
Accrued liabilities and reserves	305	
Other	420	215
	<b>33,628</b>	<b>24,939</b>
Less: Valuation allowance	(33,628)	(24,939)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

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 valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

The Company has research credit carryforwards of approximately \$1,677,000 and \$1,687,000 for federal and state income tax purposes, respectively. If not utilized, the federal credits will expire in various amounts beginning in 2009. The state credits can be carried forward indefinitely.

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

**NOTE 11 EMPLOYEE BENEFIT PLAN:**

In August 1996, the Company adopted a retirement plan (the "401(k) Plan"), which is qualified under Section 401(k) of the Internal Revenue Code of 1986. Eligible employees may make voluntary contributions to the 401(k) Plan of up to 20% of their annual compensation, not to exceed the statutory limit, and the Company may make matching contributions. During the years ended December 31, 2002 and 2001, the Company made approximately \$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 12 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 2002 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Total revenues	\$ 89	\$ 182	\$ 704	\$ 1,557
Gross margin	(143)	(53)	191	751
Loss from operations	(7,292)	(7,160)	(5,753)	(5,205)
Net loss available to common stockholders	\$ (7,072)	\$ (7,038)	\$ (5,667)	\$ (5,134)
Net loss per common share, basic and diluted	\$ (0.35)	\$ (0.35)	\$ (0.28)	\$ (0.25)
	Fiscal 2001 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Total revenues	\$ 675	\$ 951	\$ 594	\$ 249
Gross margin	675	951	460	98
Loss from operations	(5,857)	(6,959)	(9,209)	(7,627)
Net loss available to common stockholders	\$ (5,049)	\$ (6,316)	\$ (8,736)	\$ (7,301)
Net loss per common share, basic and diluted	\$ (0.26)	\$ (0.32)	\$ (0.44)	\$ (0.37)

(1)

Includes a charge of \$2,000 (\$0.10 per share) in conjunction with settlement of a lawsuit.

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

Not applicable.

**PART III****Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT****Directors**

Name and Positions with Aerogen in Addition to Director	Age	Director Continuously Since
---	-----	-----------------------------

<b>Class I Directors (term ends 2004)</b>		
Dr. Phyllis I. Gardner	52	2000
Philip M. Young	63	1994
<b>Class II Directors (term ends 2005)</b>		
Thomas R. Baruch	64	1994
Dr. Jane E. Shaw (Chairman and Chief Executive Officer)	64	1998
<b>Class III Directors (term ends 2003)</b>		
Jean-Jacques Bienaimé	49	1999
Yehuda Ivri (Chief Technical Officer)	51	1991
Bernard Collins(1)	54	2002

(1)

Mr. Collins joined the Board on March 12, 2002.

### **Business Experience of Directors**

#### *Class I Directors*

**Phyllis I. Gardner, M.D.** has served as a director of Aerogen since May 2000. Dr. Gardner is currently the Senior Associate Dean for Education and Student Affairs and Associate Professor of Molecular Pharmacology and Medicine at Stanford University School of Medicine and has been with the university since 1984. Dr. Gardner was Vice President of Research and Principal Scientist of ALZA Corporation and head of ALZA Technology Institute from 1996 to 1998. She was Principal Scientist and a consultant to ALZA from 1994 to 1996. Dr. Gardner received a B.S. in Biology from the University of Illinois and an M.D. from Harvard Medical School. Dr. Gardner serves as a director of Aronex Pharmaceuticals, Inc., a biopharmaceutical company, and BioMarin Pharmaceutical, Inc., a biotechnology company.

**Philip M. Young** has served as a director of Aerogen since 1994. Mr. Young has been a General Partner with U.S. Venture Partners, a venture capital firm, since 1990. Mr. Young was a Managing Director of Dillon Read & Co., a financial services company, and Concord Partners, a venture capital firm managed by Dillon Read, from 1986 to 1990. Mr. Young was President and CEO of Oximetrix, Inc., a privately held manufacturer of high technology medical instruments and sterile disposable products, from 1977 to 1985. Mr. Young received a B.M.E. in Mechanical Engineering from Cornell University, an M.S. from George Washington University and an M.B.A. from Harvard Business School, where he was a Baker Scholar. Mr. Young serves as a director of Zoran Corporation, a digital solutions provider, and several privately-held companies.

