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Aradigm
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Revolutionizing Pulmonary Drug Delivery

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Despite the advances of modern medicine, patients today are often forced to choose between their quality of life and compliance with treatment regimens. Dosing challenges, side effects and suboptimal results cause many drug therapies to be underutilized or even avoided. Scientific advances in drug delivery offer new choices, and Aradigm is committed to bringing revolutionary solutions to the marketplace. Our focus is on pulmonary delivery of drugs and biologics. With nine product opportunities in clinical or preclinical testing and new technologies emerging from research and development, we are excited about the potential that lies ahead. For more information, please visit our website at www.aradigm.com.

Therapeutic Targets

AERx® Devices

Cardiovascular

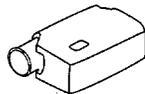
AERx Essence™ Disposable

Oncology



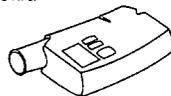
Respiratory

AERx Essence™



Endocrine

AERx Ultra™

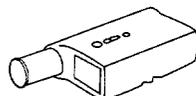


Infection

Inflammation

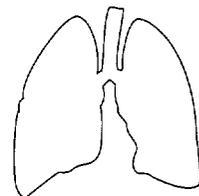
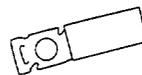
AERx® Insulin Delivery System

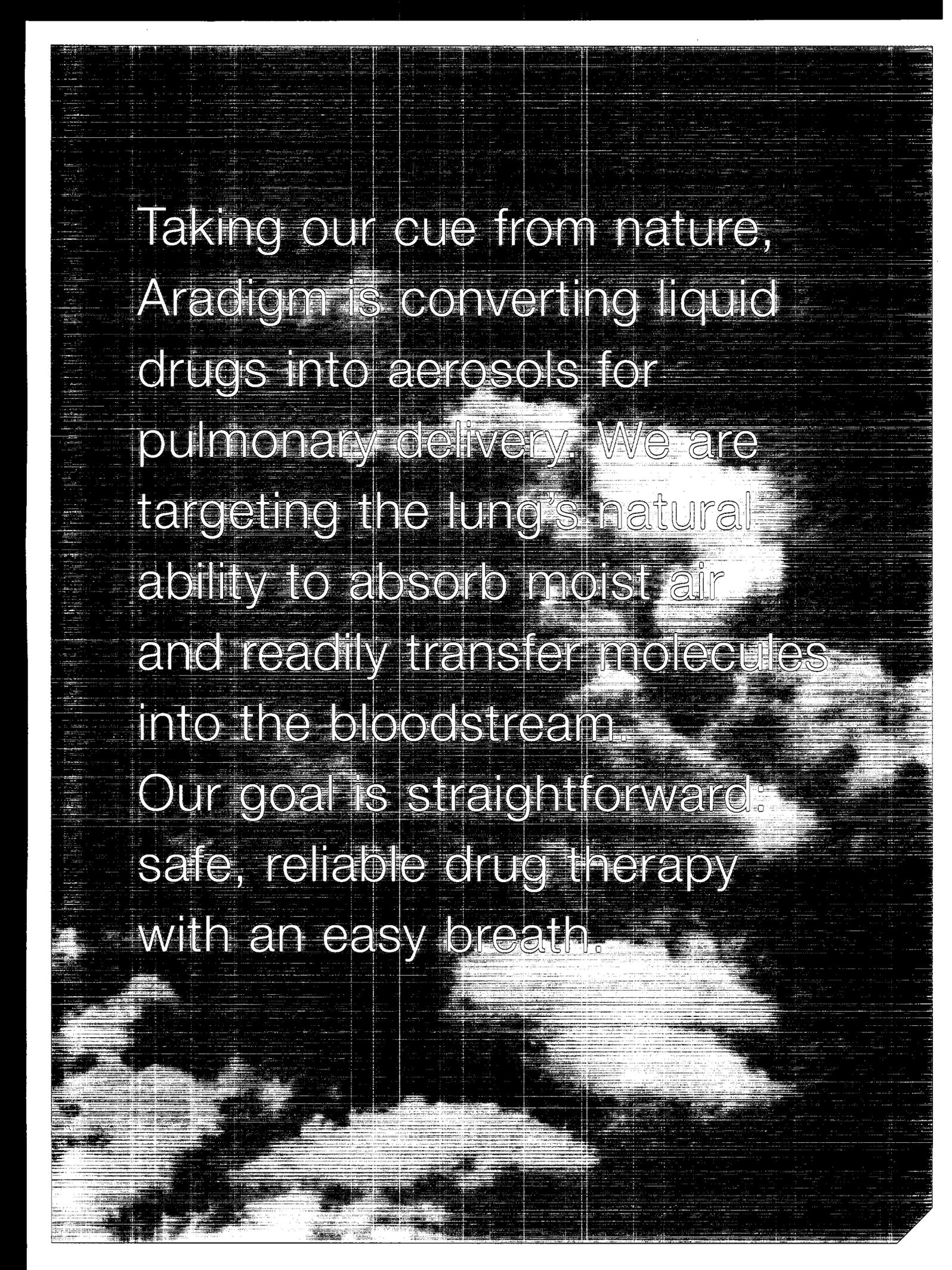
Neurology



AERx® Drug Strip

The Human Lung





Taking our cue from nature,
Aradigm is converting liquid
drugs into aerosols for
pulmonary delivery. We are
targeting the lung's natural
ability to absorb moist air
and readily transfer molecules
into the bloodstream.

Our goal is straightforward:
safe, reliable drug therapy
with an easy breath.

To Our Shareholders,

We are pleased to report that, despite turbulent times for our economy and the biotechnology sector, Aradigm remains strong. Our development programs are progressing well, and we are enthusiastic about our prospects for bringing important new therapies to people in need.

2002 Marked a Major Milestone

We initiated and are now well into Phase 3 clinical trials with the AERx® Insulin Diabetes Management System (iDMS). Our partner, Novo Nordisk, played an important role in helping us to achieve this milestone. The world leader in diabetes care, Novo Nordisk has strongly supported our iDMS program and is now working with us on plans for the final step: commercialization of what we believe will be the leading form of non-invasive insulin therapy.

Nine Clinical and Preclinical Programs

Insulin is just the beginning of what we expect to be a long list of products aimed at improving drug therapy. As a leader in pulmonary delivery of liquid formulations, Aradigm is well-positioned to increase both the performance and patient acceptability of a wide range of medical treatments.

Key areas of focus include proteins and small-molecule parenteral drugs that currently require injection or infusion, and respiratory therapies that require highly precise, dependable drug delivery to the lung. The AERx pulmonary delivery platform, our core technology, creates aerosols from liquid drug formulations and enables patients to safely self-administer their medication via inhalation. AERx therapies can be targeted to remain in the lungs to treat respiratory disease, or be absorbed through the lungs into the bloodstream to treat systemic conditions.

Strategic Product Platform

In our product development partnerships, Aradigm is supplying both inhalation devices and single-use drug strips to provide patients with precise, dependable aerosolized medications on demand. Most AERx devices are designed for use with chronic therapies, although a disposable device is being developed for vaccines and other acute applications. All AERx delivery devices utilize the same drug-containing strip, thereby enabling Aradigm to realize significant production efficiencies.

Demand for improved drug therapies is enormous. The market represented by drug delivery was estimated to be approximately \$20 billion in 2002 and is forecast to double in the next 5 years. Some analysts believe that by 2005, 20% of pharmaceuticals will include drug delivery formulations.

Broad Partnership Opportunities

As we progress into 2003, we are increasing our business development activities. Targets of opportunity include cardiovascular disease, cancer, respiratory disease, endocrine disorders, systemic infections, autoimmune and inflammatory conditions and neurologic illnesses. The first goal in any product development partnership is to identify whether the pulmonary route of administration is suitable for compounds under consideration. Aradigm has a growing database, with molecules of various sizes, solubilities and other characteristics, for use in preliminary screening and modeling. The company also has a strong track record of effectively executing feasibility studies backed by this initial data.

Aradigm brings to its partnerships a number of significant qualifications. Among them:

- The multi-faceted, clinically-tested AERx platform for transforming liquid drugs into fine-particle aerosols and dependably delivering these therapies to the lung.

- Over 300 employees representing all key development areas: aerosol science, formulation, toxicology, clinical affairs, device development/engineering, regulatory affairs, quality assurance and quality control, manufacturing, project planning and market assessment.
- Experienced senior management that collectively has brought more than 25 health care products to market in the U.S. and internationally.
- On-site drug packet and device manufacturing capabilities ranging from small-scale clinical to large-scale commercial facilities, built to GMP standards that meet both U.S. and international regulatory requirements.
- A decade of pulmonary technology innovations, with over 125 issued and allowed patents.

Financial Management

Thomas Chesterman joined the company mid-year as Senior Vice President and Chief Financial Officer. Contributing a breadth of financial expertise specific to the life sciences, he was previously



LEFT
Richard P. Thompson

RIGHT
V. Bryan Lawlis, Ph.D.

Vice President and Chief Financial Officer at a leading worldwide manufacturer of research and clinical diagnostic products.

Our key objective on the financial side of Aradigm's business is to utilize cash effectively while driving our core business forward. In early 2003, we implemented cost reductions designed to more closely align Aradigm's operations with its partnered projects. We expect to pare spending on non-reimbursed and non-core projects, largely by reallocating personnel to partnered projects.

To further increase our resources, the company entered into a definitive agreement in early 2003 with a select group of institutional investors, for a \$15 million private placement of common stock and the concurrent issuance of warrants for the purchase of common stock.

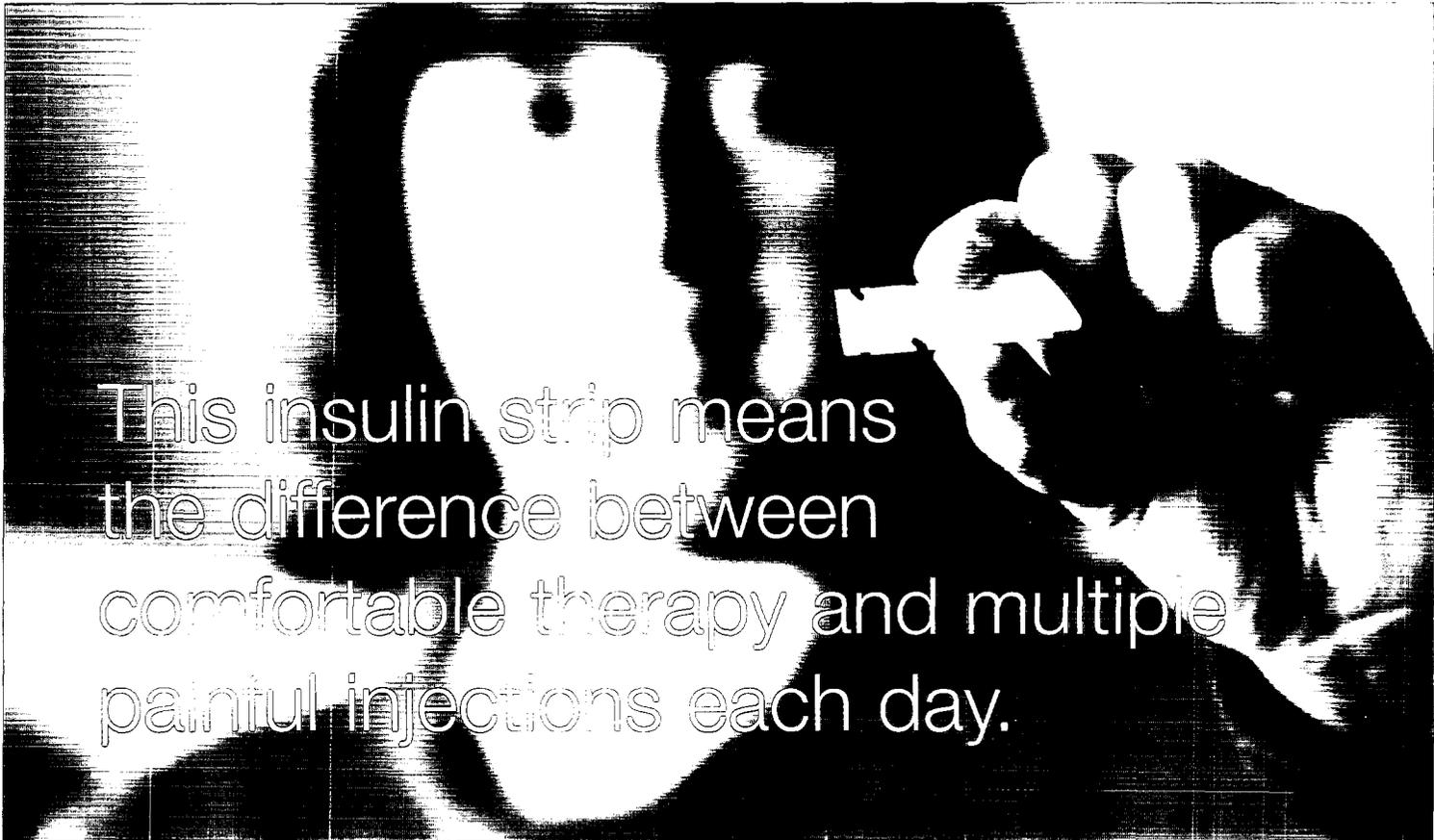
With these two initiatives, combined with our existing resources, we expect to have sufficient funding well into 2004 to execute our strategic business priorities.

Focus for 2003

Our goal is to remain at the forefront in the emerging field of pulmonary drug delivery. We are progressing into the new year determined, confident and committed—thanks in large part to the talent and hard work of Aradigm's employees. Our business focus is on three key areas: advancing the insulin program, establishing additional partnerships, and controlling operating expenses. We look forward to reporting more to you in the months ahead.

Richard P. Thompson
President, Chief Executive Officer
and Chairman of the Board

V. Bryan Lawlis, Ph.D.
Chief Operating Officer



This insulin strip means
the difference between
comfortable therapy and multiple
painful injections each day.

Insulin

Glycemic Control for Type 1 and Type 2 Diabetes

Phase 3 Clinical Trials In Progress

Beyond ending the pain and inconvenience of needle administration, aerosol drug delivery offers important therapeutic advantages. Many diabetic patients currently do not properly manage their disease due to difficulties injecting the correct amount of insulin at the right time. Aradigm and its partner, Novo Nordisk, are working to change this situation. The first Phase 3 trial of our AERx[®] Insulin Diabetes Management System (iDMS) was initiated in September 2002. This 24-month, 300-patient trial will examine the long-term safety and efficacy of the AERx system in patients with Type 1 diabetes. It will be augmented by other, shorter studies of patients with Type 1 and Type 2 diabetes.

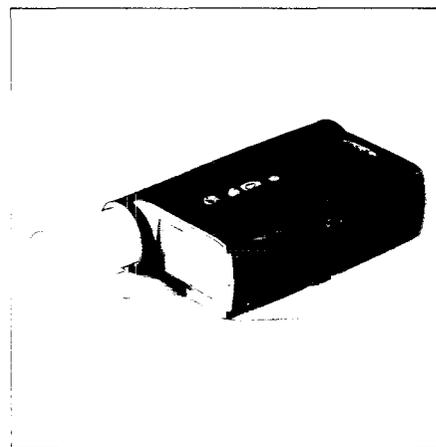
"It is a promising development for people who have diabetes to know that glycemic control may not be reliant on insulin injections. Inhaled insulin administered electronically through the sophisticated AERx iDMS should provide a viable alternative for patients to manage their disease."

Dr. Kjeld Hermansen,
Lead Investigator, University Hospital, Aarhus, Denmark

Needle-Free Diabetes Therapy

Experience in Multiple Patient Populations

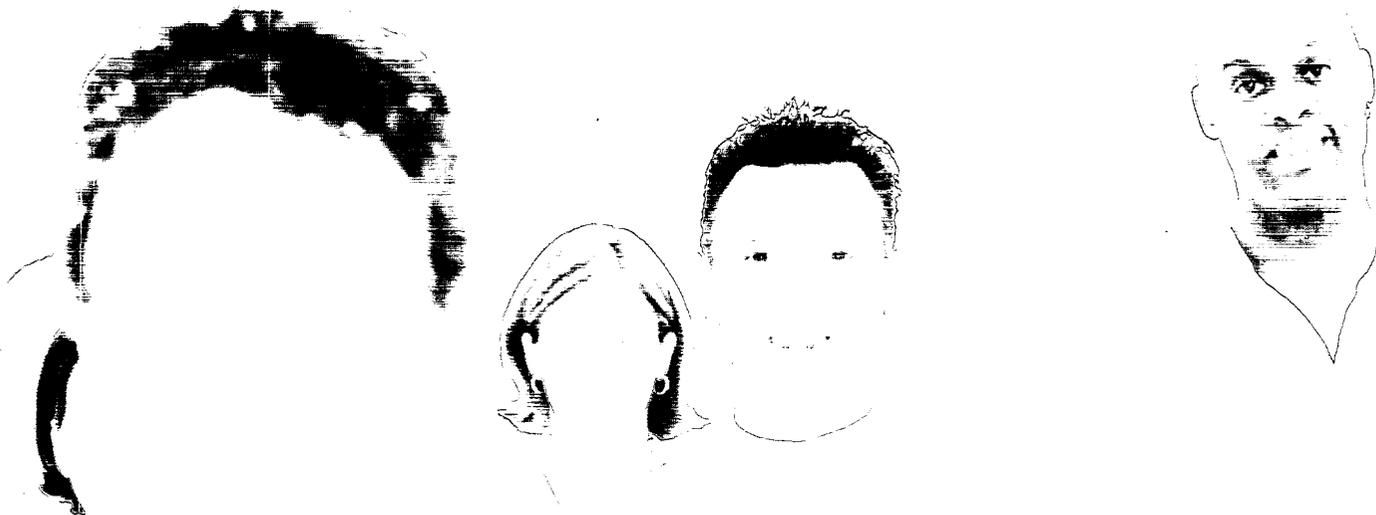
The AERx insulin delivery system has been studied extensively in healthy subjects, Type 1 and Type 2 diabetic patients, and people with compromised respiratory systems due to smoking, asthma or infections. A total of 18 studies were completed between 1996 and 2001, and other studies are in progress. Most important: in diabetic patients, the safety, efficacy and dose reproducibility have been comparable to subcutaneous insulin injections, with glycemic control comparable to intensive injected therapy; and no significant adverse effects on lung function have been reported to date.



AERx[®] Insulin Delivery Device

A World of Unmet Needs

As demonstrated in AERx® clinical trials, many types of patients may benefit from pulmonary drug delivery, regardless of their lung function or physical dexterity — including smokers, people with active lung disease, children and the elderly.



Cardiovascular

Cardiovascular disease remains the leading cause of death in industrialized countries. While effective oral medications exist for hypertension and high cholesterol levels, better solutions are greatly needed for the treatment and/or prevention of angina, congestive heart failure, arrhythmia and stroke.

Oncology

Cancer takes over half a million lives each year in the U.S. alone, and mortality among lung cancer patients is especially high. In addition, quality of life is poor due to the serious side effects of current therapies. Delivery directly to the lung has the potential to provide important advantages in the use of chemotherapeutics, adjunctive agents and symptomatic treatments.

Respiratory

Our focus in respiratory therapy is on diseases which are life-threatening or for which existing treatment is clearly suboptimal, such as cystic fibrosis and hereditary emphysema. Delivery of novel biologic therapies via the lung, including gene therapy, could potentially extend the life expectancy of patients with these diseases.



Endocrine

Beyond diabetes, other endocrine disorders such as sexual dysfunction, infertility, osteoporosis and obesity represent important targets for improved drug delivery. For example, feasibility studies with AERx-delivered testosterone open the prospect for a discreet, titratable dosing system that could be used to treat female androgen insufficiency.

Infection

Infectious diseases such as Hepatitis C continue to pose significant treatment challenges around the globe. Our work with interferon alpha-2b is one example of the AERx potential in this field. With pulmonary drug delivery, patients would not require injections from their physician. Instead, they could self-medicate on a more regular, and potentially more effective, basis at home.

Inflammation

Chronic in nature, auto-immune and inflammatory targets include psoriasis, lupus, rheumatoid arthritis and Crohn's disease. Newer biologics to treat these conditions are usually developed as injectables that would benefit from alternative, non-invasive delivery to increase their utility in a broader patient population.

Neurology

Though currently one of the larger global therapeutic market segments, neurology remains greatly under-served. Pulmonary drug delivery offers potential in numerous treatment areas — ranging from multiple sclerosis and Parkinson's disease to acute and chronic pain. The AERx Pain Management System is our first program in this important market segment.



New AERx[®] devices are
expanding therapeutic opportunities
for pulmonary drug delivery.

Next-Generation Delivery Superior Inhalation Therapies

AERx Essence™

In addition to our commercially-ready electronic devices, we now have an all-mechanical device for delivering drugs that have wider therapeutic indices, or target conditions localized in the lung. This best-in-class delivery device offers superior aerosol efficiency and reproducibility. The AERx Essence uses many of the same technology principles, such as breath flow-rate control, that we pioneered in our electronic systems.

"Our goal is to provide the highest quality products possible. We have therefore made a substantial commitment to manufacturing at Aradigm. Our partners expect accuracy, dependability and durability — and we intend to deliver."

V. Bryan Lawlis, Ph.D.
Chief Operating Officer, Aradigm

Superior Technology, Integration and Flexibility

On-Site Manufacturing

Both drug and device product manufacturing are performed at Aradigm's corporate campus in Hayward, California. Here we can maintain control over quality and supply, using engineering and production staff with specific expertise in critical areas such as systems integration. Once product designs have been clinically validated, Aradigm's team moves them into a commercial optimization phase that is designed to ensure reliable, cost-effective manufacturing. Our liquid drug production process requires a minimal number of steps from raw material to final packaging, uses standard aseptic pharmaceutical manufacturing techniques, and is expected to have a capacity of up to 750 million AERx Strips per year commercially.



Commercial-Stage AERx Strip™
Production Equipment

Clear Business Opportunities

- A leader in liquid pulmonary insulin
- Multiple pulmonary delivery platforms
- Optimal aerosol performance
- On-site manufacturing of drug strips and devices
- Strategically targeted product development pipeline
- Significant market opportunities
- Industry-leading partners
- Comprehensive intellectual property portfolio
- Solid financial strategy and infrastructure

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

Form 10-K

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2002

or

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 0-28402

Aradigm Corporation

(Exact Name of Registrant as Specified in Its Charter)

California
*(State or Other Jurisdiction of
Incorporation or Organization)*

94-3133088
*(I.R.S. Employer
Identification No.)*

3929 Point Eden Way, Hayward, CA 94545
(Address of Principal Executive Offices)

Registrant's telephone number, including area code:
(510) 265-9000

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, no par value

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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.

As of February 28, 2003, there were 50,168,003 shares of common stock outstanding. The aggregate market value of common stock held by non-affiliates of the registrant as of June 28, 2002, was approximately \$60,332,000. Shares of common stock held by each officer, director and holder of five percent or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

Items 10, 11, 12 and 13 of Part III incorporate information by reference from the Registrant's definitive proxy statement for the Annual Meeting of Shareholders to be held on May 15, 2003.

PART I

Item 1. *Business*

This Report on Form 10-K contains forward-looking statements, including, without limitation, statements regarding timing and results of clinical trials, the timing of regulatory approvals, the establishment of corporate partnering arrangements, the anticipated commercial introduction of our products and the timing of our cash requirements. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, without limitation, those mentioned in this Report and, in particular, the factors described below in Part II under the heading "Risk Factors".

Overview

Aradigm Corporation is a leading developer of advanced pulmonary drug delivery systems for the treatment of systemic conditions as well as lung diseases. Our hand-held AERx platform is being designed for the rapid and reproducible delivery of a wide range of pharmaceutical drugs and biotech compounds via pulmonary delivery or through the lung. We believe that our non-invasive AERx systems, which have been shown in clinical studies to achieve performance equivalent to injection, will be a welcome alternative to injection-based drug delivery. In addition, our systems may improve therapeutic efficacy in cases where other existing drug delivery methods, such as pills, transdermal patches or inhalers, are too slow or imprecise.

According to IMS Health Incorporated, the total United States market for injectable drugs and biologics was approximately \$34.6 billion in 2002. We believe that many of these molecules could potentially be delivered using the AERx platform.

We have tested 13 compounds in more than 55 human clinical trials involving over 1,400 patients worldwide. In September 2002, Aradigm and our partner, Novo Nordisk A/S announced the initiation of the first study of the Phase 3 clinical trials of the AERx insulin Diabetes Management System, our most advanced program. This 24-month, 300 patient study is designed to examine the long-term safety and efficacy of the system in patients with type-1 diabetes. We have been successful in attracting the attention of some of the world's leading pharmaceutical and biotechnology companies. Together, our partners have contributed cumulatively over \$117 million in contract and license revenues for the advancement of our AERx technology. Our most advanced programs are based on development partnerships with:

- Novo Nordisk A/S, the world leader in insulin products, for the needle-free delivery of insulin for diabetes; and,
- GlaxoSmithKline plc ("GlaxoSmithKline"), for the rapid, needle-free delivery of morphine to treat severe pain.

