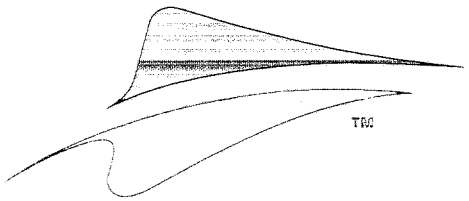
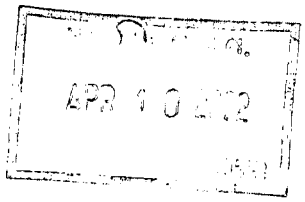
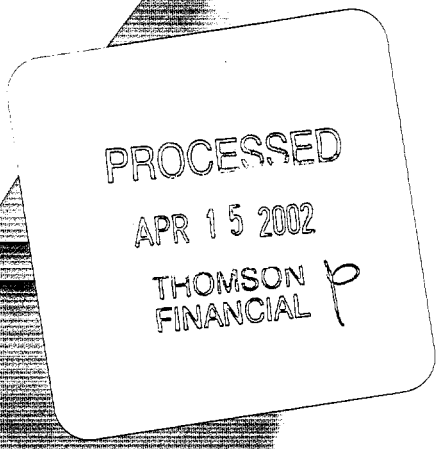




Aerogen® Inc

Annual Report 2001



subsidiary of Cardinal Health, for distribution in the United States. The product has received the necessary regulatory approvals for introduction in Europe. We anticipate the launch of the Aeroneb Pro at midyear in both Europe and the United States.

Looking ahead towards the next generation of the Aeroneb Pro, we plan to define a new paradigm for drug delivery to ventilated patients. The next generation product, already in development, will program delivery of drugs to the lung during the inspiratory phase of the breathing cycle, optimizing drug deposition in the lung. Aerogen plans to market both this second generation Aeroneb Pro, as well as proprietary drug ampoules that will interfit with it. The technology will also be available for collaborations with partners seeking to optimize delivery of their proprietary drugs to ventilated patients.

Systemic Drug Delivery Market

Our first inhaler in development for delivery of drugs to the bloodstream via the pulmonary route is the Aerodose insulin inhaler. Currently, over 154 million people worldwide are afflicted with type 1 and type 2 diabetes; many of them must inject themselves with insulin several times daily. The Aerodose insulin inhaler is designed to provide non-invasive delivery of insulin to the bloodstream, negating the use of needles. The Aerodose insulin inhaler is compact, lightweight and pocket-sized. Uniquely, it utilizes a proprietary titratable cartridge that allows patients to vary their insulin dose based on the caloric content of the meal they are about to take; the glass cartridge holds enough liquid insulin for one week of dosing on average. The inhaler is breath-actuated and provides efficient delivery of drug to the bloodstream. The product is discreet to use and very patient friendly; our goal is to provide ease of use for the patient and thereby facilitate compliance, better glucose control and better outcomes.

In 2001 we completed two Phase 2 studies using the Aerodose insulin inhaler, both with very promising results. The first study was presented at the European Society of Diabetes Association meeting in Glasgow, where we reported that within a patient, inhalation is as reproducible as subcutaneous administration in the delivery of insulin to the bloodstream. The second study evaluated dose proportionality; we determined that increasing the dose of insulin resulted in a linear increase in the level of insulin appearing in the bloodstream. The details of this study will be presented orally at the American Diabetes Association meeting in San Francisco in June of 2002.

In 2001 we signed an agreement with Diosynth, B.V., a business unit of Akzo Nobel N.V., for bulk supply of recombinant human insulin for our clinical and commercial needs. Diosynth is one of the world's leading manufacturers of active pharmaceutical ingredients, with an emphasis on biotechnology products and complex derivatives like steroids and synthetic peptides. We also signed an agreement with Disetronic Medical Systems, based in Switzerland, under which Disetronic has adapted its titration mechanism, currently used in insulin injectable pens, for use with our inhaler.

In 2002 Aerogen will continue activities associated with the selection and signing of the optimal partner for the final development, registration and commercialization of the Aerodose insulin inhaler.

Corporate Activities

In 2001 Aerogen strengthened its management team, including the appointment of John Ross to Senior Vice President of Worldwide Operations, and the promotion of Robert Fishman M.D. to Vice President of Clinical Operations.

In April 2002, we will relocate our corporate headquarters to 2071 Stierlin Court in Mountain View, California. We have leased a 64,000 square foot facility that will accommodate our expanded development and manufacturing capabilities.

The year 2001 was filled with challenges for our nation as a whole, which affected each and every one of us at the personal level; I am proud of Aerogen's accomplishments in 2001 despite these challenges. I look forward to a productive year in 2002 as we launch the Aeroneb Pro into the hospital market, partner our Aerodose insulin inhaler, and further the development of products both for ourselves and with partners.

I would like to thank our employees for their continued contributions and commitment to Aerogen, and our investors for their continued support and confidence. The future opportunities available to us are exciting, and will lead to the commercialization of products that will have a major impact on patients' lives as a result of better respiratory care. I look forward to reporting positive progress throughout the years ahead.

Jane E. Shaw
Chairman and CEO

To Our Stockholders

I am extremely pleased to be writing this letter to you following Aerogen's first complete year as a public company. I am proud of the accomplishments and progress our company made during the year 2001; we are focused on achieving greater successes in the years ahead. I would like to take this opportunity to elaborate on some of our key accomplishments during 2001, and to share with you our vision for the future.

Aerogen's business is centered on the commercialization of pulmonary drug delivery products based on our proprietary technology that forms a liquid aerosol. We are developing innovative inhaler and nebulizer products with the mission of improving respiratory therapy by providing efficient, convenient delivery of drugs to the lungs; we are also developing inhalers to provide delivery of drugs via the lungs for non-invasive delivery to the bloodstream.

Significant opportunities for Aerogen lie in leveraging our highly versatile aerosol generator. The particle size of the liquid aerosol produced by our aerosol generator determines where preferentially in the lung the drug is deposited. We have the ability to generate aerosol particles for deposition in the bronchial tree for respiratory therapy. We can also produce smaller aerosol particles for optimal deposition in the deep lung to facilitate absorption across the alveolar membrane into the bloodstream. Aerogen's aerosol generator can aerosolize virtually any drug in solution or suspension. The drug can be of small or large molecular weight; we can effectively aerosolize proteins and peptides, pharmacologically active agents which to date have been delivered largely by injection or infusion. Our aerosol generator is utilized in all Aerogen platforms - those targeting the respiratory home and hospital markets, and those for delivery of drugs to the bloodstream.

Respiratory Home Market

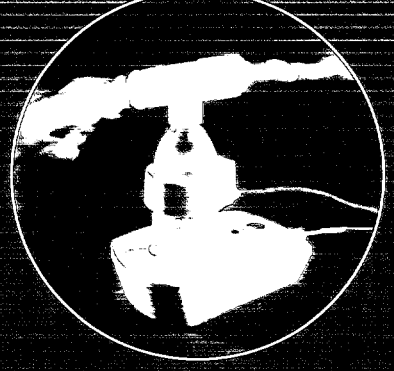
Over 30 million patients in the United States suffer from respiratory disorders, including asthma, chronic obstructive pulmonary disease and cystic fibrosis. Aerogen is initially addressing the need for improved inhalers and nebulizers that can better serve the pediatric and elderly population. Children and the elderly who suffer from respiratory disorders are often prescribed nebulizer therapy when metered dose and dry powder inhalers prove difficult or impossible to use. Many patients are reluctant to use the traditional bulky and noisy nebulizers. To address this market need, Aerogen developed the Aeroneb® Portable Nebulizer System, a simple, compact, silent nebulizer to provide effective, convenient respiratory therapy. Aerogen launched this product in the United States in June of 2001, and I am pleased to report that it has been well received by patients.

Our second delivery platform targeting the respiratory home market is an Aerodose® inhaler. Aerodose inhalers for respiratory therapy are designed to provide patients with a pocket-sized, simple to use inhaler that significantly reduces treatment time and improves dosing efficiency. Aerogen intends to build its respiratory product portfolio by using Aerodose inhalers to deliver branded generic drugs, in-licensed drugs for which aerosol delivery might be a novel route of administration, and new chemical entities. In 2001 we completed two Phase 2 studies with Aerodose inhalers delivering albuterol and ipratropium, two bronchodilator drugs that address the needs of our target market. Aerogen is also partnering with biotechnology and pharmaceutical companies to evaluate the potential for developing products using their proprietary compounds with Aerogen's inhalers, which the partners will commercialize.

Respiratory Hospital Market

Currently 4 million patient days per year are spent on ventilators in intensive care units in U.S. hospitals, and often the patients require respiratory therapy. In the emergency rooms of U.S. hospitals, 5 million patients per year are treated for respiratory problems. Treatment is currently provided by means of inefficient, small volume nebulizers, and thus we have identified a need for improved pulmonary drug delivery in these settings.

The first product Aerogen plans to introduce into the hospital market in both the United States and Europe is the Aeroneb® Professional Nebulizer System (Aeroneb Pro). The product, which is in late stage development led by our product development team in Galway, Ireland, aerosolizes medication for inhalation to patients on ventilators; it can also be used in the emergency room and on the hospital floor. It is designed to be adaptable for use with commercially available ventilators in the adult, pediatric and neonatal intensive care settings. The product is designed to offer many advantages over existing means of drug delivery to patients on ventilators, including efficient delivery of drugs to the lung and the elimination of changes to ventilator parameters during operation. It is also designed to be a very cost effective product, because it is autoclavable and therefore available for multi-patient use.



Aeroneb® Portable Nebulizer System

Aeroneb® Professional Nebulizer System in line with ventilator circuits

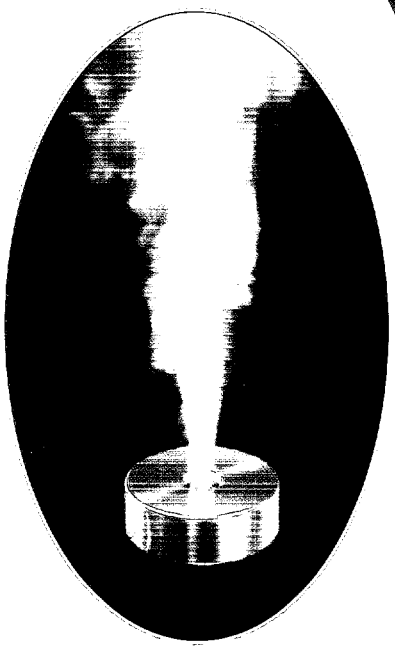
Aeroneb® Professional Nebulizer System with mouthpiece off ventilator

At Aerogen, it is our goal to become a leading specialty pharmaceutical company focusing on respiratory therapy.

Our proprietary aerosol generator technology sets new performance standards by producing precise liquid aerosol particles without using propellants or generating heat.

The aerosol generator is incorporated into each of Aerogen's innovative nebulizer and inhaler platforms. By combining our platforms with drugs targeted for respiratory therapy or delivery to the bloodstream, Aerogen is creating products that can maximize the efficiency of drug deposition in the lungs and improve therapeutic outcomes.

The opportunities for Aerogen to improve patients' lives around the globe are almost limitless.



Aerogen's Proprietary Aerosol Generator

Aerodose® insulin inhaler

Aerogen™

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, 2001

Commission File Number 0-31913

AeroGen, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	33-0488580
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
1310 Orleans Drive, Sunnyvale, CA	94089
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (408) 543-2400

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 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant as of March 25, 2002 was $26,090,174.

The number of shares of common stock outstanding as of March 25, 2002 was 20,142,657.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's annual meeting of stockholders to be held on May 14, 2002 are incorporated by reference into Part III of this Form 10-K.

AeroGen, Inc.
FORM 10-K ANNUAL REPORT
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001

TABLE OF CONTENTS

PART I

Item 1. BUSINESS

Notice Concerning Forward-Looking Statements

This Annual Report on Form 10-K ("Form 10-K") of AeroGen, Inc. ("Aerogen" or the "Company") 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 specializes in the development, manufacture and commercialization of products for the controlled delivery of drugs to the lungs, which is called pulmonary drug delivery. Drugs can be delivered via a fine mist, or aerosol, to the lungs to treat breathing-related, or respiratory, conditions such as asthma, and through the lungs to the bloodstream, or systemically, to treat diseases or conditions outside of the lungs, such as diabetes. Our core technology is based upon our proprietary aerosol generator. When incorporated in our inhaler or nebulizer platforms, this aerosol generator delivers drugs in an aerosol of a predetermined droplet size range. We believe that our drug delivery platforms will allow us to develop products that deliver drugs formulated as liquids in solutions or suspensions, from single-dose, multi-dose or patient-adjustable dosage forms. We launched our first product, the Aeroneb® Portable Nebulizer System, in June 2001. Products in development provide pulmonary drug delivery from our hand-held breath-activated inhalers, nebulizers for home use and nebulizers for use in the hospital setting, including for patients on ventilators.

We intend to create and market a respiratory disease product portfolio. Our initial products will focus on treating three respiratory diseases—asthma, chronic obstructive pulmonary disease and cystic fibrosis—and are designed to improve treatment for patients currently using inhalers or nebulizers and those receiving therapy via ventilators. The nebulizer products will deliver commercially available respiratory drugs, and the inhaler products will deliver both commercially available drugs and compounds licensed from third parties. 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 will commercialize the products developed in such collaborations.