#### *Class II Directors*

**Thomas R. Baruch** has served as a director of Aerogen since 1994. He has been a General Partner at CMEA Ventures, a venture capital firm (previously an affiliated fund of New Enterprise Associates), since 1988. Mr. Baruch was a special partner of New Enterprise Associates from 1990 to 1996. Mr. Baruch received a B.S. in Engineering from Rensselaer Polytechnic Institute and a J.D. from Capital University. Mr. Baruch serves as a director of Netro Corporation, a telecommunications

company, Symyx Technologies, a technology research company, Physiometrix Inc., a medical products company, and Aclara Biosciences, Inc., a life science company.

**Jane E. Shaw, Ph.D.** has served as Chairman of the Board of Directors and as the Company's Chief Executive Officer since 1998. Dr. Shaw was a founder and consultant 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 also 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.

#### *Class III Directors*



## Edgar Filing: AEROGEN INC - Form 10-K

**Jean-Jacques Bienaimé** has served as a director of Aerogen since 1999. Mr. Bienaimé has been the President, Chief Executive Officer and a director of Genencor International Inc., a biotechnology company, since November 2002. Mr. Bienaimé was President, Chief Executive Officer and a director of SangStat Medical Corporation, a biopharmaceutical company, from 1998 to 2002, and Chairman of its Board of Directors from October 2000 to November 2002. Mr. Bienaimé held various positions at Rhône Poulenc Rorer Inc., a leading pharmaceutical company, from 1992 to 1998, most recently as Senior Vice President of Corporate Marketing and Business Development. Mr. Bienaimé received an M.B.A. from the Wharton School at the University of Pennsylvania and a degree in Economics from Ecole Supérieure de Commerce de Paris in France. Mr. Bienaimé serves as a director of the Fox Chase Cancer Center in Philadelphia.

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

**Bernard Collins** joined the Board of Directors on March 12, 2002. Mr. Collins currently is an independent consultant in the areas of business strategy and management. From 1994 to 2000, he was the Vice President, International Operations of Boston Scientific Corporation. Prior to that time he was a management consultant and held management positions in medical device/healthcare companies. Mr. Collins received a B.A. in Industrial Psychology from the National University of Cork. He serves as a director of several privately held companies.

65

### Executive Officers

The following table provides information concerning our executive officers, including their ages, as of March 25, 2003:

Name	Position with Company	Age	Executive Officer Since
Jane E. Shaw, Ph.D.	Chief Executive Officer and Chairman of the Board of Directors	64	1998
Yehuda Ivri	Chief Technical Officer, Director and Founder	51	1991
John E. Ross	Senior Vice President, Worldwide Operations	58	2001
Robert S. Breuil	Chief Financial Officer, Vice President, Corporate Development	41	2002
Robert S. Fishman, M.D.	Vice President, Scientific Affairs	41	2001
Nancy Isaac	Vice President, Regulatory Affairs and Quality	41	2002
John S. Power	Managing Director Aerogen (Ireland) Limited and Senior Vice President, Sales	43	2000

**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 a founder and consultant 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.

**John E. Ross**, Senior Vice President of Worldwide Operations, joined Aerogen in September 2001. Prior to joining Aerogen, Mr. Ross served as Vice President and General Manager for ASTeX product group of MKS Instruments, a component and system supply company serving the semiconductor industry. He served as President and COO for ASTeX Inc., responsible for worldwide operations, from 2000 to its acquisition by MKS in 2001. Mr. Ross held a number of other senior operations positions including Senior Vice President of Operations at Topaz Technologies from 1999 to 2000, Vice President and General Manager at Applied Magnetics Corporation from 1993 to 1998, Director of Wafer Fab Operations at Read Rite Corporation from 1991 to 1993, and Executive Vice President, responsible for operations, at Tegac Corporation, a division of Motorola from 1984 to 1991. Mr. Ross holds a B.Sc. honors degree in chemistry from the University of Hull,

England.

**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

66

---

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 since July 2002, joined Aerogen in June 1998 as Director of Clinical Operations and was promoted to Vice President of Clinical Operations in 2001. Prior to joining Aerogen, Dr. Fishman was Director of Clinical Affairs at Heartport, Inc. from 1995 to 1998, 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 from 1993 to 1995. 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**, Vice President, Regulatory Affairs and Quality, joined Aerogen in August 2002. Prior to joining Aerogen she was employed by BD Biosciences, a business segment of Becton, Dickinson & Company from 1997 to 2002, most recently as Worldwide Vice President, Regulatory and Quality. Prior to BD, Ms. Isaac held a senior regulatory position at Genzyme Corporation. 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 a member of the State Bar of California.