We believe that our technology platform will provide the basis for the next generation in pulmonary drug delivery systems. Our AERx platform is based on a set of proprietary technologies, protected to date by 84 issued United States patents, that control the physical factors critical for rapid, reproducible pulmonary drug delivery. These proprietary technologies allow us to:

- utilize existing liquid formulation technology instead of more expensive dry powder processing;
- consistently create the high-quality aerosol required to reach the deep lung;
- guide patients to inhale in the most effective manner for deep lung delivery; and
- automatically monitor and control patient drug usage, allowing for better disease management.

Background — Pulmonary Drug Delivery

Today an increasing number of drugs, including nearly all biotech drugs, are delivered by injection. While injections are quick and efficient, they have inherent limitations, including inconvenience, discomfort

and risk of infection. These limitations have prompted drug manufacturers to explore alternatives such as improved oral delivery formulations, transdermal, or through the skin, patch technologies and pulmonary delivery systems. Due to the natural ability of the lung to transfer molecules into the bloodstream, pulmonary drug delivery systems are now being pursued as an alternative to injection.

Pulmonary delivery systems were originally developed to treat lung diseases by depositing aerosolized, or fine particles or mists of, medication in the large airways of the lung. These aerosols were created in medical devices, i.e. nebulizers, metered-dose inhalers and dry powder inhalers, for inhalation by the patient. While these systems have been useful in the treatment of diseases such as asthma, they generate a wide range of particle sizes, only a portion of which can reach the targeted lung tissues, and rely heavily on proper patient breathing technique to effect delivery.

Considerable recent research has been devoted to developing a means to create well-defined small particle aerosols suitable for efficient pulmonary delivery of drugs, either to treat lung diseases or for absorption into the bloodstream for systemic effect. To deliver pharmaceuticals to or through the lungs, drugs must be transformed into an aerosol that can be inhaled by the patient. In order for aerosols to be delivered to the deep lung, the individual particles must be small, three microns or less in diameter, and the velocity of these particles must be low as they pass through the upper airways and into the deep lung. The particle velocity is largely determined by how fast the patient is inhaling. Larger or fast moving particles typically get deposited in the mouth or upper airways where they cannot be absorbed and may not be effective.

Recent advances in dry powder formulation technology have made possible the creation of smaller particle aerosols suitable for more efficient deep lung delivery and several companies are developing systems based on this approach. However, most drugs being considered for pulmonary delivery are currently marketed in stable liquid formulations. We believe the extra steps involved in making dry powder formulations of these drugs will make them more difficult and costly to produce than liquid-based formulations. In addition, today's dry powder delivery systems under development continue to rely on individual patient breathing technique for the actual drug delivery. It is well documented that the typical patient frequently strays from proper inhalation technique and may not be able to maintain a consistent approach over even moderate periods of time after training. Given the need with many medications to achieve precise and reproducible dosing, variability in technique among patients or from dose to dose may compromise safety or therapeutic efficacy.

The Paradigm Solution

Our AERx technology platform is being developed to enable pulmonary delivery of a wide range of pharmaceuticals in liquid formulations for local or systemic effect. Our proprietary AERx technologies focus principally on small particle aerosol generation from liquid formulation at the point of delivery and control over patient inhalation technique in order to efficiently and reproducibly deliver the aerosol drug to the deep lung. We have developed these proprietary technologies through an integrated approach that combines expertise in physics, electrical engineering, mechanical engineering, laser engineering and pharmaceutical sciences. The key features of the AERx platform include:

Ease of Drug Formulation

The AERx platform takes advantage of existing liquid drug formulations, reducing the time, cost and risk of formulation development compared to dry powder-based technologies. The formulation technology of the AERx platform allows us to use conventional, sterile pharmaceutical manufacturing techniques. We believe that this approach will result in lower cost production methods than those used in dry powder systems because we are able to bypass entirely the complex formulation processes required for those systems. Moreover, the liquid drug formulations used in AERx systems are expected to have the same stability profile as the currently marketed versions of the same drugs.

Efficient, Precise Aerosol Generation

Our proprietary technology produces the low-velocity, small-particle aerosols necessary for efficient deposition of a drug in the deep lung. Liquid drug formulations are aerosolized from pre-packaged, single-use, disposable packets using the hand-held AERx device. Each disposable packet is comprised of a small blister package of drug adjacent to an aerosolization nozzle. The AERx device compresses the packet to push the drug through the nozzle and thereby creates the aerosol. No propellants are required since mechanical pressure is used to generate the aerosol. Each packet is used only once to avoid plugging or wearing that would degenerate aerosol quality if reused. Through this technology, we believe we can achieve highly efficient and reproducible aerosols.

Automated Breath-Controlled Delivery

Studies have shown that even well trained patients tend to develop improper inhalation technique over time, resulting in less effective therapy. The AERx electronic platform employs a patented technology to measure the patient's inhalation flow rate through the mouthpiece of the hand-held device. Indicator lights on the device guide the patient to inhale slowly and evenly for optimal drug delivery. When the desired flow rate is established early in the breath, drug delivery is automatically initiated. As a result, a consistent dose of medication is delivered each time the product is used. The flow rate can be adjusted for different patient needs; for example, a low-flow device has been developed for use by cystic fibrosis patients. Novel flow-rate controls have also been developed for Aradigm's AERx Essence™, a new, second generation all-mechanical delivery device designed for topical lung delivery and systematic delivery of small molecules.

Strategy

Our goal is to become the leader in the development and commercialization of pulmonary drug delivery products. Our strategy incorporates the following principal elements:

Establish Broad Applicability of the AERx Platform

We believe that the AERx platform will be broadly applicable to drugs that are intended for systemic delivery and for local delivery to the lung. In addition to our publicly announced late stage programs in diabetes and pain management potential applications for AERx-delivered therapy include cardiovascular disease, oncology, endocrine disorders, infections, neurological diseases, inflammatory conditions and respiratory diseases. We are conducting clinical and preclinical studies on a number of compounds to demonstrate the applicability of the AERx platform to a broad range of molecule sizes and types. We believe this strategy will maximize the number of commercial product opportunities for us and will increase the interest of potential partners in developing drugs for the AERx platform.

In addition, our work on proteins and gene vector delivery anticipates the role that genomics and proteomics are expected to play in future drug discovery. Pulmonary drug delivery may be an attractive alternative to injectable delivery of novel therapies. We believe that the capabilities of the AERx platform will make it particularly appropriate for these potential future applications.

Expand Existing and Develop New Collaborative Relationships

In order to enhance our commercial opportunities and effectively leverage our core scientific resources, we intend to continue entering into multiple collaborative relationships with pharmaceutical and biotech companies for the development and commercialization of new products utilizing our technologies. Through product development collaborations, we seek access to proprietary pharmaceutical compounds as well as to the resources necessary to conduct late stage clinical programs and obtain regulatory approvals. In addition, we will continue pursuing relationships with companies with established sales forces and distribution channels in our target markets. Where consistent with other objectives, we plan to give preference to development partners whose pipelines contain multiple products whose value could be enhanced by our AERx pulmonary drug delivery technology. By establishing such collaborative

relationships, we intend to introduce multiple new products while avoiding the need to establish drug discovery research and sales and marketing capabilities for each target market.

Create a Large and Loyal Customer Base

Our goal is to create a large and loyal customer base that will repeatedly purchase disposable AERx packets. The disposable packets are expected to generate most of our revenues and substantially all of our profits over time. The AERx devices are being designed to meet the specific needs of patients in each therapeutic category. We believe that physicians and patients will find our unique product features attractive relative to anticipated competitive products. We intend to capitalize on what we believe will be a customer preference for the value-added features of our AERx devices by pricing them competitively to help ensure ongoing repeat usage of the high-margin disposable AERx packets. We believe that patients will tend to remain loyal to a superior product for the life of the device. Accordingly, we are designing the AERx devices to last for several years.

Enhance Our Strong Proprietary Position

We believe that establishing a strong proprietary position in pulmonary drug delivery could provide an important competitive advantage in our target markets. We have aggressively pursued comprehensive patent protection of our technology and, as of February 28, 2003, had 84 issued United States patents with a number of additional United States patent applications pending. While there can be no assurance that any of our patents will provide a significant commercial advantage, these patents are intended to provide protection for important aspects of our technology, including aerosol generation, breath control, compliance monitoring and unit-dose formulation. In addition, we are maintaining as trade secrets key elements of our manufacturing technologies, particularly those associated with production of disposable unit-dose packets for the AERx systems.

Maintain Technological Leadership

We are making a substantial research and development investment to establish and maintain technological leadership in pulmonary drug delivery. This includes a research and development program to design the future generations of the AERx technology platform. The goal of this program is to access a wider range of markets, broaden our technology base, achieve manufacturing efficiencies and develop next-generation delivery devices. We are supported by the International Scientific Advisory Board whose members are global leaders in drug delivery and clinical specialties of key interest to Aradigm.

Aradigm Product Applications

We are developing the hand-held AERx platform based on a comprehensive approach to pulmonary drug delivery that includes drug formulation, aerosol generation, patient breath control and compliance monitoring technologies. We are currently developing AERx products for pain and diabetes management. In addition, we are planning to develop AERx systems for the non-invasive delivery of certain other drugs, including proteins, peptides, gene vectors and small molecules.

AERx insulin Diabetes Management System

We are developing the AERx insulin Diabetes Management System to permit patients with diabetes to non-invasively self-administer insulin. We believe that patients, when provided with a non-invasive delivery alternative to injection, will be more likely to self-administer insulin as often as needed to keep tight control of their blood glucose levels. We are developing and planning to commercialize this product in collaboration with Novo Nordisk A/S, a leader in the field of diabetes care. During the third quarter of 2002, we initiated the first study in our Phase 3 clinical program. There can be no assurance that this development program will be successful.

The Market

Unregulated glucose levels in people with diabetes are associated with short and long-term effects, including blindness, kidney disease, heart disease, amputation resulting from chronic or extended periods of reduced blood circulation to body tissue and other circulatory disorders. Patients with Type 1 diabetes do not have the ability to produce their own insulin and must self-inject insulin regularly to control their disease. Patients with Type 2 diabetes are unable to efficiently use the insulin that their body produces. While they may have some impairment in their ability to produce insulin as well, it is the defect in their ability to use insulin efficiently that leads to the addition of insulin to their treatment program. By increasing the circulating insulin concentration in their bodies, patients with Type 2 diabetes can partially overcome the inefficiency. The Diabetes Control and Complications Trial study of patients with Type 1 diabetes sponsored by National Institutes of Health indicated that insulin doses should be adjusted throughout the day in response to frequently measured blood glucose levels. The Diabetes Control and Complications Trial study showed that keeping blood glucose levels as close to normal as possible slows complications caused by diabetes. In fact, the Diabetes Control and Complications Trial study demonstrated that any sustained lowering of blood glucose levels is beneficial, even if the person has a history of poor blood glucose control. Separately, the United Kingdom Prospective Diabetes Study has also demonstrated that tighter blood glucose control can provide essentially the same benefits for patients with Type 2 diabetes.

Approximately 800,000 Americans suffer from Type 1 diabetes. All of these patients either self-inject insulin multiple times a day or use external insulin pumps. Approximately 16 million Americans have Type 2 diabetes, and the prevalence of Type 2 diabetes has increased dramatically over the past decade due to lifestyle factors such as obesity and inactivity. Type 2 patients consume the majority of insulin used in the United States due to their larger numbers. However, given their less severe impairment, many of these patients are reluctant to use injection-based therapy. We believe that this reluctance to utilize insulin-therapies contributes to approximately \$45.0 billion in annual direct costs associated with the treatment of diabetes. Through our convenient, non-invasive AERx insulin Diabetes Management System, we believe we can address this patient reluctance, reduce overall treatment costs and grow the total worldwide insulin market beyond its current level of \$3.7 billion. The leading suppliers of insulin worldwide are Novo Nordisk A/S and Eli Lilly.

The Product

Patients with diabetes often avoid or limit the amount of insulin therapy because of the pain and inconvenience of administering the drug by injection. The AERx insulin Diabetes Management System is being designed as a painless and convenient alternative to drug injection to enable patients with diabetes to comply more effectively with their insulin therapy, thereby lessening the risk of long-term complications. We also believe that the features of the AERx insulin Diabetes Management System will allow people with diabetes to achieve more consistent and precise control over their blood glucose levels. A clinical study conducted by us in healthy fasting volunteers has shown that the way an individual breathes during drug delivery has a significant effect on the pharmacokinetic (measurement of drug level in the blood) profile of the delivered insulin. We believe that the proprietary breath control technology incorporated in the AERx insulin Diabetes Management System may eliminate this potential variability as a factor in the pulmonary delivery of insulin.

Standard insulin therapies presently require that doses of insulin given by injection be adjusted in increments of one international unit, which is a standard unit of measure for insulin. We are not aware of any competitive products under development that are being designed to provide the same one unit dosing adjustability as the AERx insulin Diabetes Management System. We believe that our AERx insulin Diabetes Management System can provide a non-invasive method for delivery of insulin that would be very efficient and easily reproduced. Clinical studies conducted by us to date have demonstrated that insulin delivered via a prototype of the AERx insulin Diabetes Management System achieved maximum blood glucose reductions in healthy fasting volunteers in half the time required for subcutaneous, or under the skin, insulin injections. We believe this more rapid onset of action could allow people with diabetes to

dose themselves closer to mealtimes, better matching insulin levels to caloric intake. The reductions in blood glucose levels were also at least as reproducible in both magnitude and time to maximum reduction as subcutaneous injections.

Clinical Development

In November 2001, we successfully completed Phase 2b clinical trials for our AERx insulin Diabetes Management System, which showed that the product may be successfully used to treat Type 2 diabetes patients with insulin delivered via the pulmonary route. The Phase 2 trial was designed to investigate the safety and efficacy of pulmonary insulin via the AERx insulin Diabetes Management System compared to intensified treatment with insulin injections in patients with Type 2 diabetes. Approximately 100 patients were included for a twelve-week period in the study. The results of the study announced in June 2002 at the Annual Meeting of the American Diabetes Association in San Francisco, California showed the safety and efficacy of the AERx insulin Diabetes Management System to be comparable to an intensive subcutaneous injection regimen of insulin.

In September 2002, we, and Novo Nordisk A/S, initiated the first study in our Phase 3 clinical program for the AERx insulin Diabetes Management System. This two-year study is examining the long-term safety and efficacy of inhaled insulin in patients with Type 1 diabetes. Additional trials are scheduled to run concurrently with both Type 1 and Type 2 diabetes patients.

The Collaboration

In June 1998, we entered into a product development and commercialization agreement with Novo Nordisk A/S, the world leader in diabetes care, covering the use of the AERx insulin Diabetes Management System for the delivery of blood glucose regulating medicines. Novo Nordisk A/S has been granted worldwide sales and marketing rights to any products developed under the terms of the agreement, and we retain all manufacturing rights. For any system developed under the collaboration that receives regulatory approval, we expect to receive a share of gross profit on the sales of such products by Novo Nordisk A/S.

Pursuant to the Novo Nordisk A/S agreement, we could receive approximately \$38.0 million in milestone payments in addition to reimbursement for product development expenses and \$10.0 million in equity investments by the time the first product from the collaboration is commercialized. From the inception of partnership in June 1998 through December 31, 2002, we have received from Novo Nordisk A/S approximately \$86.1 million in product development payments, approximately \$13.0 million in milestone payments and \$10.0 million from the purchase of our common stock by Novo Nordisk A/S. From the inception of partnership in June 1998 through December 31, 2002, of the payments received approximately \$77.5 million of product development and \$4.8 million of milestone payments have been recognized as contract revenue. Additional milestone payments and product development payments will be paid by Novo Nordisk A/S if Novo Nordisk A/S and we decide to jointly develop additional AERx products under the terms of the agreement.

In October 2001, we entered into a common stock purchase agreement with Novo Nordisk Pharmaceuticals, an affiliate of Novo Nordisk A/S, pursuant to which Novo Nordisk Pharmaceuticals purchased \$20.0 million of our common stock at the fair market value. We also received the option under the agreement to sell an aggregate of up to \$25.0 million additional shares to Novo Nordisk Pharmaceuticals for the purchase price provided in the agreement by delivering written notice, or a share sales notice, to Novo Nordisk Pharmaceuticals of our election to sell additional shares. Under the terms of the agreement the number of additional shares shall be calculated by dividing the additional purchase price by the average closing price of the Company's common stock on the Nasdaq for the thirty trading days immediately prior to the date of written notice by the Company to Novo Nordisk Pharmaceuticals. Subject to certain restrictions, we may deliver a share sales notice specifying an amount between \$5.0 million and \$10.0 million for Novo Nordisk Pharmaceuticals to purchase once every three months until we have sold an aggregate of \$25.0 million worth of additional shares of common stock to Novo

Nordisk Pharmaceuticals. In addition, the sale of shares of common stock to Novo Nordisk Pharmaceuticals is subject to certain conditions, including, if applicable, obtaining any requisite shareholder approval. In July 2002, we issued 1,182,034 shares of common stock to Novo Nordisk Pharmaceuticals for an aggregate purchase price of \$5.0 million. Novo Nordisk A/S with its affiliates own approximately 20% of our total outstanding common stock on an as-converted basis as on December 31, 2002 and is considered a related party. In a separate agreement, we and Novo Nordisk A/S agreed to share manufacturing responsibilities where Novo Nordisk A/S has accepted all responsibility for high volume production beyond the capacity of our first factory. This has potentially shifted a significant future investment in additional manufacturing capacity to Novo Nordisk A/S and was accomplished without changing the basic economic arrangements of the original agreement.

AERx Pain Management System

We are developing the hand-held AERx Pain Management System as a non-invasive, patient-controlled pulmonary drug delivery product for treatment of severe pain. In December 2001, we successfully completed Phase 2b clinical trials of the AERx Pain Management System incorporating morphine sulfate for the treatment of cancer and post-operative pain. We have also evaluated in a Phase 1 clinical trial the AERx Pain Management System incorporating fentanyl. Future progress for these programs is contingent on either GlaxoSmithKline's recommitment or a new partner entering into another development agreement with us. If we enter into a development agreement with a new partner or with recommitment of GlaxoSmithKline, we will continue to pursue this program. There can be no assurance that this development program will be successful.

The Market

We have targeted breakthrough cancer pain as the first application for the AERx Pain Management System. More than four million cancer patients worldwide suffer from pain, a majority of which experience multiple breakthrough pain events each day. Breakthrough pain is defined as a sudden episode of severe pain that "breaks through" the pain level being managed by long-acting medication. We believe that the market potential for treatment of such pain events in the United States was approximately \$300.0 million in 2002.

Most pain medication taken by patients at home is delivered orally or by transdermal patch. These methods are typically slow to act and difficult to adjust to match the level of pain. Intravenous patient-controlled analgesia products, which are used primarily in hospitals, allow patients to self-administer pain medication on demand from a microprocessor-controlled infusion pump. Although effective for treating severe pain, widespread adoption of patient-controlled analgesia outside the hospital has been limited by the regular and expensive maintenance required by its use. Home use of patient-controlled analgesia can cost as much as \$4,000 per month, due partially to the home nursing required to maintain the needle site. However, there are currently no non-invasive pain management products that can match the speed of intravenous administration of narcotic analgesics for rapid relief of breakthrough pain events.

The Product

We believe that a patient-controlled, non-invasive drug delivery system that enables rapid uptake of medication could significantly expand the market for pain management in the outpatient setting. The AERx Pain Management System is expected to have features similar to current intravenous patient-controlled analgesia systems, but without the need for intravenous access and the resulting impairment of patient mobility and risk of infection. The AERx Pain Management device is being designed for patient-activated delivery in accordance with a physician-directed dosing program. The system's lockout mechanisms should reduce the risk of inappropriate dosing and a patented electronic patient identification feature should help prevent unauthorized use of the device. Dosing events are automatically recorded by the AERx device's microprocessor, allowing health care professionals to monitor patient use. We believe that these features of the AERx Pain Management System, combined with the speed of onset of pulmonary delivery, should provide a significant advance in pain management.

Clinical Development

In December 2001, we successfully completed Phase 2b clinical trials for our AERx Pain Management System. The multicenter, Phase 2b AERx morphine trials were conducted in the United States and Australia. Over 100 patients were treated in two separate studies. In a study of 16 patients with breakthrough pain from advanced cancer, AERx morphine demonstrated significantly faster onset of pain control and comparable overall pain relief when compared to an immediate release oral morphine solution. In a separate study of 89 patients with acute postoperative pain, the AERx Pain Management System was shown to provide pain relief comparable to intravenous morphine when given in similar doses. These data were presented at the American Pain Society 21st Annual Scientific Meeting held in March 2002, in Baltimore, Maryland.

If we enter into a development agreement with a new partner or with recommitment of GlaxoSmithKline, we will continue to pursue this program. There can be no assurance that this development program will be successful.

The Collaboration

In September 1997, we entered into a product development and worldwide commercialization agreement with SmithKline Beecham (now GlaxoSmithKline) covering the use of the AERx Pain Management System for the delivery of narcotic analgesics. In December 2000, the agreement was amended to transfer control of further development and provide certain other new rights to us. We also assumed responsibility for financing the remainder of all development activities under the agreement, as amended. Under the terms of the amended agreement, unless GlaxoSmithKline or we have terminated the agreement, GlaxoSmithKline can restore its rights and obligations to participate in and fund development and commercialization of the AERx Management System upon payment of a restoration fee. We have made available to GlaxoSmithKline all of the Phase 2b trial results and await their decision on further development plans. There can be no assurance that GlaxoSmithKline will elect to restore its rights. If we elect to terminate the agreement and continue or intend to continue any development activities, either alone or in collaboration with a third party, then we will be required to pay an exit fee to GlaxoSmithKline. The payment of the exit fee would not have a material impact on our financial position or operating results. We have the right to explore partnering options with other companies while this agreement is in effect. We are currently in active discussions with several alternate partners that could participate in this product if GlaxoSmithKline does not continue in its capacity. If GlaxoSmithKline elects to restore its rights under the agreement and if this system receives regulatory approval, we would expect to sell AERx hand-held devices and drug packets to, and to receive royalties on sales by, GlaxoSmithKline. Through December 31, 2001, we had received from GlaxoSmithKline and recognized as contract revenue approximately \$23.7 million in product development and milestone payments and \$10.0 million from the purchase of our common stock by GlaxoSmithKline, \$5.0 million of which was sold to GlaxoSmithKline at a 25% premium to market price. No additional product development or milestone payments were received during 2002.

Additional Potential AERx Applications

We believe that the AERx system has applicability for a range of compounds developed by pharmaceutical and biotechnology companies, including many compounds that cannot be delivered orally. Due to their large size and poor oral bioavailability, large molecules developed by the biotechnology industry are typically developed in liquid formulations and delivered by injection. We believe that the AERx platform can provide for improved delivery and increased utilization of these therapies.

We believe that we have greater experience in human clinical trials than any other company in the advanced pulmonary drug delivery market. In addition, we believe that the breadth of our human testing, which has encompassed both small molecules and large molecules for both local lung delivery and systemic delivery, is the most comprehensive ever conducted in pulmonary drug delivery.

We currently have eight programs, in addition to our collaboration with Novo Nordisk in which the use of the AERx delivery technology is being developed or evaluated across a range of drug therapies.

In addition, we have performed proactive targeting evaluations of molecules in development to determine their suitability for delivery via the AERx technology. We have identified approximately 50 candidates in the following therapeutic areas:

Cardiovascular disease	Endocrine disorder
Oncology	Infections
Neurological disease	Respiratory disease
Inflammatory conditions	

Sales and Marketing

We plan to establish additional collaborative relationships to develop and commercialize our AERx products. Through these collaborations, we intend to access resources and expertise to conduct late-stage clinical development and to market and sell AERx products. Ideal development partners will generally have both a commercial and a development presence in the target market and will also have a commitment to grow that market via our drug delivery technology. Where consistent with other objectives, we plan to give preference to development partners whose pipelines contain multiple products whose value could be enhanced by our AERx pulmonary drug delivery technology.

Manufacturing

Our clinical packet manufacturing facility was completed and validated in July 1998. We believe that it is capable of producing the AERx unit-dose packets in volumes adequate to support all of our current and anticipated clinical trials for our products under development and limited commercial requirements. Current capacity of this facility exceeds 20 million disposable packets per year.

While significant capital expenditures will be required to provide for the high-volume drug packet capacity needed to support commercialization of multiple AERx products, that capacity will be based on existing standard pharmaceutical manufacturing processes and no significant additional process development will be necessary. As a result, we believe that we can move to much higher levels of scale in a reasonably predictable manner and with minimal risk to our product development programs.