In addition to our respiratory therapy activities, we intend to develop novel pulmonary drug delivery products for systemic drug delivery. These products will be developed in collaboration with pharmaceutical and biotechnology companies. Systemic drug delivery of biotechnology products via the lungs provides significant market opportunities for us. Our first product in development for the delivery of drugs through the lungs to the bloodstream is an Aerodose® inhaler delivering insulin to treat diabetes. The Phase 1 and early Phase 2 clinical trials for this product have been completed.

Aerogen was incorporated in the state of California in November 1991 under the name Fluid Propulsion Technologies, Inc. In April 1997, our name was changed to AeroGen, Inc., and in March 1998, our domicile was changed to the state of Delaware. Our principal executive offices are located at 1310 Orleans Drive, Sunnyvale, California 94089; telephone number (408) 543-2400. In the second quarter of 2002, we are moving to 2071 Stierlin Court, Mountain View, California 94043; telephone number (650) 864-7200. Our business comprises one industry segment—the development, manufacture and commercialization of pulmonary drug delivery products.

"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

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 determines 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 droplet size.

Respiratory Diseases

The most prevalent respiratory diseases are obstructive airways diseases such as asthma and chronic obstructive pulmonary disease. Respiratory diseases are associated with impaired quality of life, reduced life expectancy and significant treatment costs. We are currently focusing on treating three respiratory diseases: asthma, chronic obstructive pulmonary disease and cystic fibrosis, as well as on improving pulmonary drug delivery for patients using nebulizers and those receiving therapy via ventilators.

Asthma is a chronic inflammatory disorder involving constriction of the muscle lining of the airways, triggered by external stimuli such as exercise or allergens. Chronic obstructive pulmonary disease is a general term used to characterize the presence of chronic bronchitis and emphysema. Chronic bronchitis is characterized by a persistent, productive cough caused by excessive airway mucus secretion. As the disease progresses, there is a chronic reduction in lung function, with at least partial reversibility following administration of bronchodilators. Emphysema is a chronic disease caused by irreversible destruction of elastin, a protein in the lungs critical to maintaining integrity of the alveolar walls, or air sacs. Emphysema is irreversible and treatment is oriented towards reducing irritation and making the patient more comfortable. The major cause of chronic bronchitis and emphysema is cigarette smoking, followed by environmental pollution, genetic makeup and chronic occupational exposure to high concentrations of irritating gases. Worldwide, chronic obstructive pulmonary disease is the only leading cause of death that still has a rising mortality rate.

Cystic fibrosis is a genetic disorder associated with dysfunction of the pancreas and liver and is one of the most common life-shortening inherited diseases in the United States. Cystic fibrosis primarily affects digestion and nutrition. Secondary effects seen in the lungs include thick mucus secretions formed and retained in the airways. Most cystic fibrosis patients experience deterioration in lung function, increased incidence of lung infection and respiratory failure over time. In the 1950s, the typical life expectancy was four years after diagnosis. Today, however, many cystic fibrosis patients live well into their 30s. Earlier diagnosis and more aggressive and effective treatment have been credited with the dramatic increase in longevity.

Systemic Drug Delivery

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 is as high as 70 square meters, and is only one to two cells thick. 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 not feasible 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. Pulmonary delivery is being evaluated to deliver 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 currently are 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, most often 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. 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.

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 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 aerosol and deliver the drug. Children, the elderly and patients with breathing difficulties often cannot achieve the strong inhalation necessary to receive 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.

Traditional nebulizers create a continuous liquid aerosol that can be inhaled by patients through a mask or mouthpiece. Nebulizers allow patients to breathe regularly, thereby requiring less patient coordination and cooperation than metered dose inhalers and dry powder inhalers. Nebulizers typically require an external power source and are therefore bulky and generally noisy. Nebulizer treatments are time-consuming and inefficient, with less than 20% of the drug reaching the lungs. The remainder of the drug either is aerosolized during the patient's exhalation or released into the surrounding air or

remains in the nebulizer. Because of these limitations, nebulizers are only appropriate for relatively inexpensive, small-molecule drugs that can be formulated and stored as liquids.

Aerosol delivery to mechanically ventilated patients currently uses either a metered dose inhaler or a nebulizer. Drugs are administered after opening the tubing connecting the patient to the ventilator, which may result in infection. In addition, dosing requires significant time and the associated expense of an attendant respiratory therapist, and is inefficient, with only a very small amount of the administered drug reaching the lungs. Ventilator performance may be impaired due to the introduction of additional air into the ventilator tubing when drug is administered. This can affect adversely the ability to monitor the patient's pulmonary function.

Several companies are developing technology to improve the efficiency and accuracy of pulmonary drug delivery. Because systemic drug delivery requires the ability to create and deliver small particles to the deep lung, research has centered around 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 also will 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.

Our Core Technology and Pulmonary Drug Delivery Platforms

Aerosol Generator

Our proprietary aerosol generator contains a domed, or curved, aperture plate which contains multiple apertures, or holes, of a discrete shape and size. The aperture plate is produced through an electroforming, or plating, process using a metal alloy which is strong, corrosion resistant and durable. The plate is placed within a vibrational element and when energy is applied to this element the aperture plate vibrates. This creates a micro-pumping action that draws drug solutions in contact with the concave surface of the plate through the apertures to form a fine droplet aerosol. The aerosol droplet size formed is proportional to the size and shape of the holes in the aperture plate. The same manufacturing process is used to produce a variety of aperture plates with holes that result in aerosol droplets of various sizes. We are able to produce a low velocity aerosol by controlling the voltage and frequency applied to the vibrational element. When the aerosol generator is incorporated into a nebulizer or inhaler platform, 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 or 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 and peptides.

Our core aerosol generator technology is being incorporated into our inhaler and nebulizer platforms. These platforms are being customized to develop a wide range of products, from the pocket-sized Aerodose inhalers to the Aeroneb® nebulizers for use with ventilators.

Aerodose Inhalers

Each of our Aerodose inhalers consists of a proprietary aerosol generator, electronic circuitry, batteries, an inhalation sensor and a drug container. These components are incorporated into small, compact inhalers that are lightweight and easy to use, and can be carried in a shirt pocket or small purse.

We believe that the Aerodose inhalers are particularly suited to address the most common complaints of physicians and their patients who require aerosolized medication. The inhalers are

designed to combine the convenience and portability of a metered dose inhaler with the ease of administration of a nebulizer, while minimizing drug waste and ensuring reproducible dosing. In a six person imaging study, we compared lung deposition of drug following delivery of the same dose of albuterol from a metered dose inhaler and an Aerodose inhaler. The Aerodose inhaler deposited, on average, 70% of the emitted dose in the lungs, compared to the metered dose inhaler, which deposited, on average, 18%. Based on these findings, we believe that the Aerodose inhalers have the potential to reduce the typical prescribed dose of drug for a metered dose inhaler by more than half, while still delivering the same amount of drug to a patient's lungs.

Aerodose inhalers are designed to span the needs of the youngest and oldest patients in our target markets. We believe the Aerodose inhalers will also address the coordination problems experienced by patients who use metered dose inhalers. Even with repeat training, many patients using metered dose inhalers have difficulty coordinating the activation of the device to release a high velocity stream of medication with the quick breath intake necessary to capture the aerosolized drug in the lungs. Because Aerodose inhalers are breath-activated and deliver a low velocity aerosol only when the inspiratory flow rate attains a certain threshold, they are expected to avoid these problems. The initial version of our breath-activation mechanism has been incorporated into the Aerodose inhalers that we are using for clinical studies. We are developing an improved inhalation sensor for use in commercial Aerodose inhalers.

Our inhalers can accommodate several dosing options. This versatility enables us to explore multiple applications of the inhalers to deliver a variety of drugs. Our proprietary dosing systems permit accurate dosing in the range of 15 to 3,000 microliters. This wide dosing range should allow us to deliver the required dose of most drugs of interest for pulmonary delivery, from small quantities of expensive, potent drugs to large quantities of less potent drugs that are sometimes needed for effective therapy.

Currently, we are designing our inhalers for use with four distinct dosing options for our inhalers: single-dose, multi-dose, dual chamber and patient adjustable canisters. The single-dose ampoule design can contain dosing volumes from 100 to 3,000 microliters. As the patient places the ampoule into the inhaler, twist off tabs are removed, allowing the release of drug to the aerosol generator. Drug flow from the ampoule to the aerosol generator is automatically coordinated with a patient's breathing until all of the prescribed dose is inhaled. We intend to use standard nebulizer packaging for the intitial single-dose canister. For drugs already packaged using standard packaging technology, we plan to use currently available high capacity manufacturing systems to produce the single-dose ampoule, without having to design and manufacture new drug packaging materials or equipment.

The multi-dose canister is intended to deliver multiple small doses of drugs from a single canister. It includes a metering valve designed to maintain sterility over multiple activations of the canister and to provide accurate dispensing of small volumes of solutions as well as the suspensions required for the delivery of certain respiratory steroids. The disposable multi-dose canister can hold up to 6,000 microliters of solution. When activated by the patient, the valve will reproducibly dispense a fixed dose of 15 to 150 microliters of drug-containing solution to the aerosol generator. The patient activates the aerosol generator to form an aerosol by inhaling at a minimum predetermined rate. We are evaluating third party contractors for the final development and manufacture of this dosing option.

The dual chamber canister design is intended to accommodate drugs that are not stable in solution during storage. While most injected drugs exist in liquid formulations, some proteins may require storage as a dry powder to extend shelf life or minimize the need for refrigeration. In a dual chamber canister, drug would be stored as a powder in one chamber and a solvent would be stored in the second chamber. The patient would depress the barrel of the canister to mix the solvent with the drug powder, thereby creating a solution. The canister is intended to function with the ease of a standard single-dose canister or multi-dose canister.

In connection with our inhaled insulin product, we are developing with Disetronic Medical Systems ("Disetronic") a patient-adjustable container to enable variable dosing of insulin by means of the Aerodose inhaler. This canister is designed to allow patients to adjust their insulin dose before each meal based on their anticipated caloric intake and other factors. We previously worked with Becton, Dickinson and Company on a titrateable container for this product; that arrangement terminated in the fall of 2001.

We are incorporating electronic controls into our inhalers to provide flexibility, control and reproducibility of drug delivery. A patient can receive a visual signal that solution has been dispensed to the aperture plate and is ready for inhalation. Once the patient's inhalation rate exceeds a predetermined rate, the aerosol generator is activated and the solution is aerosolized and inhaled. The patient's inhalation rate can be monitored throughout the inhalation cycle, allowing aerosolization of the drug-containing solution to occur only while the patient's inhalation rate is above the minimum flow rate for optimal deposition of drug in the lung. A patient can also stop inhalation mid-dose and take multiple breaths to inhale a single dose. Our electronic controls can inform a patient when the complete dose has been aerosolized. Additional electronic features to customize an inhaler for a specific drug application or dosing regimen can include a dose counter, lock-out features and patient identification to prevent misuse.

We expect that our inhalers will be purchased by patients for use over a period of one month to a number of years. Drug canisters designed to fit into the inhalers may contain a daily, weekly or monthly supply of drug, and will be replaced by the patient when the supply in the canister is exhausted. The inhaler products are being designed to be used with a customized canister intended to fit only with our inhalers.

Aeroneb® Portable Nebulizer System

Our first commercial product, the Aeroneb® Portable Nebulizer System, was introduced in the United States in June 2001 and offers many improved features compared to standard nebulizers used by patients and care providers in the home setting. This portable nebulizer weighs less than 12 ounces and can operate on four standard "AA" batteries, a car cigarette lighter or alternating current. The Aeroneb system operates silently, and aerosolizes in any position and with less wasted medication and faster medication delivery rates than standard compressor nebulizers. It incorporates a liquid feed design and generates negligible heat, minimizing drug degradation. The Aeroneb system was designed and approved for use with commercially available nebulizer solutions of respiratory drugs.

Aeroneb® Professional Nebulizer System

We are developing an application of our aerosol generator technology to deliver drugs to patients in the hospital, including during mechanical ventilation. The Aeroneb® Professional Nebulizer System (the Aeroneb Pro) is small and lightweight, allowing it to be positioned close to the patient's windpipe, thereby optimizing drug delivery in the inhaled air. The Aeroneb Pro is designed to allow the addition of medication to a nebulizer cup without opening the ventilator tubing, potentially reducing a major source of infections. The drug is aerosolized without the use of a compressor and avoids the introduction of additional air into the ventilator tubing when the drug is administered. The product is autoclavable and therefore can be used for multiple patients. We plan to introduce the product into the U.S. market in the first half of 2002. The next generation product in development is being designed to synchronize with the patient's breathing cycle to optimize drug delivery. These products are being developed primarily by our Irish subsidiary, Aerogen (Ireland) Limited, formerly Cerus Limited, which we acquired in May 2000.

