

ARADIGM CORP  
Form 10-K  
March 31, 2006

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**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, 2005**

**or**

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

**For the transition period from        to        .**

**Commission File Number: 0-28402**

**Aradigm Corporation**

*(Exact Name of Registrant as Specified in Its Charter)*

**California**

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

**94-3133088**

*(I.R.S. Employer  
Identification No.)*

**3929 Point Eden Way, Hayward, CA 94545**

*(Address of Principal Executive Offices)*

**Registrant's telephone number, including area code:**

**(510) 265-9000**

**Securities registered pursuant to Section 12(b) of the Act:**

**None**

**Securities registered pursuant to Section 12(g) of the Act:**

**Common Stock, no par value**

Indicate by check mark whether the registrant is a well-know seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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.

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and larger accelerated filer" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

The aggregate market value of registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock on June 30, 2005 was: \$73,309,693

The number of shares of the registrant's common stock outstanding as of February 28, 2006 was: 14,563,454.

**DOCUMENTS INCORPORATED BY REFERENCE**

(1) Items 10, 11, 12, 13 and 14 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 18, 2006.

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This Annual 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 Item 1A under the heading Risk Factors .

**PART I****Item 1. Business****Overview**

Aradigm Corporation is a leading developer of innovative drug delivery systems that enable patients to self-administer liquid drugs that would otherwise be given by injection. Our hand-held AERx delivery system is designed for the rapid and reproducible delivery of a wide range of pharmaceutical drugs and biotech compounds either to the lungs for respiratory conditions or through the lung to treat systemic disease. Our pen-sized, needle-free subcutaneous Intraject delivery system is designed to comfortably and rapidly deliver drugs to the subcutaneous layer of the skin, where it can gain access to the bloodstream. We believe that our patient-friendly AERx and Intraject delivery systems, which have been shown in clinical studies to achieve performance equivalent to injection, will be welcome alternatives to injection-based drug delivery. In addition, both of our systems may improve therapeutic efficacy in cases where other existing drug delivery methods, such as pills, transdermal patches, inhalers or auto injectors, are too slow or imprecise.

According to IMS Health, recognized as a global source for market intelligence, the worldwide market for biopharmaceuticals is estimated to grow to \$59 billion by 2008 with the majority of biopharmaceutical therapies requiring parenteral administration (injection). We believe that many of these molecules could potentially be delivered using the AERx and Intraject delivery systems.

Our novel and proprietary technologies are designed to deliver a wide range of pharmaceuticals. The AERx delivery system combines a single-use dosage form that delivers liquid medications through small-particle aerosol generation when combined with a breath-actuated inhalation device. Combining the delivery efficiencies of the device and patient guidance through the proper inhalation technique allows for efficient and reproducible delivery of the aerosol drug to the deep lung. The Intraject delivery system is a pen-sized, pre-filled, single-use system that enables patients and healthcare workers to deliver precise measured doses of drug to the subcutaneous layer of the skin without the use of needles. With our established technologies in late-stage clinical development, we are now broadening and advancing our portfolio of candidates. Our pipeline of candidates represents programs in late, mid and early-stage clinical development. The following table shows the technology platform, disease indication and stage of development for each program.

<b>Platform/Indication</b>	<b>Stage of Development</b>
AERx/Type 1 and Type 2 Diabetes	In Phase 3
Intraject/Migraine	Ready for Pivotal Bioequivalence Study
AERx/HCQ/Asthma	In Phase 2
AERx/Respiratory (Undisclosed)	In Phase 1
AERx/Liposomal Ciprofloxacin (Bioterrorism)	Preclinical
Pulmonary Liposomal Ciprofloxacin (Cystic Fibrosis)	Preclinical
AERx/Smoking Cessation	Preclinical
AERx/Liposomal Treprostinil	Preclinical

**Table of Contents****AERx Diabetes Management System**

The AERx insulin Diabetes Management System ( AERx iDMS ) permits patients with diabetes to non-invasively self-administer insulin. We believe that when patients are provided a non-invasive delivery alternative to injection, they will be more likely to self-administer insulin as often as needed to keep tight control of their blood-glucose levels. This product was being developed in collaboration with Novo Nordisk A/S ( Novo Nordisk ), a leader in the field of diabetes care. In January 2005, we completed the restructuring of the AERx iDMS program, pursuant to the Restructuring Agreement entered into with Novo Nordisk and Novo Nordisk Delivery Technologies Inc. ( NNDT ), a newly created wholly owned subsidiary of Novo Nordisk, in September 2004. Under our current agreement with Novo Nordisk, Novo Nordisk has assumed responsibility for the completion of development, manufacturing and commercialization of the AERx insulin product. We will be entitled to royalties on future sales of the commercialized product.