We completed the construction of a new facility for commercial scale production in 2001. We plan to internally produce the disposable nozzles, assemble the disposable unit-dose packets and fill the drug into the unit-dose packets. We will look to contract manufacturers to produce the main components and subassemblies for the AERx devices, but we plan to perform final assembly, calibration, testing and packaging of these devices ourselves. All of our manufacturing capabilities are being established at our facilities in Hayward, California.

There can be no assurance that we will not encounter unanticipated delays or expenses in establishing high-volume production capacity for AERx devices and disposable drug packets. Any such delays or expenses could harm our business.

Intellectual Property and Other Proprietary Rights

Our business and competitive position is dependent upon our ability to protect our proprietary technology and avoid infringing the proprietary rights of others. We have conducted original research on a number of aspects relating to pulmonary drug delivery. This research has led to novel ideas, which in turn have resulted in our being issued 84 United States patents to date, with 37 United States patent applications pending. In addition, we have purchased three United States patents covering inventions that are relevant to our technologies. We have 73 issued foreign patents and 108 foreign patent applications pending.

We are protecting the AERx technology platform through patents covering the AERx device, the AERx disposable drug packet and methods for using the AERx platform for specific drug delivery applications. Our patents, such as United States patents 5,469,750; 5,509,404; 5,522,385; 5,694,919; 5,735,263 and 5,855,564, address current or potential features related to the AERx device. Our United States patents 4,508,749; 5,497,763; 5,544,646; 5,718,222; 5,823,178 and 5,829,435, address current or potential features related to the AERx disposable drug packet and pertinent manufacturing methods.

We have conducted clinical studies demonstrating requirements for delivering insulin and insulin analogs by inhalation. These studies have allowed us to define various specific breathing maneuvers required for efficient, reproducible delivery of insulin and insulin analogs by inhalation. These discoveries have led to the issuance of key patents, which cover the delivery of insulin, and insulin analogs regardless of the device used (e.g., automatic or manual) or the drug formulation technique employed (e.g., liquid or powder). Examples of these patents are:

- United States patent 5,672,581, which is directed to the inspiratory or inhaled flow rate and volume at which an insulin aerosol should be released into the patient's inhalation.
- United States patent 5,884,620, which is directed to the role of total inhaled volume for the delivery of aerosolized insulin.

Our success will depend to a significant extent on our ability to obtain and enforce patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. Because the field of aerosolized drug delivery is crowded and a substantial number of patents have been issued and because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of our patents cannot be predicted. Commercialization of pharmaceutical products can also be subject to substantial delays as a result of the time required for product development, testing and regulatory approval.

Our current policy is to file patent applications on what we deem to be important technological developments that might relate to our products or methods of using our products. We also seek to protect some of these inventions through foreign counterpart applications in selected other countries. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may limit the patent protection we will be able to secure outside of the United States.

The coverage claimed in a patent application can be significantly reduced before a patent is issued, either in the United States or abroad. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated. Furthermore, patents already issued to us or our pending applications may become subject to dispute, and any disputes could be resolved against us. For example, Eli Lilly brought an action against us seeking to have one or more employees of Eli Lilly named as co-inventors on some of our patents. In addition, because patent applications in the United States are currently maintained in secrecy until patents issue and patent applications in certain other countries generally are not published until more than 18 months after they are first filed, and because publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first creator of inventions covered by pending patent applications or that we were the first to file patent applications on such inventions.

Our policy is to require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the relationship shall be kept confidential except in specified circumstances. These agreements also provide that all inventions developed by the individual on behalf of us shall be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the

invention if we wish to pursue such protection. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets or other proprietary information in the event of unauthorized use or disclosure of such information.

We also execute confidentiality agreements with outside collaborators and consultants. However, disputes may arise as to the ownership of proprietary rights to the extent that outside collaborators or consultants apply technological information developed independently by them or others to our projects, or apply our technology to other projects, and there can be no assurance that any such disputes would be resolved in our favor.

We may incur substantial costs if we are required to defend ourselves in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process and there would be no assurance that any license required under any such patent would be made available to us on acceptable terms, if at all. Litigation may also be necessary to enforce our patents against others or to protect our know-how or trade secrets. Such litigation could result in substantial expense, and there can be no assurance that any litigation would be resolved in our favor.

Competition

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. We are aware of a number of companies currently seeking to develop new products and non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems, buccal, or mouth cavity, and colonic absorption systems. Several of these companies may have developed or are developing dry powder devices that could be used for pulmonary delivery. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do. Accordingly, our competitors may succeed in developing competing technologies, obtaining Food and Drug Administration, ("FDA") approval for products or gaining market acceptance more rapidly than we can.

We believe our technology and integrated pulmonary delivery systems approach provides us with important competitive advantages in the delivery of drugs compared with currently known alternatives. While we believe that the capabilities of our AERx platform will provide us with certain important competitive advantages, new drugs or further developments in alternative drug delivery methods may provide greater therapeutic benefits, or comparable benefits at lower cost, in a given drug application than the AERx system.

Several companies are marketing and developing dry powder and other devices that could have applications for pulmonary drug delivery, including Nektar Therapeutics (formerly Inhale Therapeutics Systems) and Alkermes Pharmaceuticals, Inc. These companies also have collaborative arrangements with corporate partners for the development of pulmonary delivery systems for insulin. There can be no assurance that competitors will not introduce products or processes competitive with or superior to ours.

Government Regulation

All medical devices and drugs, including our products under development, are subject to extensive and rigorous regulation by the federal government, principally the FDA, and by state and local governments. If these products are marketed abroad, they also are subject to export requirements and to regulation by foreign governments. The regulatory clearance process is generally lengthy, expensive and uncertain. The Federal Food, Drug, and Cosmetic Act, and other federal statutes and regulations, govern or influence the development, testing, manufacture, labeling, storage, approval, advertising, promotion, sale and distribution of such products. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including warning letters, fines,

product recalls or seizures, injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

The activities required before a new drug product may be marketed in the United States include preclinical and clinical testing. Preclinical tests include laboratory evaluation of product chemistry and other characteristics and animal studies to assess the potential safety and efficacy of the product as formulated. Many preclinical studies are regulated by the FDA under a series of regulations called the current Good Laboratory Practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be replicated.

The preclinical work necessary to administer investigational drugs to human subjects is summarized in an Investigational New Drug application to the FDA. FDA regulations provide that human clinical trials may begin 30 days following submission of an Investigational New Drug application, unless the FDA advises otherwise or requests additional information. There is no assurance that the submission of an Investigational New Drug application will eventually allow a company to commence clinical trials. Once trials have commenced, the FDA may stop the trials by placing them on "clinical hold" because of concerns about, for example, the safety of the product being tested.

Clinical testing involves the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified principal investigator, usually a physician, pursuant to FDA reviewed protocol. Each clinical study is conducted under the auspices of an Institutional Review Board at each of the institutions at which the study will be conducted. An Institutional Review Board will consider, among other things, ethical factors, the safety of human subjects, informed consent requirements and the possible liability of the institution. Human clinical trials typically are conducted in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing the product in a small number of patients or normal volunteers, primarily for safety, at one or more dosage levels, as well as characterization of a drug's pharmacokinetic and/or pharmacodynamic profile. In Phase 2 clinical trials, in addition to safety, the efficacy of the product is usually evaluated in a patient population. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically dispersed sites.

A company seeking FDA approval to market a new drug must file a new drug application with the FDA pursuant to the Federal Food, Drug and Cosmetic Act. In addition to reports of the pre-clinical and clinical trials conducted under an effective Investigational New Drug application, the new drug application includes information pertaining to the preparation of the drug substance, analytical methods, drug product formulation, details on the manufacture of finished products and proposed product packaging and labeling. Submission of a new drug application does not assure FDA approval for marketing. The application review process can take a year or more to complete, although reviews of treatments for cancer and other life-threatening diseases may be accelerated or expedited. However, 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.

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 could also determine that there is insufficient data or experience with chronic administration of drugs delivered via the lung for systemic effect to demonstrate that such chronic administration is safe, and could require further studies. The FDA also may require additional clinical tests (i.e., Phase 4 clinical trials) following new drug application approval to confirm safety and efficacy.

In addition, the FDA may in some circumstances impose restrictions on the use of the drug that may be difficult and expensive to administer. 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 drug. The product testing and approval process is likely to take a substantial number of

years and involves expenditure of substantial resources. There is no guarantee that any approval will be granted on a timely basis, or at all. Upon approval, a prescription drug may only be marketed for the approved symptoms in the approved dosage forms and at the approved dosage.

Among the other requirements for drug product approval is the requirement that the prospective manufacturer conform to the FDA's Good Manufacturing Practices ("GMP") regulations for drugs. In complying with the GMP regulations, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. The FDA periodically inspects manufacturing facilities in the United States to assure compliance with applicable GMP requirements. A company's failure to comply with the GMP regulations or other FDA regulatory requirements could have a material adverse effect on that company's business.

Products marketed outside the United States that are manufactured in the United States are subject to certain FDA regulations, as well as regulation by the country in which the products are to be sold. We also would be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are marketed abroad. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries usually must be obtained prior to the marketing of the product in those countries. The approval process varies from country to country and the time required may be longer or shorter than that required for FDA approval.

We are subject to numerous federal, state and local laws relating to such matters as:

- controlled drug substances;
- safe working conditions;
- manufacturing practices;
- environmental protection;
- fire hazard control; and
- disposal of hazardous or potentially hazardous substances.

The United States Drug Enforcement Agency ("DEA"), regulates controlled drug substances, such as morphine and other narcotics. Establishments handling controlled drug substances such as morphine must be registered and inspected by the DEA and may be subject to export, import, security and production quota requirements. In addition, advertising and promotional materials are, in certain instances, subject to regulation by the Federal Trade Commission. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future or that such laws or regulations will not have a material adverse effect upon our business.

Product development and approval within this regulatory framework takes a number of years, involves the expenditure of substantial resources and is uncertain. Many drug products ultimately do not reach the market because they are not found to be safe or effective or cannot meet the FDA's other regulatory requirements. In addition, there can be no assurance that the current regulatory framework will not change or that additional regulation will not arise at any stage of our product development that may affect approval, delay the submission or review of an application or require additional expenditures by us. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of our products under development, and delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business.

International Scientific Advisory Board

We have assembled an International Scientific Advisory Board comprised of scientific and development advisors that provide expertise, on a consulting basis, in the areas of pain management, allergy and immunology, pharmaceutical development and drug delivery, but are employed elsewhere on a

full time basis. As a result, they can only spend a limited amount of time on our affairs. The International Scientific Advisory Board assists us on issues related to potential product applications, product development and clinical testing. Its members, and their affiliations and areas of expertise, include:

<u>Name</u>	<u>Affiliation</u>	<u>Area of Expertise</u>
Peter R. Byron, Ph.D.	Medical College of Virginia, Virginia Commonwealth University	Aerosol Science/ Pharmaceutics
Michael J. Cousins, M.D.	University of Sydney, Australia	Pain Management
Peter S. Creticos, M.D.	The Johns Hopkins University School of Medicine	Allergy/Immunology/ Asthma
Lorne G. Eltherington, M.D., Ph.D.	Sequoia Hospital	Pain Management
Igor Gonda, Ph.D.	Acrux Limited	Drug Delivery
Henrik Egesborg Hansen	Novo Nordisk A/S	Device Technology
Vincent H.L. Lee, Ph.D.	University of Southern California	Pharmaceutics/Drug Delivery
Lawrence M. Lichtenstein, M.D., Ph.D. . .	The Johns Hopkins University School of Medicine	Allergy/Immunology
Robert E. Ratner, M.D.	MedStar Research Institute	Endocrinology
W. Leigh Thompson, M.D., Ph.D.	CEO, Profound Quality Resources	Pharmaceutical Product Development

Employees

As of February 28, 2003, we had 285 employees, of whom 240 were in research and development and product development and 45 were in business development, finance and administration. We believe that our future success is dependent on attracting and retaining highly skilled scientific, sales and marketing and senior management personnel. Competition for such skills is intense, and there is no assurance that we will continue to be able to attract and retain high-quality employees. Our employees are not represented by any collective bargaining agreement. We consider our relations with our employees to be good.

Corporate History and Website Information

We were incorporated in California in 1991. Our principal executive offices are located at 3929 Point Eden Way, Hayward, California 94545, and our main telephone number is (510) 265-9000. Investors can obtain access to this annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and all amendments to these reports, free of charge, on our website at <http://www.aradigm.com> as soon as reasonably practicable after such filings are electronically filed with the SEC. The public may read and copy any material we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C., 20549. The public may obtain information on the operations of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site, <http://www.sec.gov>, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

MANAGEMENT

Directors and Executive Officers

The directors and executive officers of the Company and their ages as of February 28, 2003 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Richard P. Thompson	51	President, Chief Executive Officer and Chairman of the Board
Bikash K. Chatterjee	44	Vice President, Pharmaceutical Operations
Thomas C. Chesterman	43	Senior Vice President and Chief Financial Officer
Steven J. Farr, <i>Ph.D.</i>	44	Vice President, Research and Development
Maximillian D. Fiore	48	Vice President, Engineering
Klaus D. Kohl, <i>Ph.D.</i>	52	Senior Vice President and Technical Director, iDMS program
V. Bryan Lawlis, <i>Ph.D.</i>	51	Chief Operating Officer
Daniel P. Maher	46	Vice President, Program Management
Norma L. Milligin	64	Vice President, Human Resources
Babatunde A. Otulana, <i>M.D.</i>	46	Vice President, Clinical & Regulatory Affairs
Frank H. Barker(1)	72	Director
Stan M. Benson(2)	52	Director
Igor Gonda(2)	55	Director
John Nehra(1)	54	Director
Wayne I. Roe(1)	53	Director
Virgil D. Thompson(2)	63	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

Richard P. Thompson has been a director and has served as our President and Chief Executive Officer since 1994 and was named Chairman of the Board in 2000. From 1991 to 1994, he was President of LifeScan, Inc., a Johnson & Johnson Company, a diversified health care company. In 1981, Mr. Thompson co-founded LifeScan, which was sold to Johnson & Johnson in 1986. Mr. Thompson holds a B.S. in biological sciences from the University of California at Irvine and an MBA from California Lutheran College.

Bikash K. Chatterjee has served as our Vice President, Pharmaceutical Operations since March 1998. From September 1997 until March 1998, Mr. Chatterjee was our Director of Pharmaceutical Operations. From January 1992 to August 1997, Mr. Chatterjee was the plant manager for manufacturing Boehringer-Mannheim's disposable coagulation testing system. From 1988 to 1992, he held a number of senior manufacturing positions at various pharmaceutical companies, including Syntex Corporation. Mr. Chatterjee holds a B.A. in biochemistry and a B.S. in chemical engineering from the University of California at San Diego.

Thomas C. Chesterman has served as our Senior Vice President and Chief Financial Officer since August 2002. From 1996 to 2002, Mr. Chesterman was Vice President and Chief Financial Officer at Bio-Rad Laboratories, a life science research products and clinical diagnostics company. From 1993 to 1996, Mr. Chesterman was Vice President of Strategy and Chief Financial Officer of Europolitan AB, a telecommunications company. Mr. Chesterman holds a B.A. from Harvard University and an MBA, Finance and Accounting, from the University of California at Davis.

Stephen J. Farr, Ph.D., has served as our Vice President, Research and Development since July 2000. From January 1999 to June 2000, Dr. Farr was Vice President, Pharmaceutical Sciences and from January 1995 to December 1998, he was Senior Director of Pharmaceutical Sciences. From September 1985 to

December 1994, Dr. Farr was Lecturer and later Senior Lecturer in the Welsh School of Pharmacy, Cardiff University, United Kingdom. He was a founder and director of Cardiff Scintigraphics Ltd., a pharmaceutical company. Dr. Farr holds a B.Sc. in pharmacy from DeMontfort University, a Ph.D. in pharmaceuticals from the University of Wales and is a Visiting Associate Professor in the Department of Pharmaceutics, School of Pharmacy, Virginia Commonwealth University, Richmond, Virginia.

Maximillian D. Fiore has served as our Vice President, Engineering since September 1994. From January 1991 to September 1994, Mr. Fiore served as Director of Engineering at LifeScan, Inc. From November 1989 to December 1990, Mr. Fiore held various senior engineering and management positions with Abbott Laboratories, a pharmaceutical and medical device company. Mr. Fiore holds a B.S.E.E. and a B.S. in engineering from Northwestern University and an M.S.E.E. in bio-medical/microprocessor-based instrument design from the University of Wisconsin.

Klaus D. Kohl, Ph.D., has served as our Senior Vice President and Technical Director, iDMS program since August 2002. From January 2002 to August 2002, he served as Vice President, Quality. From October 2000 to December 2001, he held the position of Vice President, Quality. From 1998 to 2000, Dr. Kohl was Quality Manager of GE Bayer Silicones, a joint venture of General Electric and Bayer Corporation. From 1996 to 1998, he was Vice President of Quality Assurance, Pharmaceutical Division, Bayer Corporation North America. Dr. Kohl joined Bayer in 1985 and held various positions in quality assurance/drug product development in the United States and in Europe. Previously, Dr. Kohl spent more than seven years in basic research at the Research Center Juelich, Germany and the Max Planck Institute, Dortmund Germany. Dr. Kohl received his undergraduate degree in mathematics and physics from the University of Marburg, Germany and his Ph.D. from the University of Aachen, Germany.

V. Bryan Lawlis, Ph.D., joined in 2001 as our Chief Operating Officer. Previously, he was acting Chairman, President and Chief Executive Officer of Diosynth RTP, Inc., a biopharmaceutical company. Dr. Lawlis founded Covance Biotechnology Services, a contract biopharmaceutical manufacturing operation, and served as its President and Chief Executive Officer from 1996 to 2000, and as Chairman in 2001, when it was sold to Diosynth, a division of Akzo Nobel. From 1981 to 1996 he was employed at Genencor, Inc. and Genentech, Inc. His last position at Genentech was Vice President of Process Sciences. Dr. Lawlis holds a B.A. in microbiology from the University of Texas at Austin, and a Ph.D. in biochemistry from Washington State University.

Daniel P. Maher has served as our Vice President, Program Management and Program Director, AERx iDMS, since April 2001. From November 1998 to April 2001, Mr. Maher was Sr. Director of Program Management, and Program Director, AERx iDMS. From 1996 to 1998, he was the Director of Clinical Operations at Covance Inc., a drug development services company. Previously, Mr. Maher was Vice President of Operations at Spectra Biomedical Inc., a biotechnology company. Earlier, he was the Director of Therapeutics Project Management at Chiron Corporation and held various positions at Genentech in operations and product development, ultimately heading the Product Development Group. Mr. Maher holds a B.A. in biology from San Francisco State University and an MBA in health services management from Golden Gate University.

Norma L. Milligin has served as our Vice President, Human Resources since September 1998. From January 1995 to August 1998, Ms. Milligin worked as a consultant in the human resources area for a number of firms. From 1985 to January 1994, she held positions as Vice President of Human Resources at LifeScan, Inc and Chemtrak, Inc., a medical device company. From 1978 to 1985, she also held a number of senior human resource positions at Syntex Corporation, a pharmaceutical company. Ms. Milligin has taught organizational behavior at Pepperdine University, and holds a B.S. in business from the University of Colorado and an MBA from Pepperdine University.

Babatunde A. Otulana, M.D., has served as our Vice President, Clinical and Regulatory Affairs since October 1997. From 1991 to September 1997, Dr. Otulana was a Medical Reviewer in the Division of Pulmonary Drug Products at the Center for Drug Evaluation and Research, Food and Drug Administration. Dr. Otulana currently serves as an Assistant Clinical Professor in Pulmonary Medicine at the school of Medicine, University of California, Davis. Dr. Otulana obtained his M.D. from the

University of Ibadan, Nigeria and completed a Pulmonary Fellowship at Papworth Hospital, University of Cambridge, U.K. and at Howard University Hospital, Washington, D.C.

Frank H. Barker has been a director since May 1999. He has been the Chairman of U.S. Dermatologics, Inc., an over-the-counter pharmaceutical company, since February 1999, and was its President and Chief Executive Officer from October 1997 to February 1999. From January 1989 to January 1996, Mr. Barker served as a company group chairman of Johnson & Johnson. Mr. Barker holds a B.A. in business administration from Rollins College, Winter Park, Florida. Mr. Barker is a director of Catalina Marketing Corporation, a direct-to-consumer marketing company.

Stan M. Benson has been a director since April 2001. Mr. Benson served as Senior Vice President, Sales and Marketing of Amgen, Inc., a biotechnology company from 1995 to 2001. Prior to joining Amgen, Mr. Benson worked at Pfizer, Inc., a pharmaceutical company, for 19 years in various senior management positions. Mr. Benson received a B.A. and an M.S. from New York University. Mr. Benson is now retired.

Igor Gonda, Ph.D. has been a director since September 2001. He is the Chief Executive Officer and Managing Director of Acrux Limited, a drug delivery company in Melbourne, Australia. Dr. Gonda was our Chief Scientific Officer until December 2001 and previously held the position of Vice President, Research and Development, from October 1995 until July 2001. From February 1992 to September 1995, Dr. Gonda was a Senior Scientist and Group Leader at Genentech, Inc. Prior to that, Dr. Gonda held academic positions at the University of Aston in Birmingham, UK, and the University of Sydney, Australia. Dr. Gonda has a B.Sc. in chemistry and a Ph.D. in physical chemistry from Leeds University, UK. He is the Chairman of Scientific Boards at Aradigm Corporation and Exhale Therapeutics, Inc.

John M. Nehra has been a director since December 2001. Mr. Nehra is a Special Partner of NEA 10, a venture capital partnership, and a General Partner of NEA VI, NEA VII, NEA VIII and NEA IX. Mr. Nehra is also the managing General Partner of Catalyst Ventures, a venture capital partnership. Prior to joining NEA and its affiliated venture funds in 1989, Mr. Nehra was Managing Director of Alex Brown & Sons, an investment banking firm. Upon joining Alex. Brown in 1975, Mr. Nehra was responsible for building the firm's healthcare research and healthcare banking practice, and forming its capital markets group. Mr. Nehra is a director of Iridex Corporation and Davita Corporation and also serves on the boards of several privately held healthcare companies. Mr. Nehra holds a B.A. from the University of Michigan.

Wayne I. Roe has been a director since May 1999. Mr. Roe was Senior Vice President of United Therapeutics Corporation, a pharmaceutical manufacturer, from 1999 to 2000. He was Chairman of Covance Health Economics and Outcomes Services, Inc., a strategic marketing firm, from 1996 to 1998. From June 1988 to March 1996, Mr. Roe was the President of Health Technology Associates, a pharmaceutical industry consulting firm. Mr. Roe received a B.A. from Union College, an M.A. from the State University of New York at Albany and an M.A. from the University of Maryland. He is also a director of Ista Pharmaceuticals Inc., Aderis Pharmaceuticals Inc., Novosonics Inc. and Favril Inc. Mr. Roe currently is an independent consultant in the life sciences industry.

Virgil D. Thompson has been a director since June 1995. Since November 2002, Mr. Thompson has been President and Chief Executive Officer of Angstrom Pharmaceuticals, a pharmaceutical company. From September 2000 to November 2002, he was President, Chief Executive Officer and Director of Chimeric Therapies, Inc., a biotechnology company. From May 1999 until September 2000, he was the President, Chief Operating Officer and a Director of Bio-Technology General Corp., a pharmaceutical company. From January 1996 to April 1999, he was the President and Chief Executive Officer and a Director of Cytel Corporation, a biopharmaceutical company. From 1994 to 1996, he was President and Chief Executive Officer of Cibus Pharmaceuticals, Inc., a drug delivery device company. From 1991 to 1993 he was President of Syntex Laboratories, Inc., a pharmaceutical company. Mr. Thompson holds a B.S. in pharmacy from Kansas University and a J.D. from The George Washington University Law School. He is also a director of Questcor Pharmaceutical Corporation and Bio-Technology General Corporation.

Item 2. *Properties*

At December 31, 2002, we leased a total of approximately 253,898 square feet of office space in two office parks. We leased approximately 163,658 square feet in three buildings in an office park at 3929 Point Eden Way, Hayward, California and leased 90,240 square feet in one building in an office park located at 2704 West Winton Avenue, Hayward, California. The leases for the various office spaces expire at various times through the year 2016. Minimum annual payments under these leases will be approximately \$5.2 million in 2003 and \$5.3 million in 2004. We use this space for general administrative, product development, clinical, manufacturing and research and development purposes. We believe that our existing facilities are adequate to meet our requirements for the near term and that additional space will be available on commercially reasonable terms if needed.