Our Products

We intend to incorporate our versatile and flexible core aerosol technology into a portfolio of products, some developed for commercialization by us and some developed with partners for marketing by them. We intend to out-license our technology for applications outside of the field of pulmonary drug delivery. We believe our products will provide the following benefits:

- *Optimization and Customization of Aerosol Droplet Size.* Our aerosol generator delivers a low-velocity liquid aerosol of precisely defined 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 two microns in diameter for deposition in the deep lung for systemic drug delivery.
- *Ease of Formulation.* Drugs can be stored in liquid or dry powder form and can be aerosolized in solution or suspension. The aerosol generator uses no propellants or pressure, and generates no 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.* The Aerodose inhaler technology can be used to administer drugs as a single dose, or as a unit dose from a multi-dose canister. We are developing with Disetronic a patient-adjustable canister to deliver the required dose of insulin from the Aerodose insulin inhaler.
- *Breath-Activation.* We have developed a breath-activation feature which triggers aerosol formation and is designed to enable patients to obtain consistent dosing over one or more breaths. This feature is designed so that drug will be aerosolized only when the patient's inhalation rate has reached a predetermined threshold, which can be adjusted 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 at an appropriate rate. Our electronic controls are designed to allow us to customize inhalers 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. 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. The Aeroneb® Portable Nebulizer System is quieter and more compact than currently commercialized nebulizers. The Aeroneb Pro is lightweight, allowing it to be placed close to the ventilated patient's windpipe, providing efficient generation of aerosol close to the lung. We believe our products will require minimal patient training, will be easy to use for the very young and the elderly and have the potential to increase compliance with prescribed treatment regimens.

Aerodose Inhaler Products for Respiratory Diseases

We intend to create and market a respiratory disease product portfolio consisting of our nebulizers and Aerodose inhalers. We have initially targeted our Aerodose inhalers for delivery of drugs that are currently administered by nebulizers to the lungs of the young and the elderly. The combination of breath-activation and small residual amounts of drug as compared with conventional nebulizers is expected to allow reductions in dose volumes and treatment times. Our initial target diseases are pediatric asthma, chronic obstructive pulmonary disease and cystic fibrosis. The types of drugs currently used to treat these diseases include bronchodilators (including beta agonists and anticholinergics),

anti-inflammatories (including steroids) and mucolytics. Bronchodilators relieve the airway spasms associated with wheezing, anti-inflammatories reduce airway inflammation, and mucolytics cause thinning of the mucus in the lungs.

Our activities for 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 be licensed to partners who will undertake the studies and other activities necessary to obtain regulatory approvals in their territories. The drugs we evaluated in 2001 for commercialization by us using the Aerodose inhaler included albuterol, ipratropium and budesonide. We conducted a Phase 2 clinical study with the Aerodose albuterol inhaler in 2001, which demonstrated in asthmatic patients that to get an equal effect on bronchial dilation one needed only ⅕ to 1/10 of the dose from an Aerodose inhaler as compared with the standard albuterol dose delivered from a commercially available nebulizer. The Aerodose albuterol product is targeted for the treatment of pediatric asthma, cystic fibrosis and chronic obstructive pulmonary disease. We also conducted a Phase 2 clinical study with the Aerodose ipratropium inhaler in 2001; the results will be presented at a meeting of the American Thoracic Society in May 2002. This product is intended to target chronic obstructive pulmonary disease. We believe, based on current delivery limitations, that there is an unmet need for a portable steroid dosage form which can provide effective and rapid drug delivery suitable for use by pediatric asthma and chronic obstructive pulmonary disease patients. Until recently, treatment options for steroids for our target patient populations were limited to oral delivery, injections and use of a metered dose inhaler or dry powder inhaler. A dosage form of budesonide was recently approved for use with conventional nebulizers. We have conducted pre-clinical feasibility testing of budesonide suspensions for possible delivery via an Aerodose inhaler.

We will explore additional drugs in 2002 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 inhalers.

Feasibility is the first stage of development for one of our Aerodose inhaler 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 inhaler, our ability to aerosolize the drug and the likely stability of the drug when used with our inhaler. 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 the Aerodose inhaler for use with a particular drug. We determine the appropriate container to hold the drug in the inhaler, the method of delivery of the drug to be aerosolized, the type of breath activation mechanism 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 Aerodose inhalers to be used in the clinical studies.

After feasibility testing and preclinical development, the Aerodose inhaler products are tested in human subjects. Some of our products, such as the Aeroneb® Portable Nebulizer System and the Aeroneb® Professional Nebulizer System, do not require human clinical trials before they can be cleared for marketing. Others will require a full clinical program. Aerogen's inhaler products differ from dry powder inhalers and metered dose inhalers, in that they are combinations of devices and drugs, and therefore the regulatory pathway, and the clinical programs that will be required for product approvals, is not clear. As the regulatory requirements are discussed in detail with the U.S. Food and Drug Administration ("FDA") and clarified, it is possible that certain products will be less attractive commercial targets for Aerogen marketing than others. We explored albuterol and ipratropium as initial candidates for our Aerodose inhalers because multiple sources of the drugs themselves were available, drug supplies were reasonably priced and each drug has many years of safety data, all of

which we believed could permit a very stream-lined, efficient clinical program for the first Aerodose inhaler products. However, generic drugs such as albuterol and ipratropium are priced competitively in the marketplace, resulting in very low margins. The requirement for a larger clinical program than we originally contemplated for one or both of these Aerodose inhaler products could cause Aerogen to focus on other products with potentially higher margins.

Aeroneb® Portable Nebulizer System

The quiet and portable Aeroneb® Portable Nebulizer System is our first commercial product, launched in June of 2001. It is approved for use with commercially available nebulizer solutions. Our 510(k) application filed with the FDA was reviewed and cleared by the FDA without the need for human clinical studies. The product will provide us with commercial experience in the respiratory disease market and target the disease area for our initial Aerodose inhalers.

The Aeroneb® Portable Nebulizer System can also be used by partners and potential partners in Phase 1 clinical studies to evaluate the potential use of Aerodose inhalers for delivery of their drugs under appropriate feasibility or development agreements.

Aeroneb® Professional Nebulizer System

The Aeroneb Pro incorporates our proprietary aerosol generator. We believe that the Aeroneb Pro has the potential to provide improved drug delivery to hospitalized patients on ventilators. Our first Aeroneb Pro is expected to be sold as a stand-alone product that can be attached to any ventilator. We plan to make a 510(k) submission to the FDA for this version of the product in the first half of 2002 and to market the product through our own efforts and those of a specialty distributor in the United States, and through distributors internationally.

Additional Aerogen Products for Respiratory Therapy

Aerodose TOBI. We had a collaboration with PathoGenesis Corporation, acquired by Chiron Corporation during 2000, to develop a customized version of our Aerodose inhaler to deliver TOBI (tobramycin), an anti-infective drug used to treat cystic fibrosis patients. TOBI was approved in late 1997 as a nebulized solution for use by cystic fibrosis patients to prevent *Pseudomonas aeruginosa* lung infections. Market studies completed by PathoGenesis showed that the total time required for treatment of the cystic fibrosis patient can have an impact on the patient's compliance with the recommended TOBI treatment regimen and on the physician's assessment of a patient's likelihood of compliance. TOBI currently is given via nebulizer twice a day during alternate months, with each administration taking approximately 15 to 20 minutes per session. Early studies of TOBI delivered using Aerogen technology showed a significantly reduced treatment time. In addition, the breath activation feature of the Aerodose inhaler allowed for more efficient drug delivery and less drug waste. Chiron terminated the collaboration in late 2001. We are evaluating the potential for delivery of tobramycin from an Aerodose inhaler and/or the Aeroneb Pro for commercialization ourselves or by a partner.

Other Respiratory Products With Partners

We collaborate, and intend to continue to collaborate, with pharmaceutical and biotechnology companies to develop novel pulmonary drug delivery products for respiratory therapy. 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.

The flexibility of our technology to facilitate improved respiratory therapy has attracted potential development partners. We are currently conducting feasibility activities with potential partners with

various small and large molecules for respiratory therapy. Feasibility studies can be paid for by us or by the other company. Generally, the agreements and the activities can be cancelled at any time by the other company. 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. We currently intend to manufacture Aerodose inhalers and supply them to our partners at cost plus a small profit.

Products for Systemic Therapy

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 are developing a special Aerodose inhaler for delivery of insulin to diabetic patients. The Aerodose insulin inhaler is designed to utilize a patient-adjustable canister for pulmonary delivery of insulin, allowing patients to precisely adjust their insulin dose based on anticipated caloric intake and other factors. The product will incorporate a patient-adjustable canister being developed for us by Disetronic.

Phase 1 clinical studies using prototype patient-operated Aerodose inhalers with 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. Initial results indicated that the absorption and glucose-lowering effects of inhaled insulin, relative to injected insulin, were consistent with the published literature indicating that typically 8% to 15% of inhaled drug reaches the systemic circulation. There were no reported respiratory complaints and no measurable differences in lung function after inhalation versus injection. 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 proportionability of circulating levels of insulin following inhalation in Type II (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 May 2000, we entered into an agreement with Becton Dickinson to collaborate on the development of a patient-adjustable canister for use with the Aerodose insulin inhaler. Under the agreement, Aerogen was to develop the customized Aerodose inhaler at our own cost, and Becton Dickinson was to develop a titrateable canister at its cost. Upon entering into the agreement, Becton Dickinson made a $2.5 million equity investment in our company. In August 2001, we filed suit against Becton Dickinson in the Federal District Court in the Northern District of California concerning the agreement. In October 2001, the suit was settled, the collaboration was terminated and Aerogen is free to develop a patient-adjustable canister without Becton Dickinson. Aerogen obtained rights to use the intellectual property developed during the collaboration, Aerogen paid Becton Dickinson $2.0 million and Becton Dickinson has agreed not to sue Aerogen for infringement of any Becton Dickinson intellectual property with regard to any inhaled insulin product.

We are now developing a patient-adjustable canister with Disetronic for use in our Aerodose insulin inhaler. This change in development partner has not adversely affected the time line for the development of the product. We have agreement with Diosynth B.V., a business unit of Akzo Nobel,

for the supply of clinical and commercial quantities of recombinant human insulin for the use in the product.

We plan 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. We believe that the nature of the diabetes market requires a major pharmaceutical company partner with a diabetes franchise to market the product.

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

Technology Out-licensing

Our aerosol generator technology has proven to be of value to industries 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 will receive royalties based on net sales of units and refills, and the license 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 repellant products if such products are not introduced within specific time limits. We have been advised by the consumer company that it intends to commercialize the first product in 2003. We will continue to explore out-licensing opportunities for our technologies outside the field of pulmonary drug delivery.

Manufacturing

We plan to manufacture the 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 facility in Sunnyvale, California. This manufacturing activity will be moved to our new Mountain View facility in the second quarter of 2002. We design the remaining components of the products, such as molded parts and electronic circuitry, and outsource the manufacture of these parts to qualified vendors. The manufacture of canisters and sterile drug filling will be outsourced, minimizing the need for capital investment in specialized drug filling facilities. We plan to assemble the Aeroneb® Portable Nebulizer System in our California facilities for the near term, and we plan to assemble the Aeroneb Pro in Ireland. We currently plan to assemble the Aerodose inhalers in our California facilities.

Sales and Marketing

We have a small contract sales force promoting the Aeroneb® Portable Nebulizer System. In addition, the product is promoted by the sales force of the AirLife division of Allegiance Healthcare Corporation and several home medical equipment distributors. The Aeroneb® Portable Nebulizer System is sold in the United States through certain home medical equipment dealers, retail pharmacies, and the Allergy and Asthma Network Mothers of Asthmatics. The Aeroneb® Professional Nebulizer System will be sold to hospitals by Aerogen's contract sales force, Allegiance Healthcare and ventilator manufacturers. For our Aerodose inhaler products, we anticipate expanding our U.S. sales force, through outsourced or internal efforts or both. We intend generally to maintain the marketing rights for our Aerodose inhaler respiratory products in the United States and to commercialize the products in other countries through marketing partners or distributors. Products developed in collaboration with partner companies will generally be commercialized by the partners.

Competition

There is intense competition in the drug delivery market. We compete with pharmaceutical and biotechnology companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in developing non-invasive drug delivery dosage forms. Competing non-invasive alternatives to injectable drug delivery include oral, 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 and Inhale Therapeutic Systems, Inc., are developing competing pulmonary drug delivery dosage forms. These competing dosage forms typically are designed to treat respiratory disease or to deliver drugs systemically. Several competitors have collaborative arrangements with partners to develop inhalers for insulin. 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 disease 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 Aerodose inhaler 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 and 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.

Many competitors have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do. Accordingly, they may succeed in developing competing products and technologies, obtaining regulatory approval for products or gaining market acceptance more rapidly than we can. We believe that our products will compete on the basis of 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, 2001, we held eight issued U.S. patents and eight issued international patents. In addition, we had 27 pending U.S. patent applications and 21 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 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. 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 also provide that inventions conceived by the individual in the course of rendering services to Aerogen will be our 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 Bespak 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 Bespak, as a result of which Bespak has a license to certain of our technology. The scope of the granted license was limited to products employing technology which was disclosed by Bespak 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, other 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 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 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 take a number of years and requires substantial resources. The nature and extent of the governmental premarket review process for our products will vary depending on the regulatory categorization of particular products. Because our products may be characterized as devices, drugs or biologics, the regulatory approval path will not be the same for all of our products.