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

Standard injected 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 pulmonary delivery products under development that are being designed to provide the same one unit dosing adjustability as the AERx iDMS. We believe that our AERx iDMS can provide a non-invasive method for delivery of insulin that would be very efficient and easily reproduced and consistent with the current standards relating to dose titration with insulin therapy.

***The Market***

Unregulated glucose levels in diabetes patients are associated with a variety of 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 take insulin from an external source to survive. To avoid developing the long-term complications of the disease they must also self-inject insulin regularly throughout the day to simulate the natural pancreatic production of insulin in response to meals. Patients with Type 2 diabetes are insulin resistant and unable to efficiently use the insulin that their bodies produce, but they do not initially need external insulin to survive. However, patients with Type 2 diabetes have the same requirement to control their blood glucose levels to avoid the long-term complications of the disease. While many patients can initially maintain control with oral medications, Type 2 diabetes is a progressive disease in which the ability to use and in some cases make insulin gradually declines. Eventually, most patients with Type 2 diabetes will require external insulin to supplement their natural supply and maintain their health and avoid the long-term complications associated with diabetes.

The Diabetes Control and Complications Trial ( DCCT ) conducted from 1983 to 1993 in patients with Type 1 diabetes, which was 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 DCCT showed that keeping blood glucose levels as close to normal as possible slows complications caused by diabetes. In fact, the DCCT 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, conducted from 1983 to 1993, has also demonstrated that tighter blood-glucose control can provide essentially the same benefits for patients with Type 2 diabetes.



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According to 2005 statistics from the American Diabetes Association, approximately 20.8 million Americans suffer from either Type 1 or Type 2 diabetes. Approximately 90-95% of these Americans have Type 2 diabetes, and the prevalence of Type 2 diabetes has increased dramatically over the past decade due to lifestyle factors such as poor diet and inactivity. Type 2 patients consume the majority of insulin used in the United States due to their larger numbers and larger insulin doses. However, given the less acute nature of Type 2 diabetes, many of these patients are reluctant to take insulin by injection. Through our convenient AERx iDMS, we believe we can address this patient reluctance.

***Development and Commercialization Status***

In June 1998, we entered into a product development and commercialization agreement with Novo Nordisk, the world leader in diabetes care, covering the use of the AERx iDMS System for the delivery of blood-glucose regulating medicines.

In November 2001, we successfully completed, with our partner Novo Nordisk, Phase 2b clinical trials of our AERx iDMS, which showed that the product is expected to be successfully used to treat Type 2 diabetes patients with insulin delivered via the pulmonary route. The Phase 2b trial was designed to investigate the safety and efficacy of pulmonary insulin via the AERx iDMS compared to intensified treatment with insulin injections in patients with Type 2 diabetes. Approximately 100 patients were included for a 12-week period in the study. The results of the study, announced in June 2002 at the Annual Meeting of the American Diabetes Association in San Francisco, California, showed the safety and efficacy of the AERx iDMS to be comparable to an intensive subcutaneous injection regimen of insulin.

During the third quarter of 2002, we initiated, with our partner Novo Nordisk, the first study in our Phase 3 clinical program, a two-year study in Type 1 diabetics examining the long-term safety and efficacy of inhaled insulin. This study compared meal-time delivery of regular human insulin administered via the AERx iDMS to subcutaneously injected rapid-acting insulin aspart. Both treatment arms provided once-daily basal injections of NPH insulin. In April 2004, Aradigm and Novo Nordisk announced results from a planned 1-year interim analysis of this study. The primary endpoint of the study was safety, as shown by a variety of pulmonary function tests and chest x-rays. The pulmonary insulin arm of the study demonstrated the same safety in these tests as subcutaneous insulin. In addition, the trial demonstrated that the efficacy of AERx iDMS in terms of HbA1c levels, a key marker in controlling blood glucose, was the same as the control arm involving intensified insulin injections. However, a secondary efficacy endpoint of intra-day blood glucose control was found not to be equivalent between regular human insulin delivered via the AERx iDMS and rapid acting insulin administered subcutaneously.