Item 3. *Legal Proceedings*

In June 1998, Eli Lilly and Company filed a complaint against us in the United States District Court for the Southern District of Indiana. The complaint made various allegations against us, arising from our decision to enter into an exclusive collaboration with Novo Nordisk A/S with respect to the development and commercialization of a pulmonary delivery system for insulin and insulin analogs. We sponsored various studies of the pulmonary delivery of insulin and insulin analogs using materials supplied by Lilly under a series of agreements dating from January 1996. We and Lilly had also conducted negotiations concerning a long-term supply agreement under which Lilly would supply bulk insulin to us for commercialization in our AERx insulin Diabetes Management System, and a separate agreement under which we would license certain intellectual property to Lilly. These negotiations were terminated after we proceeded with our agreement with Novo Nordisk A/S. The complaint sought a declaration that Lilly scientists were co-inventors of patent applications filed by us relating to pulmonary delivery of an insulin analog or, in the alternative, enforcement of an alleged agreement to grant Lilly a nonexclusive license under such patent application. The complaint also contained allegations of misappropriation of trade secrets, breach of fiduciary duty, conversion and unjust enrichment and seeks unspecified damages and injunctive relief. We filed an answer denying all material allegations of the complaint and a motion for summary judgment directed against all claims in Lilly's complaint. The Court granted our motion as to Lilly's claim to enforce an alleged license agreement, for misappropriation of trade secrets, breach of fiduciary duty, conversion, estoppel and breach of contract (in part) and dismissed those claims from the case. After trial of the remaining claims in April 2002, the jury returned verdicts in favor of Aradigm and against Lilly on three of four of Lilly's asserted claims on co-inventorship and on Lilly's unjust enrichment claim. The jury returned verdicts in favor of Lilly on one of Lilly's claims of co-inventorship and on two breaches of contract claims, awarding Lilly damages of \$1 for each breach of contract claim. In June 2002, the Court entered a judgment based on and incorporating the jury's verdict. In March 2003, following disposition of various post-trial motions, the court entered final judgment based on and incorporating the jury's verdict. Either party may appeal from that Final Judgment; the deadline for such appeal is April 4, 2003. If the present final judgment is upheld, a Lilly scientist would be named co-inventor thereby giving Lilly rights of an owner, along with us, on one of our patents relating to pulmonary delivery of monomeric insulin lispro. Should Lilly appeal and ultimately succeed in that appeal, the possible consequences include reversal of the Court's decision granting Aradigm summary judgment on several of Lilly's claims or reversal of the Court's refusal to grant Lilly certain post-judgment relief it had requested. Lilly also contends that factual findings made in any trial of this case would have some effect on other patents relating to pulmonary delivery of monomeric insulin lispro. Management believes that this litigation will not have a material adverse effect on our business.

Item 4. *Submission of Matters to a Vote of Security Holders*

No matters were submitted to a vote of our security holders during the quarter ended December 31, 2002.

PART II

Item 5. *Market for the Registrant's Common Stock and Related Stockholder Matters*

Market Information

Our common stock is traded on The Nasdaq National Market under the symbol "ARDM." The following table sets forth the intra-day high and low sale prices for our common stock as reported on The Nasdaq Stock Market for the periods indicated below.

	<u>High</u>	<u>Low</u>
2001		
First Quarter	\$15.25	\$4.28
Second Quarter	8.56	4.88
Third Quarter	6.92	3.02
Fourth Quarter	7.10	3.15
2002		
First Quarter	\$ 7.29	\$4.01
Second Quarter	4.61	3.43
Third Quarter	3.99	1.94
Fourth Quarter	2.81	1.30
2003		
First Quarter (through February 28, 2003)	\$ 1.85	\$0.75

On February 28, 2003, there were 165 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends. We currently intend to retain any future earnings to finance the growth and development of our business and therefore do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

As of February 10, 2003, we issued 18,992,391 shares of our common stock at \$0.79 per share and warrants to purchase 4,273,272 shares of our common stock at \$1.07 per share to certain investors for an aggregate purchase price of approximately \$15.0 million in a private placement. The warrants are exercisable at the election of the warrant holders for a four-year term. In addition, in connection with this private placement, we have issued to certain of the investors in the private placement warrants to purchase an aggregate of 4,016,024 shares of our common stock at \$1.12 per share in exchange for the cancellation of an equal number of warrants to purchase our common stock at \$6.97 per share, held by the same investors. These securities have not been registered under the Securities Act of 1933, as amended, by virtue of Regulation D promulgated under such Act.

For information regarding securities authorized for issuance under equity compensation plans, see Item 12.

Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and notes thereto included in this Report on Form 10-K.

	Years Ended December 31,				
	2002	2001	2000	1999	1998
	(In thousands, except per share amounts)				
Statements of Operations Data:					
Contract and license revenues	\$ 28,967	\$ 28,916	\$ 20,303	\$ 16,812	\$ 17,515
Operating expenses:					
Research and development	54,680	58,836	48,176	33,625	25,549
General and administrative	10,394	9,355	9,271	7,849	8,661
Total expenses	<u>65,074</u>	<u>68,191</u>	<u>57,447</u>	<u>41,474</u>	<u>34,210</u>
Loss from operations	(36,107)	(39,275)	(37,144)	(24,662)	(16,695)
Interest income	818	1,324	3,110	1,947	1,754
Other income(2)	—	6,675	—	—	—
Interest expense and other	(642)	(1,081)	(1,528)	(888)	(513)
Net loss	(35,931)	(32,357)	(35,562)	(23,603)	(15,454)
Deemed dividend	—	(10,722)	—	—	—
Net loss applicable to common shareholders	<u>\$ (35,931)</u>	<u>\$ (43,079)</u>	<u>\$ (35,562)</u>	<u>\$ (23,603)</u>	<u>\$ (15,454)</u>
Basic and diluted loss per share applicable to common shareholders(1):					
Net loss applicable to common shareholders	<u>\$ (1.19)</u>	<u>\$ (1.98)</u>	<u>\$ (2.07)</u>	<u>\$ (1.66)</u>	<u>\$ (1.32)</u>
Shares used in computing basic and diluted loss per share applicable to common shareholders(1)	<u>30,261</u>	<u>21,792</u>	<u>17,196</u>	<u>14,216</u>	<u>11,682</u>
Balance Sheet Data:					
Cash, cash equivalents and short term investments	\$ 29,890	\$ 71,164	\$ 44,381	\$ 31,259	\$ 31,036
Working capital	14,486	48,308	19,862	22,797	16,620
Total assets	97,129	132,100	71,371	50,790	44,949
Noncurrent portion of notes payable and capital lease obligations	497	2,427	6,230	9,609	4,570
Redeemable convertible preferred stock...	30,665	30,735	—	—	—
Accumulated deficit	(189,443)	(153,535)	(110,441)	(74,904)	(51,279)
Total shareholders' equity	41,410	71,149	37,785	24,157	21,660

(1) See Note 1 of Notes to Financial Statements for an explanation of shares used in computing basic and diluted net loss per share.

(2) Other income consists of the gain related to forgiveness of outstanding notes and interests by Genentech, previously classified as an extraordinary item. The Company early adopted Statement of Financial Accounting Standard ("SFAS") 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB 13 and Technical Corrections", which requires the reclassification of this type of extraordinary item as a component of operating results.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The discussion below contains forward-looking statements that are based on the beliefs of management, as well as assumptions made by, and information currently available to management. Our future results, performance or achievements could differ materially from those expressed in, or implied by, any such forward-looking statements as a result of certain factors, including, but not limited to, those discussed in this section as well as in the section entitled "Risk Factors." This discussion should be read in conjunction with the financial statements and notes to financial statements.

Overview

Since our inception in 1991, we have been engaged in the development of pulmonary drug delivery systems. As of December 31, 2002, we had an accumulated deficit of \$189.4 million. We have not been profitable since inception and expect to incur additional operating losses over the next several years as research and development efforts, preclinical and clinical testing activities and manufacturing scale-up efforts expand and as we plan and build our late-stage clinical and early commercial production capabilities. To date, we have not had any material product sales and do not anticipate receiving any revenue from the sale of products for the next several years. The sources of working capital have been equity financings, equipment lease financings, contract and license revenues and interest earned on investments.

We have performed initial feasibility work on a number of compounds and have been compensated for expenses incurred while performing this work in several cases pursuant to feasibility study agreements with third parties. Once feasibility is demonstrated with respect to a potential product, we seek to enter into development contracts with pharmaceutical corporate partners. We currently have such agreements pursuant to which we are developing pulmonary delivery systems with Novo Nordisk A/S, to manage diabetes using insulin and other blood glucose regulating compounds, and with GlaxoSmithKline, to manage acute and breakthrough pain using opioid analgesics.

The collaborative agreement with Novo Nordisk A/S provides for reimbursement of research and development expenses as well as additional payments to us as we achieve certain significant milestones. We also expect to receive royalties from this development partner based on revenues from sales of product and to receive revenue from the manufacturing of unit dose packets and hand-held devices. We recognize revenues under the terms of our collaborative agreement as the research and development expenses are incurred, to the extent they are reimbursable. During 2002, this partner-funded program has contributed approximately 93% of our total contract revenues. Novo Nordisk A/S with its subsidiary is considered a related party.

During December 2000, GlaxoSmithKline and we amended the product development and commercialization agreement whereby we assumed full control and responsibility for conducting and financing the remainder of all development activities. Under the amendment, unless we have terminated the agreement, GlaxoSmithKline can restore its rights to participate in development and commercialization of the product upon payment of a restoration fee to us. We have made available to GlaxoSmithKline all of the Phase 2b trial results and await their decision on further development plans. There can be no assurance that GlaxoSmithKline will elect to restore its rights. If we elect to terminate the agreement and continue or intend to continue any development activities, either alone or in collaboration with a third party, we will be obligated to pay an exit fee to GlaxoSmithKline at which time all rights related to development and commercialization of the product will be returned to us. If we elect to pay the exit fee it will not have a material impact on our financial position or operating results. If we enter into a development agreement with a new partner or with recommitment of GlaxoSmithKline, we will continue to pursue this program.

In February 2001, we announced that Genentech had discontinued the development of dornase alfa using our proprietary AERx Respiratory Management System. We also entered into a new agreement allowing Genentech to evaluate the feasibility of using the AERx Pulmonary Drug Delivery System for pulmonary delivery of other Genentech compounds. Under the terms of the agreement, Genentech did not require us to repay the loan of funds required to conduct product development under the discontinued

program. As a result of forgiveness of the loan and accrued interest the company recorded during the first quarter of 2001 approximately \$6.7 million as a component of operating results. During 2001, we reimbursed Genentech \$773,000 for unspent project prepayments.

In addition to the diabetes and pain programs, we have six additional programs in development, five of which are partner funded. It is our policy not to disclose the partner and/or the drug until a long-term development agreement has been established; both parties agree to highlight a clinical advancement in the program or under special circumstances in which both parties agree to disclosure. In 2002, we announced successful clinical results from one partnered trial with interferon alpha when an abstract was accepted at a leading scientific session, in which the partner was not disclosed. In addition, a gene therapy collaboration with geneRx+ was disclosed which hold certain potentially beneficial licensing rights to Aradigm.

Critical Accounting Policies

We consider certain accounting policies related to revenue recognition, impairment of long-lived assets and the use of estimates to be critical accounting policies.

Revenue Recognition

Contract revenues consist of revenue from collaboration agreements and feasibility studies. We recognize revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). Under the agreements, revenue is recognized as costs are incurred. Deferred revenue represents the portion of all refundable and nonrefundable research payments received that have not been earned. In accordance with contract terms, milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements and, accordingly, are generally recognized as revenue either upon the completion of the milestone effort when payments are contingent upon completion of the effort or are based on actual efforts expended over the remaining term of the agreements when payments precede the required efforts. Costs of contract revenues approximate such revenue and are included in research and development expenses. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Refundable development and license fee payments are generally not refundable once the specific performance criteria are achieved.

Impairment of Long-Lived Assets

We adopted SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," on January 1, 2002. SFAS 144 superseded SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." The primary objectives of SFAS 144 are to develop one accounting model based on the framework established in SFAS 121 for long-lived assets to be disposed of by sale, and to address significant implementation issues. Our adoption of SFAS 144 did not have a material impact on our financial position or results of operations.

The Company reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values and the loss is recognized on the Statements of Operations.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes to the financial statements. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization period for payments received from

product development and license agreements as they relate to the revenue recognition of deferred revenue and assumptions for valuing options and warrants. Actual results could differ from these estimates.

Results of Operations

Years Ended December 31, 2002, 2001 and 2000

Contract Revenues. We reported revenues from collaborative contracts of \$29.0 million in 2002, compared to \$28.9 million in 2001 and \$20.3 million in 2000. The marginal increase in revenue in 2002 compared to 2001 is primarily due to increases in partner-funded project development revenue from Novo Nordisk A/S, which was \$26.9 million in 2002 compared to \$26.0 million in 2001 and contract revenue from other partner-funded programs, which was \$2.1 million in 2002 and \$1.4 million in 2001. The increase in revenue was offset by no partner-funded project development revenue from GlaxoSmithKline in 2002 compared to \$1.5 million in 2001. The revenue in 2000 consisted of \$15.4 million from partner-funded project development revenue from Novo Nordisk A/S, \$3.4 million from partner-funded project development revenue from GlaxoSmithKline, and \$1.5 million from contract revenue from other partner-funded programs. Costs associated with contract research revenue are included in research and development expenses.

Research and Development Expenses. Research and development expenses decreased in 2002 compared to 2001 and 2000. These expenses were \$54.7 million in 2002 compared to \$58.8 million in 2001 and \$48.2 million in 2000. Research and development expenses as a percentage of total operating expenses were 84% in 2002, 86% in 2001, and 84% in 2000. Research and development expenses in 2002 decreased by \$4.2 million or 7% compared to 2001, primarily due to a reduction in development efforts to support the ongoing program with Novo Nordisk A/S and the pain management program and a reduction in manufacturing scale-up efforts, but offset by increases in expenses in other funded and unfunded development programs. Research and development expenses associated with collaborative agreements approximate contract revenue as these expenses are incurred under the program agreements. Research and development expenses in 2001 increased by \$10.6 million or 22% over 2000, which was primarily due to the expansion of development efforts to support the ongoing program with Novo Nordisk A/S and, to a lesser extent, increases in development efforts for other funded and unfunded development areas including manufacturing scale-up efforts.

These expenses represent proprietary research expenses as well as the costs related to contract research revenue and include salaries and benefits of scientific and development personnel, laboratory supplies, consulting services and the expenses associated with the development of manufacturing processes. We expect research and development spending will increase over the next few years if we continue to expand our development activities to support current and potential future collaborations and initiate commercial manufacturing of the AERx systems. The increase in research and development expenditures cannot be predicted accurately as it depends in part upon continued future success and funding levels supported by our existing development collaborations, as well as obtaining new collaborative agreements.

Our lead development program is targeted at the pulmonary delivery of insulin in patients with diabetes with our partner Novo Nordisk A/S. Since the successful completion of Phase 2b clinical studies in 2001 and formal presentation of those results in 2002, we and Novo Nordisk A/S have initiated Phase 3 clinical studies in the third quarter of 2002.

Our next most advanced program is in the area of pain management with our partner GlaxoSmithKline pursuant to our development agreement for the AERx Pain Management System and the delivery of narcotic analgesics. During December 2001, we successfully completed Phase 2b clinical trial results for the AERx System in the administration of morphine. As part of our agreement with GlaxoSmithKline, we are working with them as well as presenting this data to other interested parties on taking this program forward into further clinical development. If we enter into a development agreement with a new partner or with recommitment of GlaxoSmithKline, we will continue to pursue this program.

We have six other programs in clinical development, five of which are partner funded. In 2002, one program in our pipeline completed Phase 1 studies. Future research and development efforts for these partner-funded programs are difficult to predict at this time due to their early stage of development. During the year, Phase 1 results from our self-funded trial of testosterone in post-menopausal women were announced. Any additional clinical development on this program will come from a partner, which we are currently seeking.

General and Administrative Expenses. General and administrative expenses were \$10.4 million in 2002 compared to \$9.4 million in 2001 and \$9.3 million in 2000. General and administrative expenses increased by approximately \$1.0 million or 11% in 2002 compared to 2001, as a result of higher business development expenses, including the hiring of additional personnel, and higher facility support costs. General and administrative expenses remained relatively unchanged in 2001 compared to 2000.

Interest Income. Interest income was approximately \$800,000 in 2002 compared to \$1.3 million in 2001 and \$3.1 million in 2000. The decrease in 2001 and again in 2002 was primarily due a combination of interest income being earned on lower average cash and investment balances and a decrease in interest rates earned on invested cash balances. The contribution to interest income due to the funds received from the preferred stock financing in December 2001 was not material.

Interest Expense and Other. Interest expense was approximately \$600,000 in 2002 compared to \$1.1 million in 2001 and \$1.5 million in 2000. The decrease in 2002 is primarily due to lower outstanding capital lease and equipment loan balances under various equipment and lease lines of credit. The decrease in 2001 is primarily due to the forgiveness of the loan made by Genentech in connection with product development that had been funded by them.

Other Income. As a result of adopting SFAS 145 "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" during 2002 we reclassified approximately \$6.7 million as a component of operating results, which was reported as an extraordinary gain in 2001. The amount resulted from the forgiveness of outstanding loans and accrued interest required to conduct development for the program that had been funded by Genentech.

Net Loss. We reported a net loss of \$35.9 million in 2002 compared \$32.4 million in 2001 and \$35.6 million in 2000. The lower net loss for 2001 is due to the \$6.7 million of other income included in 2001 that resulted from the forgiveness of outstanding loans and accrued interest required to conduct product development under the program funded by Genentech.

Deemed Dividend. We reported a deemed dividend of \$10.7 million in 2001, which related to the Series A redeemable convertible preferred stock financing completed in December 2001. The deemed dividend represents the discounted conversion price of the financing compared to the fair market value of our common stock on the issuance date of the preferred stock resulting in a beneficial conversion to the preferred stockholders. The value of the beneficial conversion feature is reported as a deemed dividend and is included in the calculation of net loss applicable to the common shareholders. No such deemed dividend was reported in 2002 or 2000.

Net Loss Applicable to Common Shareholders. We reported a net loss applicable to common shareholders of \$35.9 million in 2002 compared to \$43.1 million in 2001 and \$35.6 million in 2000. Net loss applicable to common shareholders in 2001 included a deemed dividend to the Series A redeemable convertible preferred stock financing completed in December 2001. The net loss applicable to common shareholders is used in the calculation for basic and diluted loss per share applicable to common shareholders.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through private placements and public offerings of our capital stock, proceeds from equipment lease financings, contract research funding and interest earned on investments. As of December 31, 2002, we had cash, cash equivalents and short-term investments of approximately \$29.9 million.

Net cash used in operating activities in 2002 was \$30.9 million compared to \$29.1 million in 2001 and \$25.8 million in 2000. The increase in net cash used in 2002 resulted primarily from an increase in net loss, decreases in accounts payable, other accrued liabilities and deferred revenue, offset by a decrease in account receivable. The decrease in accounts payable and other accrued liabilities results primarily from increased payments for expenses associated with our development programs and capital expenditures, while the decrease in deferred revenue is due primarily to our partners funding future development at a lower level. The decrease in receivables is due to the receipt of payments from our partners for billings associated with our development activities. The increase in net cash used in 2001 compared to in 2000 resulted primarily from a decrease in net loss combined with an increase in receivables offset by an increase in deferred revenue. The increase in receivables was due to invoiced, but unpaid, amounts due from partners for development activities. The increase in deferred revenue was due to payments received from our major partner to fund future program development.

Net cash used in investing activities in 2002 was \$18.6 million compared to \$14.7 million in 2001 and \$16.1 million in 2000. The increase in cash used in 2002 resulted from a combination of reductions in capital expenditures and proceeds from maturing investments offset by an increase in the purchase of investments. Capital expenditures for the current year of approximately \$11.2 million relate primarily to the acquisition of manufacturing production equipment while capital expenditures in 2001 of approximately \$37.1 million related primarily to the construction of our large-scale commercial manufacturing facility. The increase in cash used in 2001 resulted primarily from higher capital expenditures offset by a net increase in proceeds from investments of \$22.4 million.

Net cash provided by financing activities in 2002 was \$2.3 million compared to \$93.0 million in 2001 and \$53.3 million in 2000. The decrease in net cash provided by financing activities in 2002 was primarily due to a significant reduction in proceeds from the issuance of equity and an increase in principal payments on lease obligations and equipment loans. The net proceeds from issuances of common stock in 2002 were approximately \$6.1 million. The increase in net cash provided by financing activities in 2001 consisted primarily of proceeds from the exercise of two put options during the year from two of our partners, which raised net proceeds of approximately \$10.0 million, the sale of common stock during the year using a common stock equity line, which raised net proceeds of approximately \$5.5 million, the sale of common stock through a private placement in August 2001, which raised net proceeds of approximately \$13.8 million, the sale of common stock to a major partner in October 2001, which raised net proceeds of approximately \$19.9 million and the sale of redeemable convertible preferred stock in December 2001, which raised net proceeds of approximately \$45.4 million offset by payments on equipment loans. Net cash provided by financing activities in 2000 consisted primarily of proceeds from the completion of a follow-on public offering in April 2000, which raised net proceeds of \$42.6 million, the initial sale of common stock under a common stock equity line in December 2000, which raised proceeds of \$2.2 million, the sale of common stock through our employee benefit plans, which raised proceeds of \$4.0 million, notes payable supporting loans received under a collaborative development agreement with Genentech and proceeds from equipment loans.

The development of our technology and proposed products has and will continue to require a commitment of substantial funds to conduct the costly and time-consuming research and preclinical and clinical testing activities necessary to develop and refine such technology and proposed products and to bring any such products to market. Our future capital requirements will depend on many factors, including continued progress and the results of the research and development of our technology and drug delivery systems, our ability to establish and maintain favorable collaborative arrangements with others, progress with preclinical studies and clinical trials and the results thereof, the time and costs involved in obtaining regulatory approvals, the cost of development and the rate of scale-up of our production technologies, the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, and the need to acquire licenses or other rights to new technology.

We continue to review our planned operations through the end of 2003, and beyond. We particularly focus on capital spending requirements to ensure that capital outlays are not expended sooner than necessary. We expect our total capital outlays for 2003 will be approximately \$20.0 million and for 2004

will be approximately \$15.0 million. Thereafter, we would anticipate that annual capital expenditures would decrease significantly. Currently, we are contractually committed to approximately \$3.6 million of the anticipated 2003 capital outlays. We believe that approximately \$15.0 million worth of common stock issued in a private placement in February 2003, together with our existing cash balances at December 31, 2002, the \$20.0 million unused common stock purchase commitment from Novo Nordisk A/S, funding commitments from corporate development partners and interest earned on our investments should be sufficient to meet our needs for at least the next 18 months. The sale of additional common stock to Novo Nordisk A/S is subject to certain conditions. In addition, there can be no assurance that our funding commitments from corporate development partners will not be amended or terminated. If we cannot exercise our option to sell additional shares of common stock to Novo Nordisk A/S or if our current funding commitments from corporate development partners are amended or terminated, we will need to obtain additional sources of capital.

If we continue to make good progress in our development programs, we would expect our cash requirements for capital spending and operations to increase in future periods. We will need to raise additional capital to fund our capital spending and operations before we become profitable. We may seek additional funding through collaborations, borrowing arrangements or through public or private equity financings. There can be no assurance that additional financing can be obtained on acceptable terms, or at all. Dilution to shareholders may result if funds are raised by issuing additional equity securities. If adequate funds are not available, we may be required to delay, to reduce the scope of, or to eliminate one or more of our research and development programs, or to obtain funds through arrangements with collaborative partners or other sources that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish.

The following summarizes our contractual obligations at December 31, 2002, and the effect such obligations are expected to have on our liquidity and cash flows in future periods (In thousands):

<u>Contractual Obligations</u>	<u>Payment Due by Period</u>			
	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>After 3 years</u>
Capital Lease Obligations	\$ 2,403	\$ 1,890	\$ 513	\$ —
Unconditional Purchase Obligations	4,519	3,717	802	—
Operating Lease Obligations	<u>62,826</u>	<u>5,171</u>	<u>15,478</u>	<u>42,177</u>
Total Contractual Commitments	<u>\$69,748</u>	<u>\$10,778</u>	<u>\$16,793</u>	<u>\$42,177</u>

Recent Accounting Pronouncements

In June 2002, the Financial Accounting Standards Board (“FASB”) issued SFAS 146, “Accounting for Costs Associated with Exit or Disposal Activities”. The standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing, or other exit or disposal activity. SFAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. We believe that the adoption of this standard will not have a material impact on our financial position and results of operations.

In November 2002, the FASB issued FIN 45, “Guarantor’s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others.” FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of

interim or annual periods ending after December 15, 2002. The adoption of FIN 45 is not expected to have a significant impact on our financial position and results of operations.