Those of our products 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 and adherence to Good Manufacturing Practices (GMP) and quality system regulation (QSR);
- *Class II:* General controls and special controls, e.g., performance standards and postmarket surveillance; and
- *Class III:* Premarket approval.

510(k) clearance. Before a new device can be marketed, its manufacturer must obtain marketing clearance through either a premarket notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act or approval of a premarket approval application. 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 clinical studies. An investigational device exemption (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 approve the IDE. Trials must be conducted in conformance with FDA regulations and 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 the FDA finds deficiencies in the way they are being conducted. Data from clinical trials are often subject to varying interpretations that could delay, limit or prevent FDA approval. 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 12 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. We plan to file a 510(k) application for the Aeroneb Pro, and we expect that future 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 IDE application must be filed with the FDA and becomes effective prior to initiating clinical trials. 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, and 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 and sale. After approval, a new application or a supplement is required if certain modifications are made to the device, its labeling or its manufacture.

New Drug Application and Biologics License Application. The Aerodose inhaler products will be regulated as drugs or biologics if approval is requested for the inhaler with a new chemical entity or a biologic. In this instance, an Investigational New Drug Application (IND) will be required before studies in patients 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, 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 and well-controlled clinical studies demonstrating efficacy with sufficient levels of statistical assurance.

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. 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.

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 client projects that incorporate biologics, we anticipate that a BLA will be required in addition to, or separate from, any 510(k) clearance we may be required to obtain for the Aerodose inhaler itself.

European Union Clearance. Commercialization of medical devices in the European Union is regulated under a system which presently requires that all medical products sold in the European Union bear the CE mark, an international symbol of adherence to quality assurance standards and demonstrated clinical effectiveness. Compliance with the Medical Device Directive—as certified by a recognized European Competent Authority—permits the manufacturer to affix the CE mark on its products. In October 2001, we obtained the CE mark for the Aeroneb Pro. We cannot be certain that we will obtain the CE mark approval, or that we will not have delays in obtaining the CE mark approval, 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 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 regulations setting forth the FDA's current Good Manufacturing Practices, which include testing, control and documentation requirements. Other countries have similar requirements. Failure to comply with GMP 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 approval applications, withdrawal of marketing approvals and criminal prosecution.

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

Employees

We had approximately 140 full-time employees as of March 1, 2002. Approximately 20 of our total number of employees are located in 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. We believe our relations with our employees are good.

Risk Factors

We are a development stage company and almost all of our products are in an early stage of research and development, which makes it difficult to evaluate our business and prospects.

Our company must be evaluated in light of the uncertainties and complexities present in a development stage company. Other than the Aeroneb® Portable Nebulizer System introduced in 2001, and the Aeroneb® Professional Nebulizer System which we plan to introduce in 2002, our products are in an early stage of research or development. Before we can begin to sell our Aerodose inhaler products commercially, we will need to invest in substantial additional development and conduct clinical trials. To further develop such products, we will need to address engineering and design issues, including ensuring that our products deliver a consistent and predictable amount of drug to the lung and can be manufactured successfully. We cannot assure that:

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

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

We have never been profitable. Through December 31, 2001 we have incurred a cumulative deficit of approximately $67.1 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 inhaler products.

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 will need additional capital. If we cannot secure additional funding on acceptable terms, we may be required to slow our progress, curtail our operations or give up rights to some of our technologies or products.

At present, we have cash to fund our operations at the current level through calendar year 2002. Depending on the timing and nature of our marketing efforts and whether and when we enter into additional collaborations, we will need to raise additional funds to finance our operations as early as mid to late 2002. 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. We may need to seek additional funding through collaborations or through public or private equity financings. Based on the current capital markets, we cannot assure that additional financing will be available on acceptable terms or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs. Arrangements with collaborative partners may require us to relinquish rights to some of our technologies or products.

Our technology is relatively unproven, so products using our technology may not work effectively.

Since our pulmonary drug delivery technology is new and relatively unproven, most 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 technology;
- our nebulizers and inhalers 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 products are not successful, products using our Aerodose inhalers 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, the FDA and other governmental agencies in other countries will require extensive clinical trials to demonstrate their safety and efficacy. We are developing drug and inhaler combinations, each of which will require clinical testing. To date, we have completed limited clinical trials using prototype Aerodose inhalers. If we do not successfully complete appropriate clinical trials, we will not be able to commercialize our products. The results of initial clinical trials do not necessarily predict the results of more extensive clinical trials. Furthermore, we cannot be certain that clinical trials of our products will demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials.

We have limited manufacturing experience and may not be able to manufacture our products in commercial 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 are building our own manufacturing capabilities to produce key components of our products. We have manufactured only the initial launch quantities of our first product, and limited clinical supplies of other products. We currently plan to produce all of the requirements of our aerosol generators. 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 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 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 commercial scale;
- manufacturing and quality control problems will not arise as we attempt to scale-up production; or
- any scale-up of production can be achieved in a timely manner or at a commercially reasonable cost.

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

Our inhaled insulin product currently is our only product in development for systemic drug delivery, and there are many uncertainties which could cause the product to be delayed or not to reach the market at all.

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 our effectiveness in treating the disease. We cannot be sure that the results of these and/or other additional clinical trials will prove the safety and effectiveness of our product. We have not yet signed an agreement with a marketing partner to fund the additional development and clinical trials necessary to obtain regulatory approval and to commercialize the product. We cannot assure that we will be able to enter into a satisfactory agreement with a marketing partner, and we currently do not have sufficient funds to conduct the necessary clinical program 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 additional partners to conduct 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. Our Aeroneb® Portable Nebulizer System is a premium priced product, and is not expected to generate significant revenues.

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

We currently have a very limited sales and marketing staff, and many of our competitors have substantial sales and marketing programs. 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 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 significant revenues. We will initially have financial losses resulting from the marketing expenditures necessary to launch the products. Successful worldwide commercialization will depend upon finding strong 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 area, 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 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; Chiron terminated our arrangement for an Aerodose TOBI product in December 2001.

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 U.S. 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, the demand for skilled workers and the relatively low unemployment rates. 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 in the FDA, state and local government agencies, and abroad 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 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 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 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. The regulatory approval process for many of our products is unclear because our products may be classified as medical devices, drugs or biologics. As a result, we may experience greater regulatory uncertainty and longer approval timelines.

If our manufacturing facilities do not meet federal, state or 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 current GMP. We also are required to comply with the ISO 9000 series standards 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 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 certification for our California facility in July 2000. Maintaining that certification is difficult and costly. If we fail to comply with GMP requirements, the ISO 9000 series 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 GMP, the ISO 9000 series 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 will be 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.

We are moving to a new facility in Mountain View, California in the second quarter of 2002. We intend to use this facility to manufacture our products; therefore we will need to qualify the facility with the FDA and the state of California. We will also need to obtain ISO 9001 certification for this facility.

Our products may not be commercially viable if government health administration authorities, private health insurers and 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. Our first commercial product, the Aeroneb® Portable Nebulizer System, is not 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 assure that the patents we have obtained, or any patents we may obtain as a result of our pending U.S. or international patent applications, will provide any competitive advantages for our products and, in particular, our vibratory aerosolization technology, which is technology that aerosolizes liquids by vibrating a metal plate that contains holes. 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 U.S. Patent and Trademark Office, the USPTO, to determine the priority of inventions. In 1999, we settled a patent interference with U.S. Patent No. 5,261,601, assigned to Bespak. The settlement provided for a cross-license between us and Bespak, as a result of which Bespak has a license to certain of our technology, including the right to sublicense. The scope of the granted license was limited to products employing technology which was disclosed by Bespak in U.S. 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 exceed our resources.

Researching, developing and commercializing medical devices and pharmaceutical products entails 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 that 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.

Our stock price may be volatile.

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

- market conditions relating to the life sciences industry;
- investor perception of us as a company;
- securities analysts' recommendations;
- delays in the development, regulatory approval or commercialization of our products;
- announcements of technological innovations or new commercial products by us, our partners or competitors;
- failure to establish new collaborative relationships or termination of existing collaborative relationships;
- developments or disputes concerning patent or intellectual property rights;
- regulatory and pricing developments in both the United States and foreign countries;
- public concern as to the safety of drugs and drug delivery technologies;
- 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 recover to the initial public offering price or will increase in the future.

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

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, 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.

Our executive officers, directors and entities affiliated with our directors beneficially own, in the aggregate, approximately 29% of the outstanding common stock. As a result, these stockholders will be able to exercise control 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 Aerogen and will make some transactions difficult or impossible without the support of these stockholders.

Item 2. PROPERTIES

We currently are located in two contiguous facilities, approximately 25,000 square feet and 13,000 square feet, respectively, in Sunnyvale, California. We conduct our manufacturing activities in these facilities. The lease on this space have been extended through June 2002. In the second quarter of

2002, we intend to move to a 65,000 square foot facility in Mountain View, California. The lease and common area costs in the new facility will be approximately three times those in the current facility. In addition we anticipate spending approximately $3.0 million to adapt the facility for our operations.

Aerogen (Ireland) Limited leases a laboratory and office facility of approximately 2,500 square feet in Galway, Ireland on a month to month basis. In early 2002 we entered into a 980 year lease with the Irish Development Agency for approximately $183,000 for land. We estimate a new facility on the site would cost approximately $1.5 million. We do not have final plans for the building of the facility; when we do, it would likely be financed through a mortgage on the property, guaranteed by us, with the remainder provided by us in the form of a loan to our subsidiary.

Item 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings. In August 2001, we brought suit against Becton Dickinson in the Federal District Court for the Northern District of California concerning an agreement under which we had collaborated with Becton Dickinson on the development of a patient-adjustable canister for use with our Aerodose insulin product. Under the agreement, Aerogen was to develop the customized Aerodose inhaler at our own cost, and Becton Dickinson was to develop a patient-adjustable canister at its cost. In October 2001, the suit was settled, the collaboration was terminated and Aerogen is free to develop a patient-adjustable canister without Becton Dickinson. Aerogen obtained rights to use the intellectual property developed during the collaboration, Becton Dickinson has agreed not to sue Aerogen for infringement of any Becton Dickinson intellectual property with regard to any inhaled insulin product, and Aerogen paid Becton Dickinson $2.0 million.

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

None.

EXECUTIVE OFFICERS OF THE REGISTRANT

The following table provides information concerning our executive officers, including their ages, as of March 25, 2002:

Name	Age	Positions with Aerogen
Jane E. Shaw, Ph.D.	63	Chief Executive Officer and Chairman of the Board of Directors
Yehuda Ivri	50	Chief Technical Officer, Director and Founder
Casper L. de Clercq	37	Vice President, Sales and Marketing
Robert S. Fishman	40	Vice President, Clinical Operations
Carol A. Gamble	49	Vice President, General Counsel and Secretary
Deborah K. Karlson	49	Vice President and Chief Financial Officer
Michael A. Klimowicz	51	Vice President, Product Development
John S. Power	42	Vice President, European Operations and Managing Director of Aerogen (Ireland) Limited
John E. Ross	57	Senior Vice President, Worldwide Operations

Jane E. Shaw, Ph.D. has served as Chairman of our Board of Directors and as our Chief Executive Officer since 1998. Dr. Shaw was a founder and consultant of The Stable Network, a consulting company that focuses 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; IntraBiotics Pharmaceuticals, Inc., a biopharmaceutical company; and McKesson HBOC, Inc., 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.

Casper L. de Clercq has served as our Vice President, Sales and Marketing since 1999 and served as our Vice President of Business Development from 1998 to 2000. Mr. de Clercq was Director of Market Development at Heartport, Inc., a cardiovascular device company, from 1996 to 1998, and Co-founder and Vice President of Business Development at Biointerventions, Co., a biotechnology company, from 1994 to 1995. Mr. de Clercq held various positions at Diagnostic Products Corporation, a medical device company, from 1987 to 1991, and was a consultant at Bain & Company, an international strategy consulting firm, from 1984 to 1987. Mr. de Clercq received a B.A. in Biochemistry from Dartmouth College, an M.B.A. from Stanford University Graduate School of Business and an M.S. in Biological Science from Stanford University.

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

Carol A. Gamble has served as our Vice President, General Counsel and Secretary since May 2000. Previously Ms. Gamble was with ALZA Corporation, a pharmaceutical company, from 1988 to 2000, most recently as Senior Vice President and Chief Corporate Counsel. Previously, Ms. Gamble was a partner with the law firm of Heller, Ehrman, White & McAuliffe. Ms. Gamble received a B.S. in Education from Syracuse University and a J.D. from the University of California, Berkeley.

Deborah K. Karlson has served as our Chief Financial Officer since February 2000 and Vice President of Finance and Administration since 1999. Ms. Karlson was a financial consultant from 1992 until 1999, and provided consulting services to us from 1997 to 1999. Previously, Ms. Karlson was a manager with Deloitte & Touche LLP, an accounting firm. She received a B.S. in Accounting and Economics and an M.B.A. in Finance and Accounting from the Syracuse University School of Management.

Michael A. Klimowicz has served as our Vice President, Product Development since 1998. Mr. Klimowicz held a number of senior management positions at Alaris Medical Systems, a medical device company, from 1990 to 1998, most recently as Director of Product Development. Mr. Klimowicz was the Director of Biomedical Engineering at Psicor Inc., a medical services company, from 1987 to 1990. Mr. Klimowicz received a B.S. in Electrical Engineering from Western Michigan University. Mr. Klimowicz has resigned as an employee of the Company effective March 31, 2002. He has agreed to consult with the Company for the remainder of 2002.