To further examine this finding, Novo Nordisk initiated a pharmacokinetic/pharmacodynamic (pk/pd) study in these Type 1 patients. In June 2005, at the Annual Meeting of the American Diabetes Association, Novo Nordisk announced results of a study which demonstrated that the onset of action of the AERx iDMS was not significantly different than that of subcutaneous rapid acting insulin, but significantly different from regular human insulin, while the duration of action is not significantly different than regular human insulin, but significantly longer than rapid acting insulin. These findings support Novo Nordisk's conclusion that inhaled insulin via the AERx iDMS would be suitable as a meal-time insulin for Type 1 or Type 2 diabetics.

On January 26, 2005, we completed the restructuring of our AERx iDMS program, pursuant to the Restructuring Agreement entered into with NNDT.

This agreement expands Novo Nordisk's role in the development and commercialization of the AERx iDMS program, such that Novo Nordisk is responsible for commercial launch and we are entitled to receive a royalty on net sales. We are confident in Novo Nordisk's ability to successfully commercialize the AERx iDMS.

We do not have any further material financial or operational commitments for this program.



**Table of Contents****Intraject Triptan**

The Intraject delivery system is currently being developed to deliver a class of drugs called triptans in a needle-free alternative for migraine sufferers. To date, our studies have shown an overall preference by patients for the Intraject system over available needle-based therapy; we believe that this application could offer significant benefits over currently marketed products. We believe that the easy-to-use, patient friendly approach will assist patients in managing their migraines by providing the fastest possible symptom relief without the use of a needle. In November 2004, we announced clinical results from a pilot pharmacokinetic study demonstrating that Intraject with sumatriptan, a member of the triptan family of drugs, was bioequivalent to the currently injectable sumatriptan product.

Patients indicate that the most important attributes to migraine therapy are effectiveness in treating the full range of migraine symptoms and rapid pain relief. The Intraject Triptan delivery system is being designed to address many of the issues affecting injection of sumatriptan including ease of use and needle-phobia. We believe Intraject will be the first pre-filled, needle-free configuration on the market. Intraject's ease of self-administration will translate into better treatment options for patients. In addition, the ability for a patient to self-administer will eliminate the need for office visits and offer a more immediate alternative to traditional injectable sumatriptan.

Although the injectable form of the triptan drug sumatriptan is considered the leading treatment for migraine relief as a result of its rapid and sustainable onset of pain relief, needles are not popular with patients. And while oral tablets offer ease-of-use, this route is often not the best approach due to the nausea that accompanies the migraine and the slower onset of relief. We believe that migraine sufferer will recognize the benefit of combining a patient-friendly, needle-free approach with the efficacy profile of triptans as the leading class of migraine therapy drugs.

***The Market***

Migraine is a primary neurological disorder and episodes can last from four to 72 hours. According to healthcare market research leader Datamonitor, migraines affect roughly 11% of the adult population, or about 74 million people. It is estimated that the average migraine sufferer experiences up to 12 attacks per year, with most attacks being categorized as severe to very severe. Triptans have been shown to treat both the pain and the symptoms, such as nausea, phonophobia and photophobia, associated with migraines. We believe that with its novel features, Intraject Triptan could capture a significant part of the current injectable, oral and nasal migraine therapy markets.

***Development and Commercialization Status***

Prior to our acquisition of the Intraject technology, associated intellectual property and manufacturing equipment from Weston Medical Group, PLC, ( Weston ) in May 2003, Weston had conducted several clinical and preclinical studies with Intraject, in which it was demonstrated that Intraject delivery was bioequivalent to needle injections. After the acquisition of the Intraject technology, we redesigned the system to overcome potential issues with respect to reliability and ease-of-use following its commercialization. In October 2004, we announced positive results from the Clinical Performance Verification ( CPV ) trial using the final system configuration. The results supported the conclusion that the reengineered system demonstrated successful injection performance reliability and was suitable for commercialization.

Following the results from the CPV trial, we initiated a pilot pharmacokinetic study comparing Intraject sumatriptan to the currently marketed needle-injected product. The trial was a randomized, open-label, single-dose, crossover study evaluating the pharmacokinetics of sumatriptan at three injection sites (abdomen, thigh, and arm) in 18 healthy adult male and female volunteers.