In December 2002, the FASB issued SFAS 148, "Accounting for Stock-Based Compensation — Transition and Disclosure." SFAS 148 amends SFAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of SFAS 148 are effective for fiscal years ending after December 15, 2002. The adoption of SFAS 148 did not have a significant impact on our financial statements. We continue to follow the intrinsic value method of accounting as prescribed by APB 25, "Accounting for Stock Issued to Employees," to account for employee stock options.

RISK FACTORS

Except for historical information contained herein, the discussion in this Report on Form 10-K contains forward-looking statements, including, without limitation, statements regarding timing and results of clinical trials, the establishment of corporate partnering arrangements, the anticipated commercial introduction of our products and the timing of our cash requirements. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, without limitation, those mentioned in this report and in particular the factors described below.

We are an early stage company.

You must evaluate us in light of the uncertainties and complexities present in an early stage company. Virtually all of our potential products are in an early stage of research or development. Our potential drug delivery products require extensive research, development and pre-clinical and clinical testing. Our potential products also may involve lengthy regulatory reviews before they can be sold. Because none of our products has yet received approval by the FDA, we cannot assure you that our research and development efforts will be successful, any of our potential products will be proven safe and effective or regulatory clearance or approval to sell any of our potential products will be obtained. Because we have validated only one manufacturing facility, we cannot assure you that any of our potential products can be manufactured in commercial quantities or at an acceptable cost or marketed successfully. Failure to achieve commercial feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or successfully market products will negatively impact our business.

We have a history of losses and anticipate future losses.

We have never been profitable, and through December 31, 2002, we have incurred a cumulative deficit of approximately \$189.4 million. We have not had any material product sales and do not anticipate receiving any revenue from product sales in 2003. 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; and
- plan and build our commercial production capabilities.

To achieve and sustain profitability, we must, alone or with others, develop, obtain regulatory approval for, manufacture, market and sell products using our drug delivery platform. We cannot assure investors that we will generate sufficient product or contract research revenue to become profitable or to sustain profitability.

We may not be able to develop our products successfully.

Many of our products are at an early stage of development. Before we can begin to sell our products commercially, we will need to invest in substantial additional development and conduct clinical testing. In order to further develop many of our products, we will need to address engineering and design issues. We cannot assure you that we will be successful in addressing these designs, engineering and manufacturing issues. Additionally, we will need to formulate and package drugs for delivery by our AERx systems. We cannot assure you that we will be able to do this successfully.

Even if our pulmonary delivery technology has been successfully developed and is commercially feasible, for a range of large and small molecule drugs, we cannot assure you that such applications will be commercially acceptable. For the AERx systems to be commercially viable, we will need to demonstrate that drugs delivered by the AERx systems:

- are safe and effective;
- will not be subject to physical or chemical instability over time and under differing storage conditions; and
- do not suffer from other problems that would affect commercial viability.

While our development efforts are at different stages for different products, we cannot assure you that we will successfully develop any products. We may also abandon some or all of our proposed products. If we cannot develop potential products in a timely manner, our business will be impaired.

We may not be able to commercialize products successfully.

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

- safety;
- efficacy;
- ease of use; and
- price.

There can be no assurance that our products will be competitive with respect to these factors or that our partners will be able to successfully market any of them in a timely manner.

We depend on collaborative partners and need additional collaborative partners.

Our commercialization strategy depends on our ability to enter into agreements with collaborative partners. In particular, our ability to successfully develop and commercialize the AERx insulin Diabetes Management System depends on our development partnership with Novo Nordisk A/S.

Novo Nordisk A/S has agreed to:

- undertake certain collaborative activities with us;
- design and conduct advanced clinical trials;
- fund research and development activities with us;
- pay us fees upon achievement of certain milestones; and
- purchase product at a defined premium, pay royalties and/or share gross profits if and when we commercialize a product.

The development and commercialization of the AERx insulin Diabetes Management System will be delayed if Novo Nordisk A/S fails to conduct these collaborative activities in a timely manner or at all. In

addition, our development partners could terminate these agreements and we have no assurance that we will receive any development and milestone payments. If we do not receive development funds or achieve milestones set forth in the agreements, or if any of our development partners breach or terminate their agreement, our business will be impaired.

Although we have development arrangements with other collaborative partners, our arrangement with Novo Nordisk A/S is our only active funded development agreement. For the year ended December 31, 2002, this partner-funded program contributed approximately 93% of our total contract revenues. Our agreement with Novo Nordisk A/S can be terminated under certain conditions, including by either party on limited written notice, by Novo Nordisk A/S by limited prior written notice upon the occurrence of certain events, and by either party upon 30 days' written notice in the event that the other party commits a material breach under the agreement and fails to remedy such breach within 60 days' notice of such breach.

We will also need to enter into agreements with other corporate partners to conduct the clinical trials, manufacturing, marketing and sales necessary to commercialize other potential products. In addition, our ability to apply the AERx system to any proprietary drugs will depend on our ability to establish and maintain corporate partnerships or other collaborative arrangements with the holders of proprietary rights to such drugs. We cannot assure you that we will be able to establish such additional corporate partnerships or collaborative arrangements on favorable terms or at all, or that our existing or future corporate partnerships or collaborative arrangements will be successful. In December 2000, our agreement with GlaxoSmithKline was amended and we assumed full control and responsibility for conducting and financing the remainder of all development activities. In February 2001, we mutually agreed with Genentech to discontinue our development program for dornase alfa. We also can not assure you that our existing or future corporate partners or collaborators will not pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors. We could have disputes with our existing or future corporate partners or collaborators. Any such disagreements could lead to delays in the research, development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor. If any of our corporate partners or collaborators do not develop or commercialize any product to which it has obtained rights from us, our business could be impaired.

We have limited manufacturing experience.

We have validated only a single clinical manufacturing facility for disposable packets for our various AERx systems. We anticipate spending significant amounts to attempt to provide for the high-volume manufacturing required for multiple AERx products, and much of this spending will occur before our products are approved. There can be no assurance that:

- the design requirements of the AERx system will make it feasible for us to develop it beyond the current prototype;
- manufacturing and quality control problems will not arise as we attempt to scale-up; or
- any scale-up can be achieved in a timely manner or at a commercially reasonable cost.

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

We are building our own manufacturing capabilities for the production of key components of our AERx drug delivery systems. We plan to internally produce the disposable nozzles, assemble the disposable unit-dose packets and fill the drug into the unit-dose packets. We have limited experience in manufacturing disposable unit-dose packets and there can be no assurance that we can successfully do so in high volumes, in a timely manner, at an acceptable cost, or at all.

We intend to use contract manufacturers to produce key components, assemblies and subassemblies in the clinical and commercial manufacturing of our AERx devices. There can be no assurance that we will

be able to enter into or maintain satisfactory contract manufacturing arrangements. Certain components of our products may be available, at least initially, only from single sources. There can be no assurance that we could find alternate suppliers for any of these components. A delay of or interruption in production resulting from any supply problem could have a material adverse effect on our business.

We will need additional capital and our ability to find additional funding is uncertain.

Our operations to date have consumed substantial and increasing amounts of cash. We expect the negative cash flow from operations to continue in the foreseeable future. We will need to commit substantial funds to develop our technology and proposed products. We will have to continue to conduct costly and time-consuming research and preclinical and clinical testing to develop, refine and commercialize our technology and proposed products. Our future capital requirements will depend on many factors, including:

- progress in researching and developing our technology and drug delivery systems;
- our ability to establish and maintain favorable collaborative arrangements with others;
- progress with preclinical studies and clinical trials;
- time and costs to obtain regulatory approvals;
- costs of development and the rate at which we expand our production technologies;
- costs of preparing, filing, prosecuting, maintaining and enforcing patent claims; and
- our need to acquire licenses or other rights to technology.

Since inception, we have financed our operations primarily through private placements and public offerings of our capital stock, proceeds from equipment lease financings, contract research funding and interest earned on investments.

We anticipate that we will be able to maintain current and planned operations for at least the next 18 months, including capital spending requirements of approximately \$20 million in 2003, with approximately \$15 million worth of common stock issued in a private placement in February 2003, together with our existing cash balance at December 31, 2002, the \$20 million unused common stock purchase commitment from Novo Nordisk A/S, funding commitments from corporate development partners, and projected interest; however, there can be no assurances that these sources of funding will be sufficient or that our cash requirements will not change. The sale of additional common stock to Novo Nordisk A/S is subject to certain conditions, including, if applicable, obtaining any requisite shareholder approval. In addition, there can be no assurance that our funding commitments from corporate development partners will not be amended or terminated. If we cannot exercise our option to sell additional shares of common stock to Novo Nordisk A/S or if our current funding commitments from corporate development partners are amended or terminated, we will need to obtain additional sources of capital.

We will need to raise additional capital to fund our capital spending and operations before we become profitable. We may seek additional funding through collaborations, borrowing arrangements or through public or private equity financing. We cannot assure you that additional financing can be obtained on acceptable terms, or at all. Dilution to shareholders may result if funds are raised by issuing additional equity securities. If adequate funds are not available, we may be required to delay, to reduce the scope of, or to eliminate one or more of our research and development programs, or to obtain funds through arrangements with collaborative partners or other sources that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish.

We depend upon proprietary technology and the status of patents and proprietary technology is uncertain.

Our business and competitive position is dependent upon our ability to protect our proprietary technology and avoid infringing the proprietary rights of others. We have conducted original research on a number of aspects relating to pulmonary drug delivery. While we cannot assure you that any of our patents will provide a significant commercial advantage, these patents are intended to provide protection for important aspects of our technology, including methods for aerosol generation, devices used to generate aerosols, breath control, compliance monitoring certain pharmaceutical formulations, design of dosage forms and their manufacturing, and testing methods. In addition, we are maintaining as trade secrets some of the key elements of our manufacturing technologies, particularly those associated with production of disposable unit-dose packets for the AERx systems.

Our success will depend to a significant extent on our ability to obtain and enforce patents, maintain trade secret protection and operate without infringing on the proprietary rights of third parties. Because the field of aerosolized drug delivery is crowded and a substantial number of patents have been issued and because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of our patents cannot be predicted. Commercialization of pharmaceutical products can also be subject to substantial delays as a result of the time required for product development, testing and regulatory approval.

We also seek to protect some of these inventions through foreign counterpart applications in selected other countries. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may limit the patent protection we will be able to secure outside of the United States.

The coverage claimed in a patent application can be significantly reduced before a patent is issued, either in the United States or abroad. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated. Furthermore, patents already issued to us or our pending applications may become subject to dispute, and any disputes could be resolved against us. For example, Eli Lilly and Company has brought an action against us seeking to have one or more employees of Eli Lilly named as co-inventors on one of our patents. In addition, because patent applications in the United States are currently maintained in secrecy until patents issue, and patent applications in certain other countries generally are not published until more than 18 months after they are first filed, and because publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first creator of inventions covered by pending patent applications or that we were the first to file patent applications on such inventions.

Our policy is to require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. We cannot assure you, however, that these agreements will provide meaningful protection for our inventions, trade secrets or other proprietary information in the event of unauthorized use or disclosure of such information.

We also execute confidentiality agreements with outside collaborators and consultants. However, disputes may arise as to the ownership of proprietary rights to the extent that outside collaborators or consultants apply technological information developed independently by them or others to our projects, or apply our technology to other projects, and we cannot assure you that any such disputes would be resolved in our favor.

We may incur substantial costs if we are required to defend ourselves in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of

the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process and we cannot assure you that any license required under any such patent would be made available to us on acceptable terms, if at all. Litigation may also be necessary to enforce our patents against others or to protect our know-how or trade secrets. Such litigation could result in substantial expense, and we cannot assure you that any litigation would be resolved in our favor.

We may not obtain regulatory approval for our products on a timely basis, or at all.

All medical devices and new drugs, including our products under development, are subject to extensive and rigorous regulation by the federal government, principally the FDA, and by state and local government agencies. Such regulations govern the development, testing, manufacture, labeling, storage, approval, advertising, promotion, sale and distribution of such products. Medical devices or drug products that are marketed abroad are also subject to regulation by foreign governments.

The process for obtaining FDA approvals for drug products is generally lengthy, expensive and uncertain. Securing FDA approvals often requires applicants to submit extensive clinical data and supporting information to the FDA. Even if granted, the FDA can withdraw product clearances and approvals for failure to comply with regulatory requirements or upon the occurrence of unforeseen problems following initial marketing.

The activities required before a new drug product may be marketed in the United States include pre-clinical and clinical testing and submission of a new drug application with the FDA. Preclinical tests include laboratory evaluation of product chemistry and other characteristics and animal studies to assess the potential safety and efficacy of the product as formulated. Clinical testing involves the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified principal investigator, usually a physician, pursuant to a FDA reviewed protocol.

Human clinical trials typically are conducted in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing the product in a small number of patients or normal volunteers, primarily for safety, at one or more dosage levels, as well as characterization of a drug's pharmacokinetic and/or pharmacodynamic profile. In Phase 2 clinical trials, in addition to safety, the efficacy of the product is usually evaluated in a patient population. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at geographically disperse sites. All of the phases of clinical studies must be conducted in conformance with FDA's bioresearch monitoring regulations.

We cannot assure you that we will be able to obtain necessary regulatory approvals on a timely basis, if at all, for any of our potential products. Even if granted, regulatory approvals may include significant limitations on the uses for which products may be marketed. Moreover, we cannot assure you that any required approvals, once obtained, will not be withdrawn or that we will remain in compliance with other regulatory requirements. If we, or manufacturers of our components, fail to comply with applicable FDA and other regulatory requirements, we, and they, are subject to sanctions, including:

- warning letters;
- fines;
- product recalls or seizures;
- injunctions;
- refusals to permit products to be imported into or exported out of the United States;
- withdrawals of previously approved marketing applications; and
- criminal prosecutions.

Manufacturers of drugs also are required to comply with the applicable GMP requirements, which relate to product testing, quality assurance and maintaining records and documentation. We cannot assure

you that we will be able to comply with the applicable GMP and other FDA regulatory requirements for manufacturing as we expand our manufacturing operations, which would impair our business.

In addition, to market our products in foreign jurisdictions, we and our partners must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety and quality. We cannot assure you that we will obtain regulatory approvals in such jurisdictions or that we will not incur significant costs in obtaining or maintaining any foreign regulatory approvals. If approvals to market our products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our business would be impaired.

Because certain of our clinical studies involve narcotics, we are registered with the DEA, and our facilities are subject to inspection and DEA export, import, security and production quota requirements. We cannot assure you that we will not be required to incur significant costs to comply with DEA regulations in the future or that such regulations will not otherwise harm our business.

The results of preclinical and clinical testing are uncertain.

Before we can file for regulatory approval for the commercial sale of our potential AERx products, the FDA will require extensive preclinical and clinical testing to demonstrate their safety and efficacy. To date, we have tested prototype patient-operated versions of our AERx systems with morphine, insulin and dornase alfa on a limited number of individuals in Phase 1 and Phase 2 clinical trials and have initiated a Phase 3 clinical trial for our AERx insulin Diabetes Management System. If we do not or cannot complete these trials or progress to more advanced clinical trials, we may not be able to commercialize our AERx products.

Completing clinical trials in a timely manner depends on, among other factors, the enrollment of patients. Our ability to recruit patients depends on a number of factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the existence of competitive clinical trials. Delays in planned patient enrollment in our current or future clinical trials may result in increased costs, program delays or both.

Although we believe the limited data we have regarding our potential products is encouraging, the results of initial preclinical and clinical testing do not necessarily predict the results that we will get from subsequent or more extensive preclinical and clinical testing. Furthermore, we cannot assure you that clinical trials of these products will demonstrate that these products 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 promising results in earlier trials. If we cannot adequately demonstrate that any therapeutic product we are developing is safe and effective, regulatory approval of that product would be delayed or prevented, which would impair our business.

We are also developing applications of our AERx platform for the delivery of other compounds. These applications are in early stages of development and we do not yet know the degree of testing and development that will be needed to obtain necessary marketing approvals from the FDA and other regulatory agencies. We cannot assure you that these applications will prove to be viable or that any necessary regulatory approvals will be obtained in a timely manner, if at all.

In addition, the FDA may require us to provide clinical data beyond what is currently planned to demonstrate that the chronic administration of drugs delivered via the lung for systemic effect is safe. We cannot assure you that we will be able to present such data in a timely manner, or at all.

We are in a highly competitive market and our competitors may develop alternative therapies.

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. We are aware of a number of companies such as Alkermes Pharmaceuticals,

Inc. and Nektar Therapeutics (formerly Inhale Therapeutic Systems) that are currently seeking to develop new products and non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems, buccal and colonic absorption systems. Several of these companies may have developed or are developing dry powder devices that could be used for pulmonary delivery. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than we can.

We depend on key personnel and must continue to attract and retain key employees.

We depend on a small number of key management and technical personnel. Losing any of these key employees could harm our business and operations. Our success also depends on our ability to attract and retain additional highly qualified marketing, management, manufacturing, engineering and research and development personnel. We face intense competition in our recruiting activities and may not be able to attract or retain qualified personnel.

We may be exposed to product liability.

Researching, developing and commercializing medical devices and therapeutic products entail significant product liability risks. The use of our products in clinical trials and the commercial sale of such products may expose us to liability claims. These claims might be made directly by consumers or by pharmaceutical companies or others selling such products.

Companies often address the exposure of such risk by obtaining product liability insurance. Although we currently have product liability insurance, there can be no assurance 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.

Third-party reimbursement for our products is uncertain.

In both domestic and foreign markets, sales of our potential products depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. Third-party payers often challenge the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. We cannot assure you that any of our products will be reimbursable by third-party payers. In addition, we cannot assure you 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 pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement.

We use hazardous materials.

Our operations involve use of hazardous and toxic materials, chemicals and various radioactive compounds that generate hazardous, toxic and radioactive wastes. Although we believe that our safety procedures for handling and disposing of such materials comply with all state and federal regulations and standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any damages that result and such liability could exceed the resources of our business.

Our stock price is likely to remain volatile.

The market prices for securities of many companies in the drug delivery industry, including ours, 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:

- investor perception of us;
- analyst recommendations;
- fluctuations in our operating results;
- market conditions relating to the drug delivery industry;
- announcements of technological innovations or new commercial products by us or our competitors;
- publicity regarding actual or potential developments relating to products under development by us or our competitors;
- failure to establish new collaborative relationships;
- developments or disputes concerning patent or proprietary rights;
- delays in the development or approval of our product candidates;
- regulatory developments in both the United States and foreign countries;
- public concern as to the safety of drug delivery technologies;
- period-to-period fluctuations in financial results;
- future sales of substantial amounts of common stock by shareholders; or
- economic and other external factors.

In the past, class action securities litigation has often been instituted against companies following periods of volatility in the market price of their securities. Any such litigation instigated against us could result in substantial costs and a diversion of management's attention and resources.

Our common stock has traded below one dollar and may become subject to de-listing from the Nasdaq National Market.

The Nasdaq has a \$1.00 per share minimum bid requirement, pursuant to which our common stock could be de-listed from the Nasdaq National Market if it trades below \$1.00 for 30 consecutive trading days and does not subsequently trade above \$1.00 for 10 consecutive days. If we are unable to meet the Nasdaq requirements to maintain listing on the Nasdaq National Market our common stock could trade on the OTC Bulletin Board or in the "pink sheets" maintained by the National Quotation Bureau, Inc. Such alternatives are generally considered to be less efficient markets, and our stock price, as well as the liquidity of our common stock, will be adversely impacted as a result.

We have implemented certain anti-takeover provisions.

Certain provisions of our articles of incorporation and the California General Corporation Law could discourage a third party from acquiring, or make it more difficult for a third party to acquire, control of us without approval of our board of directors. These provisions could also limit the price that certain investors might be willing to pay in the future for shares of our common stock. Certain provisions allow the board of directors to authorize the issuance of preferred stock with rights superior to those of the common stock. We are also subject to the provisions of Section 1203 of the California General Corporation Law which requires a fairness opinion to be provided to our shareholders in connection with their consideration of any proposed "interested party" reorganization transaction.

We have adopted a shareholder rights plan, commonly known as a "poison pill". The provisions described above, our poison pill and provisions of the California General Corporation Law may discourage, delay or prevent a third party from acquiring us.

Item 7A. *Quantitative and Qualitative Disclosure About Market Risk*

Market Risk Disclosure

In the normal course of business, our financial position is routinely subject to a variety of risks, including market risk associated with interest rate movement. We regularly assess these risks and have established policies and business practices to protect against these and other exposures. As a result, we do not anticipate material potential losses in these areas.

As of December 31, 2002, we had cash, cash equivalents and short-term investments of \$29.9 million consisting of cash and highly liquid, short-term investments. The market value of our short-term investments will decline by an immaterial amount if market interest rates increase, and therefore, our exposure to interest rate changes has been immaterial. Declines of interest rates over time will, however, reduce our interest income from our short-term investments. Our outstanding equipment lease lines and capital lease obligations are all at fixed interest rates and, therefore, have minimal exposure to changes in interest rates.

Item 8. *Financial Statements and Supplementary Data*

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Shareholders
Aradigm Corporation

We have audited the accompanying balance sheets of Aradigm Corporation as of December 31, 2002 and 2001, and the related statements of operations, redeemable convertible preferred stock and shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. 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 in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aradigm Corporation at December 31, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 7, 2003

ARADIGM CORPORATION
BALANCE SHEETS

	December 31,	
	2002	2001
	(In thousands, except shares data)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 22,800	\$ 69,965
Short-term investments	7,090	1,199
Receivables		
Related parties	—	631
Unrelated parties	282	718
	282	1,349
Current portion of notes receivable from officers and employees	136	145
Prepaid and other current assets	1,457	812
Total current assets	31,765	73,470
Property and equipment, net	63,233	57,940
Noncurrent portion of notes receivable from officers and employees	169	160
Long-term investments	1,553	—
Other assets	409	530
Total assets	\$ 97,129	\$ 132,100
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,951	\$ 5,297
Accrued clinical and cost of other studies	291	703
Accrued compensation	2,195	1,761
Deferred revenue	10,682	11,115
Current portion of capital lease obligations	1,753	3,526
Other accrued liabilities	407	2,760
Total current liabilities	17,279	25,162
Noncurrent portion of deferred revenue	6,170	2,327
Capital lease obligations, less current portion	497	2,427
Noncurrent portion of deferred rent	1,108	300
Commitments and contingencies		
Redeemable convertible preferred stock, no par value; 5,000,000 shares authorized; issued and outstanding shares: 2,001,236 in 2002 and 2001; liquidation preference of \$48,430 in 2002 and 2001	30,665	30,735
Shareholders' equity:		
Common stock, no par value, 100,000,000 shares authorized; issued and outstanding shares: 31,157,612 in 2002; 29,536,383 in 2001	230,853	224,738
Deferred compensation	—	(54)
Accumulated deficit	(189,443)	(153,535)
Total shareholders' equity	41,410	71,149
Total liabilities, redeemable convertible preferred stock and shareholders' equity	\$ 97,129	\$ 132,100

See accompanying notes.

ARADIGM CORPORATION
STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	<u>2002</u>	<u>2001</u>	<u>2000</u>
	(In thousands, except per share data)		
Contract and license revenues			
Related parties	\$ 26,864	\$ 26,031	\$ 15,410
Unrelated parties	<u>2,103</u>	<u>2,885</u>	<u>4,893</u>
Total revenues	<u>28,967</u>	<u>28,916</u>	<u>20,303</u>
Research and development	54,680	58,836	48,176
General and administrative	<u>10,394</u>	<u>9,355</u>	<u>9,271</u>
Total expenses	<u>65,074</u>	<u>68,191</u>	<u>57,447</u>
Loss from operations	(36,107)	(39,275)	(37,144)
Interest income	818	1,324	3,110
Other income related to forgiveness of Genentech note	—	6,675	—
Interest expense and other	<u>(642)</u>	<u>(1,081)</u>	<u>(1,528)</u>
Net loss	(35,931)	(32,357)	(35,562)
Deemed dividend	<u>—</u>	<u>(10,722)</u>	<u>—</u>
Net loss applicable to common shareholders	<u><u>\$(35,931)</u></u>	<u><u>\$(43,079)</u></u>	<u><u>\$(35,562)</u></u>
Basic and diluted loss per share applicable to common shareholders:			
Net loss applicable to common shareholders	<u><u>\$ (1.19)</u></u>	<u><u>\$ (1.98)</u></u>	<u><u>\$ (2.07)</u></u>
Shares used in computing basic and diluted loss per share applicable to common shareholders	<u><u>30,261</u></u>	<u><u>21,792</u></u>	<u><u>17,196</u></u>

See accompanying notes.

