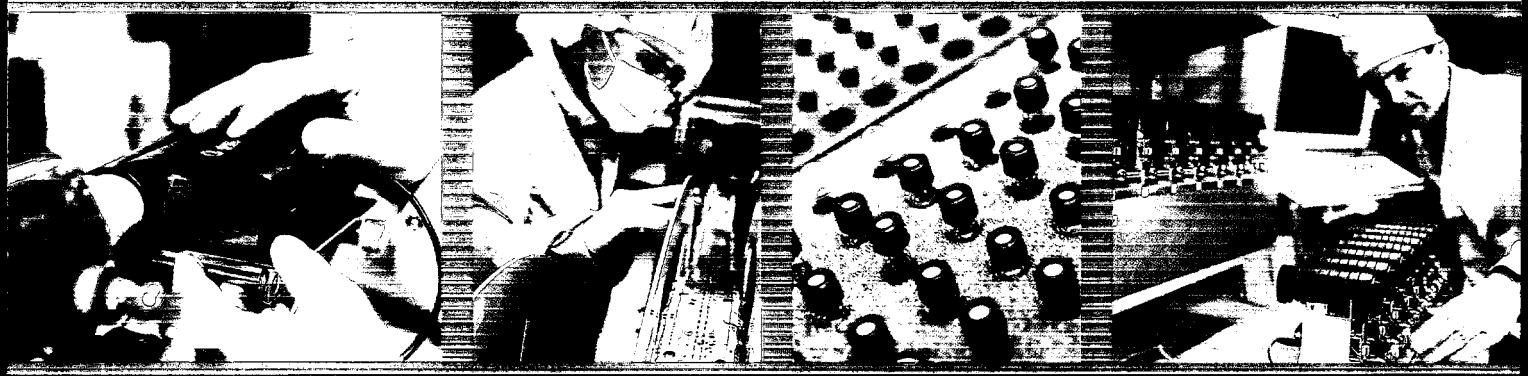
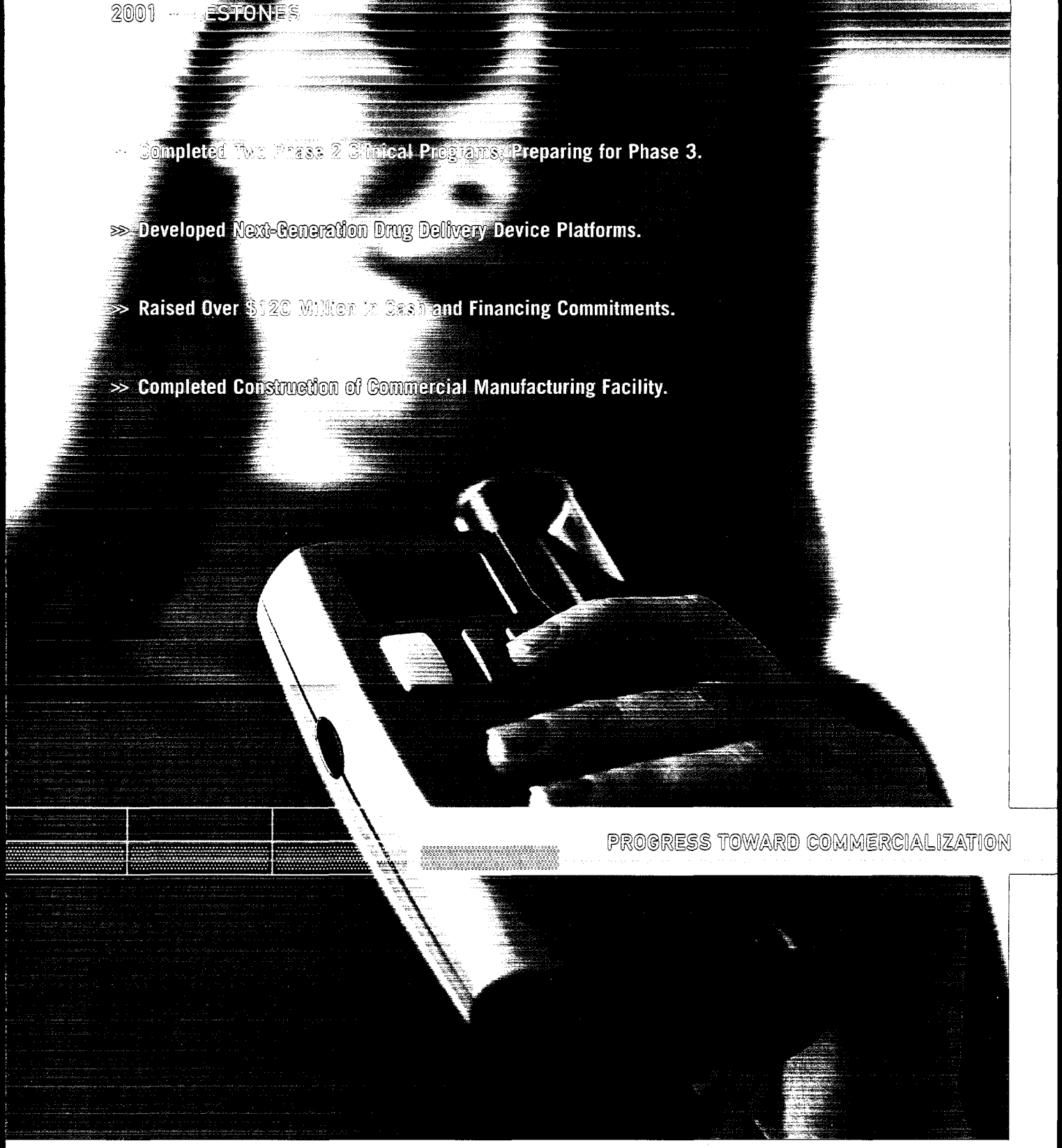
Aradigm
A/S
1E. 12/31/01

Innovators in Pulmonary Drug Delivery

Aradigm (Nasdaq: ARDM) is an innovator in drug delivery, focused on providing rapid-onset, non-invasive aerosol products that offer substantial advantages over needle injections and slow-to-act oral medications. The Company's AERx® systems enable patients to comfortably inhale a liquid mist of drug, readily treating respiratory conditions or a wide range of systemic diseases. With more than 1000 subjects treated to date in clinical studies, AERx systems are demonstrating clear benefits, such as giving the user the ability to easily take medications in almost any setting, the security of knowing that effective therapy is only minutes away, and the potential for achieving increased patient compliance with prescribed treatments. Aradigm's lead programs target inhaled insulin, diabetes management and pain management.

For more information, please visit the website at www.aradigm.com.





2001 ... ESTONES

... Completed Two Phase 2 Clinical Programs, Preparing for Phase 3.

>> Developed Next-Generation Drug Delivery Device Platforms.

>> Raised Over $120 Million in Cash and Financing Commitments.

>> Completed Construction of Commercial Manufacturing Facility.

PROGRESS TOWARD COMMERCIALIZATION

The pattern of holes that recurs throughout this report represents a key feature of our technology: the laser-drilled nozzles of the AERx Strip™ drug packet used in all AERx systems. Our patented AERx Strip converts liquid drug formulations into an aerosol mist and is designed to provide precise, consistent deep lung delivery.

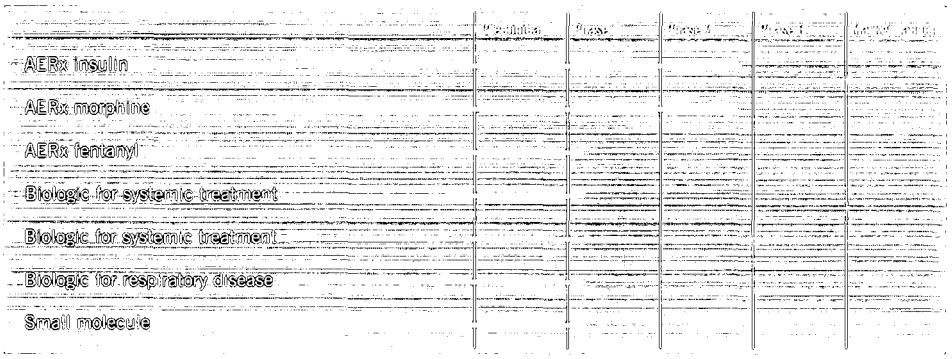
This is a highly productive time for our company. Not only are we building momentum in our diabetes management and pain management programs, we also are advancing several partner-funded feasibility studies through clinical and preclinical testing. Aradigm's commercial opportunities are significant and growing.

Clinical Success: Insulin Program How the patient inhales and how the aerosol is created are critical—no matter what technology is used. Our AERx® insulin delivery system is unique in our industry. It electronically guides the patient through the inhalation process, converts the drug into a fine-particle mist, and releases insulin only when the patient inhales correctly. Our goal is to provide freedom from mealtime injections of short-acting insulin, without sacrificing therapeutic accuracy. Although our progress has been less rapid than anticipated, clinical results demonstrate that we are on the right track. Based on clinical results to date, both the safety and efficacy of our AERx system have been comparable to intensified subcutaneous insulin injection therapy. In addition, our AERx system is delivering insulin into the blood faster than regular injections, enabling patients to time their dosing close to meals for better insulin control. We are taking great care as we move forward and are confident of our readiness to begin Phase 3 trials with our partner, Novo Nordisk A/S, the world leader in insulin and diabetes care.

Clinical Success: Morphine Program We also are obtaining excellent results in our pain management program. The AERx system provides injectable-quality therapy, without the pain and inconvenience. Clinical data are demonstrating that the time to peak drug concentration in the blood is as fast as can be achieved with direct intravenous (IV) injection. Equally important, the dose-to-dose reproducibility within the patient is comparable to IV. Our partner in pain management is GlaxoSmithKline, a world leader in oncology therapy and supportive care.

ADDRESSING MAJOR NEEDS

PRODUCT PIPELINE

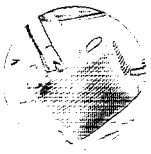


ARADIGM ACHIEVED MAJOR MILESTONES IN 2001, ENABLING US TO ADVANCE OUR PRODUCT DEVELOPMENTS AND FURTHER STRENGTHEN OUR INFRASTRUCTURE.

Diversified AERx Device Technology All of Aradigm's unique therapeutic products include hand-held devices that convert liquid medications into aerosols and deposit those medications deep into the lung. The commercially-ready technology used in our AERx insulin and AERx morphine programs provides a sophisticated, electronic approach to drug delivery, for maximum control over the treatment process. Building on the success of this technology platform, we are developing a family of AERx devices, including a smaller electronic version (AERx Ultra™) as well as a mechanical version (AERx Essence™), to address a variety of new commercial opportunities.

Manufacturing Progress We have completed construction of Aradigm's commercial-scale pharmaceutical facility and are in the process of validating systems and bringing in equipment for large-scale manufacturing runs. This facility will be responsible for producing the AERx Strip™ drug packets used in various AERx systems. Our separate clinical-scale operations will continue to supply product used in human trials. Importantly, Aradigm's production process for liquid drugs employs manufacturing techniques that are inherently more efficient, higher yielding and more cost-effective than the processes used for alternative dry powder products.