In November 2004, we completed the pilot pharmacokinetic study with positive results, showing that sumatriptan delivered by Intraject met all bioequivalence criteria and demonstrated statistically equivalent pharmacokinetics to the marketed injectable product. Specifically, the comparability of Intraject to the subcutaneous needle-injected sumatriptan product was established at all three injection sites using standard

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bioequivalence criteria of peak concentration achieved in blood plasma (C<sub>max</sub>) and total drug concentration in blood plasma achieved over time (AUC).

In June 2005, we completed a clinical study that showed that Intraject with sumatriptan achieved bioequivalence to the currently marketed subcutaneous-injected product and that patients, who were naïve to using Intraject, could self-administer themselves in the thigh, abdomen or arm.

In December 2005, we completed the manufacture of supplies of Intraject sumatriptan to support final stability testing and clinical trial requirements. The supplies of Intraject sumatriptan were produced using our commercial-scale equipment housed by our supply chain partners. With this milestone achieved, and commercial-scale production now explicitly demonstrated, we believe that we do not need to further invest in this platform, pending partnering of the product. Upon partnering, we can initiate the remaining pivotal bioequivalence study.

We believe that the triptan family of drugs represents a significant opportunity for the Intraject system and is the focus of our current partnering discussions.

### **AERx Hydrochloroquine**

Our AERx Hydrochloroquine ( HCQ ) program is investigating a novel aerosolized formulation of HCQ as a treatment for asthma. In oral formulations, HCQ is currently a treatment for lupus and rheumatoid arthritis and seen as an alternative to steroid therapy. It is our belief that a targeted local pulmonary delivery application combined with a patented formulation could result in an innovative asthma treatment. Currently, the HCQ program is in Phase 2 clinical trials and is partnered with APT Pharmaceuticals ( APT ), a privately held biotechnology company. The program has advanced following a positive Phase 1 study in healthy volunteers, which has determined that AERx-delivered HCQ had a favorable safety and tolerability profile.

Asthma is a common chronic disorder of the lungs characterized by airway inflammation, airway hyperresponsiveness or airway narrowing due to certain stimuli. For patients with asthma, allergens, environmental stimuli or viral respiratory infections could trigger an immune-mediated response that could lead to reversible airway obstruction. Primary symptoms of asthma include coughing, wheezing, shortness of breath and tightness of the chest. Symptoms can vary widely in frequency in degree as some patients have virtually no symptoms while others are permanently afflicted. Despite several treatment options, asthma remains a major medical problem associated with high morbidity and large economic costs to the society. Many patients cannot control their disease adequately with the current treatment options and end up in hospital emergency rooms. HCQ administered using the AERx system enables targeted delivery of the drug directly to the lower airways, achieving immediately a high concentration at the affected site while keeping the plasma levels of HCQ low. We believe that this therapeutic product that combines the advantages of an innovative formulation with the targeted delivery of the AERx system has the potential to offer significant advantages over existing asthma treatments.

### ***The Market***

According to Datamonitor, a leader in market intelligence, in 2005 asthma affected 41.5 million people, with the highest prevalence occurring in the U.S. and U.K., with 9.5 million of those affected being children. The annual treatment costs of asthma, including indirect costs, are estimated to be \$16.1 billion in the US and \$16.3 billion in the EU.

### ***Development and Commercialization Status***

Following favorable Phase 1 safety study results, we entered into Phase 2 clinical trials. Phase 2 trials are larger in size than Phase 1 and are designed to determine the dosing safety and efficacy of the product.

APT is funding development of the clinical program and is responsible for funding any activities we might undertake in this program. We are continuing commercialization discussions, which are dependent on future

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clinical results. We believe that this product may have similar anti-inflammatory properties to inhaled steroids but with a potentially improved safety profile.

### **Liposomal Ciprofloxacin**

Each of our two liposomal ciprofloxacin programs combine a novel patented formulation with a powerful anti-infective being studied to treat bio-terrorism-related disease and infections related to cystic fibrosis ( CF ). The first of our two programs is our liposomal ciprofloxacin bioterrorism program, which is partnered with the Canadian Department of Defense to develop a treatment and prophylaxis for inhaled anthrax. Ciprofloxacin, or cipro, as it is more commonly known, is a widely used anti-infective agent used to treat a variety of bacterial infections. As part of this partnership we have licensed the rights to a formulation of the drug that is designed to (1) enhance the duration of action of the drug in the lung and (2) enable better interaction of the drug with the disease target.