**John Power**, Managing Director Aerogen (Ireland) Limited and Senior Vice President Sales, has served as Senior Vice President Sales since January 2003 and as Aerogen's Vice President, European Operations and as 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 as 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.

#### Section 16(a) Beneficial Ownership Reporting Compliance

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

To our knowledge, based solely on a review of the copies of such forms filed with the SEC and written representations that no other reports were required to be filed during the fiscal year ended December 31, 2001, our directors, executive officers and greater than 10% stockholders complied with all Section 16(a) filing requirements except as follows:

Mr. Bienaimé inadvertently filed one late Form 4 concerning one open market purchase in May 2002, of 1,000 shares of the company's common stock at a price per share of \$1.36.

Mr. Breuil, Mr. Power, Mr. Ross, Mr. Ivri, Dr. Fishman and Ms. Isaac each inadvertently filed one late Form 4 to report one stock option grant by the Company under the Company's stock plans in December 2002.

67

---

#### Item 11. EXECUTIVE COMPENSATION

## Edgar Filing: AEROGEN INC - Form 10-K

The following table sets forth certain information relating to compensation paid or accrued for services in all capacities during the fiscal years indicated with respect to Dr. Jane E. Shaw, the Company's Chairman and Chief Executive Officer and each of the Company's other four most highly compensated executive officers at December 31, 2002 (the "Named Executive Officers").

Name and Principal Positions	Annual Compensation			Securities Underlying Options	All Other Compensation
	Year	Salary (1)	Bonus		
Jane E. Shaw, Ph.D.	2002	\$ 271,188			
Chairman and	2001	\$ 300,000		125,000	
Chief Executive Officer	2000	\$ 240,000	\$ 50,000	233,333	
John E. Ross(2)	2002	\$ 240,774	\$ 25,000	45,000	
Senior Vice President	2001	\$ 64,080	\$ 25,000	157,000	
Worldwide Operations	2000				
Robert S. Fishman, M.D.	2002	\$ 203,638		45,000	
Vice President	2001	\$ 178,161		87,000	
Scientific Affairs	2000	\$ 163,368		8,333	
Yehuda Ivri	2002	\$ 191,736		45,000	
Chief Technical Officer	2001	\$ 181,159		7,500	
	2000	\$ 160,022			
Robert S. Breuil(3)	2002	\$ 136,125		182,500	
	2001				
Chief Financial Officer and	2000				
Vice President Corporate Development					

- (1) Amounts shown include compensation earned and received by the Named Executive Officers as well as amounts deferred at the election of such persons under the Company's Tax Deferral Investment Plan.
- (2) Mr. Ross joined the Company in September 2001.
- (3) Mr. Breuil joined the Company in April 2002.

68

The following table sets forth information relating to options granted in 2002 to the Named Executive Officers. In addition, in accordance with the rules of the SEC, the table shows hypothetical gains that would exist for such options based on assumed rates of annual compound stock price appreciation of 5% and 10% per year from the date the options were granted over the full option term.

Name	Individual Grants				Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(1)(4)	
	Number of Securities Underlying Options Granted(2)	Percent of Total Options Granted to Employees in Fiscal Year(3)	Exercise Price Per Share(4)	Expiration Date	5% Per Year	10% Per Year
Jane E. Shaw, Ph.D.						
John E. Ross	45,000	4.76%	\$ 0.37	12/10/12	\$ 10,471	\$ 26,536
Robert Fishman, M.D.	45,000	4.76%	\$ 0.37	12/10/12	\$ 10,471	\$ 26,536
Yehuda Ivri	45,000	4.76%	\$ 0.37	12/10/12	\$ 10,471	\$ 26,536
Robert S. Breuil	137,500	19.31%	\$ 1.62	03/12/12	\$ 140,086	\$ 355,006

Edgar Filing: AEROGEN INC - Form 10-K

	Individual Grants			Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(1)(4)	
	45,000	\$ 0.37	12/10/12	\$ 10,471	\$ 26,536