Appointment of COO In late 2001, we welcomed V. Bryan Lawlis, Ph.D., as chief operating officer of Aradigm. He is responsible for all activities associated with product development and manufacturing. Dr. Lawlis has 20 years of experience managing teams which have brought an array of biotechnology products to market. Most recently, he was chairman, president and chief executive officer of Covance Biotechnology Services, which he grew to a significant position in contract biomanufacturing. He also served as vice president of process sciences at Genentech, directing the development of manufacturing processes, formulations and drug delivery for major therapies.



AERx ADVANTAGES

Convenient Therapy

AERx systems are portable enough to be carried wherever the patient goes, ready to provide therapy with a comfortable inhalation. The aerosolized drug disperses in the lung, treating respiratory conditions or passing into the bloodstream to treat systemic diseases.

Simple to Use

Whether a fully featured electronic system or entirely mechanical, each AERx drug delivery device is designed for easy use by all types of patients. In ongoing clinical studies, our hand-held AERx devices have been used successfully by people who have active pulmonary disease, by smokers, and even by children.

Safe and Reliable

All AERx systems are designed to provide consistent dosing. In addition, the most sophisticated systems enable health care professionals to program drug dosage levels and dosing intervals, download patient usage data, and include mechanisms to prevent misuse or abuse.

Other Management News Dan Maher has been promoted to vice president of project management. Previously serving as senior director of project management for our AERx insulin program, he came to Aradigm three years ago with more than two decades of operations and project management experience with such companies as Genentech, Chiron and Covance. Babatunde Otulana, M.D., our vice president for clinical and regulatory affairs, was appointed to a four-year term as a member of the FDA advisory committee for Anesthesiology and Respiratory Therapy Devices. Igor Gonda, Ph.D., who served as our chief scientific officer, departed Aradigm to head a new drug delivery venture in Melbourne, Australia; however, he continues to work with our company both as a member of our board of directors and as chairman of our scientific advisory board. Stephen Farr, Ph.D., our vice president of research and development, joined leading experts in diabetes research and clinical practice at the May 2001 Diabetes Di@Logue meeting in Geneva, Switzerland, to discuss new therapies for the treatment of diabetes.

Financing Our Growth In addition to product development funding from our corporate partners, Aradigm raised over $120 million in cash and commitments during 2001. Approximately $73 million came from private placements of common stock with institutional investors. In addition, our insulin partner, Novo Nordisk, invested $25 million in Aradigm common stock during the year and made a commitment to invest another $25 million over time, at our option. As of December 31, 2001, cash, cash equivalents and short-term investments totaled approximately $71.2 million.

POSITIONED FOR SUCCESS

Liquid Formulations

AERx systems can take advantage of lower-cost liquid drug formulation technology. Importantly, since most therapeutic proteins and small-molecule parenteral drugs are already formulated as liquids with established IV safety profiles, their use in our AERx systems is relatively straightforward. Furthermore, liquid formulations allow for improved dose titration.

Cost Effective

All AERx systems are designed for years of reliable use, and they employ the same sterile drug packaging technology, enabling us to realize manufacturing efficiencies. The single-use AERx Strip™ drug packets, which are loaded into the device, incorporate a laser-drilled aerosol nozzle that converts liquid drugs into consistent, fine-particle aerosols.

Highly Versatile

Aradigm's proprietary technologies allow us to regulate the size and deposition of aerosolized droplets. Such control enables AERx systems to deliver a wide range of pharmaceutical agents either locally or systemically — including proteins, peptides and DNA, as well as small-molecule drugs.

AERx ADVANTAGES

AS WE LOOK AHEAD, 2002 PROMISES TO BE ANOTHER YEAR OF SUBSTANTIAL PROGRESS, ADVANCING ARADIGM ON A STEADY PATH TOWARD THE MARKETPLACE.

Upcoming Milestones We are excited about the future for Aradigm. Key events during 2002 include: presentation of our AERx morphine pain management data at the American Pain Society meeting; initiation of Phase 3 clinical trials for the AERx insulin diabetes management program; presentation of insulin data at the American Diabetes Association meeting; preparations for Phase 3 pain management clinical trials; and continued pursuit of promising feasibility programs and new commercial partnerships.

Our strategy is to capture near-term opportunities by targeting products that have the potential to reach the market quickly. At the same time, we are establishing the broad applicability of our technology by conducting feasibility studies for diverse therapeutic agents, with the goal of expanding our future revenue base. We are selecting our biotechnology and pharmaceutical partners not only for access to their proprietary compounds, but also for their ability to effectively launch products and penetrate key markets. Furthermore, we continue to build our proprietary patent position as we expand our technology base.

Thank you for your support and confidence. We look forward to reporting continued progress during 2002.

Richard P. Thompson
President, Chief Executive Officer and Chairman of the Board
March 18, 2002

Shown at left: V. Bryan Lawlis, Ph.D., Chief Operating Officer. At right: Richard P. Thompson, President, Chief Executive Officer and Chairman of the Board.

Diabetes Management

- Phase 2b trials with insulin completed in 2001; Phase 3 trials scheduled to begin in 2002
- Safety, efficacy and dose reproducibility shown comparable to subcutaneous insulin injection
- More rapid reduction of blood glucose levels, compared with injectable insulin therapy, demonstrated in fasting patients

We believe pulmonary insulin has the potential to redefine insulin therapy for patients and physicians, not only by offering an alternative to needle injections, but also by provoking new thinking about diabetes management and insulin therapy. Intensified treatment with insulin, delivered at mealtimes, is advocated by leading diabetologists for preventing the long-term complications of this disease. The key is patient compliance. As Mads Krogsgaard Thomsen, executive vice president and chief science officer at Novo Nordisk, states: "It is our goal to improve the quality of life for people with diabetes, and we believe the AERx® insulin diabetes management system will help us accomplish this goal by providing a convenient way to dose insulin."

Pain Management

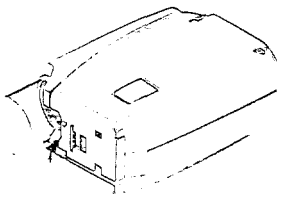
- Phase 2b trials with morphine completed in late 2001; plans being made for Phase 3 trials
- Safety, efficacy and dose reproducibility shown comparable to intravenous morphine injection
- Time to reach plasma concentrations of morphine is as fast as intravenous injection

The need for opioid pain relief—without injections—is substantial. Despite available medications, many patients suffering with pain continue to be undertreated, especially those with fluctuating pain that "breaks through" baseline analgesic medication. AERx drug delivery may provide the solution. Richard Rauck, M.D., an anesthesiologist and pain control expert at Wake Forest University, has been an investigator in the AERx morphine cancer pain study. "The morphine delivery system being developed by Aradigm represents a significant breakthrough in pain management," he says. "With its rapid onset of pain relief, the AERx system provides unique in-home management of pain in cancer patients."

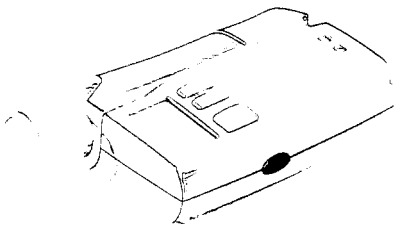
PATIENT-FRIENDLY THERAPIES

A Family of AERx Systems

In addition to our current, commercially-ready AERx technology, we are developing next-generation drug delivery devices to address new opportunities for superior inhalation therapy. AERx Ultra™ is a smaller electronic system that maintains the precision of our original AERx device. AERx Essence™ is an all-mechanical platform, designed to deliver drugs with wider therapeutic indices or those that target conditions localized within the lung.



AERx Essence™



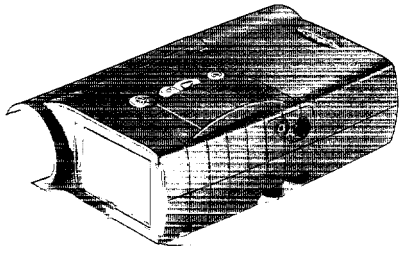
AERx Ultra™

Other Opportunities

- Several investigational products, with development funded by corporate partners, are in human clinical trials
- Multiple types of therapies are being studied, including proteins as well as small molecules
- Feasibility of pulmonary delivery has been achieved in humans, expanding the prospects for AERx systems

To date, over 30 human clinical studies have been completed with more than 1,000 subjects. These include not only our diabetes management and pain management programs, but also clinical feasibility trials which span the range of drug therapies—from off-patent drugs to the emerging products of biotechnology. As we look to the future, Aradigm's strategy is to create a robust product pipeline for major markets worldwide.

We are particularly pleased to see that AERx systems offer significant potential for delivering proteins, peptides, nucleic acids and gene therapies that currently are administered by injection or infusion and cannot be delivered orally. Inhalation therapy could potentially expand the market for these important therapies and increase their convenience to patients. "The major technology hurdles with AERx systems have been resolved," notes Babatunde Otulana, M.D., vice president for clinical and regulatory affairs at Aradigm. "We are now concentrating on new product applications, and these consist largely of biologicals from major pharmaceutical and biotech companies. Potential treatment targets include systemic diseases, such as cancer and related disorders, neurological illnesses, chronic renal failure, infection and inflammation, as well as respiratory conditions such as asthma and chronic obstructive pulmonary disease (COPD).



AERx® Insulin Delivery System

Replacing Needle Injections

Patients can't wait to throw away their needles! But beyond ending the pain and inconvenience, there are important therapeutic reasons for alternative routes of drug delivery. Many diabetic patients, for example, currently do not properly manage their disease due to emotional and psychological barriers associated with self-administered insulin injections. Similarly, a large number of other patients are unable to fully realize the benefits of biotechnology products that require injections or infusions along with costly, time-consuming physician office visits.

INVESTMENT HIGHLIGHTS

Aradigm Corporation

>> Clinical Proof-of-Concept with Insulin and Additional Drugs

>> Insulin Entering Phase 3 Clinical Trials in 2002.

>> Multiple Biopharma Partnerships in Clinical Trials.

>> Large Target Markets with Expansion Opportunities.

>> Partnered with Leading Pharma Companies.

>> Efficient, Commercial-Scale Manufacturing.

>> Outstanding Intellectual Property Portfolio.

>> Strong Financial Position and Broad Infrastructure.