The second program utilizing liposomal ciprofloxacin is in the treatment and control of respiratory infections in Cystic Fibrosis (CF). Our intention is to advance this program through clinical development and seek a partner at a point closer to commercial launch.

#### ***The Market***

CF affects roughly 30,000 children and adults in the United States and roughly 60,000 worldwide. According to the Centers for Disease Control, the majority of studies done in the early 1990 s state that the annual direct medical care costs for an individual with CF were \$15,000 to \$20,000 (1996 dollars).

CF is a genetic disease that commonly affects a person s breathing and digestion patterns. The disease is caused by an abnormal protein that does not allow the normal passage of chloride into and out of certain cells, including those that line the lungs and pancreas. As a result, these cells produce thick, sticky mucus and other secretions. This mucus then clogs the lungs, causing breathing problems and with those affected individuals suffering from frequent lung infections could lead to irreversible lung damage and possible death. When infections occur, they are typically treated at home or in the hospitals with a number of oral antibiotics or using nebulizers and compressors for antibiotic inhalations, for which only one product is approved. A greater choice of effective and safe antibiotic therapy appears desirable.

#### ***Development and Commercialization Status***

We expect to initiate preclinical studies for liposomal ciprofloxacin in 2006.

The Liposomal Ciprofloxacin CF product is a self-initiated program designed to be advanced into development and then partnered at an appropriate time. We believe that the combined features of the AERx delivery system including targeted local lung delivery and a novel formulation of a powerful anti-infective could effectively and safely treat many of the lung infections that face patients with CF. We intend to continue this program until we have demonstrated a proof of concept, at which point, we may partner the program.

### **AERx Smoking Cessation**

Our AERx Smoking Cessation product is based on the capabilities of the AERx system to titrate and deliver accurate doses of small droplet aerosols to the deep lung for systemic uptake. When nicotine is combined with our delivery system, different doses can be delivered providing patients and physicians with an easy to use, efficient and accurate delivery system that is ideally suited for downward titration of inhaled nicotine doses over time. We believe that by creating a product that produces a pharmacokinetic profile that mimics the high peaks resulting from inhalation of tobacco smoke, we will be addressing an unmet need for patients wanting to quit but unable to do so due to their addiction.

#### ***The Market***

According to Decision Resources, the smoking cessation market is expected to increase to nearly \$1.5 billion by 2007. Currently the market is dominated by nicotine replacement in multiple delivery forms

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including transdermal patches, gums, and nasal sprays. These therapies, which are available over the counter, are designed to wean smokers off the habit by providing a measured dose of nicotine without the smoke and tar of a cigarette.

According to the American Heart Association, approximately 48 million Americans smoke cigarettes, most of whom either want to quit or are actively trying to quit. Since 1965, more than 40 percent of all adults who have ever smoked have quit with more than four in five smokers saying that they want to quit. With good smoking cessation programs, only 20 to 40 percent of participants who smoke more than 25 cigarettes a day are able to quit smoking and stay off cigarettes for at least one year. We believe our product could significantly improve the effectiveness of smoking cessation programs and expand the market size for these treatments.

### ***Development and Commercialization Status***

We are currently working on formulation development and finalizing the clinical development program.

We have signed an intellectual property access agreement with an undisclosed global pharmaceutical company on this program granting them access to our recently issued patents in the area of the pulmonary delivery of nicotine to effect smoking cessation. Any further activities we undertake on this program would need to be funded by a partner or grant.

### **AERx Treprostinil**

Our AERx Treprostinil product is a novel, sustained-release inhaled liposomal formulation for the treatment of pulmonary arterial hypertension ( PAH ).

Patients with PAH experience elevated blood pressure in the pulmonary arteries. Symptoms of the disease include fatigue, shortness of breath on exertion, chest pain and dizziness. When left untreated, the median survival time following diagnosis may be as short as three years.

### ***The Market***

According to Decision Resources, in 2003, PAH affected over 130,000 people worldwide with sales of related medical treatments of \$600 million per year and related medical treatments expected to reach \$1.2 billion by 2013.

### ***Development and Commercialization Status***

We expect to complete the first preclinical testing of selected formulations within the next few months.