- (1) The closing price of the Company's Common Stock as reported on the Nasdaq SmallCap Market was \$0.37 on December 31, 2002 and \$0.28 on March 26, 2003. Actual gains, if any, on stock option exercises are dependent on the future performance of the Company's Common Stock. There can be no assurance that any of the values reflected in the table will be achieved.
- (2) All options were granted for a term of ten years. All unvested options are subject to earlier termination in the event of the termination of the employee's relationship with Aerogen. For Mr. Ross, Dr. Fishman, Mr. Ivri and Mr. Breuil, the \$0.37 options vest in 36 equal monthly installments beginning December 31, 2002. For Mr. Breuil, 100,000 of the \$1.62 options vest as follows: 25% vest on April 8, 2003 and the remaining 75% vest in 36 equal monthly installments beginning April 8, 2003. For Mr. Breuil, 37,500 of the \$1.62 options vest as follows: 20% vest on June 30, 2002, 40% vest on December 31, 2002 and 40% vest on June 30, 2003.
- (3) Based on options to purchase a total of 944,901 shares of Common Stock granted during the fiscal year ended December 31, 2002.
- (4) Options were granted at an exercise price equal to the fair market value of Aerogen Common Stock on the date of the grant. Potential realizable value assumes appreciation from the value at the time of grant. Value at the time of grant is equal to the exercise price per share times the number of shares covered by the option.

The following table sets forth, with respect to the Named Executive Officers, certain information relating to options held by such officers during the fiscal year ended December 31, 2002.

Executives	Shares Acquired on Exercise	Value Realized	Number of Securities Underlying Unexercised Options at Year End (1)		Value of Unexercised In-the-Money Options at Fiscal Year End (2)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Jane E. Shaw, Ph.D.			233,333	125,000		
John E. Ross			61,250	141,250		
Robert S. Fishman, M.D.			67,749	89,250		
Yehuda Ivri			5,000	47,500		
Robert S. Breuil			22,500	160,000		

- (1) Certain of the options granted before 2001 may be exercised under the Company's early exercise program; however, any shares purchased early are subject to repurchase by the Company at the exercise price if the employee's service with the Company terminates. The repurchase right lapses over time.
- (2) Market value of the Company's Common Stock at fiscal year end based on the closing sales price as reported on the Nasdaq Stock Market on December 30, 2002 (\$0.37) minus the exercise price of "in-the-money" options.

The Company has a 2000 Non-Employee Directors' Stock Option Plan, approved by the stockholders in November 2000, that provides for the automatic grant of options to purchase shares of Common Stock to non-employee directors. Any director first elected to the Board after November 2000 will receive an initial option to purchase 15,000 shares of Common Stock, vesting one third on the first anniversary of the date of grant, and the remainder in 24 equal monthly installments thereafter. In addition, on the date of each annual meeting of stockholders, each non-employee director will receive an annual option to purchase 5,000 shares of Common Stock, vesting in equal monthly installments over

## Edgar Filing: AEROGEN INC - Form 10-K

36 months. The exercise price of options granted under this plan will be the fair market value of the Common Stock on the date of the grant. Under this plan, all of the members of the Board on May 14, 2002, the date of Aerogen's 2002 annual stockholders' meeting, received an option to purchase 5,000 shares of Common Stock at an exercise price of \$1.40 per share under this plan, Mr. Collins also received an initial option to purchase 15,000 shares of Common Stock at a exercise price of \$1.62 per share on March 12, 2002, when he joined the Board. Directors currently receive no cash compensation from Aerogen for their service as members of the Board, or for their attendance at Board or committee meetings.

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

### Compensation Committee Interlocks and Insider Participation

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

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

The following table sets forth the beneficial ownership of the Company's Common Stock as of March 24, 2003, except as otherwise noted, (i) by each person, entity or "group" of persons or entities known by the Company to be beneficial owners of more than 5% of the Company's Common Stock, (ii) by each director, and each of the Named Executive Officers listed in the Summary Compensation Table, and (iii) by all executive officers and directors as a group. Percentage ownership is based on 20,403,747 shares of Common Stock outstanding on March 24, 2003. Except as described below, each person has sole voting and investment power with respect to the Common Stock described in the table.

70

Unless otherwise indicated, the address of each of the individuals named below is: c/o Aerogen, Inc., 2071 Stierlin Court, Mountain View, California 94043.