GREAT OUTLOOK FOR 2002

COMMON STOCK LISTING

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

PRICE RANGE OF COMMON STOCK

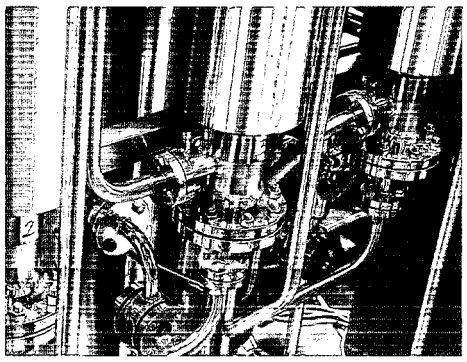
2001	High	Low
1st Qtr	$15.25	$4.28
2nd Qtr	8.56	4.88
3rd Qtr	6.92	3.02
4th Qtr	7.10	3.15

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
http://www.Equiserve.com

Years Ended December 31, (in thousands, except for per share amounts)	2001	2000	1999	1998	1997
STATEMENTS OF OPERATIONS DATA:					
Contract and license revenues	$ 28,916	$ 20,303	$ 16,812	$ 17,515	$ 3,685
Operating expenses:					
Research and development	58,836	48,176	33,625	25,549	13,452
General and administrative	9,355	9,271	7,849	8,661	6,012
Total operating expenses	68,191	57,447	41,474	34,210	19,464
Loss from operations	(39,275)	(37,144)	(24,662)	(16,695)	(15,779)
Interest income	1,324	3,110	1,947	1,754	1,329
Interest expense and other	(1,081)	(1,528)	(888)	(513)	(234)
Loss before extraordinary item	$(39,032)	$(35,562)	$(23,603)	$(15,454)	$(14,684)
Extraordinary item	6,675	–	–	–	–
Net loss	$(32,357)	$(35,562)	$(23,603)	$(15,454)	$(14,684)
Deemed dividend	(10,722)	–	–	–	–
Net loss applicable to common shareholders	$(43,079)	$(35,562)	$(23,603)	$(15,454)	$(14,684)
Basic and diluted loss per share applicable to common shareholders:					
Loss before extraordinary item	$ (2.28)	$ (2.07)	$ (1.66)	$ (1.32)	$ (1.43)
Extraordinary item	0.30	–	–	–	–
Net loss per share applicable to common shareholders	$ (1.98)	$ (2.07)	$ (1.66)	$ (1.32)	$ (1.43)
Shares used in computing basic and diluted loss per share applicable to common shareholders	21,792	17,196	14,216	11,682	10,280
BALANCE SHEETS DATA:					
Cash, cash equivalents and short-term investments	$ 71,164	$ 44,381	$ 31,259	$ 31,036	$ 24,305
Working capital	48,307	19,862	22,797	16,483	15,999
Total assets	132,101	71,371	50,790	44,949	30,294
Noncurrent portion of notes payable and capital lease obligations	2,727	6,230	9,609	4,570	2,139
Convertible preferred stock	30,735	–	–	–	–
Accumulated deficit	(142,813)	(110,441)	(74,904)	(51,279)	(35,827)
Total shareholders' equity	71,149	37,785	24,157	21,660	18,659



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, 2002, there were approximately 138 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.

Except for historical information contained herein, this report contains forward-looking statements that involve risk and uncertainties, including 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 Statements, including the Company's annual report on Form 10-K.

Aradigm
2001

FORM 10-K

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, 2001

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	94-3133088
(State or Other Jurisdiction of Incorporation or Organization)	*(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 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, 2002, there were 29,543,883 shares of common stock outstanding. The aggregate market value of common stock held by non-affiliates of the Registrant was approximately $65,317,000 based upon the closing price of the common stock on February 28, 2002 on The Nasdaq Stock Market. 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 17, 2002.

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 comparable 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 was approximately $20 billion in 2000. Of this market, we believe that drugs with aggregate sales in excess of $7 billion could potentially be delivered using the AERx platform. In addition, most biotech compounds currently under development rely on injection as their primary means of delivery.

We have tested 11 compounds in human clinical trials, including Phase 2b clinical trials that were successfully completed during the fourth quarter of 2001. We have attracted the attention of some of the world's leading pharmaceutical and biotechnology companies, who have contributed cumulatively over $88 million in contract revenue 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
- SmithKline Beecham, now GlaxoSmithKline plc, 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 77 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 a primary 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 actual 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 to effect 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 Aradigm 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 liquid formulation technology of the AERx platform allows us to use standard, 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 wear 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 platform employs a patented technology to electronically measure the patients 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.

Individual AERx systems can also be designed to incorporate features desirable for the particular therapeutic application through customization of the patient interface. For example, the electronic inhaler can record information, such as the date, the time and the name of the drug on each dose delivered. An AERx system can also be configured to impose timed programmable lockouts and to limit access to the inhaler to authorized users. We can even design the system to allow the patient to adjust the dosage administered from an individual packet if that degree of precision is required for effective therapy.

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. Many patients suffering from pain, diabetes, obesity, cancer, AIDS, Parkinson's disease, multiple sclerosis, hepatitis, growth hormone deficiency and other debilitating chronic diseases currently can only get effective treatment by injection. In addition to two major collaborations, 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, including small and large proteins and other substances to distribute genetic materials in the body. 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, thereby reducing our dependence on any single product.

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. Many new drugs developed as a result of information garnered from efforts to sequence and study the human genome will be composed of protein or DNA. Pulmonary drug delivery may be the only viable non-invasive way to deliver many of these new therapies. We believe that the capabilities of the AERx platform will make it particularly attractive for these potential future applications.

Focus on Quicker-to-Market Opportunities

Our principal commercial development efforts have been focused on product opportunities that have the potential to reach the market quickly. As part of this effort, we seek to minimize development risk by focusing on marketed drugs that are well characterized and have demonstrated safety profiles. This approach is evidenced by the drugs (insulin and morphine) that underlie our two leading development programs.

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 and expertise necessary to conduct late stage clinical trials 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. For example, we believe that our existing two development partners have the potential to develop additional products using our AERx 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 device is being designed to be a convenient hand-held unit that has features that 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 device by pricing the device 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 device 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, 2002, had 77 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 reduce the size and weight of our hand-held devices.

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. We successfully completed a Phase 2b clinical trial in November 2001. We are now focused on preparing for Phase 3 clinical trials, which Novo Nordisk currently intends to commence during the summer of 2002. 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 bodies produce. 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.

We believe that approximately 800,000 Americans suffer from Type 1 diabetes. Virtually all of them are on daily insulin injection therapy, and most are currently monitoring their own blood glucose level. According to the Center for Disease Control, as of 2000, approximately ten million Americans had been diagnosed with Type 2 diabetes. These Type 2 diabetes 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 failure to comply with recommended therapies contributes to approximately $45 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 1999 levels of $3.6 billion. The leading supplier of insulin is Novo Nordisk, followed by Eli Lilly, and these two companies together account for more than 90% of the worldwide insulin market.

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 2000, we presented data that showed that as the dose of insulin inhaled from our AERx system is increased, both the blood level of insulin and its ability to reduce glucose in the blood are increased proportionally. A publication by Brunner et al at the American Diabetes Association (ADA) meeting in San Antonio, Texas, showed proportionately increasing blood levels of insulin with increasing AERx insulin doses in 18 female and male, non-smoking, Type 1 diabetic subjects. The euglycaemic clamp method, which is a method by which the effect of insulin is measured by the incremental amount of glucose required to keep the blood glucose level constant in the body, used in this study demonstrated a linear or proportional response to the insulin delivery as measured by the glucose infusion rate. The efficiency of the amount of insulin packaged in an AERx dosage form relative to insulin injected from a syringe was approximately 13%. We presented similar results from a study of AERx insulin given immediately before a standard meal, compared to insulin given by subcutaneous injection 30 minutes prior to the meal. A study by Kipnes et al in 20 Type 1 diabetics was presented at the European Association for the Study of Diabetes (EASD) meeting in Jerusalem, Israel. The AERx system efficiency compared to subcutaneous insulin injections was 16% when comparing blood insulin levels and 17% when comparing blood glucose levels. These data mean that insulin, when inhaled, may require six to eight times more drug than when it is injected to have the same effect. We also completed a number of concurrent clinical studies in both healthy subjects and in diabetic subjects in 2000 in preparation for the upcoming pivotal trials.

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 showed the AERx insulin Diabetes Management System to be at least as effective as intensified subcutaneous injections of insulin.

The Collaboration

In June 1998, we entered into a product development and commercialization agreement with Novo Nordisk, the world leader in insulin therapy, covering the use of the AERx insulin Diabetes Management System for the delivery of blood glucose regulating medicines. Novo Nordisk 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, which receives regulatory approval, we expect to receive a share of gross profit on the sales of such products by Novo Nordisk.

Pursuant to the Novo Nordisk agreement, we could receive approximately $38 million in milestone payments in addition to reimbursement for product development expenses and $10 million in equity investments by the time the first product from the collaboration is commercialized. Through December 31, 2001, we received from Novo Nordisk approximately $61.3 million in product development payments, approximately $7 million in milestone payments and $10 million from the purchase of our common stock by Novo Nordisk, $5 million of which was sold at a 25% premium to market price. Through December 31, 2001, of the payments received approximately $51.9 million of product development and $3.5 million of milestone payments have been recognized as contract revenue. Additional milestone payments and product development payments will be paid by Novo Nordisk if Novo Nordisk 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, Inc., an affiliate of Novo Nordisk A/S, pursuant to which Novo Nordisk Pharmaceuticals purchased $20 million of our common stock at the fair market price. We also have the option under the agreement to sell an aggregate of up to $25 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. Subject to certain restrictions, we may deliver a sale shares notice specifying an amount between $5 million and $10 million for Novo Nordisk Pharmaceuticals to purchase once every three months until we have sold an aggregate of $25 million additional shares of common stock to Novo Nordisk Pharmaceuticals. The sale of additional shares is subject to certain conditions, including, among other things, Novo Nordisk not owning more than 45% of our outstanding common stock and the accuracy of certain representations. Novo Nordisk and its affiliates currently own approximately 23% of our outstanding common stock. In a separate agreement, we and Novo Nordisk agreed to share manufacturing responsibilities where Novo Nordisk 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 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. We are developing and plan to commercialize this product in collaboration with GlaxoSmithKline. In October 2001, we successfully completed Phase 2b clinical trials of the AERx Pain Management System. We will be working with GlaxoSmithKline to determine the next steps for the AERx morphine program. Future progress for this program is contingent on either GlaxoSmithKline recommitting to this program or a new partner entering into another development agreement with us. We will continue to prepare this program towards commencement of Phase 3 clinical trials, which could occur 6 to 12 months after entering into a development agreement with a new partner. There can be no assurance that this development program will be successful.

The Market

We have targeted cancer pain and other chronic pain as the first two applications 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 relates to extreme levels of pain the patient experiences that is above and beyond the pain level being managed by routine use of medication. The market for potent narcotic analgesics (pain killers) to treat such pain events in the United States in 2000 was approximately $3.8 billion.

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 and improve the management of pain in the hospital. 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

System is being designed to be programmed to allow for patient-activated delivery in accordance with a physician-directed dosing program. Lockout mechanisms being designed for the product should eliminate the risk of inappropriate dosing, and a patented electronic patient identification feature should prevent unauthorized use of the device. An automatically maintained dosing event diary kept by the AERx Pain Management System is designed to allow a physician to closely monitor patient use. We believe that these features of the AERx Pain Management System, combined with the inherent speed of onset of pulmonary delivery, should provide a significant advance in pain management with important applications in both the home and hospital settings.