John S. Power has served as our Vice President, European Operations and as the Managing Director, Aerogen (Ireland) Limited since May 2000. Mr. Power was the founder and Managing Director of Cerus Limited (now Aerogen Ireland), from 1998 to 2000. Mr. Power was Engineering Manager in Mechanical Development at Nellcor Puritan Bennett Incorporated, a medical products company, from 1993 to 1997, and an engineering consultant to various companies from 1988 to 1992. Registered at I. Eng. status from UK Engineering Council, Mr. Power holds qualifications in both computer and mechanical and production engineering and a MBA from Oxford Brookes University, Oxford, England.

John E. Ross 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 Tegal 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.

PART II

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

Our Common Stock has been traded on the NASDAQ Stock Market® under the symbol AEGN since November 10, 2000. The high and low sales price for the period since the stock began trading was as follows:

	High	Low
4Q '00 (from November 10, 2000)	$13.938	$7.625
1Q '01	$11.50	$3.875
2Q '01	$ 8.75	$3.40
3Q '01	$ 7.20	$3.52
4Q '01	$ 5.30	$2.01

As of March 25, 2002, there were approximately 210 holders of record of Aerogen Common Stock. Aerogen has not paid any dividends on our Common Stock and has no present intention to do so, as we expect to continue investing in our business, and incurring losses, for several years.

There were no sales of unregistered securities in the year ended December 31, 2001.

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 related notes (Item 8 of this Form 10-K). The consolidated financial data for periods prior to the periods covered by the financial statements included in Item 8 of this Form 10-K are derived from audited financial statements not included in this document.

	For the Years Ended, December 31,					Cumulative Period From November 18, 1991 (date of inception) to December 31,
	2001	2000	1999	1998	1997	2001
	(in thousands, except per share data)					
Consolidated Statements of Operations Data:						
Total revenues	$ 2,469	$ 5,832	$ 468	$ 85	$ 328	$ 9,899
Costs and expenses:						
Cost of products sold and manufacturing start-up costs	285	—	—	—	—	285
Research and development	21,698	16,219	7,910	4,392	3,961	56,969
Selling, general and administrative	8,138	4,143	2,076	1,600	1,509	18,859
Litigation settlement	2,000	—	—	—	—	2,000
Purchased in-process research and development	—	3,500	—	—	—	3,500
Total costs and expenses	32,121	23,862	9,986	5,992	5,470	81,613
Loss from operations	(29,652)	(18,030)	(9,518)	(5,907)	(5,142)	(71,714)
Interest income, net	2,250	1,160	550	345	87	4,573
Net loss	(27,402)	(16,870)	(8,968)	(5,562)	(5,055)	(67,141)
Dividends related to beneficial conversion feature of preferred stock	—	(16,517)	—	—	—	(16,517)
Net loss attributable to common stockholders	$(27,402)	$(33,387)	$(8,968)	$(5,562)	$(5,055)	$(83,658)
Net loss per common share, basic and diluted	$ (1.39)	$ (7.30)	$ (4.95)	$ (3.47)	$ (3.40)	
Shares used in computing net loss per common share, basic and diluted	19,681	4,576	1,811	1,603	1,487	

	December 31,				
	2001	2000	1999	1998	1997
	(in thousands)				
Consolidated Balance Sheets Data:					
Cash, cash equivalents and available-for-sale securities	$ 36,077	$ 60,976	$ 7,809	$ 17,499	$ 5,904
Working capital	33,457	60,639	7,408	16,825	5,383
Total assets	43,468	66,712	9,674	18,608	7,108
Long-term obligations, less current portion	212	184	100	480	778
Convertible preferred stock	—	—	31,476	31,476	15,819
Deficit accumulated during the development stage	(67,141)	(39,739)	(22,869)	(13,901)	(10,027)
Total stockholders' equity (deficit)	38,531	64,228	(23,013)	(14,140)	(10,285)

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

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

Overview

AeroGen, Inc. ("Aerogen" or "we") was incorporated in November 1991. We specialize in the controlled delivery of drugs to the lungs. Our core technology is based upon a 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.

We are in the development stage and since inception have devoted substantially all of our efforts to the development of products. We have an accumulated deficit of approximately $67.1 million as of December 31, 2001. We expect to incur significant additional operating losses over the next several years and expect cumulative losses to increase primarily due to the expansion of our research and development activities, an increase in the number and size of clinical trials, the costs associated with the manufacturing and marketing of our products, 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, 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. The Aeroneb product incorporates Aerogen's core technology. We have recorded revenues of $185,000 associated with sales of the Aeroneb product and related parts as of December 31, 2001. The product has been promoted in the United States by a small contract sales force, the AirLife division of Allegiance Healthcare and several home medical equipment distributors.

We perform feasibility and initial development work to customize our Aerodose 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 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 workplan, 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 commercialized. We also expect to receive revenue from manufacturing of the products. We recognize research and development revenues as reimbursable research and development expenses are incurred.

In May 2000, we acquired all the voting stock of Cerus Limited, now Aerogen (Ireland) Limited, for 1,725,000 shares of Series E convertible preferred stock. The total purchase consideration was approximately $6.0 million, including transaction costs of approximately $150,000. Cerus was a development stage company developing products under a license from us using our core aerosol generator technology.

We anticipate launching the first product developed by our Irish subsidiary, a nebulizer we call the Aeroneb® Professional Nebulizer System, in the United States and Europe in the first half of 2002. This product is designed for use in the hospital setting, including patients on ventilators. Other products for the hospital market are at significantly earlier stages of development.

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.

We have incurred stock-based compensation expenses of $1.3 million, $0.8 million and $0.1, for the years ended December 31, 2001, 2000 and 1999, respectively. As of December 31, 2001, there was approximately $4.1 million of deferred stock-based compensation, which will be amortized to expense on a straight line basis through 2004. We anticipate incurring additional stock-based compensation expense in the future as a result of fluctuations in the market value of our common stock, which will continue to have a direct impact on the value of common stock options held by non-employees.

Aerogen had federal and state net operating loss carryforwards of approximately $58.6 million and $26.6 million, respectively, as of December 31, 2001. We also had aggregate federal and state research and development tax credit carryforwards as of December 31, 2001 of approximately $2.0 million. 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.

Critical accounting policies and estimates

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

We 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 not made reductions to revenue for any customer programs or incentive offerings such as special pricing agreements or promotions, as no such programs have been in place. If we determined to take 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.
- We have an Irish subsidiary, which accounted for approximately 8% of our net loss for the year ended December 31, 2001 and 5% of our assets and 7% of our total liabilities as of December 31, 2001. 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 are 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 to be the functional currency. Accordingly we had cumulative translation gains (losses) of approximately ($80,000) and $20,000, which were in accumulated other comprehensive income (loss) on our balance sheets at December 31, 2001 and 2000, respectively. During 2001 and 2000, translation adjustments of ($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.

Results of Operations

Comparison of years ended December 31, 2001, 2000 and 1999

Research and development revenues. Research and development revenues were $2.0 million in 2001, $5.8 million in 2000, and $0.5 million in 1999. The revenue decrease in 2001 as compared to 2000 resulted from decreased development activities for PathoGenesis of $1.1 million and decreased development activities for a biotechnology company of $2.8 million. The revenue increase in 2000 as compared to 1999 resulted from development activities performed for PathoGenesis of $2.9 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. Assuming no additional partnerships, we expect research and development revenues for 2002 to be lower than those for 2001.

Product Sales. Product sales were $0.2 million in 2001 and none in 2000 and 1999. We launched our first commercial product, the Aeroneb® Portable Nebulizer System, in June 2001. We anticipate sales volume will increase somewhat in 2002.

Royalty, fee and other revenues. Royalty, fee and other revenues were $0.3 million in 2001 and none in 2000 and 1999. The 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 and manufacturing start-up costs. Cost of products sold and manufacturing start-up costs were $0.3 million in 2001, compared with none in 2000 and 1999. The cost of products sold and manufacturing start-up costs was high as a percentage of product sales (154%) due primarily to low yields associated with start-up of the commercial manufacturing processes for our first product. We anticipate that costs per unit will decrease over time as we refine our manufacturing processes and focus on cost reduction following our move, mid-2002, into a new facility, which will incorporate more automated manufacturing processes and improved environmental controls.

Research and development expenses. Research and development expenses were $21.7 million in 2001, $16.2 million in 2000 and $7.9 million in 1999. Research and development expenses increased in 2001 as compared to 2000, primarily due to the expansion of product development activities for the respiratory products we plan to market ourselves. Research and development expenses also increased in 2001 for our Aerodose® insulin inhaler, which we intend to commercialize with a partner. The increase is 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 increased in 2000 as compared to 1999, primarily reflecting the increase in research and development activities for partners and, to a lesser extent, expenses of $2.5 million associated with our technology and products. The increase is largely attributable to outside professional services of $3.8 million, including design and engineering services, and to internal salary and benefit costs of $1.2 million.

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

Selling, general and administrative expenses. Selling, general and administrative expenses were $8.1 million in 2001, $4.1 million in 2000 and $2.1 million in 1999. The increase in 2001 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 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 primarily due to payroll related increases of $0.8 million associated with the general and administrative infrastructure including, but not limited to, 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. An incremental $0.1 million of stock compensation expense was amortized in 2001.

The increase in 2000 as compared to 1999 was due to increased general and administrative expenses of $1.6 million and increased sales and marketing expenses of approximately $0.5 million. General and administrative expenses for 2000 increased primarily due to increased amortization of stock-based compensation of $0.7 million, increased payroll related of $0.5 million and increased professional services of $0.5 million. Sales and marketing expenses for 2000 increased primarily due to increased payroll related of $0.2 million and increased professional services associated with advertising and primarily market research of $0.1 million.

We expect selling, general and administrative expenses to increase because our sales force was in place for only part of 2001, and as we commercialize new products in mid-2002 and thereafter.

Litigation settlement. In October 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 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 has not yet been approved for sale by regulatory authorities.

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.

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).

Interest income. Interest income was $2.3 million in 2001, $1.2 million in 2000 and $0.6 million in 1999. The increase in interest income 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. Interest expense was $2,000 in 2001, $38,000 in 2000 and $76,000 in 1999. The decrease in interest expense was primarily due to repayments of borrowings under an equipment lease financing agreement.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through equity financings, research and development revenues and the interest earned on related proceeds. We have received approximately $98.0 million aggregate net proceeds from sales of our common and preferred stock through December 31, 2001, including approximately $44.5 million of net proceeds from our initial public offering in November 2000. From inception through December 31, 2001, expenditures for operating activities and capital acquisitions were approximately $62.2 million.

As of December 31, 2001, we had cash, cash equivalents and available-for-sale securities of approximately $36.1 million. Net cash used in operating activities was $23.7 million, $11.3 million and $8.8 million for the years ended December 31, 2001, 2000 and 1999, 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 used by investing activities was $9.9 million, $7.3 million and $6.7 million for the years ended December 31, 2001, 2000 and 1999, respectively, and resulted primarily from the purchase of available-for-sale securities and the acquisition of property and equipment, partially offset by proceeds from maturities of available-for-sale securities.

Net cash provided by financing activities was $0.5 million, $65.6 million and $(0.3) million for the years ended December 31, 2001, 2000 and 1999, respectively. 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 will require 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 such products to market. Our future capital requirements and operating expenses will depend on many factors including, but not limited to, research and development activities, the timing, cost, extent and results of clinical trials, our success in licensing drugs for use in our products, regulatory approvals, the status of competitive products, 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.

Based upon our current plans, we believe that our cash, cash equivalents and available-for-sale securities will be sufficient to meet our capital requirements through calendar year 2002. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves many risks and uncertainties, and actual results could vary materially. We will need to raise additional funds in 2002 through public or private financings, collaborative relationships or other arrangements. 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. The factors described above will impact our future capital requirements and the adequacy of our available funds. Our failure to raise capital when needed would have a material adverse effect on our business.

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 July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard, or SFAS, No. 141 "Business Combinations" which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, "Business Combinations", and FASB Statement No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises". SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions apply to all business combinations initiated after June 30, 2001.

In July 2001, the FASB issued SFAS No. 142 "Goodwill and Other Intangible Assets," ("SFAS No. 142") which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, "Intangible Assets". SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 15, 2001. In accordance with SFAS No. 142, goodwill, will not be systematically amortized but rather beginning January 1, 2002, we will perform an annual assessment for impairment by applying a fair-value-based test. We will also reclassify the unamortized balance of acquired workforce to goodwill.

In October 2001, the FASB issued SFAS No. 144 ("SFAS No.144"),"Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS No. 144 supersedes FASB Statement No. 121 "Accounting for the Impairment of Long-lived Assets and for Long-Lived Assets to be Disposed of," and APB 30, ("Opinion 30") "Reporting the Results of Operations—reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions Relating to Extraordinary Items"; however, SFAS No. 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS No. 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. We are in the process of evaluating the impact of implementation on our financial position and results of operations.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk. Interest rate risk represents the risk of loss that may impact our financial position, operating results or cash flows due to changes in interest rates. This exposure is directly related to our normal operating activities. 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 dollar (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.