ARADIGM CORPORATION

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY

	Redeemable Convertible Preferred Stock		Common Stock		Shareholder Notes Receivable	Deferred Compensation	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount				
	(In thousands, except shares data)							
Balances at December 31, 1999.....	—	\$ —	14,749,777	\$ 99,603	\$(163)	\$(379)	\$ (74,904)	\$ 24,157
Issuance of common stock for cash, Net	—	—	2,989,795	44,676	—	—	—	44,676
Issuance of common stock under the employee stock purchase plan	—	—	129,414	1,058	—	—	—	1,058
Issuance of common stock upon exercise of stock options	—	—	318,676	2,940	—	—	—	2,940
Issuance of common stock for services	—	—	728	3	—	—	—	3
Issuance of warrants for services	—	—	—	293	—	—	—	293
Issuance of common stock for warrants	—	—	78,565	—	—	—	—	—
Repayment of shareholders' notes	—	—	—	—	32	—	—	32
Amortization of deferred compensation	—	—	—	—	—	163	—	163
Comprehensive loss:								
Net loss	—	—	—	—	—	—	(35,562)	(35,562)
Other comprehensive income (loss):								
Net change in unrealized gain on Available-for-sale investments	—	—	—	—	—	—	25	25
Total comprehensive loss	—	—	—	—	—	—	(35,537)	(35,537)
Balances at December 31, 2000.....	—	—	18,266,955	148,573	(131)	(216)	(110,441)	37,785
Issuance of common stock for cash, net of issuance costs of \$956	—	—	10,881,733	49,189	—	—	—	49,189
Issuance of common stock under the employee stock purchase plan	—	—	357,146	1,326	—	—	—	1,326
Issuance of common stock upon exercise of stock options	—	—	30,549	204	—	—	—	204
Issuance of redeemable convertible preferred stock for cash, net of issuance costs of \$3,000 and proceeds from issuance of warrants of \$14,724	2,001,236	30,735	—	14,724	—	—	—	14,724
Deemed non-cash dividend on redeemable convertible preferred stock	—	—	—	10,722	—	—	(10,722)	—
Repayment of shareholders' notes	—	—	—	—	131	—	—	131
Amortization of deferred compensation	—	—	—	—	—	162	—	162
Comprehensive loss:								
Net loss	—	—	—	—	—	—	(32,357)	(32,357)
Other comprehensive income (loss):								
Net change in unrealized loss on available-for-sale investments	—	—	—	—	—	—	(15)	(15)
Total comprehensive loss	—	—	—	—	—	—	(32,372)	(32,372)
Balances at December 31, 2001.....	2,001,236	30,735	29,536,383	224,738	—	(54)	(153,535)	71,149
Issuance of common stock for cash, net of issuance costs of \$79	—	—	1,182,034	4,921	—	—	—	4,921
Issuance of common stock under the employee stock purchase plan	—	—	431,695	1,157	—	—	—	1,157
Issuance of common stock upon exercise of stock options	—	—	7,500	26	—	—	—	26
Issuance of options to purchase common stock for services	—	—	—	11	—	—	—	11
Issuance costs related to prior year's sale of convertible preferred stock	—	(70)	—	—	—	—	—	—
Amortization of deferred compensation	—	—	—	—	—	54	—	54
Comprehensive loss:								
Net loss	—	—	—	—	—	—	(35,931)	(35,931)
Other comprehensive income (loss):								
Net change in unrealized loss on available-for-sale investments	—	—	—	—	—	—	23	23
Total comprehensive loss	—	—	—	—	—	—	(35,908)	(35,908)
Balances at December 31, 2002.....	2,001,236	\$30,665	31,157,612	\$230,853	\$ —	\$ —	\$(189,443)	\$ 41,410

See accompanying notes.

ARADIGM CORPORATION
STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2002	2001	2000
	(In thousands)		
Cash flows from operating activities:			
Net loss	\$(35,931)	\$(32,357)	\$(35,562)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,749	4,500	3,213
Other income related to forgiveness of Genentech note	—	(6,675)	—
Retirement of capital assets	114	—	—
Issuance of warrants and common stock for services	11	48	296
Amortization of deferred compensation	54	162	163
Changes in operating assets and liabilities:			
Receivables	1,067	(1,279)	3,816
Other current assets	(645)	(77)	278
Other assets	121	213	(401)
Accounts payable	(3,346)	403	2,654
Accrued compensation	434	515	(29)
Accrued liabilities	(2,765)	375	2,129
Deferred rent	808	300	—
Deferred revenue	3,410	4,788	(2,370)
Net cash used in operating activities	<u>(30,919)</u>	<u>(29,084)</u>	<u>(25,813)</u>
Cash flows from investing activities:			
Capital expenditures	(11,157)	(37,117)	(14,376)
Purchases of available-for-sale investments	(12,105)	(5,732)	(26,764)
Proceeds from maturities of available-for-sale investments	4,685	28,167	25,052
Net cash used in investing activities	<u>(18,577)</u>	<u>(14,682)</u>	<u>(16,088)</u>
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	6,104	50,671	48,674
Proceeds from issuance of redeemable convertible preferred stock, net	(70)	45,459	—
Notes payable	—	—	2,756
Proceeds from repayments of shareholder notes	—	131	32
Notes receivable from officers and employees	—	(186)	11
Proceeds from equipment loans	—	—	4,051
Payments on capital lease obligations and equipment loans	(3,703)	(3,076)	(2,238)
Net cash provided by financing activities	<u>2,331</u>	<u>92,999</u>	<u>53,286</u>
Net increase (decrease) in cash and cash equivalents	(47,165)	49,233	11,385
Cash and cash equivalents at beginning of year	69,965	20,732	9,347
Cash and cash equivalents at end of year	<u>\$ 22,800</u>	<u>\$ 69,965</u>	<u>\$ 20,732</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest	<u>\$ 499</u>	<u>\$ 899</u>	<u>\$ 855</u>
Non-cash investing and financing activities:			
Issuance of options to purchase common stock for services	<u>\$ 11</u>	<u>\$ 48</u>	<u>\$ 296</u>
Issuance of warrants in conjunction with private placement of common stock	<u>\$ —</u>	<u>\$ 979</u>	<u>\$ —</u>
Redeemable convertible preferred stock deemed, non-cash dividend	<u>\$ —</u>	<u>\$ 10,722</u>	<u>\$ —</u>

See accompanying notes.

ARADIGM CORPORATION
NOTES TO FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Organization and Basis of Presentation

Aradigm Corporation (the "Company") is a California corporation engaged in the development and commercialization of non-invasive pulmonary drug delivery systems. The Company does not anticipate receiving any revenue from the sale of products in the upcoming year. Principal activities to date have included obtaining financing, recruiting management and technical personnel, securing operating facilities, conducting research and development, and expanding commercial production capabilities. These factors indicate that the Company's ability to continue its research, development and commercialization activities are dependent upon the ability of management to obtain additional financing as required.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization period for payments received from product development and license agreements as they relate to the revenue recognition of deferred revenue and assumptions for valuing options, warrants and deemed dividend. Actual results could differ from these estimates.

Cash and Cash Equivalents and Investments

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company places its cash and cash equivalents in money market funds, commercial paper, corporate notes and market auction preferreds. The Company's short-term investments consist of commercial paper and corporate notes with maturities ranging from three to twelve months. The Company's long-term investments consist of a corporate note with maturity of 413 days from purchase date.

The Company classifies its investments as available-for-sale. Available-for-sale investments are recorded at fair value with unrealized gains and losses reported as other comprehensive income (loss) in a separate component of the statements of redeemable convertible preferred stock and shareholders' equity until realized. Fair values of investments are based on quoted market prices, where available. Realized gains and losses, which have been immaterial to date, are included in interest and other income and are derived using the specific identification method for determining the cost of investments sold. Dividend and interest income is recognized when earned.

Depreciation and Amortization

The Company records property and equipment at cost and calculates depreciation using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over the shorter of the term of the lease or useful life of the improvement. The estimated useful lives of property and equipment are as follows:

Machinery and equipment	5 to 7 years
Furniture and fixtures	5 to 7 years
Lab equipment	5 to 7 years
Computer equipment and software	3 to 5 years
Leasehold improvements	5 to 17 years

ARADIGM CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

Impairment of Long-Lived Assets

The Company reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values and the loss is recognized on the Statements of Operations.

The Company adopted Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," on January 1, 2002. SFAS 144 superseded SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." The primary objectives of SFAS 144 are to develop one accounting model based on the framework established in SFAS 121 for long-lived assets to be disposed of by sale, and to address significant implementation issues. Our adoption of SFAS 144 did not have a material impact on our financial position or results of operations.

Revenue Recognition

Contract revenues consist of revenue from collaboration agreements and feasibility studies. The Company recognizes its revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements" Under the agreements, revenue is recognized as costs are incurred. Deferred revenue represents the portion of all refundable and nonrefundable research payments received that have not been earned. In accordance with contract terms, milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements and, accordingly, are generally recognized as revenue either upon the completion of the milestone effort when payments are contingent upon completion of the effort or are based on actual efforts expended over the remaining term of the agreements when payments precede the required efforts. Costs of contract revenues approximate such revenue and are included in research and development expenses. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Refundable development and license fee payments are generally not refundable once the specific performance criteria are achieved.

Research and Development

Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and research-related overhead expenses. Research and development expenses under collaborative and government grants approximate the revenue recognized under such agreements. The Company expenses research and development costs as such costs are incurred.

Stock Based Compensation

The Company has elected to follow Accounting Principles Board Opinion No. ("APB") 25, "Accounting for Stock Issued to Employees", and related interpretations in accounting for its employee stock options, including Financial Accounting Standard Board Interpretation ("FIN") 44 "Accounting for Certain Transactions Involving Stock Compensation". Compensation expense is based on the difference, if any, between the fair value of the Company's common stock and the exercise price of the option or share right on the measurement date, which is typically the date of grant. This amount is recorded as "Deferred stock compensation" in the Balance Sheets and amortized as a charge to operations over the vesting period of the applicable options or share rights. In accordance with SFAS 123, "Accounting for Stock-Based Compensation," as amended by SFAS 148, "Accounting for Stock-Based Compensation — Transition and

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS — (Continued)

Disclosure,” the Company has provided, below, the pro forma disclosures of the effect on net loss and loss per share as if SFAS 123 had been applied in measuring compensation expense for all periods presented.

	<u>Years ended December 31,</u>		
	<u>2002</u>	<u>2001</u>	<u>2000</u>
Net loss applicable to common shareholders — as reported . .	\$(35,931)	\$(43,079)	\$(35,562)
Add:			
Stock-based employee compensation expense included in reported net income	54	162	163
Less:			
Total stock-based employee compensation expense determined under fair value based method for all awards	<u>(7,455)</u>	<u>(6,397)</u>	<u>(4,188)</u>
Pro forma net loss applicable to common shareholders	<u>\$(43,332)</u>	<u>\$(49,314)</u>	<u>\$(39,587)</u>
Basic and diluted net loss per share applicable to common shareholders —			
As reported	\$ (1.19)	\$ (1.98)	\$ (2.07)
Pro forma	\$ (1.43)	\$ (2.26)	\$ (2.30)

The Company accounts for options and warrants issued to nonemployees under SFAS 123 and Emerging Issues Task Force Issue No. (“EITF”) 96-18. The value of options and warrants are periodically remeasured over their vesting terms.

Income Taxes

The Company uses the liability method to account for income taxes as required by SFAS 109, “Accounting for Income Taxes”. Under this method, deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Net Loss Per Share

Historical net loss per share has been calculated under SFAS 128, “Earnings Per Share.” Basic net loss per share on a historical basis is computed using the weighted average number of shares of common stock outstanding less the weighted average number of shares subject to repurchase. There were no shares subject to repurchase in the years ended December 31, 2002, 2001 and 2000. No diluted loss per share information has been presented in the accompanying statements of operations since potential common shares from stock options, warrants and redeemable convertible preferred stocks are antidilutive. For the years ended December 31, 2002, 2001 and 2000, the total number of shares excluded from diluted loss per share relating to these securities was 8,283,600, 10,038,525 and 2,232,633 shares, respectively.

Employee Benefit Plans

The Company has a 401(k) Plan which stipulated that all full-time employees with at least three months of employment can elect to contribute to the 401(k) Plan, subject to certain limitations, up to 20% of salary on a pretax basis. During December 2000, the Company approved a change to the employment qualification period from three months to one month of employment and approved an employer match program that became effective during 2001. Subject to a maximum dollar match contribution of \$5,250 per year, the Company will match 50% of the first 6% of the employee’s contribution on a pretax basis. The Company expensed total employer matching contributions of \$527,000, \$273,000 and \$0 in 2002, 2001 and 2000, respectively.

ARADIGM CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

Significant Concentrations

Although the Company has had development arrangements with other collaborative partners, the arrangement with Novo Nordisk A/S is its only active, funded development agreement. For the year ended December 31, 2002, this partner-funded program contributed approximately 93% of total contract revenues. The agreement with Novo Nordisk A/S can be terminated under certain conditions, including by either party on limited written notice, by Novo Nordisk A/S by limited prior written notice upon the occurrence of certain events, and by either party upon 30 days' written notice in the event that the other party commits a material breach under the agreement and fails to remedy such breach within 60 days' notice of such breach. Novo Nordisk A/S is considered to be a related party due to its ownership interest in the Company.

Comprehensive Income (Loss)

SFAS 130, "Reporting Comprehensive Income", requires unrealized gains or losses on the Company's available-for-sales securities to be recorded in other comprehensive income (loss). Total comprehensive loss has been disclosed in the statement of redeemable convertible preferred stock and shareholders' equity.

Changes in Accounting Principles

In December 2002, the Company adopted SFAS 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections". Previous to the issuance of SFAS 145, SFAS 4 had required that all gains and losses from extinguishment of debt were to be aggregated and, if material, classified as an extraordinary item, net of related income tax effect. SFAS 145 rescinds SFAS 4 and the related required classification of extraordinary items. Companies are required to retroactively adopt SFAS 145 for fiscal years beginning after May 15, 2002, and interim periods within those fiscal years, although early adoption is permitted. As a result of adopting SFAS 145, the Company reclassified the \$6.7 million previously recorded in 2001 as extraordinary gain related to forgiveness of outstanding notes and interest by Genentech, as a component of operating results.

Recent Accounting Pronouncements

In October 2001, the Financial Accounting Standards Board issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), which addresses financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of", and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations for a disposal of a segment of a business". SFAS 144 is effective for fiscal years beginning after December 15, 2001. The Company adopted SFAS 144 on January 1, 2002 and has determined that SFAS 144 does not have a significant impact on the Company's historical financial position and results of operations.

In July 2002, the FASB issued SFAS 146, "Accounting for Costs Associated with Exit or Disposal Activities". The standard requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Examples of costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing, or other exit or disposal activity. SFAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The Company believes that the adoption of this standard will not have a material impact on the Company's financial position and results of operations.

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS — (Continued)

In November 2002, the FASB issued FIN 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." FIN 45 elaborates on the existing disclosure requirements for most guarantees, including residual value guarantees issued in conjunction with operating lease agreements. It also clarifies that at the time a company issues a guarantee, the company must recognize an initial liability for the fair value of the obligation it assumes under that guarantee and must disclose that information in its interim and annual financial statements. The initial recognition and measurement provisions apply on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The adoption of FIN 45 is not expected to have a significant impact on the company's financial position and results of operations.

In December 2002, the FASB issued SFAS 148, "Accounting for Stock-Based Compensation — Transition and Disclosure." SFAS 148 amends SFAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirements of SFAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The adoption of SFAS 148 did not have a significant impact on the company's financial statements. The company continues to follow the intrinsic value method of accounting as prescribed by APB 25, "Accounting for Stock Issued to Employees," to account for employee stock options.

In January 2003, the FASB issued FIN 46, "Consolidation of Variable Interest Entities." FIN 46 requires a variable interest entity to be consolidated by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A variable interest entity is a corporation, partnership, trust, or any other legal structures used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. A variable interest entity often holds financial assets, including loans or receivables, real estate or other property. A variable interest entity may be essentially passive or it may engage in research and development or other activities on behalf of another company. The consolidation requirements of FIN 46 apply immediately to variable interest entities created after January 31, 2003. The consolidation requirements apply to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply to all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The Company has evaluated the impact of FIN 46 and does not believe that it has any investment in variable interest entity.

Reclassifications

Certain reclassifications of prior year amounts have been made to conform with current year presentation.

ARADIGM CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

2. Financial Instruments

Cash Equivalents and Investments

The following summarizes the Company's fair value of cash equivalents and investments (amounts in thousands):

	December 31,	
	2002	2001
Cash equivalents:		
Money market fund	\$ 4,903	\$ 2,845
Commercial paper	<u>17,846</u>	<u>67,068</u>
	<u>\$22,749</u>	<u>\$69,913</u>
Short-term investments:		
Corporate notes	\$ 4,590	\$ 1,199
Market auction preferreds	<u>2,500</u>	<u>—</u>
	<u>\$ 7,090</u>	<u>\$ 1,199</u>
Long-term investments:		
Corporate notes	\$ 1,553	\$ —
	<u>\$ 1,553</u>	<u>\$ —</u>

As of December 31, 2002 and 2001, the difference between the fair value and the amortized cost of available-for-sale securities was \$23,000 and \$15,000 for 2002 and 2001, respectively. As of December 31, 2002, the average portfolio duration was approximately 130 days, and the contractual maturity of all short-term investments did not exceed 105 days from the balance sheet date.

3. Property and Equipment

Property and equipment consist of the following (amounts in thousands):

	December 31,	
	2002	2001
Machinery and equipment	\$ 17,807	\$ 14,053
Furniture and fixtures	1,862	1,653
Lab equipment	3,986	3,428
Computer equipment and software	5,654	5,073
Leasehold improvements	<u>11,600</u>	<u>5,055</u>
	40,909	29,262
Less accumulated depreciation and amortization	<u>(17,944)</u>	<u>(13,186)</u>
	22,965	16,076
Construction in progress	<u>40,268</u>	<u>41,864</u>
Property and equipment, net	<u>\$ 63,233</u>	<u>\$ 57,940</u>

At December 31, 2002 and 2001, property and equipment include assets under capitalized leases of approximately \$11,936,000 and \$13,080,000, respectively. Accumulated depreciation related to leased assets at December 31, 2002 and 2001, was approximately \$9,377,000 and \$7,864,000, respectively.

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS — (Continued)

4. Leases and Commitments

Amounts borrowed under the Company's equipment lease lines of credit bear interest at rates ranging from 9.8% to 14.6% and are collateralized by the related equipment. Under the terms of the lease agreements, the Company has the option to purchase the leased equipment at a negotiated price at the end of each lease term. The Company leases its office, laboratory and manufacturing facilities under several operating leases expiring through the year 2016.

Future minimum lease payments under noncancelable operating and capital leases at December 31, 2002 are as follows (amounts in thousands):

	<u>Operating Leases</u>	<u>Capital Leases</u>
Years ending December 31:		
2003	\$ 5,171	\$ 1,890
2004	5,334	513
2005	5,499	—
2006	4,645	—
2007 and thereafter	<u>42,177</u>	<u>—</u>
Total minimum lease payments	<u>\$62,826</u>	2,403
Less amount representing interest		<u>(153)</u>
Present value of future lease payments		2,250
Current portion of capital lease obligations		<u>(1,753)</u>
Noncurrent portion of capital lease obligations		<u>\$ 497</u>

Certain of the Company's operating leases have rent escalation clauses and accordingly, the Company recognizes rent expense on a straight-line basis. At December 31, 2002, the Company had \$1,100,000 of deferred rent.

For the years ended December 31, 2002, 2001 and 2000, rent expense under operating leases totaled \$5,898,000, \$5,476,000, and \$3,896,000, respectively.

At December 31, 2002, the Company is contractually committed to \$4,519,000 of the anticipated 2003 capital outlays.

5. Contingencies

In June 1998, Eli Lilly and Company filed a complaint against us in the United States District Court for the Southern District of Indiana. The complaint made various allegations against us, arising from our decision to enter into an exclusive collaboration with Novo Nordisk A/S with respect to the development and commercialization of a pulmonary delivery system for insulin and insulin analogs. We sponsored various studies of the pulmonary delivery of insulin and insulin analogs using materials supplied by Lilly under a series of agreements dating from January 1996. We and Lilly had also conducted negotiations concerning a long-term supply agreement under which Lilly would supply bulk insulin to us for commercialization in our AERx insulin Diabetes Management System, and a separate agreement under which we would license certain intellectual property to Lilly. These negotiations were terminated after we proceeded with our agreement with Novo Nordisk A/S. The complaint sought a declaration that Lilly scientists were co-inventors of patent applications filed by us relating to pulmonary delivery of an insulin analog or, in the alternative, enforcement of an alleged agreement to grant Lilly a nonexclusive license under such patent application. The complaint also contained allegations of misappropriation of trade

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS — (Continued)

secrets, breach of fiduciary duty, conversion and unjust enrichment and seeks unspecified damages and injunctive relief. We filed an answer denying all material allegations of the complaint and a motion for summary judgment directed against all claims in Lilly's complaint. The Court granted our motion as to Lilly's claim to enforce an alleged license agreement, for misappropriation of trade secrets, breach of fiduciary duty, conversion, estoppel and breach of contract (in part) and dismissed those claims from the case. After trial of the remaining claims in April 2002, the jury returned verdicts in favor of Aradigm and against Lilly on three of four of Lilly's asserted claims on co-inventorship and on Lilly's unjust enrichment claim. The jury returned verdicts in favor of Lilly on one of Lilly's claims of co-inventorship and on two breaches of contract claims, awarding Lilly damages of \$1 for each breach of contract claim. In June 2002, the Court entered a judgment based on and incorporating the jury's verdict. In March 2003, following disposition of various post-trial motions, the court entered final judgment based on and incorporating the jury's verdict. Either party may appeal from that Final Judgment; the deadline for such appeal is April 4, 2003. If the present final judgment is upheld, a Lilly scientist would be named co-inventor thereby giving Lilly rights of an owner, along with us, on one of our patents relating to pulmonary delivery of monomeric insulin lispro. Should Lilly appeal and ultimately succeed in that appeal, the possible consequences include reversal of the Court's decision granting Aradigm summary judgment on several of Lilly's claims or reversal of the Court's refusal to grant Lilly certain post-judgment relief it had requested. Lilly also contends that factual findings made in any trial of this case would have some effect on other patents relating to pulmonary delivery of monomeric insulin lispro. Management believes that this litigation will not have a material adverse effect on our business.

6. Redeemable Convertible Preferred Stock

Redeemable Convertible Preferred Stock and Common Stock Warrants

During December 2001, the Company completed a \$48.4 million Series A redeemable convertible preferred stock ("preferred stock") financing. Under the terms of the financing, the Company sold to a group of investors 2,001,236 shares of preferred stock at a purchase price of \$24.20 per share. Each share of preferred stock is convertible into four shares of common stock. The Company also issued warrants to the investors to purchase 5,203,212 shares of common stock at an exercise price of \$6.97 per share. Issuance costs of approximately \$3.0 million were accounted for as a reduction to proceeds from the preferred stock financing.

During the first two years, the preferred stock is entitled to cumulative dividends, which shall accrue at an annual rate of 6%, payable only when and if declared by the Board of Directors. At the option of the Company, dividends may be paid in either cash or in shares of common stock, which will be valued at a price equal to the then current market price. The current market price of the common stock on any dividend payment date shall be based on the closing price of the Company's common stock as quoted on the Nasdaq Stock Market. There were no dividends declared as of December 31, 2002.

Each share of preferred stock, together with accrued and unpaid dividends, is convertible, at the option of the holder, into four shares of common stock. The conversion rate is fixed and not subject to any adjustments except for stock splits, stock dividends, combinations, reorganizations, mergers or other similar events. Each share of outstanding preferred stock will automatically convert into common stock upon either the closing of a registered underwritten public offering covering the offer and sale of common stock with gross proceeds to the Company exceeding \$25 million or the date on which the common stock closing bid price has been above \$10.59 per share for at least twenty consecutive trading days.

Upon any liquidation, dissolution, redemption or winding up of the Company, whether voluntary or involuntary, the holders of outstanding preferred stock will be entitled to a liquidation preference, equal to the original issue price plus all accrued and unpaid dividends (as adjusted for any stock dividends,

ARADIGM CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

combinations, splits, recapitalizations and other similar events) to the preferred holders. Any remaining assets will be available for distribution to holders of common stock.

Each holder of preferred stock shall have a number of votes equal to the number of shares of common stock issuable upon conversion of such holder's shares of preferred stock and shall have voting rights and powers equal to the voting rights and powers of the Company's common stock.