Clinical Development

In 2000, we reported the start of a Phase 2b study using the AERx Pain Management System to deliver inhaled morphine to cancer patients and also the results of two completed clinical studies involving inhaled fentanyl (narcotic agent) via the AERx Pain Management System.

The two fentanyl studies were conducted at the Centre for Anaesthesia and Pain Management Research, University of Sydney at Royal North Shore Hospital, Sydney, Australia. The first study involved 10 healthy volunteers and was designed to evaluate the safety and pharmacokinetic profile of inhaled fentanyl. The subjects received two inhalations of fentanyl via the AERx Pain Management System followed one week later by an intravenous drip of fentanyl. Results showed an average inhaled bioavailability (the fraction of drug dosage in each unit-dose packet absorbed into the blood) of 67% from the AERx Pain Management System, with a plasma or blood profile very similar to that of the intravenous injection. This means that inhaled fentanyl may require one-third more drug than the injectable form to have the same effect. These data were presented at the 29th Annual Meeting of the American College of Clinical Pharmacology held in September 2000, in Chicago, Illinois.

The second trial on fentanyl via the AERx Pain Management System was an open-label (where the patient knows which drug they are taking) study of 20 cancer patients who were experiencing breakthrough pain episodes and who were receiving opioid-based pain management. Results of this study showed that all patients were able to achieve satisfactory breakthrough pain relief using the AERx Pain Management System. The average time to satisfactory pain relief was 10 minutes (range 6-24 minutes) which is similar to that reported for intravenous fentanyl. Ninety percent of patients expressed very good to excellent pain relief on the AERx Pain Management System. The results of this study were presented at the 19th Annual Scientific Meeting of the American Pain Society held in November 2000, in Atlanta, Georgia.

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 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.

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 anticipate that GlaxoSmithKline will review its restoration election after the delivery of Phase 2b trial results, which will be made available to them in the first

half of 2002, but 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 discussions with several alternate partners that may 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 million from the purchase of our common stock by GlaxoSmithKline, $5 million of which was sold to GlaxoSmithKline at a 25% premium to market price. No additional product development or milestone payments were received during 2001.

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 six programs that are developing or evaluating the use of the AERx delivery technology across a range of drug therapies. In addition to our collaboration with Novo Nordisk, these programs include a Stage II grant from the National Institutes of Health to evaluate the use of the AERx platform for delivery of gene therapies.

In addition to the above active programs, we have conducted feasibility testing across a broad range of molecules, including three additional compounds where we have conducted early phase clinical trials that we believe could be pursued in the future. Some of these molecules are listed below:

- Chronic bronchitis and emphysema drugs
- Antibodies
- Gene therapies
- Asthma drugs
- Hematopoetic factors
- Human growth factors
- Anti-obesity drugs
- Migraine drugs
- Anti-Parkinson's drugs
- Interleukins
- Interferons
- Antibiotics

Sales and Marketing

We plan to establish additional collaborative relationships, similar to our agreement with Novo Nordisk, 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 50 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 too 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 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 77 United States patents to date, with 34 United States patent applications pending. In addition, we have purchased three United States patents covering inventions that are relevant to our technologies. We have 51 issued foreign patents and 82 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.
- United States patent 5,888,477, which is directed to the delivery of monomeric, or fast acting, insulin by inhalation.

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 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. 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, bucal, 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, or 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 Inhale Therapeutic Systems and Alkermes Pharmaceuticals. 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, or 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.

For example, the United States Drug Enforcement Agency, or 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:

Name	Affiliation	Area of Expertise
Peter Byron, Ph.D.	Medical College of Virginia, Virginia Commonwealth University	Aerosol Science/ Pharmaceutics
Michael Cousins, M.D.	University of Sydney, Australia	Pain Management
Peter Creticos, M.D.	The Johns Hopkins University School of Medicine	Allergy/Immunology/Asthma
Lorne Eltherington, M.D., Ph.D.	Sequoia Hospital	Pain Management
Igor Gonda, PhD	Acrux Limited	Drug Delivery
Henrik Egesborg Hansen	NovoNordisk	Device Technology
Vincent Lee, Ph.D.	USC School of Pharmacy	Drug Delivery
Lawrence M. Lichtenstein, M.D., Ph.D	The Johns Hopkins University School of Medicine	Allergy/Immunology
Robert Ratner, M.D.	Medlantic Research Institute	Endocrinology
Christopher Saudek, M.D.	The John Hopkins University School of Medicine	Endocrinology
Leigh Thompson, M.D., Ph.D.	CEO, Profound Quality Resources	Pharmaceutical Product Development

Employees

As of February 28, 2002, we had 307 employees, of whom 262 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.

MANAGEMENT

Directors and Executive Officers

The directors and executive officers of the Company and their ages as of February 28, 2002 are as follows:

Name	Age	Position
Richard P. Thompson	50	President, Chief Executive Officer and Director
Bikash K. Chatterjee	43	Vice President, Operations
Steven J. Farr, Ph.D.	42	Vice President, Pharmaceutical Sciences
Maximillian D. Fiore	47	Vice President, Engineering
Klaus D. Kohl, Ph.D.	51	Vice President, Quality
V. Bryan Lawlis, Ph.D.	50	Chief Operating Officer
Dan P. Maher	46	Vice President, Project Management
Norma L. Milligin	63	Vice President, Human Resources
Babatunde A. Otulana, M.D	44	Vice President, Clinical & Regulatory Affairs
Frank H. Barker(1)	71	Director
Stan M. Benson(2)	51	Director
Igor Gonda(2)	54	Director
John Nehra(1)	53	Director
Wayne I. Roe(1)	51	Director
Virgil D. Thompson(2)	62	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.

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. Dr. Farr holds a B.Sc. in pharmacy from DeMontfort University, a Ph.D. in pharmaceutics 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 Vice President, Quality, since October 2000. 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 7 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. 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, Project Management and Program Director, AERx iDMS, since April 2001. From November 1998 to April 2001, Mr. Maher was Sr. Director of Project Management, and Program Director, AERx iDMS. From 1996 to 1998, he was the Director of Clinical Operations at Chiron Corporation. Previously, Mr. Maher was Vice President of Operations at Spectra Biomedical Inc. 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., a Johnson & Johnson Company, and Chemtrak, Inc., a medical device company. From 1978 to 1985, she also held a number of senior human resource positions at Syntex Corporation. 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 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. From 1991 to 1997, Dr. Otulana also served as an Assistant Professor of Medicine in the Division of Pulmonary and Critical Care Medicine, Howard University Hospital. Dr. Otulana obtained his M.D. from the University of Ibadan, Nigeria and completed a Pulmonary Fellowship at Papworth Hospital, University of Cambridge, United Kingdom.

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. He is also a director of Aderis Pharmaceuticals, Inc. 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 was elected director by our Board of Directors in 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 Celeris 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 Favrille Inc. Mr. Roe currently is an independent consultant in the life sciences industry.

Virgil D. Thompson has been a director since June 1995. Since September 2000, he has been 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, 2001, 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 $4.9 million and $5.1 million in 2002 and 2003, respectively. 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 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. The complaint sought a declaration that Lilly scientists were co-inventors of a patent application 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 has issued two written rulings on our motion substantially limiting the claims against us. Specifically, 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. The Court denied our motion as to Lilly's claims for declaratory relief, unjust enrichment and breach of contract (in part), based on factual disputes between the parties, and those issues remain to be resolved. We recently filed a motion asking the Court to reconsider summary judgment on the inventorship and unjust enrichment claims, based on evidence recently produced by Lilly; the Court denied our motion but we may raise those issues again. Lilly filed a motion seeking to add several new patents to the case, but withdrew that motion after our opposition papers were filed and after discussion with the Court. Trial was set for November 2001, but has been continued to April 22, 2002 due to a conflict on the Court's calendar. The risks to us should Lilly prevail in this case are that Lilly would be given rights of an owner, along with us, on one of our patents relating to pulmonary delivery of monomeric, or fast acting, insulin lispro and/or that Lilly would be awarded damages on its remaining claims for breach of contract and unjust enrichment. 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 we have meritorious defenses against each of Eli Lilly's remaining claims and that this litigation will not have a material adverse effect on our business. However, there can be no assurance that we will prevail in this case.

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, 2001.

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 Stock 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.

	High	Low
2000		
First Quarter	$44.25	$10.50
Second Quarter	19.25	13.25
Third Quarter	25.00	11.19
Fourth Quarter	26.88	13.19
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 (through February 28, 2002)	$ 7.29	$ 4.01

On February 28, 2002, there were 138 holders of record of our common stock. On March 14, 2002, the last sale price reported on the Nasdaq National Market for the common stock was $4.05 per share.

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

On December 14, 2001, we issued 2,001,236 shares of our Series A Convertible Preferred Stock to certain institutional investors for an aggregate purchase price of $48.4 million in a private placement. Each share of Series A preferred stock is convertible at any time into four shares of our common stock, for an aggregate of 8,004,944 shares of common stock. In connection with the sale, we issued warrants to purchase an aggregate of 5,203,212 shares of our common stock at an exercise price of $6.97 per share. The warrants are exercisable at the election of the warrant holders for a five-year term. The sale and issuance of the preferred stock and warrants was deemed to be exempt from registration under the Securities Act of 1933, as amended, by virtue of Regulation D promulgated under such Act. Each purchaser represented that it was an accredited investor within the meaning of Rule 501(a) of the Act and that it was acquiring the securities for investment only and not with the view to the distribution thereof.

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,				
	2001	2000	1999	1998	1997
	(In thousands, except per share amounts)				
Statements of Operations Data:					
Contract and license revenues	$ 28,916	$ 20,303	$ 16,812	$ 17,515	$ 3,685
Operating expenses:					
Research and development	58,836	48,176	33,625	25,549	13,452
General and administrative	9,355	9,271	7,849	8,661	6,012
Total expenses	68,191	57,447	41,474	34,210	19,464
Loss from operations	(39,275)	(37,144)	(24,662)	(16,695)	(15,779)
Interest income	1,324	3,110	1,947	1,754	1,329
Interest expense and other	(1,081)	(1,528)	(888)	(513)	(234)
Net loss before extraordinary gain	(39,032)	(35,562)	(23,603)	(15,454)	(14,684)
Extraordinary gain	6,675	—	—	—	—
Net loss	$ (32,357)	$ (35,562)	$(23,603)	$(15,454)	$(14,684)
Deemed dividend	(10,722)	—	—	—	—
Net loss applicable to common shareholders	$ (43,079)	$ (35,562)	$(23,603)	$(15,454)	$(14,684)
Basic and diluted loss per share applicable to common shareholders(1):					
Loss before extraordinary gain	$ (2.28)	$ (2.07)	$ (1.66)	$ (1.32)	$ (1.43)
Extraordinary gain	0.30	—	—	—	—
Net loss applicable to common shareholders	$ (1.98)	$ (2.07)	$ (1.66)	$ (1.32)	$ (1.43)
Shares used in computing basic and diluted loss per share applicable to common shareholders(1)	21,792	17,196	14,216	11,682	10,280
Balance Sheet Data:					
Cash, cash equivalents and investments	$ 71,164	$ 44,381	$ 31,259	$ 31,036	$ 24,305
Working capital	48,308	19,862	22,797	16,483	15,999
Total assets	132,100	71,371	50,790	44,949	30,294
Noncurrent portion of notes payable and capital lease obligations	2,727	6,230	9,609	4,570	2,139
Redeemable convertible preferred stock	30,735	—	—	—	—
Accumulated deficit	(153,535)	(110,441)	(74,904)	(51,279)	(35,827)
Total shareholders' equity	71,149	37,785	24,157	21,660	18,659

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

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, 2001, we had an accumulated deficit of $153.6 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 during 2002. The sources of working capital have been equity financings, equipment lease financings, contract 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 plc, to manage acute and breakthrough pain using opioid analgesics.