We plan to expand our overseas operations. As a result, 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.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

AEROGEN, INC.
(a development stage enterprise)
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT ACCOUNTANTS

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of AeroGen, Inc. (a development stage enterprise) and its subsidiary at December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 and, cumulatively, from November 18, 1991 (date of inception) through December 31, 2001, 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.

PricewaterhouseCoopers LLP

San Jose, California
February 1, 2002

AEROGEN, INC.

(a development stage enterprise)

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	December 31, 2001	December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,714	$ 48,810
Available-for-sale securities	20,363	12,166
Accounts receivable	193	762
Inventories	488	—
Prepaid expenses and other current assets	1,201	1,201
Total current assets	37,959	62,939
Property and equipment, net	2,889	1,905
Goodwill and other intangible assets, net	1,362	1,823
Other assets	1,258	45
Total assets	$ 43,468	$ 66,712
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,181	$ 915
Accrued liabilities	3,321	1,385
Total current liabilities	4,502	2,300
Deferred rent	223	—
Other long-term liabilities	212	184
Total liabilities	4,937	2,484
Commitments (Note 6)		
Stockholders' equity:		
Common stock, par value: $0.001:		
Authorized: 95,000 shares		
Issued and outstanding: 20,148 and 19,916 shares at December 31, 2001 and 2000, respectively	20	20
Convertible preferred stock, par value: $0.001:		
Authorized: 5,000 shares		
Issued and outstanding: none at December 31, 2001 and 2000	—	—
Additional paid-in capital	110,428	110,692
Notes receivable from stockholders	(693)	(665)
Deferred stock-based compensation, net	(4,069)	(6,095)
Accumulated other comprehensive income (loss)	(14)	15
Deficit accumulated during the development stage	(67,141)	(39,739)
Total stockholders' equity	38,531	64,228
Total liabilities and stockholders' equity	$ 43,468	$ 66,712

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

AEROGEN, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Years Ended December 31,			Cumulative Period from November 18, 1991 (date of inception) to December 31, 2001
	2001	2000	1999	
Revenues:				
Research and development	$ 2,034	$ 5,832	$ 468	$ 9,464
Product sales	185	—	—	185
Royalty, fee and other	250	—	—	250
Total revenues	2,469	5,832	468	9,899
Costs and expenses:				
Cost of products sold and manufacturing start-up costs	285	—	—	285
Research and development(1)	21,698	16,219	7,910	56,969
Selling, general and administrative(2)	8,138	4,143	2,076	18,859
Litigation settlement	2,000	—	—	2,000
Purchased in-process research and development	—	3,500	—	3,500
Total costs and expenses	32,121	23,862	9,986	81,613
Loss from operations	(29,652)	(18,030)	(9,518)	(71,714)
Interest income	2,252	1,198	626	4,870
Interest expense	(2)	(38)	(76)	(297)
Net loss	(27,402)	(16,870)	(8,968)	(67,141)
Dividends related to the beneficial conversion feature of preferred stock	—	(16,517)	—	(16,517)
Net loss attributable to common stockholders	$(27,402)	$(33,387)	$(8,968)	$(83,658)
Net loss per common share, basic and diluted	$ (1.39)	$ (7.30)	$ (4.95)	
Shares used in computing net loss per common share, basic and diluted	19,681	4,576	1,811	

(1) Including stock-based compensation expense of $902,000, $652,000 and $72,000 in 2001, 2000 and 1999, respectively, and $1,626,000 for the cumulative period from November 18, 1991 (date of inception) to December 31, 2001.

(2) Including stock-based compensation expense of $364,000, $177,000 and $38,000 in 2001, 2000 and 1999, respectively, and $579,000 for the cumulative period from November 18, 1991 (date of inception) to December 31, 2001.

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

AEROGEN, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE PERIOD FROM NOVEMBER 18, 1991 (DATE OF INCEPTION) TO DECEMBER 31, 2001

(in thousands, except per share amounts)

	Common Stock		Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount						
Issuance of common stock to founder at $0.0015 per share for cash in November 1991	1,334	$ 2	$ —	$ —	$ —	$—	$ —	$ 2
Note receivable from stockholder	—	—	—	(69)	—	—	—	(69)
Issuance of common stock at $0.12 per share for cash and note receivable in July 1994	333	40	—	(35)	—	—	—	5
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	—	(69)	(69)
Net loss	—	—	—	—	—	—	(355)	(355)
Balances, December 31, 1994	1,667	42	—	(104)	—	—	(424)	(486)
Issuance of common stock pursuant to exercise of stock options at $0.12 per share for cash in April	3	—	—	—	—	—	—	—
Repurchase of common stock at $0.12 per share in connection with cancellation of note receivable from stockholders in May	(264)	(31)	—	32	—	—	—	1
Repayment of note receivable from stockholder in November	—	—	—	3	—	—	—	3
Accrued interest on notes receivable from stockholders	—	—	—	(7)	—	—	—	(7)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	—	(209)	(209)
Net loss	—	—	—	—	—	—	(754)	(754)
Balances, December 31, 1995	1,406	11	—	(76)	—	—	(1,387)	(1,452)
Issuance of common stock at $0.24 per share for services rendered in May	6	2	—	—	—	—	—	2
Notes receivable from stockholders	—	—	—	(200)	—	—	—	(200)
Issuance of common stock pursuant to exercise of stock options at $0.12 and $0.24 per share for cash in August and September	7	1	—	—	—	—	—	1
Accrued interest on notes receivable from stockholders	—	—	—	(5)	—	—	—	(5)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	—	(516)	(516)
Net loss	—	—	—	—	—	—	(2,174)	(2,174)
Balances, December 31, 1996	1,419	14	—	(281)	—	—	(4,077)	(4,344)
Issuance of common stock at $0.24 per share for note receivable in January	284	68	—	(68)	—	—	—	—
Issuance of common stock at $0.24 per share for services rendered in May	3	1	—	—	—	—	—	1
Issuance of common stock pursuant to exercise of stock options at $0.12 and $0.24 per share for cash throughout the year	82	16	—	—	—	—	—	16
Accrued interest on notes receivable from stockholders	—	—	—	(8)	—	—	—	(8)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	—	(895)	(895)
Net loss	—	—	—	—	—	—	(5,055)	(5,055)
Balances, December 31, 1997	1,788	99	—	(357)	—	—	(10,027)	(10,285)

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

AEROGEN, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF STOCKOLDERS' EQUITY (DEFICIT)

FOR THE PERIOD FROM NOVEMBER 18, 1991 (DATE OF INCEPTION) TO DECEMBER 31, 2001

(in thousands, except per share amounts)

(continued)

	Common Stock		Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount						
Balances, December 31, 1997	1,788	99	—	(357)	—	—	(10,027)	(10,285)
Accretion to redemption value of redeemable convertible preferred stock	—	—	—	—	—	—	(954)	(954)
Reincorporation into a Delaware corporation	—	(97)	97	—	—	—	—	—
Removal of redemption provision for Series A, B and C in conjunction with issuance of Series D	—	—	—	—	—	—	2,642	2,642
Issuance of common stock at $0.30 per share for a note receivable in January	467	—	140	(140)	—	—	—	—
Repurchase of common stock at $0.24 per share in connection with cancellation of note receivable in January	(209)	—	(50)	72	—	—	—	22
Issuance of common stock at $0.60 per share for a note receivable in December	90	—	54	(54)	—	—	—	—
Issuance of common stock pursuant to exercise of stock options at $0.30-$0.60 per share for cash throughout the year	47	—	11	—	—	—	—	11
Accrued interest on notes receivable from stockholders	—	—	—	(14)	—	—	—	(14)
Net loss	—	—	—	—	—	—	(5,562)	(5,562)
Balances, December 31, 1998	2,183	2	252	(493)	—	—	(13,901)	(14,140)
Issuance of common stock pursuant to exercise of stock options at $0.12-$0.60 per share for cash throughout the year	127	—	35	—	—	—	—	35
Accrued interest on notes receivable from stockholders	—	—	—	(17)	—	—	—	(17)
Unrealized loss on available-for-sale securities	—	—	—	—	—	(33)	—	(33)
Deferred stock-based compensation	—	—	668	—	(668)	—	—	—
Amortization of deferred stock compensation	—	—	—	—	110	—	—	110
Net loss	—	—	—	—	—	—	(8,968)	(8,968)
Balances, December 31, 1999	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)
Note receivable from stockholder	—	—	—	(50)	—	—	—	(50)
Repayment of notes receivable from stockholder	—	—	—	25	—	—	—	25
Issuance of common stock in conjunction with initial public offering at $12.00 per share for cash in November, 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 at $0.24 to $3.00 per share for cash and notes receivable from stockholders throughout the year	477	1	348	(106)	—	—	—	243
Repurchase of common stock at $0.60 per share throughout the year	(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.

AEROGEN, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE PERIOD FROM NOVEMBER 18, 1991 (DATE OF INCEPTION) TO DECEMBER 31, 2001

(in thousands, except per share amounts)

(continued)

	Common Stock		Additional Paid-In Capital	Notes Receivable From Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficit)
	Shares	Amount						
Balances, December 31, 2000	19,916	20	110,692	(665)	(6,095)	15	(39,739)	64,228
Issuance of common stock pursuant to employee stock purchase plan at $3.05 and $2.06 per share for cash in April and October, respectively	189	—	448	—	—	—	—	448
Issuance of common stock upon exercise of stock options at $0.24 to $3.00 per share for cash throughout the year	57	—	56	—	—	—	—	56
Repurchase of common stock at $0.60 per share throughout the year	(14)	—	(8)	—	—	—	—	(8)
Deferred stock-based compensation, net of cancellations	—	—	(760)	—	760	—	—	—
Amortization of deferred stock-based compensation	—	—	—	—	1,266	—	—	1,266
Accrued interest on notes receivable from stockholders	—	—	—	(28)	—	—	—	(28)
Changes in unrealized gain (loss) on available-for-sale securities	—	—	—	—	—	71	—	71
Foreign currency translation	—	—	—	—	—	(100)	—	(100)
Net loss	—	—	—	—	—	—	(27,402)	(27,402)
Balances, December 31, 2001	20,148	$ 20	$110,428	$(693)	$(4,069)	$(14)	$(67,141)	$ 38,531

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

AEROGEN, INC.

(a development stage enterprise)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,			Cumulative Period From November 18, 1991 (date of inception) to December 31, 2001
	2001	2000	1999	
Cash flows from operating activities:				
Net loss	$(27,402)	$(16,870)	$ (8,968)	$(67,141)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	1,112	895	494	3,218
Loss on disposal of property and equipment	1	—	—	6
Common stock issued for services received	—	—	—	2
Purchased in-process research and development	—	3,500	—	3,500
Accrued interest on notes receivable from stockholders	(28)	(24)	(17)	(103)
Amortization of deferred stock-based compensation	1,266	829	110	2,205
Changes in operating assets and liabilities:				
Accounts receivable	569	(337)	(319)	(87)
Inventories	(488)	—	—	(488)
Prepaid expenses and other current assets	—	(811)	(272)	(1,201)
Accounts payable	266	397	111	1,120
Accrued liabilities	1,936	940	129	3,178
Deferred rent	223	—	—	223
Other	(1,174)	151	(20)	(1,068)
Net cash used in operating activities	(23,719)	(11,330)	(8,752)	(56,636)
Cash flows from investing activities:				
Acquisition of property and equipment	(1,853)	(1,547)	(638)	(5,584)
Purchases of available-for-sale securities	(21,340)	(14,990)	(28,565)	(64,895)
Proceeds from maturities of available-for-sale securities	13,300	8,844	22,545	44,689
Cash acquired, net	—	392	—	392
Net cash used in investing activities	(9,893)	(7,301)	(6,658)	(25,398)
Cash flows from financing activities:				
Proceeds from issuance of common stock	504	44,746	35	45,321
Repurchase of common stock	(8)	(8)	—	(16)
Proceeds from issuance of convertible preferred stock, net	—	21,252	—	52,728
Proceeds from issuance of note payable	—	—	—	1,113
Principal payments under lease obligations	—	—	—	(43)
Repayment of note payable	—	(354)	(302)	(1,113)
Issuance of note receivable from stockholder	—	(50)	—	(319)
Repayment of note receivable from stockholder	—	25	—	49
Net cash provided by (used in) financing activities	496	65,611	(267)	97,720
Effect of exchange rate changes on cash	20	8	—	28
Net increase (decrease) in cash and cash equivalents	(33,096)	46,988	(15,677)	15,714
Cash and cash equivalents at beginning of period	48,810	1,822	17,499	—
Cash and cash equivalents at end of period	$ 15,714	$ 48,810	$ 1,822	$ 15,714
Supplemental disclosure of noncash investing and financing activities:				
Acquisition of property and equipment under capital lease	$ —	$ —	$ —	$ 40
Exchange of stockholder note receivable for common stock	$ —	$ 106	$ —	$ 367
Repurchase of common stock in connection with cancellation of note receivable from stockholder	$ —	$ —	$ —	$ 82
Convertible preferred stock issued for acquisition	$ —	$ 5,813	$ —	$ 5,813
Accretion to redemption value of redeemable convertible preferred stock	$ —	$ —	$ —	$ 2,642
Removal of redemption provision for convertible preferred stock	$ —	$ —	$ —	$ 2,642
Deferred stock-based compensation	$ 760	$ 6,366	$ 668	$ 7,794
Conversion of convertible preferred stock into common stock	$ —	$ 58,796	$ —	$ 58,796
Supplemental disclosure of cash flow information:				
Cash paid during period for interest	$ 2	$ —	$ 76	$ 286

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

NOTE 1—FORMATION AND BUSINESS OF THE COMPANY:

AeroGen, Inc., the "Company", was incorporated in the state of California on November 18, 1991 to develop products using an aerosol generator to aerosolize liquids. The Company was reincorporated in the state of Delaware in 1998. At the time of the reincorporation, the Company's outstanding California corporation preferred and common stock was exchanged on a one-for-one basis for Delaware corporation preferred and common stock. The related change in par value was recorded as an adjustment to additional paid in capital and common stock.