	Amount and Nature Of Beneficial Ownership of Common Stock (1)	Percent of Outstanding Shares
<b>Five Percent Holders:</b>		
Mazama Capital Management, Inc.(2) One S.W. Columbia, Suite 1860 Portland, OR 97258	3,626,200	17.8%
Entities Affiliated with U.S. Venture Partners(3) 2735 Sand Hill Road Menlo Park, CA 94025	1,936,142	9.5%
Entities Affiliated with Chemicals and Materials Enterprise Associates, Limited Partnership(4) One Embarcadero Center, Suite 3250 San Francisco, CA 94111-3600	1,447,292	7.1%
Entities Affiliated with Interwest Partners(5) 3000 Sand Hill Road Building 3, Suite 255 Menlo Park, CA 94025	1,264,549	6.2%

### Directors and Executive Officers:

Edgar Filing: AEROGEN INC - Form 10-K

	Amount and Nature Of Beneficial Ownership of Common Stock (1)	Percent of Outstanding Shares
Jane E. Shaw, Ph.D.(6)	547,424	2.7%
Thomas R. Baruch(7)	1,468,957	7.2%
Jean-Jacques Bienaimé(8)	24,766	*
Robert S. Breuil(9)	54,583	*
Bernard Collins(10)	19,605	*
Robert S. Fishman(11)	104,482	*
Phyllis I. Gardner, M.D.(12)	24,999	*
Nancy Isaac(13)	1,333	*
Yehuda Ivri(14)	1,071,666	5.2%
John S. Power(15)	428,087	2.1%
John E. Ross(16)	76,667	*
Philip M. Young(17)	1,957,808	9.6%
<b>All executive officers and directors as a group (12 persons)(18)</b>	<b>5,780,377</b>	<b>27.5%</b>

\*

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

(1) Includes outstanding stock options that will be vested on or before May 23, 2003, to purchase shares of the Company's Common Stock, and shares repurchasable by the Company, as described in the footnotes below.

(2) Information is as provided by the holder in its Schedule 13G/A filed with the SEC on September 11, 2003. As to such shares, the holder has indicated in its Schedule 13G/A that it has sole voting power as to 2,220,100 and sole dispositive power with respect to 3,626,200 shares.

(3) Information is as provided by the holder in its Schedule 13G filed with the SEC as of February 13, 2001 and confirmed by written communication to the Company on March 4, 2003. Includes 1,674,763 shares held by U.S. Venture Partners IV, L.P., 203,295 shares held by Second Ventures II, L.P. and 58,084 shares held by USVP Entrepreneur Partners II, L.P. (collectively, the "USVP Entities"). Presidio Management Group IV, L.P. is the general partner of the USVP Entities. Philip M. Young, a director of Aerogen, is a general partner of Presidio Management Group IV, L.P. and shares voting and dispositive power with respect to these shares. Mr. Young disclaims

71

beneficial ownership of the shares held by the USVP Entities within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934.

(4) Information is as provided by the holder in its Schedule 13G/A filed with the SEC on February 10, 2003. Includes 1,299,144 shares held by Chemical and Materials Enterprise Associates, Limited Partnership (CMEA) and 148,148 shares held by CMEA Life Sciences Fund, L.P. NEA Chemicals and Materials Partners, Limited Partnership ("CMEA Partners") is a general partner of CMEA. The individual general partners of CMEA Partners are Cornelius C. Bond, Jr., Nancy L. Dorman, Richard Kramlich, Thomas C. McConnell and Charles W. Newhall III. Donald R. Murfin is also a general partner of CMEA. Mr. Baruch, a director of Aerogen, is a general partner of CMEA and also a general partner of CMEA Life Sciences Fund, L.P. In such capacity, he has shared voting power and shared dispositive power with respect to all of the shares. Mr. Baruch disclaims beneficial ownership of the shares held by Chemical and Materials Enterprise Associates, Limited Partnership and CMEA Life Sciences Fund, L.P. within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934.

(5) Information is as provided by the holder in its Schedule 13G/A filed with the SEC on February 13, 2003. Includes 37,486 shares held by Interwest Investors VI, LP and 1,227,063 shares held by Interwest Partners VI, LP. The voting and dispositive power with respect

## Edgar Filing: AEROGEN INC - Form 10-K

to these shares is shared by the managing directors of Interwest Management Partners VI LLC (Harvey B. Cash, Alan W. Crites, Philip T. Gianos, W. Scott Hedrick, W. Stephen Holmes, Robert R. Momsen and Arnold L. Oronsky) and the venture member of Interwest Management Partners VI LLC (Gilbert H. Kliman).