The collaborative agreement with Novo Nordisk 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 2001, this partner-funded program has contributed approximately 90% of our total contract revenues.

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 under the amended agreement upon payment of a restoration fee to us. We anticipate that GlaxoSmithKline will review its restoration election upon the delivery of Phase 2b trial results, which will be made available to them in the first half of 2002, but 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. If we elect to pay the exit fee it will not have a material impact on our financial position or operating results. This development program is currently being funded through existing working capital.

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. Forgiveness of the loan and accrued interest resulted in an extraordinary gain during the first quarter of 2001 of approximately $6.7 million. During 2001, we reimbursed Genentech $773,000 for unspent project prepayments.

In addition to the diabetes and pain management programs, we have three additional partner-funded programs and a gene therapy effort, which is funded through the National Institutes of Health. It is our policy not to disclose the partner or the drug until we have entered into long-term development agreements with a partner.

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 that require the use of significant judgements and estimates relating to matters that are inherently uncertain and may result in materially different results under different assumptions and conditions.

Revenue Recognition

Contract revenues consist of revenue from collaboration agreements and feasibility studies. We recognize revenue under the agreements 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 review for impairment whenever events or changes in circumstances indicates that the carrying amount of property and equipment may not be recoverable under the provisions of Statement of Financial Accounting Standards No. 121, Accounting for the Impairment of Long-Lived Assets and for Long Lived Assets to be Disposed Of. If it is determined that an impairment loss has occurred based on expected future cash flows, 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, 2001, 2000 and 1999

Contract Revenues. We reported revenues from collaborative contracts of $28.9 million in 2001, compared to $20.3 million in 2000 and $16.8 million in 1999. The revenue increase in 2001 and 2000 results primarily from an increase in partner-funded project development revenue from Novo Nordisk, which was $26 million in 2001 compared to $15.4 million in 2000 and $8.7 million in 1999. The revenue increase in 2001 and 2000 was partially offset by a reduction in partner-funded project development revenue principally from GlaxoSmithKline, which was $1.5 million in 2001 compared to $3.4 million in 2000 and $5.2 million in 1999. Costs associated with contract research revenue are included in research and development expenses.

Research and Development Expenses. Research and development expenses have increased each year since our inception. These expenses were $58.8 million in 2001 compared to $48.2 million in 2000 and $33.6 million in 1999. Research and development expenses as a percentage of total operating expenses were 86% in 2001, 84% in 2000 and 81% in 1999. Research and development expenses in 2001 increased by $10.7 million or 22% over 2000, which was primarily due to the expansion of development efforts to support the ongoing program with Novo Nordisk and, to a lessor extent, increases in development efforts for other funded and unfunded development areas including manufacturing scale-up efforts. Research and development expenses in 2000 increased by $14.6 million or 43% over 1999, which was due to the expansion of research and development efforts to support the ongoing programs with Novo Nordisk and Genentech including an expansion of manufacturing scale-up efforts. Research and development expenses associated with collaborative agreements approximate contract revenue as these expenses are incurred under the program agreements.

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.

Currently, our lead development program is developing pulmonary delivery systems to manage diabetes using insulin and other blood glucose regulating compounds with our partner Novo Nordisk. During November 2001, Novo Nordisk and we successfully completed a Phase 2b clinical trial using the AERx insulin Diabetes Management System. We are now focused on preparing for Phase 3 clinical trials, which Novo Nordisk intends to commence during the summer of 2002.

Our next major program is with our partner GlaxoSmithKline pursuant to our development agreement, as amended, which covers the use of the AERx Pain Management System for the delivery of narcotic analgesics. During December 2001, we successfully completed Phase 2b clinical trials for the AERx morphine Pain Management System. We will be working with GlaxoSmithKline to determine the next steps for the AERx morphine program. Future progress for this program is contingent on either GlaxoSmithKline recommitting to this program or our entering into another development agreement with a new partner. We continue to move forward with this program for a Phase 3 start, which could occur in early 2003.

We have three other partner-funded programs and a gene therapy effort, which is funded through the National Institutes of Health, that are all in early Phase 1 clinical trials. Though Phase 1 clinical trials are expected to be completed in 2002, future research and development efforts for these partner-funded programs are difficult to predict at this time due to their early stage of development.

General and Administrative Expenses. General and administrative expenses were $9.4 million in 2001 compared to $9.3 million in 2000 and $7.8 million in 1999. General and administrative expenses remained relatively unchanged in 2001 compared to 2000. General and administrative expenses increased by approximately $1.4 million or 18% in 2000 compared to 1999, as a result of additional personnel and leased facilities to support our expansion of research, development and manufacturing activities and increased efforts to develop collaborative relationships with new corporate partnerships.

Interest Income. Interest income was $1.3 million in 2001 compared to $3.1 million in 2000 and $1.9 million in 1999. The decrease in 2001 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. The increase in 2000 was primarily due to us maintaining larger average cash and investment balances, which resulted from the receipt of research development funding and milestone payments from collaborative partners and the completion of a follow-on public offering in April 2000 and the initial sale of common stock under an existing common stock equity line in December 2000.

Interest Expense and Other. Interest expense was $1.1 million in 2001 compared to $1.5 million in 2000 and $0.9 million in 1999. The decrease in 2001 is primarily due to the cancellation of the loan made by Genentech in connection with product development that had been funded by them. The increase in 2000 is due to higher outstanding capital lease and equipment loan balances under various equipment and lease lines of credit and interest expense accrued on increasing loan balances made by Genentech in connection with the product development agreement that had been funded by them.

Extraordinary Gain. During 2001, we reported an extraordinary gain of approximately $6.7 million. The extraordinary gain resulted from the cancellation of outstanding loans and accrued interest required to conduct product development with the program that had been funded by Genentech.

Net Loss. We reported a net loss of $32.4 million in 2001, compared to $35.6 million in 2000 and $23.6 million in 1999. The decrease in net loss for 2001 is primarily due to the $6.7 million extraordinary gain resulting from the cancellation of outstanding loans and accrued interest required to conduct product development under the program that had been funded by Genentech offset by an increase in net loss from operations, which was $39.3 million in 2001 and $37.1 million in 2000 and a decrease in interest income, which was $1.3 million in 2001 and $3.1 million in 2000. The increase in net loss for 2000 was primarily due to increased research and development activities relating primarily to the Genentech program, unfunded programs and activities for our commercial scale-up efforts.

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.

Net Loss Applicable to Common Shareholders. We reported a net loss applicable to common shareholders of $43.1 million in 2001, which 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, 2001, we had cash, cash equivalents and short-term investments of approximately $71.2 million.

Net cash used in operating activities in 2001 was $29.1 million compared to $25.8 million in 2000 and $27.0 million in 1999. The increase in net cash used in 2001 resulted primarily from an increase in net loss before extraordinary gain combined with an increase in receivables offset by an increase in deferred revenue. The decrease in net loss was primarily due to the forgiveness of outstanding loans and accrued interest under the cancellation of the development agreement with Genentech. The increase in receivables was due to invoiced, but unpaid, amounts due from partners for development activities. The increase in deferred revenue is due to payments received from our major partner to fund future program development. The decrease in net cash used in 2000 resulted primarily from increases in accounts payable and accrued liabilities combined with a decrease in receivables, partially offset by an increase in net loss and a decrease in deferred revenue. The increase in accounts payable and accrued liabilities is due to increased activity associated with our development programs including capital expenditures. The decrease in receivables is due to us receiving payments from our partners for all billable activities associated with the development programs. The decrease in deferred revenue is due primarily to our partners funding future development activity soon after year-end. The increase in net loss was primarily due to accelerated activity with several development programs including manufacturing commercial scale-up.

Net cash used in investing activities in 2001 was $14.7 million compared to $16.1 million in 2000 and $6.0 million in 1999. The increase in cash used in 2001 resulted primarily from higher capital expenditures offset by a net increase in proceeds from investments. The increase in cash used in 2000 resulted primarily from higher capital expenditures.

Net cash provided by financing activities in 2001 was $93.0 million compared to $53.3 million in 2000 and $31.6 million in 1999. 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 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. The increase in 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 will 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 2002, 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 2002 will be approximately $25 million and for 2003 will be approximately $20 million. Thereafter, we would anticipate that annual capital expenditures would decrease significantly. Currently, we are contractually committed to less than $5 million of the anticipated 2002 capital outlays. We believe that our existing cash balances at December 31, 2001, together with the $25 million unused common stock purchase commitment from Novo Nordisk, funding commitments from corporate development partners and interest earned on our investments should be sufficient to meet our needs for at least the next twelve months. The sale of additional common stock to Novo Nordisk 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 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, 2001, and the effect such obligations are expected to have on our liquidity and cash flows in future periods (In thousands):

		Payments Due by Period		
Contractual Obligations	Total	Less than 1 year	1-3 years	After 3 years
Capital Lease Obligations	$ 6,586	$ 4,006	$ 2,580	$ —
Unconditional Purchase Obligations	5,000	5,000	—	—
Operating Lease Obligations	66,537	4,925	15,725	45,887
Total Contractual Commitments	$78,123	$13,931	$18,305	$45,887

Recent Financial Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued Statements of Financial Standards (SFAS) No. 141, "Business Combinations", and SFAS No. 142, "Goodwill and Other Intangible Assets". The new rules require business combinations initiated after June 30, 2001 to be accounted for using the purchase method of accounting and goodwill acquired after this date will no longer be amortized, but will be subject to annual impairment tests. All other intangible assets will continue to be amortized over their estimated useful lives. Companies are required to adopt SFAS No. 142 for fiscal years beginning after December 31, 2001. The Company did not complete any business combinations through the twelve months ended December 31, 2001, as a result these standards did not have a material impact on its financial position or operating results.

In August 2001, the FASB issued FASB Statement No. 144 (FAS 144), "Accounting for the Impairment or Disposal of Long-lived Assets". FAS 144 supercedes FASB Statement No. 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 — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business (as previously defined in that Opinion). This Statement also amends ARB No. 51, Consolidated Financial Statements, to eliminate the exception to consolidation of a subsidiary for which control is likely to be temporary. Companies are required to adopt FAS 144 for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, but early adoption is encouraged. The Company has not yet determined the impact this standard will have on its financial position and results of operations, although it does not anticipate that the adoption of this standard will have a material impact on the Company's financial position or results of operations.