Summary of Preferred Stock and Warrant Accounting

The net proceeds of the preferred stock offering were reduced by approximately \$14.7 million, representing the value assigned to the common stock warrants issued with the preferred stock. The warrants were valued using the Black Scholes option pricing model with the following assumptions: estimated volatility of 87%, risk-free interest rate of 4.71%, no dividend yield, and an expected life of 5 years. After reducing the \$48.4 million proceeds by the value of the warrants, the remaining proceeds were used to compute a discounted conversion price in accordance with EITF 00-27, "Application of EITF Issue No. 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios to Certain Convertible Instruments." The discounted conversion price is compared to the fair market value of the Company's common stock on the issuance date of the preferred stock resulting in a beneficial conversion feature of approximately \$10.7 million, which represents the difference between the fair market value of the Company's common stock and the discounted conversion price. The value of the beneficial conversion feature is reported on the Statements of Operations as a deemed dividend and is included in the calculation of net loss applicable to the common shareholders.

In July 2001, the SEC staff made a staff announcement, "Classification and Measurement of Redeemable Securities", (EITF D-98) which clarifies Rule #5-02.28 of Regulation S-X, which was previously adopted in accounting series Release No. 268, "Presentation in Financial Statements of Redeemable Preferred Stock". This announcement addresses financial statement classification and measurement of securities subject to mandatory redemption requirements or whose redemption is outside of the control of the issuer. Rule 5-02.28 requires preferred securities that are redeemable for cash or other assets to be classified outside of permanent equity if they are redeemable (1) at a fixed or determinable price on a fixed or determinable date (2) at the option of the holder, or (3) upon the occurrence of an event that is not solely within the control of the issuer.

The preferred stock agreement provides that a mandatory redemption is triggered if a change in control occurs. Accordingly the Company has classified the preferred stock outside of permanent equity.

7. Shareholders' Equity

In July 2002, the Company raised \$5 million through the sale of 1,182,034 shares of common stock at a price of \$4.23 per share to Novo Nordisk Pharmaceuticals, Inc. ("Novo Nordisk Pharmaceuticals"), an affiliate of Novo Nordisk A/S. This sale was made under the terms of the Stock Purchase Agreement entered into in October 2001 with Novo Nordisk Pharmaceuticals.

In February 2002, the Company filed a Certificate of Amendment to the Company's amended and restated Articles of Incorporation with the Secretary of State of the State of California to increase the Company's authorized number of shares of common stock from 40,000,000 to 100,000,000 shares. The additional shares of common stock authorized by the amendment have rights identical to the common stock of the Company outstanding immediately before the filing of the amendment. Issuances of common stock from the additional authorized shares do not affect the rights of the holders of the Company's common stock and preferred stock outstanding immediately before the filing of the amendment, except for

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NOTES TO FINANCIAL STATEMENTS — (Continued)

effects that may be incidental to increasing the number of shares of the Company's common stock outstanding, such as dilution of the earnings per share and voting rights of holders of other common stock.

In January 2001, the Company raised \$5 million through the sale of 339,961 shares of common stock at a price of \$14.71 per share to GlaxoSmithKline plc ("GlaxoSmithKline"). The sale was made pursuant to the exercise of a put option by the Company under the terms of the collaboration agreement with GlaxoSmithKline.

In June 2001, the Company raised \$5 million through the sale of 708,216 shares of common stock at a price of \$7.06 per share to Novo Nordisk A/S. The sale was made pursuant to the exercise of a put option by the Company under the terms of the collaboration agreement with Novo Nordisk A/S.

In August 2001, the Company completed a private placement of shares of common stock for gross proceeds of \$14.6 million to a group of institutional investors. Under the terms of the private placement, the Company sold 3,639,316 shares of common stock at a price of \$4.00 per share.

In October 2001, the Company entered into a common stock purchase agreement with Novo Nordisk Pharmaceuticals. Under the terms of the agreement, Novo Nordisk Pharmaceuticals committed to purchase up to \$45 million of the Company's common stock, of which 5,665,723 shares for \$3.53 per share, were purchased for a total purchase price of \$20 million, ten business days after the effective date of the agreement. The number of initial shares was calculated by dividing the initial purchase price by the average of the closing prices of the Company's common stock on the Nasdaq for the thirty trading days immediately prior to the effective date. Pursuant to the terms of the agreement, the Company may elect to sell at its option, subject to certain conditions, between \$5 million and \$10 million of additional shares to Novo Nordisk Pharmaceuticals once every three months beginning December 1, 2001 until the remaining \$25 million has been invested. The number of additional shares shall be calculated by dividing the additional purchase price by the average closing price of the Company's common stock on the Nasdaq for the thirty trading days immediately prior to the date of written notice by the Company to Novo Nordisk Pharmaceuticals. Novo Nordisk Pharmaceuticals will hold the shares to be purchased under the agreement for at least two years from the effective date of each purchase, subject to certain conditions.

In April 2000, the Company completed a follow-on public offering of common stock, which raised approximately \$42.6 million in net proceeds with the issuance of 2,875,000 shares of common stock.

In November 2000, the Company entered into a common stock purchase agreement ("Acqua Agreement") with Acqua Wellington North American Equities Fund, Ltd ("Acqua"), a Bahamas based company, establishing a common stock equity line. Pursuant to the equity line, Acqua, subject to the Company's satisfaction of certain conditions, had committed to purchase up to \$50 million of the Company's common stock over a period not to exceed 20 months, at a discount to a 20-day weighted average trading price ranging from 5% to 7%. The amount that the Company could draw down for any draw down pricing period is dependent upon a number of factors, including the Company's stock price, trading volume and threshold price set during the draw down pricing period. The Company filed a registration statement with the Securities and Exchange Commission in November 2000 related to the common stock available for sale under the equity agreement. During December 2000, the Company raised approximately \$2,172,000 through the sale of 114,795 shares of common stock at an average price of \$18.92 per share under the terms of the Acqua Agreement. The fair market value of the Company's common stock on the closing date was \$15.50 per share. During February 2001, the Company raised \$5 million through the sale of 436,110 shares of common stock at an average price of \$11.46 per share under the terms of the Acqua Agreement. The fair market value of the Company's common stock on the closing date was \$13.25 per share. During July 2001, the Company raised \$539,000 through the sale of 92,407 shares of common stock at an average price of \$5.84 per share under the terms of the Acqua

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NOTES TO FINANCIAL STATEMENTS — (Continued)

Agreement. The fair market value of the Company's common stock on the closing date was \$4.80 per share. The Acqua Agreement was terminated pursuant to its terms on July 3, 2002.

Reserved Shares

At December 31, 2002, the Company had 5,910,798 shares of its common stock reserved for issuance upon exercise of common stock warrants, 6,466,851 shares for issuance upon exercise of options under all plans, 8,004,944 shares for issuance upon conversion of preferred stock and 123,174 available authorized shares under the Employee Stock Purchase Plan.

Other Common Stock Warrants

In October 2002, the Company issued warrants in connection with a financial relations service agreement that entitles the holder to purchase 75,000 shares of common stock, 25,000 of which are exercisable at \$1.99 per share, 25,000 shares of which are exercisable at \$2.39 per share and 25,000 shares of which are exercisable at \$2.79 per share. 15,000 shares vested at the execution of the agreement and the remaining shares shall vest based on the achievement of various performance benchmarks set forth in the agreement. The Company valued the vested warrants using the Black-Scholes option pricing model and deemed the amount to be immaterial. The warrants are exercisable through October 1, 2007.

In August 2001, the Company issued warrants in connection with the private placement of common stock that entitles investors to purchase 363,929 shares of common stock at an exercise price of \$5.41 per share or a 15% premium to the Nasdaq National Market price on the closing date. The Company valued the warrants using the Black-Scholes option pricing model using the following assumptions: estimated volatility of 78%, risk-free interest rate of 6.2%, no dividend yield, and an expected life of 4 years, and recorded approximately \$978,969 as issuance costs related to the private placement. These warrants are exercisable through August 21, 2005.

During September 2000, the Company issued a warrant in connection with an operating lease agreement that entitles the holder to purchase 25,000 shares of common stock at an exercise price of \$21.72. This warrant is fully vested, nonforfeitable and is exercisable through September 2007. The Company valued the warrant using the Black-Scholes option pricing model at \$293,000 and is amortizing the value the warrant over the term of the operating lease agreement, which is 15 years.

In January 1999, the Company issued a warrant to the placement agent of the private placement of common stock that entitles the holder to purchase 36,425 shares of common stock at an exercise price of \$10.50 per share. The Company valued the warrant using the Black-Scholes option pricing model and recorded approximately \$221,500 as issuance costs related to the private placement. This warrant is exercisable through June 2004.

In January and December 1998, the Company issued warrants in connection with an operating lease agreement that entitles the holder to purchase 50,000 and 60,000 shares of common stock at an exercise price of \$10.94 and \$10.16 per share, respectively. These warrants are fully vested, nonforfeitable and are exercisable through December 2005. The Company valued the warrants using the Black-Scholes option pricing model and is amortizing the value of the warrants over the term of the operating lease agreement, which is 17 years.

In April 1998, the Company issued warrants to the placement agents of the private placement of common stock that entitles the holders to purchase 166,665 shares of common stock at an exercise price of \$12.42 per share. The Company valued the warrants using the Black-Scholes option pricing model and recorded approximately \$765,000 as issuance costs related to the private placement. These warrants are exercisable through June 2003. During November 2000, one of the placement agents exercised 69,433

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NOTES TO FINANCIAL STATEMENTS — (Continued)

shares of common stock using a provision of the warrant that allows the holder to purchase common stock in lieu of cash or net issue exercise whenever the fair market value of the Company's common stock exceeds the exercise price of the warrant. The placement agent received a net issue exercise of 32,931 shares of common stock.

1996 Non-Employee Directors' Stock Option Plan

The 1996 Non-Employee Directors' Stock Option Plan (the "Directors' Plan") authorized 225,000 shares of common stock for issuance under the plan. Options granted under the Directors' Plan expire no later than ten years from date of grant. The option price shall be at 100% of the fair value on the date of grant as determined by the Board of Directors. The options generally vest quarterly over a period of one year. During 2000, the Board of Directors approved the termination of the Directors' Plan. No more options can be granted under the plan after its termination. The termination of the Directors' Plan will have no effect on the options already outstanding.

The following is a summary of activity under the Directors' Plan:

	Shares Available for Grant of Options	Options Outstanding		Weighted Average Exercise Price
		Number of Shares	Price Per Share	
Balance at December 31, 1999	128,432	74,068	\$6.00 – \$14.25	\$10.03
Options granted	(84,356)	84,356	\$6.13 – \$24.13	\$20.43
Options exercised	—	(27,500)	\$6.00 – \$14.25	\$ 7.53
Options cancelled	(44,076)	(2,500)	\$14.25	\$14.25
Balance at December 31, 2000	—	128,424	\$6.00 – \$24.13	\$17.31
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled	—	—	—	—
Balance at December 31, 2001	—	128,424	\$6.00 – \$24.13	\$17.31
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled	—	(22,500)	\$6.00 – \$14.25	\$11.50
Balance at December 31, 2002	—	105,924	\$8.25 – \$24.13	\$18.55

Exercise Price Range	Options Outstanding and Exercisable		
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
\$ 8.25 – \$ 8.44	26,568	\$ 8.33	6.3
\$14.25	7,500	\$14.25	5.4
\$21.56 – \$24.13	71,856	\$22.77	7.4
	<u>105,924</u>	\$18.55	7.0

1996 Equity Incentive Plan

In April 1996, the Company's Board of Directors adopted and the Company's shareholders approved the 1996 Equity Incentive Plan (the "Plan"), which amended and restated the 1992 Stock Option Plan. Options granted under the Plan may be either incentive or non-statutory stock options. As of

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NOTES TO FINANCIAL STATEMENTS — (Continued)

December 31, 2002, the Company had 7,736,705 shares of common stock authorized for issuance under the Plan. Options granted under the Plan expire no later than ten years from the date of grant. For incentive and non-statutory stock option grants, the option price shall be at least 100% and 85%, respectively, of the fair value on the date of grant, as determined by the Board of Directors. If at any time the Company grants an option, and the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. During May 2001, the Company's shareholders approved an amendment to the Plan to include an evergreen provision. The evergreen provision will automatically increase the number of shares reserved under the Plan, subject to certain limitations, by 6% of the issued and outstanding Common Stock of the Company or such lesser number of shares as determined by the Board of Directors on the date of the annual meeting of shareholders of each fiscal year beginning 2001 and ending 2005. The aggregate increase in the number of shares reserved under the evergreen provision will not exceed 8,000,000 shares.

Options granted under the 1996 Equity Incentive Plan are immediately exercisable subject to repurchase provisions, and the shares acquired generally vest over a period of four years from the date of grant. The Plan also provides for a transition from employee to consultant status without termination of the vesting period as a result of such transition. Under the Plan, employees may exercise options in exchange for a note payable to the Company. As of December 31, 2002 and 2001, there were no outstanding notes receivable from shareholders. Any unvested stock issued is subject to repurchase agreements whereby the Company has the option to repurchase unvested shares upon termination of employment at the original issue price. The common stock has voting rights but does not have resale rights prior to vesting. The Company has repurchased a total of 38,294 shares in accordance with these agreements. During 2002, the Company granted options to purchase 2,149,280 shares of common stock, none of which were exercised subject to repurchase agreements.

The following is a summary of activity under the Plan:

	Options Outstanding			
	Shares Available for Grant of Options	Number of Shares	Price Per Share	Weighted Average Exercise Price
Balance at December 31, 1999	1,656,041	2,097,906	\$ 0.10 - \$14.63	\$ 9.72
Options granted	(1,308,325)	1,308,325	\$10.50 - \$24.13	\$17.29
Options exercised	—	(291,176)	\$ 0.10 - \$23.56	\$ 9.16
Options cancelled	<u>394,577</u>	<u>(394,577)</u>	\$ 5.33 - \$22.50	\$12.24
Balance at December 31, 2000	742,293	2,720,478	\$ 0.33 - \$24.13	\$13.05
Options authorized	1,152,812	—	—	—
Options granted	(1,960,310)	1,960,310	\$ 3.34 - \$12.94	\$ 5.36
Options exercised	—	(30,549)	\$ 5.33 - \$10.63	\$ 6.70
Options cancelled	<u>561,215</u>	<u>(561,215)</u>	\$ 3.44 - \$23.00	\$10.77
Balance at December 31, 2001	496,010	4,089,024	\$ 0.33 - \$24.13	\$ 9.74
Options authorized	1,783,393	—	—	—
Options granted	(2,149,280)	2,149,280	\$ 1.42 - \$ 4.82	\$ 4.20
Options exercised	—	(7,500)	\$3.44	\$ 3.44
Options cancelled	<u>457,970</u>	<u>(457,970)</u>	\$ 1.42 - \$23.00	\$ 6.19
Balance at December 31, 2002	<u>588,093</u>	<u>5,772,834</u>	\$ 0.33 - \$24.13	\$ 7.86

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NOTES TO FINANCIAL STATEMENTS — (Continued)

Exercise Price Range	Options Outstanding and Exercisable		
	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
\$ 0.33 – \$ 0.43	33,375	\$ 0.37	1.3
\$ 0.57	5,874	\$ 0.57	3.1
\$ 1.42 – \$ 2.00	11,450	\$ 1.67	7.9
\$ 2.60 – \$ 3.73	1,360,475	\$ 3.44	9.2
\$ 4.00 – \$ 6.00	2,139,830	\$ 5.13	8.6
\$ 6.53 – \$ 9.75	614,872	\$ 8.08	6.5
\$ 9.88 – \$14.50	818,972	\$12.07	5.6
\$14.88 – \$22.00	544,362	\$17.10	7.6
\$22.50 – \$24.13	<u>243,624</u>	\$22.58	7.2
	<u>5,772,834</u>	\$ 7.86	7.9

The Company recorded deferred compensation of approximately \$704,000 for the difference between the grant price and the fair value of certain of the Company's common stock options granted in 1998. This amount is being amortized over the vesting period of the individual options. There were no such grants in 2002, 2001 and 2000. Amortization of deferred compensation recognized in the years ended December 31, 2002, 2001 and 2000 was approximately \$54,000, \$162,000 and \$163,000, respectively. The weighted average fair value of options granted during 2002, 2001 and 2000 with an exercise price equal to the fair value of the Company's common stock on the date of grant was \$2.67, \$3.59 and \$11.08, respectively.

Pro forma information regarding net loss and basic and diluted net loss per share is required by SFAS 123, which also requires that the information be determined as if the Company had accounted for its employee and non-employee director stock options granted subsequent to December 31, 1994 under the fair value method prescribed by this statement. The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions: a risk-free interest rate of 3.9%, 4.2%, and 6.2% for the years ended December 31, 2002, 2001 and 2000, respectively; a dividend yield of 0.0%; the annual volatility factor of the expected market price of the Company's common stock for 2002, 2001 and 2000 are 87.0%, 87.0%, and 78.0% respectively; and a weighted average expected option life of four years.

Employee Stock Purchase Plan

At a Special Meeting of Shareholders held in February 2002, the number of shares under the Purchase Plan increased by 500,000 shares to 1,250,000 shares of common stock. Employees generally will be eligible to participate in the Purchase Plan if they have been continuously employed by the Company for at least ten days prior to the first day of the offering period and are customarily employed at least 20 hours per week and at least five months per calendar year and are not a 5% or greater stockholder. Shares may be purchased under the Purchase Plan at 85% of the lesser of the fair market value of the common stock on the grant date or purchase date. Employee contributions, through payroll deductions, are limited to fifteen percent of earnings or \$25,000, whichever is less.

As of December 31, 2002 a total of 1,126,826 shares have been issued under the Purchase Plan, leaving a balance of 123,174 available authorized shares. Due to the low number of shares available, employee payroll deductions were frozen in November 2002, pending shareholder approval of additional shares under the Purchase Plan.

Under SFAS No. 123, pro forma compensation cost is reported for the fair value of the employees' purchase rights, which was estimated using the Black-Scholes model and the following assumptions for

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NOTES TO FINANCIAL STATEMENTS — (Continued)

2002; expected volatility of 87.0%; risk-free interest rates of 3.9%; an average expected life of four years and a dividend yield of 0.0%. The weighted-average fair value of the purchase rights granted was \$2.70 per share in 2002.

8. Collaborative Agreements

Novo Nordisk A/S

In June 1998, the Company executed a development and commercialization agreement with Novo Nordisk A/S to jointly develop a pulmonary delivery system for administering insulin by inhalation. In addition, the agreement provides Novo Nordisk A/S with an option to develop the technology for delivery of other compounds. Under the terms of the agreement, Novo Nordisk A/S has been granted exclusive rights to worldwide sales and marketing rights for any products developed under the terms of the agreement.

Through December 31, 2002, the Company received from Novo Nordisk A/S approximately \$99.1 million in product development and milestone payments and, of this amount, the Company has recognized approximately \$82.3 million as contract revenue. In future periods, the Company could receive up to \$124 million in additional product development and nonrefundable milestone payments.

In 1998, the Company raised \$5.0 million through the sale of common stock to Novo Nordisk A/S at a 25% premium to the fair market price. In June 2001, the Company raised an additional \$5 million through the sale of common stock to Novo Nordisk A/S at the fair market price. In October 2001, the Company entered into a new common stock purchase agreement with Novo Nordisk Pharmaceuticals. Under the new agreement, Novo Nordisk Pharmaceuticals committed to purchase up to \$45 million of the Company's common stock at fair market value specified in the agreement of, which \$20 million was invested initially. The Company has the right at its option, subject to certain conditions, to sell between \$5 million and \$10 million of additional shares to Novo Nordisk Pharmaceuticals once every three months beginning December 1, 2001 until the remaining amount of \$25 million has been invested. In July 2002, the Company raised \$5 million through the sale of common stock to Novo Nordisk Pharmaceuticals under the terms of the agreement. At December 31, 2002, Novo Nordisk A/S and its affiliates currently own approximately 20% of the Company's total outstanding common stock on an as-converted basis. Novo Nordisk A/S will fund all product development costs incurred by the Company under the terms of the agreement, while Novo Nordisk A/S and the Company will co-fund final development of the AERx device. The Company will be the initial manufacturer of all the products covered by the agreement and will receive a share of the overall gross profits resulting from Novo Nordisk A/S's sales of the products. For the years ended December 31, 2002, 2001 and 2000, the Company recognized contract revenues of \$26.9 million, \$26.0 million and \$15.4 million, respectively.

GlaxoSmithKline

The Company executed a development and commercialization agreement with GlaxoSmithKline in September 1997. The agreement covered the use of the AERx Pain Management System for the delivery of narcotic analgesics and the companies intended to collaborate on the development of the products within this field. Under the terms of the agreement, GlaxoSmithKline was granted exclusive worldwide sales and marketing rights to the AERx Pain Management System for use with such analgesics, and the Company retained all manufacturing rights. If the system received regulatory approval, the Company intended to sell devices and drug packets to GlaxoSmithKline and would receive royalties on developed product sold by GlaxoSmithKline.

During December 2000, the Company and GlaxoSmithKline amended the product development and commercialization agreement whereby the Company assumed full control and responsibility for conducting

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS — (Continued)

and financing the remainder of all development activities. Under the amendment, unless GlaxoSmithKline or the Company terminate the agreement for other reasons, GlaxoSmithKline can restore its rights and obligations to participate in and fund development and commercialization of product under the amended agreement upon payment of a restoration fee to the Company. In the event GlaxoSmithKline elects to restore its rights under the amended agreement, revenue will be recognized for the portion of the restoration fee that represents reimbursement of development costs not previously reimbursed by GlaxoSmithKline, but incurred by the Company through the date of the election. Any remaining fees will be deferred and amortized over the estimated remaining development period of the amended development agreement. The Company has made available to GlaxoSmithKline all of the Phase 2b trial results and await their decision on further development plans. There can be no assurance that GlaxoSmithKline will elect to restore its rights. If the Company elects to terminate the agreement and continues or intends to continue any development activities, either alone or in collaboration with a third party, then the Company is required to pay an exit fee to GlaxoSmithKline. The payment of the exit fee would not have a material impact on the Company's financial position or operating results.

Through December 31, 2001, the Company had received from GlaxoSmithKline and recognized as contract revenue approximately \$23.7 million in product development and milestone payments. No product development and milestone payments were received during 2002. In 1997, the Company raised \$5 million through the sale of common stock to GlaxoSmithKline at a 25% premium to the fair market price. In January 2001, the Company raised an additional \$5 million through the sale of common stock to GlaxoSmithKline at the fair market price. For the years ended December 31, 2002, 2001 and 2000, the Company recognized contract revenue of zero dollars, \$1.5 million and \$3.4 million, respectively.

Genentech

The Company entered into an agreement with Genentech in May 1999. The agreement was to develop the drug dornase alfa in the AERx system. Dornase alfa is the active ingredient in the currently marketed Genentech product, Pulmozyme. The agreement provided that development expenses incurred by Aradigm would be reimbursed by Genentech in the form of loans supported by promissory notes bearing interest at two percent over the prime rate, which was 11.5% at December 31, 2000. Principal and unpaid accrued interest was due at the earlier of 15 days after FDA approval or seven years after the effective date of the collaborative agreement or May 21, 2006. The Company would also receive certain milestone payments at various points of product development. In September 2000, the Company received a milestone payment of \$500,000 for the successful completion of a U.S. Phase 2a clinical trial of the AERx Pulmonary Drug Delivery System for the delivery of dornase alfa to patients with cystic fibrosis.

In February 2001, the Company announced that it had mutually agreed with Genentech to discontinue the development of dornase alfa using the Company's proprietary AERx system. The companies also announced that they would be entering into a new agreement allowing Genentech to evaluate feasibility of using the AERx Pulmonary Drug Delivery System for pulmonary delivery of other Genentech compounds. Under the terms of the agreement, Genentech would not require the Company to repay the loan of funds required to conduct product development under the discontinued program. Forgiveness of the loan and accrued interest resulted in other income of approximately \$6,675,000 during the first quarter of 2001. During 2001, the Company refunded Genentech approximately \$773,000 for unspent project prepayments.

The Company receives revenue from other partner-funded programs. These programs are generally early stage feasibility programs and may not necessarily develop into long-term development agreements with the partners.

ARADIGM CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

Significant partner payments, contract and milestone revenues and deferred revenue are as follows (amounts in thousands):

	December 31,		
	<u>2002</u>	<u>2001</u>	<u>2000</u>
Deferred revenue — beginning balance	\$13,442	\$ 8,654	\$11,024
Partner payments:			
Novo Nordisk A/S	30,794	32,054	13,879
GlaxoSmithKline	—	—	2,617
Other partner-funded programs	<u>1,583</u>	<u>1,650</u>	<u>1,437</u>
Total partner payments	<u>32,377</u>	<u>33,704</u>	<u>17,933</u>
Contract revenue recognized:			
Novo Nordisk A/S	26,864	26,030	15,411
GlaxoSmithKline	—	1,524	3,379
Other partner-funded programs	<u>2,103</u>	<u>1,362</u>	<u>1,513</u>
Total contract revenue recognized	<u>28,967</u>	<u>28,916</u>	<u>20,303</u>
Deferred revenue — ending balance	16,852	13,442	8,654
Less: Noncurrent portion of deferred revenue	<u>(6,170)</u>	<u>(2,327)</u>	<u>(2,032)</u>
Current portion of deferred revenue	<u>\$10,682</u>	<u>\$11,115</u>	<u>\$ 6,622</u>

9. Related Party Transactions

Novo Nordisk A/S and its affiliate, Novo Nordisk Pharmaceuticals, Inc., are considered related parties and at December 31, 2002 own approximately 20% of the Company's total outstanding common stock (on an as-converted basis).