- (6) Includes 233,333 shares issuable upon exercise of options that are or will be exercisable within 60 days of March 24, 2003 (of which 77,778 shares would be repurchasable by the Company under certain circumstances), and 14,814 shares held by the Carpenter Family Trust, in which Dr. Shaw has an economic interest.
- (7) See Note 4 above. Also includes 21,666 shares issuable to Mr. Baruch upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003, of which 5,556 shares would be repurchasable by the Company under certain circumstances.
- (8) Includes 21,666 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003, of which 1,042 shares would be repurchasable by the Company under certain circumstances.
- (9) Consists of shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003.
- (10) Includes 7,500 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003.
- (11) Includes 76,999 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003, of which 2,778 shares would be repurchasable by the Company under certain circumstances.
- (12) Includes 21,666 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003, of which 3,819 shares would be repurchasable by the Company under certain circumstances.
- (13) Consists of shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003.
- (14) Includes 10,000 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003.

72

---

- (15) Includes 34,667 shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003.
- (16) Consists of shares issuable upon the exercise of options that are or will be exercisable within 60 days of March 24, 2003.
- (17) See Note 2 above. Also includes 21,666 shares issuable upon the exercise by Mr. Young of options that are or will be exercisable within 60 days of March 24, 2003, of which 5,556 shares would be repurchasable by the Company under certain circumstances.
- (18) Includes shares described in the notes above as applicable to directors and current executive officers.

For a tabular description of the Company's equity compensation plans, see Item 5 of this Form 10-K.

### Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

the preferred stock has converted.

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

*Transactions with Officers and Directors.* Yehuda Ivri, Aerogen's Founder and Chief Technical Officer, has three notes payable to the Company. On May 6, 1994, the Company received a promissory note for the principal amount of \$69,009. The note bears annual interest of 6.43%, with principal and interest due the earlier of May 5, 2003 or 90 days after the date of termination of Mr. Ivri's service with the Company. On August 15, 1996, the Company received a promissory note from Mr. Ivri for the principal amount of \$200,000. The note originally bore no interest and the entire principal balance was due on the earliest of (i) August 14, 2001, (ii) 90 days after Mr. Ivri's Common Stock was no longer subject to a lock-up agreement with the underwriters of the Company's initial public offering, or (iii) the date Mr. Ivri's service with the Company terminates pursuant to Mr. Ivri's resignation or is terminated by the Company for cause. This note was amended effective December 31, 2001 to provide that (i) interest will accrue on the outstanding principal at a rate of 4.38% per annum beginning January 1, 2002, (ii) principal and interest will be due on the earlier of termination of Mr. Ivri's service with the Company or December 31, 2006, and (iii) Mr. Ivri will pay the Company a portion of the proceeds of certain of his sales of Company Common Stock until his notes to the Company have been paid in full. On July 21, 2000, the Company received a promissory note from Mr. Ivri for the principal amount of \$50,000. The note bears interest at the rate of 6.62%, and the principal and interest are due on the earlier of (i) July 21, 2005 or (ii) the date at which Mr. Ivri's service with the Company terminates. These latter two notes are secured by 166,666 shares of Mr. Ivri's Common Stock. On December 31, 2002, the principal and accrued interest outstanding on the loans to Mr. Ivri totaled \$370,689.

In 1998, Aerogen received a recourse note from Dr. Jane E. Shaw, the Company's Chairman and Chief Executive Officer, in the aggregate principal amount of \$140,000, in connection with her purchase of 466,666 shares of Common Stock. The note bore annual interest of 5.93%, with original principal and interest due January 28, 2002. Certain portions of the Common Stock may be repurchased by the Company at the original purchase price if Dr. Shaw's service with the Company

73

---

terminates. This repurchase right lapses over time. During 2001, the highest balance of principal and accrued interest outstanding on the loan was \$149,444. The note was repaid in full in January 2002.

#### **Item 14. CONTROLS AND PROCEDURES**

Within 90 days prior to the filing date of this report, we carried out an evaluation, under the supervision and the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective and timely in alerting them to material information required to be included in our periodic SEC reporting. It should be noted that the design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

In addition, we reviewed our internal controls, and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of their last evaluation.