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 Food and Drug Administration or is yet in Phase 3 clinical trial development, 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, 2001, we have incurred a cumulative deficit of approximately $153.6 million. We have not had any material product sales and do not anticipate receiving any revenue from product sales in 2002. 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.

Our AERx systems are at an early stage of development and we are currently testing them using hand-held prototypes. Before we can begin to sell the AERx systems commercially, we will need to invest in substantial additional development and conduct preclinical and clinical testing. In order to further develop our AERx systems, we will need to address engineering and design issues, which include ensuring that the AERx systems can deliver a reproducible amount of drug into the bloodstream and can be manufactured successfully as hand-held systems. We cannot assure you that we will be successful in addressing these design, 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 is commercially feasible, it may not be commercially acceptable across a range of large and small molecule drugs. 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.

Novo Nordisk 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 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 is our only active funded development agreement. For the year ended December 31, 2001, this partner-funded program contributed approximately 90% of our total contract revenues. Our agreement with Novo Nordisk can be terminated under certain conditions, including by either party on limited written notice,

by Novo Nordisk 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. Nor can we 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 only 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 the next 12 months, including capital spending requirements that will be approximately $25 million, with proceeds from the sale of Series A preferred stock and warrants to purchase common stock in December 2001, committed funding from our corporate development partners, primarily Novo Nordisk, 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 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 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 prevail in our defense of Eli Lilly's complaint against us.

At this time, we are involved in an outstanding lawsuit with Eli Lilly and Company whereby Eli Lilly is making various allegations against us, originally arising from our decision to enter into an exclusive collaboration with Novo Nordisk with respect to the development and commercialization of a pulmonary delivery system for insulin and insulin analogs. Following our motion for summary judgment directed against all eight claims in Eli Lilly's original complaint, Eli Lilly's claims for declaratory relief, unjust enrichment and breach of contract (in part) currently remain.

The risks to us should Eli Lilly prevail in this case are that Eli Lilly would be given the rights of an owner, along with us, on one patent relating to pulmonary delivery of monmeric insulin lispro and/or that Eli Lilly

would be awarded damages on its remaining claims for breach of contract and unjust enrichment. There can be no assurance that we will prevail in this case.

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 Food and Drug Administration, or 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 includes 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 Good Manufacturing Practices, or 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 Drug Enforcement Agency, or 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. 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 and Inhale Therapeutic Systems, Inc. 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, bucal 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 payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. 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 payors. 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.

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, 2001, we had cash, cash equivalents and short-term investments of $71.2 million consisting of cash and highly liquid, short-term investments. 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.

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, 2001 and 2000, 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, 2001. 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, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 15, 2002

ARADIGM CORPORATION

BALANCE SHEETS
(In thousands, except shares data)

	December 31, 2001	December 31, 2000
Assets		
Current assets:		
Cash and cash equivalents	$ 69,965	$ 20,732
Short-term investments	1,199	23,649
Receivables	1,349	70
Current portion of notes receivable from officers and employees	145	—
Other current assets	812	735
Total current assets	73,470	45,186
Property and equipment, net	57,940	25,323
Noncurrent portion of notes receivable from officers and employees	160	119
Other assets	530	743
Total assets	$ 132,100	$ 71,371
Liabilities, Redeemable Convertible Preferred Stock and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 5,297	$ 4,894
Accrued clinical and cost of other studies	703	517
Accrued compensation	1,761	1,246
Deferred revenue	11,115	6,622
Other accrued liabilities	2,760	2,234
Current portion of notes payable	—	6,712
Current portion of capital lease obligations	3,526	3,099
Total current liabilities	25,162	25,324
Noncurrent portion of deferred revenue	2,327	2,032
Capital lease obligations and other, less current portion	2,727	6,230
Commitments and contingencies		
Redeemable convertible preferred stock, no par value; 5,000,000 shares authorized; issued and outstanding shares; 2001 - 2,001,236; 2000 - zero; liquidation preference of $48,430 and $0 in 2001 and 2000, respectively	30,735	—
Shareholders' equity:		
Common stock, no par value, 40,000,000 shares authorized; issued and outstanding shares: 2001 - 29,536,383; 2000 - 18,266,955	224,738	148,573
Shareholder notes receivable	—	(131)
Deferred compensation	(54)	(216)
Accumulated deficit	(153,535)	(110,441)
Total shareholders' equity	71,149	37,785
Total liabilities, redeemable convertible preferred stock and shareholders' equity	$ 132,100	$ 71,371

See accompanying notes.

ARADIGM CORPORATION

STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Years Ended December 31,		
	2001	2000	1999
Contract and license revenues	$ 28,916	$ 20,303	$ 16,812
Operating expenses:			
Research and development	58,836	48,176	33,625
General and administrative	9,355	9,271	7,849
Total expenses	68,191	57,447	41,474
Loss from operations	(39,275)	(37,144)	(24,662)
Interest income	1,324	3,110	1,947
Interest expense and other	(1,081)	(1,528)	(888)
Net loss before extraordinary gain	(39,032)	(35,562)	(23,603)
Extraordinary gain	6,675	—	—
Net loss	(32,357)	(35,562)	(23,603)
Deemed dividend	(10,722)	—	—
Net loss applicable to common shareholders	$(43,079)	$(35,562)	$(23,603)
Basic and diluted loss per share applicable to common shareholders:			
Loss before extraordinary gain	$ (2.28)	$ (2.07)	$ (1.66)
Extraordinary gain	0.30	—	—
Net loss applicable to common shareholders	$ (1.98)	$ (2.07)	$ (1.66)
Shares used in computing basic and diluted loss per share applicable to common shareholders	21,792	17,196	14,216

See accompanying notes.

ARADIGM CORPORATION

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' EQUITY

(In thousands, except shares data)

	Redeemable Convertible Preferred Stock		Common Stock		Shareholder Notes	Deferred	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Receivable	Compensation	Deficit	Equity
Balances at December 31, 1998	—	$ —	12,163,616	$ 73,768	$(288)	$(541)	$ (51,279)	$ 21,660
Issuance of common stock for cash, net	—	—	2,428,338	24,798	—	—	—	24,798
Issuance of common stock under the employee stock purchase plan	—	—	98,860	713	—	—	—	713
Issuance of common stock upon exercise of stock options	—	—	58,963	324	—	—	—	324
Repayment of shareholders' notes	—	—	—	—	125	—	—	125
Amortization of deferred compensation	—	—	—	—	—	162	—	162
Comprehensive loss:								
Net loss	—	—	—	—	—	—	(23,603)	(23,603)
Other comprehensive income (loss):								
Net change in unrealized loss on available-for-sale investments	—	—	—	—	—	—	(22)	(22)
Total comprehensive loss	—	—	—	—	—	—	(23,625)	(23,625)
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

See accompanying notes.

ARADIGM CORPORATION

STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2001	2000	1999
Cash flows from operating activities:			
Net loss	$(32,357)	$(35,562)	$(23,603)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,500	3,213	2,356
Extraordinary gain related to forgiveness of Genentech note	(6,675)	—	—
Loss on sale of equipment	—	—	15
Issuance of warrants and common stock for services	48	296	—
Amortization of deferred compensation	162	163	162
Changes in operating assets and liabilities:			
Receivables	(1,279)	3,816	(3,112)
Other current assets	(77)	278	(421)
Other assets	213	(401)	(126)
Accounts payable	403	2,654	261
Accrued compensation	515	(29)	14
Accrued liabilities	675	2,129	(902)
Deferred revenue	4,788	(2,370)	(1,649)
Net cash used in operating activities	(29,084)	(25,813)	(27,005)
Cash flows from investing activities:			
Capital expenditures	(37,117)	(14,376)	(4,349)
Proceeds for sale of equipment	—	—	14
Purchases of available-for-sale investments	(5,732)	(26,764)	(30,841)
Proceeds from maturities of available-for-sale investments	28,167	25,052	29,178
Net cash used in investing activities	(14,682)	(16,088)	(5,998)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	50,671	48,674	25,835
Proceeds from issuance of redeemable convertible preferred stock and common stock warrants, net	45,459	—	—
Notes payable	—	2,756	3,956
Proceeds from repayments of shareholder notes	131	32	125
Notes receivable from officers	(186)	11	5
Proceeds from equipment loans	—	4,051	3,294
Payments on capital lease obligations and equipment loans	(3,076)	(2,238)	(1,630)
Net cash provided by financing activities	92,999	53,286	31,585
Net increase (decrease) in cash and cash equivalents	49,233	11,385	(1,418)
Cash and cash equivalents at beginning of year	20,732	9,347	10,765
Cash and cash equivalents at end of year	$ 69,965	$ 20,732	$ 9,347
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 899	$ 855	$ 820
Non-cash investing and financing activities:			
Issuance of warrants and common stock for services	$ 48	$ 296	$ —
Issuance of warrants in conjunction with private placement of common stock	$ 979	$ —	$ —
Redeemable convertible preferred stock deemed, non-cash dividend	$ 10,722	$ —	$ —

See accompanying notes

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 significant 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 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 and corporate notes. The Company's short-term investments consist of commercial paper and corporate notes with maturities ranging from three to twelve months.

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

Impairment of Long-Lived Assets

The Company reviews for impairment whenever events or changes in circumstances indicates that the carrying amount of property and equipment may not be recoverable under the provisions of Statement of

Financial Accounting Standards No. 121, Accounting for the Impairment of Long-Lived Assets and for Long Lived Assets to be Disposed Of. If it is determined that an impairment loss has occurred based on expected future cash flows, the loss is recognized on the Statements of Operations.

Revenue Recognition

Contract revenues consist of revenue from collaboration agreements and feasibility studies. The Company recognizes revenue under the agreements 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. 25, "Accounting for Stock Issued to Employees" (APB 25), and related interpretations in accounting for its employee stock options. This election was made because the alternative fair value accounting provided for under Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), requires the use of option valuation models that were not developed for use in valuing employee stock options.

The Company accounts for options and warrants issued to nonemployees under SFAS 123 and Emerging Issues Task Force Issue No. 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 Statement of Financial Accounting Standards No. 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 Statement of Financial Accounting Standards No. 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. In the years ended December 31, 2001, 2000 and 1999, the weighted average number of shares subject to repurchase were zero, zero and 48,000, respectively. 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, 2001, 2000 and 1999, the total number of shares excluded from diluted loss per share relating to these securities was 10,038,525, 2,232,633 and 899,319 shares, respectively.

Employee Benefit Plans

The Company has a 401(k) Plan which stipulates 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. The Company's option to provide matching contributions had not been done to date. 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, the Company will match 50% of the first 6% of the employee's contribution on a pretax basis, but not to exceed $5,250 per year. During 2001, the Company expensed total employer matching contributions of $273,000.