The Company is a development stage enterprise and since inception has devoted substantially all of its efforts to developing its products, including engaging in research and development activities with and without partners, raising capital and recruiting personnel. The Company has incurred net losses since inception and is expected to incur substantial losses for the next several years. To date, the Company has funded its operations primarily through the sale of equity securities, 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.

These financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Management believes its cash and cash equivalents and available for-sale securities as of December 31, 2001 will be sufficient to meet the Company's capital and operating requirements for the next 12 months. The Company will require additional financing in the future and may raise funds by selling shares of its common or preferred stock through private placement or public offering, by collaborative relationships or other arrangements. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company. Additional equity or debt financing may involve substantial dilution to the Company's stockholders, restrictive covenants or high interest costs. Collaborative arrangements, if necessary to raise additional funds, may require the Company to relinquish rights to certain products, technologies or marketing territories. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the Company's business, operating results and financial condition.

The Company's long term liquidity also depends upon its ability to attract and maintain collaborative relationships, to increase revenues from the sale of its products, to develop and market new products and ultimately, to achieve profitability.

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 requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the

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

Cash and cash equivalents

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

Available-for-sale securities

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

Inventories

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

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 Financial Accounting Standards No. 142 ("FAS 142"), goodwill and other intangible assets will not be systematically amortized, but rather, beginning with fiscal year 2002, the Company will perform an annual assessment for impairment by applying a fair-value-based test.

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.

Concentration of credit risk and other risks and uncertainties

The Company maintains its cash and cash equivalents in accounts with three 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.

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 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 the necessary approvals. If the Company is denied approval or if approval is delayed, 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.

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

One company accounted for 90% of accounts receivable at December 31, 2000 and two companies accounted for 50% and 47% of revenues during the year ended December 31, 2000.

Three companies accounted for 75%, 11% and 11% of revenues during the year ended December 31, 1999.

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. 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 expenditures associated with products not yet approved by regulatory authorities are 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 its local currency as its functional currency. Assets and liabilities are translated at exchange rates in effect at the balance sheet date and income and expense accounts at average exchange rates during the period. Resulting translation adjustments are recorded directly to a separate component of stockholders' equity.

Income taxes

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

Segments

The Company operates in one segment, using one measurement of profitability to manage its business. As of December 31, 2001 and 2000, 70% and 48%, respectively, of all long-lived assets were maintained in the United States. For the years ended December 31, 2001, 2000 and 1999, and for the cumulative period from November 18, 1991 (date of inception) to December 31, 2001, 97%, 99%, 100% and 98%, respectively, of revenues were generated in the United States.

Accounting for stock-based compensation

The Company uses the intrinsic value method of Accounting Principles Board Opinion No. 25 ("APB No. 25"), "Accounting for Stock Issued to Employees," and Financial Accounting Standards Board Interpretation No. 44 ("FIN 44") "Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25," in accounting for its employee stock options, and presents disclosure of pro forma information required under SFAS No. 123,"Accounting for Stock-Based Compensation."

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force ("EITF") Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services" which require that such equity instruments are recorded at their fair value on the measurement date, which is typically the date of grant. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

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, 2001, 2000 and 1999 and for the cumulative period from November 18, 1991 (date of inception) to December 31, 2001.

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, warrants and convertible preferred stock. Options, warrants and convertible preferred stock 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,		
	2001	2000	1999
		(in thousands)	
Net loss per common share, basic and diluted:			
Net loss	$(27,402)	$(16,870)	$(8,968)
Dividends related to beneficial conversion feature of preferred stock	—	(16,517)	—
Net loss attributable to common stockholders	$(27,402)	$(33,387)	$(8,968)
Weighted average common shares outstanding	20,001	4,983	2,243
Less: Weighted average shares subject to repurchase	(320)	(407)	(432)
Weighted average shares used in computing basic and diluted net loss per common share	19,681	4,576	1,811

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

	December 31,		
	2001	2000	1999
	(in thousands)		
Options to purchase common stock	3,463	1,337	708
Common stock subject to repurchase	133	507	307
Convertible preferred stock	—	—	27,864
Warrants, based on common stock equivalents	32	32	32

Recent accounting pronouncements

In July 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 141 "Business Combinations" which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, "Business Combinations", and FASB Statement No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises". SFAS No. 141 requires that all business combinations be accounted for using one method, the purchase method. The provisions apply to all business combinations initiated after June 30, 2001.

In July 2001, the FASB issued SFAS No. 142 "Goodwill and Other Intangible Assets," ("SFAS No. 142") which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, "Intangible Assets". SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective for fiscal years beginning after December 15, 2001. In accordance with SFAS No. 142, beginning January 1, 2002, goodwill will not be systematically amortized but rather, the Company will perform an annual assessment for impairment by applying a fair-value-based test. The Company will also reclassify the unamortized balance of acquired workforce to goodwill.

In October 2001, the FASB issued SFAS No. 144 ("SFAS No.144"),"Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS No. 144 supersedes FASB Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of," and APB 30, ("Opinion 30") "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions Relating to Extraordinary Items", however, SFAS No. 144 retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. SFAS No. 144 addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. The Company is in the process of evaluating the impact of implementation on the Company's financial position and 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 $2.0 million, in equal installments in October 2001 and February 2002. The litigation settlement was immediately expensed to operations, as the technology acquired will be used in conjunction with a product that has not yet been approved for sale by regulatory authorities.

NOTE 4—BALANCE SHEET COMPONENTS:

Available-for-sale securities at December 31, 2001 and 2000 are summarized as follows:

	December 31,					
	2001			2000		
	Amortized Cost Basis	Unrealized Gain	Fair Market Value	Amortized Cost Basis	Unrealized Loss	Fair Market Value
	(in thousands)					
Government notes	$20,297	$66	$20,363	$ —	$—	$ —
Corporate paper	—	—	—	12,171	(5)	12,166
	$20,297	$66	$20,363	$12,171	$(5)	$12,166

All available-for-sale securities mature within one year. There were no realized gains or losses on sales of available-for-sale securities for 2001, 2000, 1999 and, cumulatively, for the period from November 18, 1991 (date of inception) to December 31, 2001.

Inventories are summarized as follows:

	December 31,	
	2001	2000
	(in thousands)	
Raw materials	$354	$—
Work in process	99	—
Finished goods	35	—
	$488	$—

Property and equipment consists of the following:

	December 31,	
	2001	2000
	(in thousands)	
Laboratory, computer and office equipment	$ 3,550	$ 2,664
Furniture	604	493
Leasehold improvements	685	649
Construction-in-progress	820	—
	5,659	3,806
Less: Accumulated depreciation and amortization	(2,770)	(1,901)
	$ 2,889	$ 1,905

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,	
	2001	2000
	(in thousands)	
Goodwill	$1,827	$1,918
Acquired workforce	95	100
	1,922	2,018
Less: Accumulated amortization	(560)	(195)
	$1,362	$1,823

Accrued liabilities consists of the following:

	December 31,	
	2001	2000
	(in thousands)	
Payroll and related expense	$ 843	$ 570
Deferred revenues	200	250
Litigation settlement	1,000	—
Other accrued liabilities	1,278	565
	$3,321	$1,385

NOTE 5—OTHER LONG-TERM LIABILITIES:

In April 1999, Cerus Limited established an Irish Revenue approved Business Expansion Scheme ("BES") under which it raised $216,308. 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 $208,000, when translated as of December 31, 2001. 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:

Facilities leases

In October 2001 the Company leased facilities in Mountain View, CA under an operating lease that expires in 2012. The Company has contracted for certain improvements to be made on this new facility. The improvements are estimated to cost approximately $3.0 million.

The Company will maintain its facilities in Sunnyvale, CA through June 2002, when it anticipates the move into the Mountain View facility will be completed. Minimum rental commitments under all non-cancelable operating leases in effect at December 31, 2001 were:

	Years ending December 31, (in thousands)
2002	$ 2,371
2003	2,375
2004	2,452
2005	2,531
2006	2,614
Thereafter	14,657
Total minimum payments	$27,000

The Company leases its office facilities in Ireland on a month-to-month basis. Subsequent to year-end the Company entered into a 980 year land lease from the Irish Development Agency for 0.7 acres for approximately $183,000. 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 $1.2 million letter of credit to remain in effect for the entire length of the lease. The letter of credit is secured by investments of $1.2 million, which are included in other assets at December 31, 2001.

Under the terms of the Sunnyvale lease, the Company may be obligated to return certain portions of the facility to shell condition at the end of the lease and to provide the lessor with a letter of credit in the amount of $90,000. The estimated cost of this demolition work ($100,000) is included in accrued liabilities at December 31, 2001 and 2000. The letter of credit is secured by a term deposit of $90,000, which is included in other current assets at December 31, 2001 and 2000.

Rent expense for 2001, 2000 and 1999 and for the cumulative period from November 18, 1991 (date of inception) to December 31, 2001 was approximately $1,148,000, $776,000 and $565,000, and $3,395,000, respectively.

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 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:

During 2000, the Company issued 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 7,498,223 shares of Series F convertible preferred stock at $2.25 per share for gross proceeds of $16,871,002. Certain of these issuances resulted in charges associated with the beneficial conversion feature of $16,516,574, 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 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.

As of December 31, 1999, the convertible preferred stock consisted of (in thousands, except per share amounts):

	Number of Shares Authorized	Number of Shares Issued and Outstanding	Carrying Value	Liquidation Preference Per Share	Dividends Per Share
Series A	3,846	3,846	$ 1,461	$0.39	$0.0312
Series B	4,487	4,487	3,489	$0.78	$0.0624
Series C	9,375	9,245	9,180	$1.00	$ 0.08
Series D	10,286	10,286	17,346	$1.75	$ 0.14
	27,994	27,864	$31,476		

NOTE 8—STOCKHOLDERS' EQUITY (DEFICIT):

Convertible preferred stock

As of December 31, 2001 and 2000 the Company has authorized 5,000,000 shares of convertible preferred stock, $0.001 par value, none of which was issued and outstanding.

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, 2001.

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, 2001 and 2000 are 69,453 and 306,972 shares subject to repurchase, respectively.

Stock Option Plans

The Company has reserved shares of common stock for issuance under several stock incentive plans (the "Plans"). Under the 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). Prior to the Company's initial public offering, fair market value was determined by the Board of Directors. 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. All options granted prior to December 14, 2000 are immediately exercisable, generally vest over four years, and expire ten years from date of grant. Unvested shares obtained by early exercise are subject to repurchase by the Company upon termination of the holder's service to the Company. At December 31, 2001 and 2000, 63,619 and 201,234 shares of common stock, respectively, were subject to the Company's repurchase rights.

At the date of the stockholders' meeting in 2001, and annually thereafter, the authorized shares available for issuance under the Company 2000 stock 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 August 2000, the Board of Directors adopted the 2000 Non-Employee Directors' Stock Option Plan ("2000 Non-Employee Plan") under which 250,000 shares of common stock were reserved for issuance. The stockholders approved the 2000 Non-Employee Plan in November 2000. Under the terms of the 2000 Non-Employee Plan, each new non-employee director elected on or after the effectiveness of an initial public offering of the Company's common stock, will be granted an option to purchase 15,000 shares of common stock, which vest 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 vest 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.

Activity under the Plans has been as follows:

	Shares Available for Grant	Number of Options Outstanding	Exercise Price	Aggregate Price	Weighted Average Exercise Price
		(in thousands, except per share amounts)			
Balances, January 1, 1999	318	610	$0.12-$3.75	$ 239	$0.39
Reservation of shares	133	—	—	—	—
Options granted	(439)	439	$0.60	263	$0.60
Options exercised	—	(127)	$0.12-$0.60	(35)	$0.27
Options canceled	214	(214)	$0.12-$0.60	(78)	$0.36
Balances, December 31, 1999	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	—	$0.30-$0.60	—	$0.57
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	—	$0.60	—	$0.60
Balances, December 31, 2001	703	3,463	$0.24-$10.06	$13,435	$3.88

The options outstanding and currently vested at December 31, 2001, by price exercise, are as follows:

	Options Outstanding		
Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life (in Years)	Number of Options Vested
	(in thousands)		(in thousands)
$ 0.24	2	5.07	2
$ 0.30	3	6.38	3
$ 0.60	181	7.58	90
$ 3.00	728	8.33	150
$ 3.01	853	9.95	—
$ 3.75	33	8.55	12
$ 4.36	319	9.70	2
$ 4.50	116	8.66	38
$ 4.54	118	9.35	5
$ 5.00	908	9.15	88
$ 6.19	66	9.52	—
$ 6.75	32	8.75	9
$ 7.50	82	8.81	22
$10.06	22	8.95	6
	3,463		427

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.