### **PART IV**

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

- (a) Documents filed as part of this Annual Report on Form 10-K:

74

---



**REPORT OF INDEPENDENT ACCOUNTANTS ON FINANCIAL STATEMENT SCHEDULE**

To the Board of Directors of Aerogen, Inc.:

Our audits of the consolidated financial statements referred to in our report dated February 3, 2003 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  
February 3, 2003

75

1. Consolidated Financial Statements: (See Index to Consolidated Financial Statements)
2. Financial Statement Schedule: 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
<b>Provision for inventories</b>				
Fiscal year ended 2000	\$	\$	\$	\$
Fiscal year ended 2001	\$	\$ 30	\$	\$ 30
Fiscal year ended 2002	\$ 30	\$ 15	\$	\$ 45

76

3. Exhibits:

No.	Note	Description of Exhibit Document
3.2	(7)	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	(1)*	Stock Purchase Agreement between Aerogen, Inc. and PathoGenesis Corporation, dated March 13, 2000

## Edgar Filing: AEROGEN INC - Form 10-K

No.	Note	Description of Exhibit Document
4.5	(1)*	Stock Purchase Agreement between Aerogen, Inc. and Becton, Dickinson and Company, dated May 10, 2000
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
10.7	(8)	Settlement Agreement between Becton, Dickinson and Company and Aerogen, Inc. dated October 1, 2001
10.8	(1)	Settlement Agreement between Bepak plc and Aerogen, Inc. and Tenax Corporation dated March 4, 1999
10.9	(1)	Agreement for the Acquisition By Way of Exchange of the Entire Issued "A" Share Capital of Cerus Limited, dated May 25, 2000
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
21.1		Subsidiaries of Aerogen, Inc.
23.1		Consent of independent accountants
99.1		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

77

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-K for the year ended December 31, 2001 as filed with the Securities and Exchange Commission on March 27, 2002.



Edgar Filing: AEROGEN INC - Form 10-K

Name	Title	Date
Thomas R. Baruch		
/s/ YEHUDA IVRI		
Yehuda Ivri	Director	March 27, 2003
/s/ JEAN-JACQUES BIENAIMÉ		
Jean-Jacques Bienaimé	Director	March 27, 2003
/s/ PHILIP M. YOUNG		
Philip M. Young	Director	March 27, 2003

79

/s/ BERNARD COLLINS		
Bernard Collins	Director	March 27, 2003
/s/ ROBERT S. BREUIL		
Robert S. Breuil	Chief Financial Officer and Vice President, Corporate Development ( <i>Principal Financial and Accounting Officer</i> )	March 27, 2003

80

**CERTIFICATIONS**

I, Jane E. Shaw, certify that:

1. I have reviewed this annual report on Form 10-K of Aerogen, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances in which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

## Edgar Filing: AEROGEN INC - Form 10-K

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 27, 2003

/s/ JANE E. SHAW

---

Jane E. Shaw, Ph.D.  
*Chairman and Chief Executive Officer*  
*(Principal Executive Officer)*

81

---

### CERTIFICATIONS

I, Robert S. Breuil, certify that:

1. I have reviewed this annual report on Form 10-K of Aerogen, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances in which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in

Edgar Filing: AEROGEN INC - Form 10-K

this annual report;

4.

The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a)

designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b)

evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

(c)

presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5.

The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a)

all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b)

any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6.

The registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 27, 2003

/s/ ROBERT S. BREUIL

---

Robert S. Breuil  
Chief Financial Officer  
(Principal Financial Officer)

82

---

QuickLinks

Edgar Filing: AEROGEN INC - Form 10-K

Aerogen, Inc. FORM 10-K ANNUAL REPORT FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002 TABLE OF CONTENTS

PART I

Item 1. BUSINESS

Item 2. PROPERTIES

Item 3. LEGAL PROCEEDINGS

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

PART II

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

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

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

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

AEROGEN, INC. INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT ACCOUNTANTS

AEROGEN, INC. CONSOLIDATED BALANCE SHEETS (in thousands, except per share amounts)

AEROGEN, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share amounts and footnotes)

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

AEROGEN, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (in thousands) (continued)

AEROGEN, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (in thousands) (continued)

AEROGEN, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

AEROGEN, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Item 11. EXECUTIVE COMPENSATION

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

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Item 14. CONTROLS AND PROCEDURES

PART IV

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

SIGNATURES

POWERS OF ATTORNEY

CERTIFICATIONS

CERTIFICATIONS