Significant Concentrations

Although the Company has had development arrangements with other collaborative partners, the arrangement with Novo Nordisk is our only active, funded development agreement. For the year ended December 31, 2001, this partner-funded program contributed approximately 90% of total contract revenues. The agreement with Novo Nordisk can be terminated under certain conditions, including by either party on limited written notice, by Novo Nordisk 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.

Comprehensive Income (Loss)

Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" (SFAS 130), 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.

Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued Statements of Financial Standards (SFAS) No. 141, "Business Combinations", and SFAS No. 142, "Goodwill and Other Intangible Assets". The new rules require business combinations initiated after June 30, 2001 to be accounted for using the purchase method of accounting and goodwill acquired after this date will no longer be amortized, but will be subject to annual impairment tests. All other intangible assets will continue to be amortized over their estimated useful lives. Companies are required to adopt SFAS No. 142 for fiscal years beginning after December 31, 2001. The Company did not complete any business combinations through the twelve months ended December 31, 2001, as a result these standards did not have a material impact on its financial position or operating results.

In August 2001, the FASB issued FASB Statement No. 144 (FAS 144), "Accounting for the Impairment or Disposal of Long-lived Assets". FAS 144 supercedes FASB Statement No. 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 — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business (as previously defined in that Opinion). This Statement also amends ARB No. 51, Consolidated Financial Statements, to eliminate the exception to

consolidation of a subsidiary for which control is likely to be temporary. Companies are required to adopt FAS 144 for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, but early adoption is encouraged. The Company has not yet determined the impact this standard will have on its financial position and results of operations, although it does not anticipate that the adoption of this standard will have a material impact on the Company's financial position or results of operations.

Reclassifications

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

2. Financial Instruments

Cash Equivalents and Short-term Investments

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

	December 31,	
	2001	2000
Cash equivalents:		
Money market fund	$ 2,845	$ 3,343
Commercial paper	67,068	17,168
	$69,913	$20,511
Short-term investments:		
Commercial paper	$ —	$ 9,522
Corporate notes	1,199	14,127
	$ 1,199	$23,649

As of December 31, 2001 and 2000, the difference between the fair value and the amortized cost of available-for-sale securities was $15,000 and $25,000 for 2001 and 2000, respectively. As of December 31, 2001, the average portfolio duration was approximately nine days, and the contractual maturity of any single investment did not exceed 46 days from the balance sheet date.

3. Property and Equipment

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

	December 31, 2001	2000
Machinery and equipment	$ 14,053	$11,259
Furniture and fixtures	1,653	1,489
Lab equipment	3,428	2,480
Computer equipment and software	5,073	3,095
Leasehold improvements	5,055	4,848
	29,262	23,171
Less accumulated depreciation and amortization	(13,186)	(8,686)
	16,076	14,485
Construction in progress	41,864	10,838
Property and equipment, net	$ 57,940	$25,323

At December 31, 2001 and 2000, property and equipment include assets under capitalized leases of approximately $13,080,000 and $13,675,000, respectively. Accumulated depreciation related to leased assets at December 31, 2001 and 2000, was approximately $7,864,000 and $5,209,000, respectively.

4. Leases and Commitments

Amounts borrowed under the Company's equipment lease lines of credit bear interest at rates 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. In March 2001, the Company amended its warehouse facility lease to reduce the leased space by 36,640 square feet. 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, 2001 are as follows (amounts in thousands):

	Operating Leases	Capital Leases
Years ending December 31:		
2002	$ 4,925	$ 4,006
2003	5,081	2,067
2004	5,241	513
2005	5,403	—
2006 and thereafter	45,887	—
Total minimum lease payments	$66,537	6,586
Less amount representing interest		(633)
Present value of future lease payments		5,953
Current portion of capital lease obligations		(3,526)
Noncurrent portion of capital lease obligations		$ 2,427

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, 2001, the Company had $300,000 deferred rent expense, which is included in capital lease obligations on the balance sheet.

For the years ended December 31, 2001, 2000 and 1999, rent expense under operating leases totaled $5,476,000, $3,896,000 and $2,449,000, respectively.

5. Contingencies

In June 1998, Eli Lilly and Company ("Lilly") filed a complaint against the Company in the United States District Court for the Southern District of Indiana. The complaint made various allegations against the Company, arising from the Company's decision to enter into an exclusive collaboration with Novo Nordisk with respect to the development and commercialization of a pulmonary delivery system for insulin and insulin analogs. The Company has 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. The Company and Lilly had also conducted negotiations concerning a long-term supply agreement under which Lilly would supply bulk insulin to the Company for commercialization in the Company's AERx insulin Diabetes Management System, and a separate agreement under which the Company would license certain intellectual property to Lilly. These negotiations were terminated after the Company proceeded with its agreement with Novo Nordisk. The complaint sought a declaration that Lilly scientists were co-inventors of a patent application filed by the Company 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. The Company 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 has issued two written rulings on the Company's motion substantially limiting the claims against the Company. Specifically, the Court granted the Company's 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. The Court denied the Company's motion as to Lilly's claims for declaratory relief, unjust enrichment and breach of contract (in part), based on factual disputes between the parties, and those issues remain to be resolved. The Company recently filed a motion asking the Court to reconsider summary judgment on the inventorship and unjust enrichment claims, based on evidence recently produced by Lilly; the Court denied the Company's motion, but the Company may raise those issues again. Lilly filed a motion seeking to add several new patents to the case; Lilly withdrew that motion after the Company filled its opposition papers and after discussion with the Court. Trial was set for November 2001, but has been continued to April 22, 2002 due to a conflict on the Court's calendar. The risks to the Company should Lilly prevail in this case are that Lilly would be given rights of an owner, along with the Company, on one of the Company's patents relating to pulmonary delivery of monomeric insulin lispro and/or that Lilly would be awarded damages on its remaining claims for breach of contract and unjust enrichment. 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 it has meritorious defenses against each of Eli Lilly's remaining claims and that this litigation will not have a material adverse effect on the Company's financial position, results of operations or cash flows. However, there can be no assurance that the Company will prevail in this case.

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, 2001.

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, 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 January 2001, the Company raised $5 million through the sale of 339,961 common shares 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 ("Novo Nordisk"). 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.

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, Inc., an affiliate of Novo Nordisk A/S. Under the terms of the agreement, Novo Nordisk Pharmaceuticals has committed to purchase up to $45 million of the Company's common stock, in which the initial shares of $20 million ("initial purchase price") was purchased 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 greater of (a) 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, and (b) the average of such closing prices for the five trading days immediately prior to the effective date. In addition, 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 aggregate amount of $25 million has been reached. 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 including, among other things, Novo Nordisk not owning more than 45% of the Company's common stock and the accuracy of certain representations. During October 2001, the Company raised $20 million through the sale of 5,665,723 shares of common stock at a price of $3.53 per in accordance with terms of the agreement.

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, has 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 may 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 has 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 Agreement. The fair market value of the Company's common stock on the closing date was $4.80 per share. In August 2001, the Company committed not to use the equity line.

Reserved Shares

At December 31, 2001, the Company had 5,835,798 shares of its common stock reserved for issuance upon exercise of common stock warrants and 4,713,458 shares for issuance upon exercise of options under all plans.

Other Common Stock Warrants

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 0.78, 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 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 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 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	Number of Shares	Price Per Share	Weighted Average Exercise Price
Balance at December 31, 1998	150,000	75,000	$6.00 - $14.25	$ 9.30
Options granted	(21,568)	21,568	$8.25 - $8.44	$ 8.35
Options exercised	—	(22,500)	$6.00	$ 6.00
Options cancelled	—	—	—	—
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 Outstanding and Exercisable		
Exercise Price Range	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
$6.00 - $8.44	34,068	$ 7.82	5.8
$14.25	22,500	$14.25	2.3
$21.56 - $24.13	71,856	$22.77	8.4
$6.00 - $24.13	128,424	$17.31	6.7

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 December 31, 2001, the Company had 5,953,312 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 lessor 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, 2001 and 2000, notes receivable from shareholders were outstanding of zero dollars and $131,000, respectively. These notes generally bear interest at 6% and are due and payable in regular installments over a five-year period. 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 full amount of the notes receivable from shareholders are secured by a pledge of shares of the Company's common stock. The Company has repurchased a total of 38,294 shares in accordance with these agreements. During 2001, the Company granted options to purchase 1,960,310 shares of common stock, none of which were exercised subject to repurchase agreements.

The following is a summary of activity under the Plan:

	Shares Available for Grant of Options	Number of Shares	Price Per Share	Weighted Average Exercise Price
Balance at December 31, 1998	251,039	1,719,371	$0.10 - $14.63	$ 9.77
Options authorized	1,820,000	—	—	—
Options granted	(475,347)	475,347	$6.19 - $12.00	$ 9.42
Options exercised	—	(36,463)	$0.37 - $12.25	$ 5.19
Options cancelled	60,349	(60,349)	$5.33 - $14.63	$11.03
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	394,577	(394,577)	$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	561,215	(561,215)	$3.44 - $23.00	$10.77
Balance at December 31, 2001	496,010	4,089,024	$0.33 - $24.13	$ 9.74

	Options Outstanding and Exercisable		
Exercise Price Range	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
$0.33 - $0.43	34,125	$ 0.37	2.2
$0.57	5,874	$ 0.57	4.1
$2.00	3,450	$ 2.00	4.2
$3.34 - $4.88	824,850	$ 3.74	9.7
$5.11 - $7.44	1,105,752	$ 6.27	8.6
$8.25 - $12.25	1,091,675	$10.85	5.9
$12.56 - $18.75	703,050	$15.55	8.1
$19.19 - $24.13	320,248	$22.20	7.6
$0.33 - $24.13	4,089,024	$ 9.72	7.9

The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock-Based Compensation" ("APB 25"), which requires use of option pricing valuation models that were not developed for use in valuing employee stock options. Under APB 25, the Company has generally recognized no compensation expense with respect to such awards.

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 2001, 2000 and 1999. Amortization of deferred compensation recognized in the years ended December 31, 2001, 2000 and 1999 was approximately $162,000, $163,000 and $162,000, respectively. The weighted average fair value of options granted during 2001, 2000 and 1999 with an exercise price equal to the fair value of the Company's common stock on the date of grant was $3.59, $11.08 and $4.98, 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 4.2%, 6.2% and 5.2% for the years ended December 31, 2001, 2000 and 1999, respectively; a dividend yield of 0.0%; the annual volatility factor of the expected market price of the Company's common stock for 2001, 2000 and 1999 are 87.0%, 78.0% and 64.1%, respectively; and a weighted average expected option life of four years.

For purposes of pro forma disclosure, the estimated fair value of the options is amortized to expense over the vesting period of the options using the straight-line method. Pro forma information on the above basis is as follows (amounts in thousands, except per share amounts):

	Years ended December 31,		
	2001	2000	1999
Net loss applicable to common shareholders — as reported	$(43,079)	$(35,562)	$(23,603)
Pro forma net loss applicable to common shareholders	$(49,314)	$(39,587)	$(26,087)
Basic and diluted net loss per share applicable to common shareholders — as reported	$ (1.98)	$ (2.07)	$ (1.66)
Pro forma basic and diluted net loss per share applicable to common shareholders	$ (2.26)	$ (2.30)	$ (1.85)

The pro forma impact of options on the net less applicable to common shareholders for the years ended December 31, 2001, 2000 and 1999 is not representative of the effects on the pro forma net income (loss) for future years, as future years will include the effects of additional years of stock option grants.