At the date of the stockholders' meeting in 2001, and annually thereafter 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 the December 31, 2001, 187,876 shares of common stock have been purchased under the Purchase Plan and 267,011 shares remain available for purchase.

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

Pro forma disclosure

The Company has adopted the disclosure only provisions of SFAS No. 123. Since the Company became a public entity in 2000, the fair value of all options granted subsequent to the initial public offering are calculated using the Black-Scholes option-pricing model. The Company previously calculated the fair value of each option on the date of grant using the minimum value method as prescribed by SFAS No. 123. The assumptions used are primarily as follows:

	Years Ended December 31,		
	2001	2000	1999
Stock option plans:			
Risk-free interest rate	4.54%	6.45%	5.71%
Expected life (in years)	4	5	5
Dividend yield	—	—	—
Expected volatility	100%	70%	—

The weighted average grant date fair value, as defined by SFAS 123, of options granted during the years ended December 31, 2001, 2000 and 1999 was $3.42, $1.66, and $0.10 per share, respectively.

	Years Ended December 31,		
	2001	2000	1999
Stock purchase plans:			
Risk-free interest rate	3.37%	—	—
Expected life (in years)	2	—	—
Dividend yield	—	—	—
Expected volatility	100%	—	—

The weighted average grant date fair value, as defined by SFAS 123, of purchase awards under the Company's Purchase Plan was $1.21, $0, and $0, per share, for the years ended December 31, 2001, 2000 and 1999 respectively.

Pro forma net loss and net loss per share

Had compensation costs been determined based upon the fair value at the grant date, consistent with the methodology prescribed under SFAS No. 123, for awards granted under its stock option plans and stock purchase plan, the Company's pro forma net loss and pro forma basic and diluted net loss per share under SFAS No. 123 would have been as follows:

	Years Ended December 31,		
	2001	2000	1999
	(in thousands, except per share amounts)		
Net loss attributable to common stockholders—as reported	$(27,402)	$(33,387)	$(8,968)
Net loss attributable to common stockholders—pro forma	$(29,699)	$(33,725)	$(8,994)
Net loss per share, basic and diluted—as reported	$ (1.39)	$ (7.30)	$ (4.95)
Net loss per share, basic and diluted—pro forma	$ (1.51)	$ (7.37)	$ (4.97)

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.

Deferred stock-based compensation

During 2000 and 1999, the Company issued options to certain employees under the 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, 2001, 2000 and 1999 the Company had recorded cumulative deferred compensation related to these options in the amounts of $5,755,000, $6,092,000 and $332,000, net of cancellations, respectively, of which $1,168,000, $584,000 and $9,000 had been amortized to expense during 2001, 2000 and 1999, 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 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,		
	2001	2000	1999
Risk-free interest rate	5.02%	5.81%	6.05%
Expected life (in years)	10	10	10
Dividend yield	—	—	—
Expected volatility	100%	70%	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 recorded cumulative deferred stock-based compensation of $519,000, $942,000 and $336,000 as of December 31, 2001, 2000 and 1999 respectively, of which $98,000, $245,000, and $101,000 has been amortized to expense in 2001, 2000 and 1999, 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 expire on June 30, 2002 and October 14, 2004, respectively. 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 and is collateralized by 166,666 shares of common stock. This loan has been extended until December 31, 2006 and now bears 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, 2001 and 2000, $364,627 and $354,589 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 officers of the Company in exchange for common stock. The notes bear interest at 5.93% and 4.51%, and are due in January and December 2002, respectively. At December 31, 2001, $149,444 and $61,388 of principal and interest were outstanding on these notes, respectively. At December 31, 2000, $141,079 and $58,739 of principal and interest were outstanding on these notes, respectively. The loans are collateralized by 450,666 and 90,000 shares of common stock, respectively. The $149,444 note was repaid in full in January 2002.

In April 2000, the Company received full recourse notes receivable from two officers of the Company in exchange for common stock. Each note bears interest at 6.71% and is due in April 2004. Each loan is collateralized by 90,000 shares of common stock. At December 31, 2001 and 2000, $117,820 and $110,422 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 a development stage company 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

Acquired workforce and goodwill has been 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's products was not established and, accordingly, wrote off the corresponding amounts to acquired in-process research and development. Approximately $0.5 million 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.

The unaudited pro forma financial information, had the acquisition of Cerus occurred at the beginning of each period presented below, giving effect to an acquisition adjustment for the elimination of acquired in-process research and development is as follows:

	Years Ended December 31,	
	2000	1999
Revenue	$ 5,942	$ 757
Net loss attributable to common stockholders	$(13,724)	$(9,746)
Net loss attributable to common share, basic and diluted	$ (3.00)	$ (5.38)

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 the beginning of the earliest period presented, nor is it necessarily indicative of future operating results.

NOTE 10—INCOME TAXES:

At December 31, 2001, the Company has approximately $58.6 million and $26.6 million in Federal and California net operating loss carryforwards, respectively, which expire through the year 2021. United States Federal income tax regulations may restrict the utilization of the operating loss and tax credit carryforwards in the case of an "ownership change" of the Company.

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

	December 31,	
	2001	2000
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 21,475	$ 12,933
Research and development tax credit carryforwards	1,731	1,027
Research and development capitalization	1,203	—
Depreciation and amortization	240	244
Stock-based compensation	75	238
Other	215	91
	24,939	14,533
Less: valuation allowance	(24,939)	(14,533)
	$ —	$ —

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

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 year ended December 31, 2001, the Company made approximately $8,000 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 2001 Quarter Ended			
	March 31,	June 30,	September 30,(1)	December 31,
Total revenues	$ 675	$ 951	$ 594	$ 249
Loss from operations	(5,857)	(6,959)	(9,209)	(7,627)
Net loss attributable 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)

	Fiscal 2000 Quarter Ended			
	March 31,	June 30,(2)	September 30,(3)	December 31,
Total revenues	$ 1,139	$ 2,429	$ 1,572	$ 692
Loss from operations	(2,726)	(6,509)	(3,981)	(4,814)
Net loss attributable to common stockholders	(2,638)	(6,628)	(19,959)	(4,162)
Net loss per common share, basic and diluted	$ (1.28)	$ (2.93)	$ (8.77)	$ (.36)

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

(2) Includes a charge of $3,500 ($1.55 per share) for purchase of in-process research and development in conjunction with acquisition of Cerus Limited.

(3) Includes charges of $16,307 ($7.16 per share) related to the beneficial conversion feature of preferred stock.

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

Aerogen incorporates by reference the information concerning our directors set forth under the heading "Election of Directors" in our definitive Proxy Statement for our Annual Meeting of Stockholders to be held on May 14, 2002 (the "Proxy Statement") and the information under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement. Information concerning our executive officers appears at the end of Part I of this Form 10-K.

Item 11. EXECUTIVE COMPENSATION

Aerogen incorporates by reference the information set forth under the headings "Summary Compensation Table," "Fiscal Year 2001 Option Grants," "Aggregated Option Exercises in 2001 and Fiscal Year End Option Values," "Certain Executive Arrangements" and "Certain Transactions" in the Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Aerogen incorporates by reference the information set forth under the heading "Beneficial Stock Ownership" in the Proxy Statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Aerogen incorporates by reference the information set forth under the heading "Certain Transactions" in the Proxy Statement.

PART IV

Item 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

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

1. Consolidated Financial Statements: (See accompanying Index to Consolidated Financial Statements)
2. Financial Statement Schedules: None

3. Exhibits:

No.	Note	Description of Exhibit Document
3.2	(1)	Amended and Restated Certificate of Incorporation of AeroGen, Inc.
3.4	(1)	Amended and Restated Bylaws of AeroGen, Inc.
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 June 20, 1995, to purchase common stock of AeroGen, Inc. issued to Venture Lending & Leasing, Inc.
4.3	(1)	Warrant, dated October 14, 1997, to purchase Series C preferred stock of AeroGen, Inc. issued to Venture Lending & Leasing II, Inc.
4.4	(1)*	Warrant, dated October 14, 1997, to purchase Series C preferred stock of AeroGen, Inc. issued to Venture Lending & Leasing, Inc.
4.5	(1)	Stock Purchase Agreement between AeroGen, Inc. and PathoGenesis Corporation, dated March 13, 2000
4.6	(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	(1)	Sublease between AeroGen, Inc. and MicroBar dated April 3, 1997
10.8	(1)	Sublease between AeroGen, Inc. and MicroBar dated August 9, 1999
10.9		Amendment to Sublease Agreement between AeroGen, Inc. and MicroBar dated as of December 12, 2002
10.10		Settlement Agreement between Becton, Dickinson and Company and AeroGen, Inc. dated October 1, 2001
10.11	(1)	Settlement Agreement between Bespak plc and AeroGen, Inc. and Tenax Corporation dated March 4, 1999
10.12	(1)	Agreement for the Acquisition By Way of Exchange of the Entire Issued "A" Share Capital of Cerus Limited, dated May 25, 2000
10.13	(2)	Amended and Restated 1996 Stock Option Plan
10.14	(4)	AeroGen, Inc. Restated Executive Severance Benefit Plan
10.15	(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

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

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

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

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

(5) Incorporated by reference to AeroGen's Form 10-Q for the quarter ended September 30, 2001 as filed with the Securities and Exchange Commission on November 14, 2001.

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

(b) No Form 8-K reports were filed during the quarter ended December 31, 2001.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on our behalf by the undersigned, thereunto duly authorized, in the City of Sunnyvale, State of California, on the 25th day of March, 2002.

AEROGEN, INC.

By: /s/ JANE E. SHAW

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

POWERS OF ATTORNEY

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

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

/s/ JANE E. SHAW
Jane E. Shaw, Director and
Chief Executive Officer
Date: March 25, 2002

/s/ PHYLLIS I. GARDNER
Phyllis I. Gardner, Director
Date: March 25, 2002

/s/ THOMAS R. BARUCH
Thomas R. Baruch, Director
Date: March 25, 2002

/s/ YEHUDA IVRI
Yehuda Ivri, Director
Date: March 25, 2002

/s/ JEAN-JACQUES BIENAIMÉ
Jean-Jacques Bienaimé, Director
Date: March 25, 2002

/s/ PHILIP M. YOUNG
Philip M. Young, Director
Date: March 25, 2002

Bernard Collins, Director
Date: March , 2002

/s/ DEBORAH K. KARLSON
Deborah K. Karlson, Vice President
and Chief Financial Officer
Date: March 25, 2002

CORPORATE OFFICERS

Jane E. Shaw
Chief Executive Officer

Casper L. de Clercq
Vice President, Sales and Marketing

Robert S. Fishman
Vice President, Clinical Operations

Carol A. Gamble
Vice President, General Counsel and Secretary

Yehuda Ivri
Chief Technical Officer

Deborah K. Karlson
Vice President and Chief Financial Officer

John S. Power
Vice President, European Operations

John E. Ross
Senior Vice President, Worldwide Operations

BOARD OF DIRECTORS

Jane E. Shaw
Chairman and Chief Executive Officer,
AeroGen, Inc.

Thomas R. Baruch
General Partner, CMEA Ventures,
a venture capital firm

Jean-Jacques Bienaimé
Chairman, Chief Executive Officer and Director,
SangStat Medical Corporation, a
biopharmaceutical company

Bernard Collins
General management consultant

Phyllis I. Gardner, M.D.
Senior Associate Dean for Education and
Student Affairs and Associate Professor of
Molecular Pharmacology and Medicine,
Stanford University School of Medicine

Yehuda Ivri
Founder and Chief Technical Officer,
AeroGen, Inc.

Philip M. Young
General Partner, U.S. Venture Partners,
a venture capital firm

ANNUAL MEETING

The Annual Meeting of Stockholders
of AeroGen, Inc.
will be held at 9:00 a.m.
on Tuesday, May 14, 2002
at 2071 Stierlin Court
Mountain View, California 94043

FORM 10-K AVAILABILITY

The Company's Annual Report on
Form 10-K for the year ended
December 31, 2001 is included in
this Annual Report to Stockholders

INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP
San Jose, California

SHARES TRADED

AeroGen, Inc. Common Stock is listed for
trading on The NASDAQ Stock Market®
under the symbol "AEGN"

TRANSFER AGENT

Mellon Investor Services LLC

STOCKHOLDER INQUIRIES

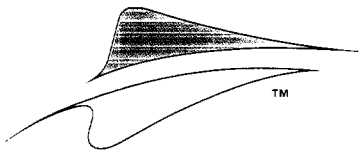
Inquiries regarding changes of address, lost
certificates and transfer requirements
should be directed to:

Mellon Investor Services LLC
By Mail: P.O. Box 3315
South Hackensack, NJ 07606
(800) 356-2017 or (201) 329-8660
www.mellon-investor.com

NEW CORPORATE OFFICES

2071 Stierlin Court
Mountain View, California 94043
(650) 864-7300 Tel
(650) 864-7350 Fax

www.aerogen.com



Aerogen®

2071 Stierlin Court
Mountain View, California 94043