Development and License Agreement

In June 1998, the Company executed a development and commercialization agreement with Novo Nordisk A/S to jointly develop a pulmonary delivery system for administering insulin by inhalation. Under the terms of the agreement, Novo Nordisk A/S has been granted exclusive rights to worldwide sales and marketing rights for any products developed under the terms of the agreement. Through December 31, 2002, the Company received from Novo Nordisk A/S approximately \$99.1 million in product development and milestone payments and, of this amount, the Company has recognized approximately \$82.3 million as contract revenue. In future periods, the Company could receive up to \$124 million in additional product development and nonrefundable milestone payments. Novo Nordisk A/S will fund all product development costs incurred by the Company under the terms of the agreement, while Novo Nordisk A/S and the Company will co-fund final development of the AERx device. The Company will be the initial manufacturer of all the products covered by the agreement and will receive a share of the overall gross profits resulting from Novo Nordisk A/S's sales of the products. For the years ended December 31, 2002, 2001 and 2000, the Company recognized contract revenues of \$26.9 million, \$26.0 million and \$15.4 million, respectively. Receivable due to the Company from Novo Nordisk A/S was \$0 and \$631,000 at December 31, 2002 and 2001, respectively.

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS — (Continued)

Securities Purchase Agreements

Since the inception of the collaboration in June 1998 through December 31, 2002, the Company raised \$10 million through the sale of common stock to Novo Nordisk A/S. In October 2001, the Company entered into a new common stock purchase agreement with Novo Nordisk Pharmaceuticals. Under the new agreement, Novo Nordisk Pharmaceuticals has committed to purchase up to \$45 million of the Company's common stock, at fair market value specified in the agreement of which \$20 million was invested initially. The Company has the right at its option, subject to certain conditions, to sell between \$5 million and \$10 million of additional shares to Novo Nordisk Pharmaceuticals once every three months beginning December 1, 2001 until the remaining amount of \$25 million has been invested. In July 2002, the Company raised \$5 million through the sale of common stock to Novo Nordisk Pharmaceuticals under the terms of the agreement.

10. **Income Taxes**

There is no provision for income taxes because the Company has incurred operating losses. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for tax purposes.

Significant components of the Company's deferred tax assets are as follows (amounts in thousands):

	December 31,	
	2002	2001
Net operating loss carryforward	\$ 54,900	\$ 48,000
Deferred revenue	6,700	4,400
Research and development credits	9,200	6,500
Capitalized research and development	2,000	—
Other	1,200	700
Total deferred tax assets	74,000	59,600
Valuation allowance	(74,000)	(59,600)
Net deferred tax assets	\$ —	\$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$14,400,000 and \$12,939,000 during 2002 and 2001, respectively.

Deferred tax assets related to carryforwards at December 31, 2002 include approximately \$1,600,000 associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders' equity.

As of December 31, 2002, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$151,000,000 which expire in the years 2006 through 2022, and federal research and development tax credits of approximately \$6,000,000, which expire in the years 2006 through 2022. As of December 31, 2002, the Company had net operating loss carryforwards for state income tax purposes of approximately \$59,000,000 which expire in the years 2004 through 2013 and state research and development tax credits of approximately \$4,700,000 which do not expire.

Utilization of the Company's net operating loss may be subject to substantial annual limitation due to ownership change limitations provided by the Internal revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss before utilization.

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS — (Continued)

11. Quarterly Results of Operations (Unaudited)

Following is a summary of the quarterly results of operations for the years ended December 31, 2002 and 2001 (amounts in thousands):

	<u>March 31, 2002</u>	<u>June 30, 2002</u>	<u>September 30, 2002</u>	<u>December 31, 2002</u>
Contract and license revenues	\$ 8,118	\$ 7,295	\$ 5,951	\$ 7,603
Operating expenses:				
Research and development	14,313	14,588	13,660	12,119
General and administrative	2,458	2,809	2,636	2,491
Total expenses	<u>16,771</u>	<u>17,397</u>	<u>16,296</u>	<u>14,610</u>
Loss from operations	(8,653)	(10,102)	(10,345)	(7,007)
Interest income	291	210	164	154
Interest expense and other	(166)	(84)	(100)	(293)
Net loss	<u>\$ (8,528)</u>	<u>\$ (9,976)</u>	<u>\$ (10,281)</u>	<u>\$ (7,146)</u>
Basic and diluted loss per share applicable to common shareholders:				
Net loss	<u>\$ (0.29)</u>	<u>\$ (0.34)</u>	<u>\$ (0.34)</u>	<u>\$ (0.23)</u>
Shares used in computing basic and diluted loss per share applicable to common shareholders	<u>29,544</u>	<u>29,723</u>	<u>30,597</u>	<u>31,158</u>
	<u>March 31, 2001</u>	<u>June 30, 2001</u>	<u>September 30, 2001</u>	<u>December 31, 2001</u>
Contract and license revenues	\$ 6,687	\$ 8,520	\$ 6,889	\$ 6,820
Operating expenses:				
Research and development	14,160	15,298	14,890	14,488
General and administrative	2,328	2,322	2,233	2,472
Total expenses	<u>16,488</u>	<u>17,620</u>	<u>17,123</u>	<u>16,960</u>
Loss from operations	(9,801)	(9,100)	(10,234)	(10,140)
Interest income	668	299	167	190
Other income(1)	6,675	—	—	—
Interest expense and other	(262)	(364)	(216)	(239)
Net loss	(2,720)	(9,165)	(10,283)	(10,189)
Deemed dividend	—	—	—	(10,722)
Net loss applicable to common stockholders	<u>\$ (2,720)</u>	<u>\$ (9,165)</u>	<u>\$ (10,283)</u>	<u>\$ (20,911)</u>
Basic and diluted loss per share applicable to common shareholders:				
Net loss applicable to common shareholders	<u>\$ (0.14)</u>	<u>\$ (0.47)</u>	<u>\$ (0.48)</u>	<u>\$ (0.77)</u>
Shares used in computing basic and diluted loss per share applicable to common shareholders	<u>18,838</u>	<u>19,338</u>	<u>21,581</u>	<u>27,319</u>

(1) Other income consists of the gain related to forgiveness of outstanding notes and interests by Genentech, previously classified as an extraordinary item. The Company early adopted Statement of Financial Accounting Standard ("SFAS") 145, "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB 13 and Technical Corrections", which requires the reclassification of this type of extraordinary item as a component of operating results.

ARADIGM CORPORATION
NOTES TO FINANCIAL STATEMENTS — (Continued)

12. Subsequent Events (unaudited)

Sales of Unregistered Securities

As of February 10, 2003, the Company issued 18,992,391 shares of common stock at \$0.79 per share and warrants to purchase 4,273,272 shares of the common stock at \$1.07 per share to certain investors for an aggregate purchase price of approximately \$15.0 million in a private placement. The warrants are exercisable at the election of the warrant holders for a four-year term. In addition, in connection with this private placement, the Company has issued to certain of the investors in the private placement warrants to purchase an aggregate of 4,016,024 shares of its common stock at \$1.12 per share in exchange for the cancellation of an equal number of warrants to purchase the common stock at \$6.97 per share, held by the same investors. These securities have not been registered under the Securities Act of 1933, as amended, by virtue of Regulation D promulgated under such Act.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

PART III

Item 10. *Directors and Executive Officers of the Registrant*

Identification of Directors

The information required by this Item concerning the Company's directors is incorporated by reference from the section captioned "Proposal 1: Election of Directors" contained in the Company's Definitive Proxy Statement related to the Annual Meeting of Shareholders to be held May 15, 2003, to be filed by the Company with the Securities and Exchange Commission (the "Proxy Statement").

Identification of Executive Officers

The information required by this Item concerning our executive officers is set forth in Part I of this Report.

Section 16(a) Compliance

The information regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, required by this Item is incorporated by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement.

Item 11. *Executive Compensation*

The information required by this Item is incorporated by reference from the section captioned "Executive Compensation" contained in the Proxy Statement.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

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

Item 13. *Certain Relationships and Related Transactions*

The information required by this Item is incorporated by reference from the sections captioned "Certain Transactions" and "Executive Compensation" contained in the Proxy Statement.

Item 14. *Control Procedures*

(a) *Evaluation of disclosure controls and procedures:* Our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-14)(c) and 15(d)-14(c) under the Securities Exchange Act of 1934, as amended) within 90 days of filing of this Form 10-K (the "Evaluation Date") and, based on that evaluation, concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective to timely alert management to material information relating to Aradigm Corporation during the period when our periodic reports are being prepared.

(b) *Changes in internal controls:* There were no significant changes in the Company's internal controls or other factors that could significantly affect those controls subsequent to the date of the Company's evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

PART IV

Item 15. *Exhibits, Financial Statements Schedules, and Reports on Form 8-K*

(a) (1) Financial Statements.

Included in Part II of this Report:

	<u>Page in Form 10-K</u>
Report of Ernst & Young LLP, Independent Auditors	38
Balance Sheets — December 31, 2002 and 2001	39
Statements of Operations — Years ended December 31, 2002, 2001 and 2000	40
Statements of Redeemable Convertible Preferred Stock and Shareholders' Equity — Years ended December 31, 2002, 2001 and 2000	41
Statements of Cash Flows — Years ended December 31, 2002, 2001 and 2000.....	42
Notes to Financial Statements	43

(2) Financial Statement Schedules.

None.

(3) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
3.1(1)	Amended and Restated Articles of Incorporation of the Company.
3.2(5)	Bylaws of the Company, as amended.
3.3(15)	Certificate of Determination of Series A Junior Participating Preferred Stock.
3.4(14)	Certificate of Determination and Preferences of Series A Convertible Preferred Stock.
3.5(15)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.6(15)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5 and 3.6.
4.2(1)	Specimen common stock certificate.
10.1(1)(2)	Form of Indemnity Agreement between the Registrant and each of its directors and officers.
10.2(2)(11)	Equity Incentive Plan, as amended (the "Equity Incentive Plan").
10.3(1)(2)	Form of the Company's Incentive Stock Option Agreement under the Equity Incentive Plan.
10.4(1)(2)	Form of the Company's Non-statutory Stock Option Agreement under the Equity Incentive Plan.
10.5(1)(2)	Form of the Company's Non-Employee Directors' Stock Option Plan.
10.6(1)(2)	Form of the Company's Non-statutory Stock Option Agreement under the Non-Employee Directors' Stock Option Plan.
10.7(2)(16)	Employee Stock Purchase Plan, as amended.
10.8(1)(2)	Form of the Company's Employee Stock Purchase Plan Offering Document.
10.9(1)	Master Lease Agreement and Warrant, between the Company and Comdisco, Inc., dated June 9, 1995.
10.11(4)*	Product Development and Commercialization Agreement between the Company and SmithKline Beecham PLC.
10.11(3)	Lease Agreement for the property located at 3911 Trust Way, Hayward, California, dated March 17, 1997, between the Company and Hayward Point Eden I Limited Partnership.

<u>Exhibit No.</u>	<u>Description</u>
10.11a(3)	First Amendment to Lease dated December 22, 1997, between the Company and Hayward Point Eden I Limited Partnership.
10.11b(3)	Second Amendment to Lease, dated January 28, 1998, between the Company and Hayward Point Eden I Limited Partnership.
10.12(3)	Lease Agreement for the property located in Phase V of the Britannia Point Eden Business Park in Hayward, California, dated January 28, 1998, between the Company and Britannia Point Eden, LLC.
10.13(5)	Common Stock Purchase Agreement dated April 3, 1998, between the Company and the purchasers named therein.
10.14(5)*	Development and License Agreement, dated June 2, 1998, between the Company and Novo Nordisk A/S.
10.15(6)	Rights Agreement, dated as of August 31, 1998, between the Company and Bank Boston, N.A.
10.15a(15)	Amendment to Rights Agreement, dated as of October 22, 2001, by and between the Company and Fleet National Bank.
10.15b(15)	Amendment to Rights Agreement, dated as of December 6, 2001, by and between the Company and EquiServe Trust Company.
10.16(7)	Common Stock Purchase Agreement dated January 27, 1999, between the Company and the purchasers named therein.
10.17(8)	Lease Agreement for the property located at 2704 West Winton Avenue, Hayward, California, dated September 11, 2000, between the Company and Winton Industrial Center, Inc.
10.17a(12)	Amendment No. 1 to Standard Office/Warehouse Lease, dated March 1, 2001, by and between the Company and Winton Industrial Center, Inc.
10.18(8)	Lease Agreement for the property located at 3930 Point Eden Way, Hayward, California, dated July 1, 2000, between the Company and Hayward Point Eden I Limited Partnership.
10.19(9)	Common Stock Purchase Agreement, dated as of November 3, 2000, by and between the Company and Acqua Wellington North American Equities Fund, Ltd.
10.20(10)*	Amendment to GlaxoSmithKline agreement executed in December 2000.
10.21(13)	Securities Purchase Agreement, dated as of August 21, 2001, by and among the Company and the purchasers named therein.
10.22(15)	Stock Purchase Agreement, dated as of October 22, 2001, by and between the Company and Novo Nordisk Pharmaceuticals, Inc.
10.23*(15)	First Amendment to Development and License Agreement, dated as of October 22, 2001, between the Company and Novo Nordisk A/S.
10.24(14)	Securities Purchase Agreement, dated as of December 11, 2001, by and among the Company and the purchasers named therein.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney. Reference is made to the signature page.
99.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* The Company has sought confidential treatment for portions of the referenced exhibit.

- (1) Incorporated by reference to the indicated exhibit in the Company's Registration Statement on Form S-1 (No. 333-4236), as amended.
- (2) Represents a management contract or compensatory plan or arrangement.
- (3) Incorporated by reference to Company's Annual Report on Form 10-K for the year ended December 31, 1997, as amended.
- (4) Incorporated by reference to the Company's Form 8-K filed on November 7, 1997.

- (5) Incorporated by reference to the Company's Form 10-Q filed on August 14, 1998.
- (6) Incorporated by reference to the Company's 8-K filed on September 2, 1998.
- (7) Incorporated by reference to the indicated exhibit in the Company's Registration Statement on Form S-3 (No. 333-72037), as amended.
- (8) Incorporated by reference to the Company's Form 10-Q filed on November 13, 2000.
- (9) Incorporated by reference to the Company's Form 8-K filed on December 11, 2000.
- (10) Incorporated by reference to the Company's Form 10-K filed for the year ended December 31, 2000.
- (11) Incorporated by reference to the Company's definitive proxy statement filed on April 11, 2001.
- (12) Incorporated by reference to the Company's Form 10-Q filed on August 13, 2001.
- (13) Incorporated by reference to the Company's Form S-3 (No. 333-69614), as amended.
- (14) Incorporated by reference to the Company's Form S-3 (No. 333-76584).
- (15) Incorporated by reference to the Company's Form 10-K filed for the year ended December 31, 2001.
- (16) Incorporated by reference to the Company's definitive proxy statement filed on January 4, 2002.

(b) Reports on Form 8-K.

None.

(c) Index to Exhibits.

See Exhibits listed under Item 14(a)(3).

(d) Financial Statement Schedules.

CERTIFICATION

I, Richard P. Thompson, certify that:

1. I have reviewed this annual report on Form 10-K of Aradigm Corporation;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ RICHARD P. THOMPSON

Richard P. Thompson
President and Chief Executive Officer

Date: March 19, 2003

CERTIFICATION

I, Thomas C. Chesterman, certify that:

1. I have reviewed this annual report on Form 10-K of Aradigm Corporation;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - d) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - e) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ THOMAS C. CHESTERMAN

Thomas C. Chesterman
Senior Vice President and Chief Financial Officer

Date: March 19, 2003

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
3.1(1)	Amended and Restated Articles of Incorporation of the Company.
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4.2(1)	Specimen common stock certificate.
10.1(1)(2)	Form of Indemnity Agreement between the Registrant and each of its directors and officers.
10.2(2)(11)	Equity Incentive Plan, as amended (the "Equity Incentive Plan").
10.3(1)(2)	Form of the Company's Incentive Stock Option Agreement under the Equity Incentive Plan.
10.4(1)(2)	Form of the Company's Non-statutory Stock Option Agreement under the Equity Incentive Plan.
10.5(1)(2)	Form of the Company's Non-Employee Directors' Stock Option Plan.
10.6(1)(2)	Form of the Company's Non-statutory Stock Option Agreement under the Non-Employee Directors' Stock Option Plan.
10.7(2)(16)	Employee Stock Purchase Plan, as amended.
10.8(1)(2)	Form of the Company's Employee Stock Purchase Plan Offering Document.
10.9(1)	Master Lease Agreement and Warrant, between the Company and Comdisco, Inc., dated June 9, 1995.
10.11(4)*	Product Development and Commercialization Agreement between the Company and SmithKline Beecham PLC.
10.11(3)	Lease Agreement for the property located at 3911 Trust Way, Hayward, California, dated March 17, 1997, between the Company and Hayward Point Eden I Limited Partnership.
10.11a(3)	First Amendment to Lease dated December 22, 1997, between the Company and Hayward Point Eden I Limited Partnership.
10.11b(3)	Second Amendment to Lease, dated January 28, 1998, between the Company and Hayward Point Eden I Limited Partnership.
10.12(3)	Lease Agreement for the property located in Phase V of the Britannia Point Eden Business Park in Hayward, California, dated January 28, 1998, between the Company and Britannia Point Eden, LLC.
10.13(5)	Common Stock Purchase Agreement dated April 3, 1998, between the Company and the purchasers named therein.
10.14(5)*	Development and License Agreement, dated June 2, 1998, between the Company and Novo Nordisk A/S.
10.15(6)	Rights Agreement, dated as of August 31, 1998, between the Company and Bank Boston, N.A.
10.15a(15)	Amendment to Rights Agreement, dated as of October 22, 2001, by and between the Company and Fleet National Bank.
10.15b(15)	Amendment to Rights Agreement, dated as of December 6, 2001, by and between the Company and EquiServe Trust Company.
10.16(7)	Common Stock Purchase Agreement dated January 27, 1999, between the Company and the purchasers named therein.
10.17(8)	Lease Agreement for the property located at 2704 West Winton Avenue, Hayward, California, dated September 11, 2000, between the Company and Winton Industrial Center, Inc.

<u>Exhibit No.</u>	<u>Description</u>
10.17a(12)	Amendment No. 1 to Standard Office/Warehouse Lease, dated March 1, 2001, by and between the Company and Winton Industrial Center, Inc.
10.18(8)	Lease Agreement for the property located at 3930 Point Eden Way, Hayward, California, dated July 1, 2000, between the Company and Hayward Point Eden I Limited Partnership.
10.19(9)	Common Stock Purchase Agreement, dated as of November 3, 2000, by and between the Company and Acqua Wellington North American Equities Fund, Ltd.
10.20(10)*	Amendment to GlaxoSmithKline agreement executed in December 2000.
10.21(13)	Securities Purchase Agreement, dated as of August 21, 2001, by and among the Company and the purchasers named therein.
10.22(15)	Stock Purchase Agreement, dated as of October 22, 2001, by and between the Company and Novo Nordisk Pharmaceuticals, Inc.
10.23*(15)	First Amendment to Development and License Agreement, dated as of October 22, 2001, between the Company and Novo Nordisk A/S.
10.24(14)	Securities Purchase Agreement, dated as of December 11, 2001, by and among the Company and the purchasers named therein.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney. Reference is made to the signature page.
99.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* The Company has sought confidential treatment for portions of the referenced exhibit.

- (1) Incorporated by reference to the indicated exhibit in the Company's Registration Statement on Form S-1 (No. 333-4236), as amended.
- (2) Represents a management contract or compensatory plan or arrangement.
- (3) Incorporated by reference to Company's Annual Report on Form 10-K for the year ended December 31, 1997, as amended.
- (4) Incorporated by reference to the Company's Form 8-K filed on November 7, 1997.
- (5) Incorporated by reference to the Company's Form 10-Q filed on August 14, 1998.
- (6) Incorporated by reference to the Company's 8-K filed on September 2, 1998.
- (7) Incorporated by reference to the indicated exhibit in the Company's Registration Statement on Form S-3 (No. 333-72037), as amended.
- (8) Incorporated by reference to the Company's Form 10-Q filed on November 13, 2000.
- (9) Incorporated by reference to the Company's Form 8-K filed on December 11, 2000.
- (10) Incorporated by reference to the Company's Form 10-K filed for the year ended December 31, 2000.
- (11) Incorporated by reference to the Company's definitive proxy statement filed on April 11, 2001.
- (12) Incorporated by reference to the Company's Form 10-Q filed on August 13, 2001.
- (13) Incorporated by reference to the Company's Form S-3 (No. 333-69614), as amended.
- (14) Incorporated by reference to the Company's Form S-3 (No. 333-76584).
- (15) Incorporated by reference to the Company's Form 10-K filed for the year ended December 31, 2001.
- (16) Incorporated by reference to the Company's definitive proxy statement filed on January 4, 2002.

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-76584, No. 333-69614, No. 333-52081, No. 333-72037 and No. 333-48384) of Aradigm Corporation and in the related Prospectus' and the Registration Statements on Form S-8 (No. 333-85244, No. 333-63116, No. 333-15947, No. 333-62039 and No. 333-92169) of our report dated February 7, 2003, with respect to the financial statements of Aradigm Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2002.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 19, 2003

Corporate Information

BOARD OF DIRECTORS

Richard P. Thompson
Chairman of the Board, President
and Chief Executive Officer
Aradigm

Frank H. Barker
Former Group Chairman
Johnson & Johnson

Stan M. Benson
Former Senior Vice President of
Sales and Marketing, Amgen Inc.

Igor Gonda, Ph.D.
Chief Executive Officer and
Managing Director, Acrux Limited
Former Chief Scientific Officer,
Aradigm

John Nehra
Special Partner,
New Enterprise Associates 10

Wayne I. Roe
Former Chairman,
Covance Health Economics and
Outcomes Services, Inc.

Virgil D. Thompson
President, Chief Executive
Officer and Director,
Angstrom Pharmaceuticals Inc.

EXECUTIVE OFFICERS

Richard P. Thompson
Chairman of the Board, President
and Chief Executive Officer

V. Bryan Lawlis, Ph.D.
Chief Operating Officer

Thomas C. Chesterman
Senior Vice President and
Chief Financial Officer

Klaus D. Kohl, Ph.D.
Senior Vice President
and Technical Leader
iDMS

Stephen J. Farr, Ph.D.
Vice President, Research and
Development

Babatunde A. Otulana, M.D.
Vice President, Clinical and
Regulatory Affairs

Bikash K. Chatterjee
Vice President, Pharmaceutical
Operations

Maximillian D. Fiore
Vice President, Engineering

Daniel P. Maher
Vice President, Program
Management

Norma L. Milligin
Vice President, Human Resources

COMMON STOCK LISTING

Aradigm's common stock is listed on the Nasdaq National
Market. Symbol: ARDM

PRICE RANGE OF COMMON STOCK

2002	High	Low
1st Qtr	\$7.29	\$4.01
2nd Qtr	4.61	3.43
3rd Qtr	3.99	1.94
4th Qtr	2.81	1.30

TRANSFER AGENT AND REGISTRAR

Communications concerning stock transfer requirements, lost
certificates and change of address should be directed to:

Equiserve Trust Company
P.O. Box 43010
Providence, RI 02940-3010
816.843.4299
www.Equiserve.com

INVESTOR RELATIONS

Aradigm Corporation
3929 Point Eden Way
Hayward, CA 94545
510.265.9000
Fax: 510.265.0277
email: investor@aradigm.com

SHAREHOLDERS

As of February 28, 2003, there were approximately
164 holders of record of the Company's common stock.

Aradigm has not paid dividends since its inception and
does not intend to pay dividends on its common stock
in the foreseeable future.

Aradigm, AERx, AERx Strip, AERx Ultra and AERx Essence
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Except for historical information contained herein, this report
contains forward-looking statements that involve risk and
uncertainties, including clinical results, regulatory approval of
the Company's products, the timely availability and acceptance
of new products, the impact of competitive products and
pricing, and the management of growth, as well as the other
risks detailed from time to time in Aradigm Corporation's
Securities and Exchange Commission (SEC) Registration
filings, including the Company's annual report on Form 10-K.



ARADIGM
CORPORATION

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Hayward, CA 94545
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