Employee Stock Purchase Plan

At the Annual Meeting of shareholders held in May 2001, the number of shares under the Employee Stock Purchase Plan (the "Purchase Plan") increased by 250,000 shares to 750,000 shares of common stock. 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. As of December 31, 2001 a total of 695,131 shares have been issued under the Purchase Plan.

8. Collaborative Agreements

Novo Nordisk

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

Through December 31, 2001, the Company received from Novo Nordisk approximately $68.3 million in product development and milestone payments and, of this amount, the Company has recognized approximately $55.4 million as contract revenue. In future periods, the Company could receive up to $120 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 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 at the fair market price. In October 2001, the Company entered into a common stock purchase agreement with Novo Nordisk Pharmaceuticals, Inc., an affiliate of Novo Nordisk A/S. Under the terms of the agreement, Novo Nordisk Pharmaceuticals has committed to purchase up to $45 million of the Company's common stock, in which the initial shares of $20 million was purchased at fair market value. In addition, the Company may elect to sell at its option, subject to certain conditions including among other things, Novo Nordisk not owning more than 45% of the Company's common stock and the accuracy of certain representations, between $5 million and $10 million of additional shares to Novo Nordisk Pharmaceuticals once every three months beginning December 1, 2001 until the aggregate amount of $25 million has been reached. Novo Nordisk will fund all product development costs incurred by the Company, while Novo Nordisk 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's sales of the products. For the years ended December 31, 2001, 2000 and 1999, the Company recognized contract revenues of $26.0 million, $15.4 million and $8.7 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 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 anticipates that GlaxoSmithKline will review its restoration election upon the delivery of Phase 2b trial results, which will be made available to them in the first half of 2002, but 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 2001. 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, 2001, 2000 and 1999, the Company recognized contract revenue of $1.5 million, $3.4 million and $5.2 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 has 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 an extraordinary gain during the first quarter of 2001 of approximately $6,675,000. 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.

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

	December 31,		
	2001	2000	1999
Deferred revenue — beginning balance	$ 8,654	$11,024	$12,673
Partner payments:			
Novo Nordisk	32,054	13,879	9,482
GlaxoSmithKline	—	2,617	2,040
Other partner-funded programs	1,650	1,437	3,641
Total partner payments	33,704	17,933	15,163
Contract revenue recognized:			
Novo Nordisk	26,030	15,411	8,692
GlaxoSmithKline	1,524	3,379	5,187
Other partner-funded programs	1,362	1,513	2,933
Total contract revenue recognized	28,916	20,303	16,812
Deferred revenue — ending balance	13,442	8,654	11,024
Less: Noncurrent portion of deferred revenue	(2,327)	(2,032)	(3,663)
Current portion of deferred revenue	$11,115	$ 6,622	$ 7,361

9. Income Taxes

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,	
	2001	2000
Net operating loss carryforward	$ 48,000	$ 38,600
Deferred revenue	4,400	3,461
Research and development credits	6,500	3,980
Other	700	620
Total deferred tax assets	59,600	46,661
Valuation allowance	(59,600)	(46,661)
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 $12,939,000 and $17,033,000 during 2001 and 2000, respectively.

Deferred tax assets related to carryforwards at December 31, 2001 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, 2001, the Company had net operating loss carryforwards for federal income tax purposes of approximately $121,000,000 which expire in the years 2006 through 2021, and federal research and development tax credits of approximately $4,600,000, which expire in the years 2006 through 2021.

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.

10. Quarterly Results of Operations (Unaudited)

Following is a summary of the quarterly results of operations for the years ended December 31, 2001 and 2000 (amounts in thousands):

	March 31, 2001	June 30, 2001	September 30, 2001	December 31, 2001
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	16,488	17,620	17,123	16,960
Loss from operations	(9,801)	(9,100)	(10,234)	(10,140)
Interest income	668	299	167	190
Interest expense and other	(262)	(364)	(216)	(239)
Net loss before extraordinary gain	(9,395)	(9,165)	(10,283)	(10,189)
Extraordinary gain	6,675	—	—	—
Net loss	(2,720)	(9,165)	(10,283)	(10,189)
Deemed dividend	—	—	—	(10,722)
Net loss applicable to common stockholders	$(2,720)	$(9,165)	$(10,283)	$(20,911)
Basic and diluted loss per share applicable to common shareholders:				
Loss before extraordinary gain	$ (0.50)	$ (0.47)	$ (0.48)	$ (0.77)
Extraordinary gain	0.36	—	—	—
Net loss applicable to common shareholders	$ (0.14)	$ (0.47)	$ (0.48)	$ (0.77)
Shares used in computing basic and diluted loss per share applicable to common shareholders	18,838	19,338	21,581	27,319

	March 31, 2000	June 30, 2000	September 30, 2000	December 31, 2000
Contract and license revenues	$ 5,700	$ 4,804	$ 4,715	$ 5,084
Operating expenses:				
Research and development	10,896	11,509	11,974	13,797
General and administrative	2,073	2,453	2,399	2,346
Total expenses	12,969	13,962	14,373	16,143
Loss from operations	(7,269)	(9,158)	(9,658)	(11,059)
Interest income	395	969	936	810
Interest expense and other	(321)	(367)	(413)	(427)
Net loss	$(7,195)	$(8,556)	$(9,135)	$(10,676)
Basic and diluted net loss per share	$ (0.48)	$ (0.48)	$ (0.51)	$ (0.59)
Shares used in computing basic and diluted net loss per share	14,846	17,810	17,967	18,141

11. Subsequent Events

Increase in Authorized Shares

On February 8, 2002, the Shareholders of Aradigm Corporation approved an amendment of the Company's Articles of Incorporation to increase the authorized number of shares of Common Stock from 40 million to 100 million shares, and approved the Company's Employee Stock Purchase Plan, as amended, to increase the aggregate number of shares of Common Stock authorized for issuance under such plan by 500,000 shares.

Options Granted to Officers and Directors

During February 2002, the Board of Directors approved granted under the 1996 Equity Incentive Plan (the "Plan") with an exercise price of $4.82 per share to several directors and executive officers in an aggregate amount of 140,000 shares and 1,000,000 shares, respectively. Options granted under the Plan expire no later than ten years from the date of grant. The option price was at 100% of the fair value on the date of grant as determined by the Board of Directors. Options granted to the directors will vest quarterly over a period of one year. Options granted to the executive officers will vest quarterly over a period of four years.

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 17, 2002, 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*

The information required by this Item is incorporated by reference from the section captioned "Security Ownership of Certain Beneficial Owners and Management" 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.

PART IV

Item 14. *Exhibits, Financial Statements Schedules, And Reports On Form 8-K*

(a)(1) Financial Statements.

Included in Part II of this Report:

	Page in Form 10-K
Report of Ernst & Young LLP, Independent Auditors	38
Balance Sheets — December 31, 2001 and 2000	39
Statements of Operations — Years ended December 31, 2001, 2000 and 1999	40
Statements of Redeemable Convertible Preferred Stock and Shareholders' Equity — Years ended December 31, 2001, 2000 and 1999	41
Statements of Cash Flows — Years ended December 31, 2000, 2000 and 1999	42
Notes to Financial Statements	43

(2) Financial Statement Schedules.

None.

(3) Exhibits.

3.1 (1)	Amended and Restated Articles of Incorporation of the Company.
3.2 (5)	Bylaws of the Company, as amended.
3.3	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	Certificate of Amendment of Amended and Restated Articles of Incorporation of Aradigm Corporation.
3.6	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)(11)	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.
10.10(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	Amendment to Rights Agreement, dated as of October 22, 2001, by and between the Company and Fleet National Bank.
10.15b	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	Stock Purchase Agreement, dated as of October 22, 2001, by and between the Company and Novo Nordisk Pharmaceuticals, Inc.
10.23*	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 page 54.

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* 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.

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(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).

(b) Reports on Form 8-K.

The Company did not file any reports on Form 8-K during the three month period ended December 31, 2001.

(c) Index to Exhibits.

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

(d) Financial Statement Schedules.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Hayward, State of California, on the 28th day of March, 2002.

ARADIGM CORPORATION

By: /s/ RICHARD P. THOMPSON
Richard P. Thompson
President and Chief Executive Officer

KNOWN ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, jointly and severally, Richard P. Thompson and Michael Molkentin, and each one of them, attorneys-in-fact for the undersigned, each with power of substitution, for the undersigned in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or their substitutes, may do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his name.

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

Signature	Title	Date
/s/ RICHARD P. THOMPSON Richard P. Thompson	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2002
/s/ MICHAEL MOLKENTIN Michael Molkentin	Acting Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2002
/s/ FRANK H. BARKER Frank H. Barker	Director	March 28, 2002
/s/ STAN M. BENSON Stan M. Benson	Director	March 28, 2002
/s/ IGOR GONDA Igor Gonda	Director	March 28, 2002
/s/ JOHN M. NEHRA John M. Nehra	Director	March 28, 2002
/s/ WAYNE L. ROE Wayne L. Roe	Director	March 28, 2002
/s/ VIRGIL D. THOMPSON Virgil D. Thompson	Director	March 28, 2002

EXHIBIT INDEX

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(15) Incorporated by reference to the Company's Form S-3 (No. 333-69614), as amended.

(16) Incorporated by reference to the Company's Form S-3 (No. 333-76584).

EXHIBIT 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Prospectus constituting part of the Registration Statements on Form S-3 (No. 333-76584, No. 333-69614, No. 333-52081, No. 333-72037 and No. 333-48384) and the Registration Statements on Form S-8 (No. 333-63116, No. 333-15947, No. 333-62039 and No. 333-92169) of our report dated February 15, 2002, with respect to the financial statements of Aradigm Corporation included in the Annual Report (Form 10-K) for the year ended December 31, 2001.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 25, 2002

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ARADIGM

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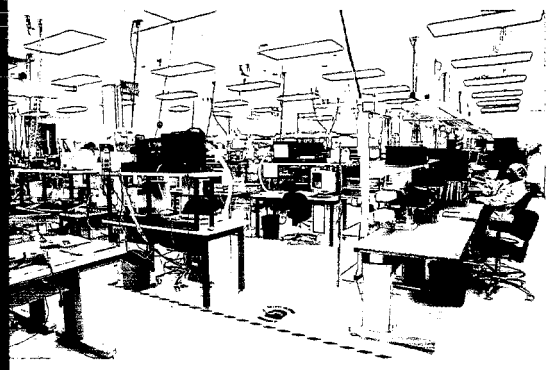
www.aradigm.com

1536-10-K-02

ARADIGM

ADVANCING DRUG DELIVERY



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