We have a commercial agreement with United Therapeutics, a leader in cardiovascular therapies, to deliver an aerosolized formulation of their drug treprostinil, marketed as Remodulin, an approved and marketed intravenously or subcutaneously delivered prostacyclin analogue. United Therapeutics has agreed to fund our activities in this program. We believe that the AERx delivery system offers a non-invasive and more direct approach to treatment over the currently available methods.

### **Potential Product Applications**

Our AERx and Intraject technology platforms are both positioned to address multiple therapeutic disease areas and with compounds that cannot be delivered orally or large molecules delivered by injection. We have demonstrated to date, in many human clinical trials, effective deposition and, where required, systemic absorption of a wide variety of drugs including small molecules, peptides and proteins. We are developing the hand-held AERx system 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 applications in respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD), as well as conducting investigations in cardiovascular disease, neurological disease, and inflammatory conditions. In addition, we are targeting the development of the AERx system for the non-invasive delivery of certain other drugs, including proteins, peptides and small molecules.

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While we are assessing the feasibility of the AERx delivery system with compounds in various therapeutic areas we do not typically disclose information relating to the specifics of these studies (including the drug or partner involved) until the program moves into a later stage of development or at an earlier time that is mutually agreed upon with the partner.

We also believe that substantial opportunities exist within multiple disease areas for our Intraject system. Intraject's ability to allow for a rapid, comfortable administration in a patient-friendly format is well suited for chronically delivered therapies that once needed to be administered by physicians. While our initial application for our Intraject delivery system is within the triptan class of drugs, we have also identified and are pursuing multiple viscous and non-viscous liquid drugs given by injection in the areas of inflammatory, neurological and infectious diseases. To date, we have demonstrated in clinical trials the applicability of our platforms in a variety of diseases.

### **Drug Delivery Technology Background**

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 technologies, needle-free systems and pulmonary delivery systems. We believe that our AERx and Intraject systems can address these limitations.

### **Pulmonary Delivery Background**

The natural ability of the lung to transfer molecules into the bloodstream makes pulmonary drug delivery systems an alternative method to injection. Originally developed to treat lung diseases, pulmonary delivery deposits aerosolized (fine particles or mists) medication in the large airways of the lung. These aerosols were created in medical devices, such as nebulizers, metered-dose inhalers and dry powder inhalers, for inhalation by the patient. While these systems have been useful in the treatment of certain diseases such as asthma, they generate a wide range of particle sizes, only a portion of which can reach the targeted lung tissues and they rely heavily on proper patient breathing technique to ensure appropriate 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 a pharmaceutical to or through the lungs, the drug must be transformed into an aerosol that can be inhaled by the patient. In order for an aerosol 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. Large or fast-moving particles typically get deposited in the mouth or upper airways, where they cannot be absorbed and may not be effective. Most drugs being considered for pulmonary delivery are currently marketed in stable liquid formulations. The older systems for aerosolization of liquids—nebulizers—suffer from many weaknesses, including inefficiency, inconvenient use (lack of portability, long period of administration.) The ability to make small micron size droplets from a hand-held device that incorporates breath control is, in our view, the preferred method of delivery of many medications. For example, we believe the extra steps involved in making dry powder formulations of drugs for use in dry powder inhalers will make them more difficult and expensive to produce than liquid-based formulations. In addition, today's dry-powder delivery systems under development continue to rely on individual patient breathing technique for the actual drug delivery. It is well documented that the typical patient frequently strays from proper inhalation technique and may not be able to maintain a consistent approach over even moderate periods of time after training. Since precise and reproducible dosing with medications is necessary to ensure safety or therapeutic efficacy, any variability in breathing technique among patients or from dose to dose may negatively impact the effectiveness of an inhaled drug.

**Table of Contents****The Aradigm Solution for Pulmonary Delivery*****AERx***

We have demonstrated in the laboratory and in many human clinical trials that our AERx enables pulmonary delivery of a wide range of pharmaceuticals in liquid formulations for local or systemic effect. Our proprietary AERx technologies focus principally on delivering liquid medications through small-particle aerosol generation and controlling patient-inhalation technique for efficient and reproducible delivery of 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 system takes advantage of existing liquid-drug formulations, reducing the time, cost and risk of formulation development compared to dry-powder-based technologies. The formulation technology of the AERx system allows us to use conventional, sterile pharmaceutical manufacturing techniques. We believe that this approach will result in lower cost production methods than those used in dry powder systems because we are able to bypass entirely the complex formulation processes required for those systems. Moreover, the liquid drug formulations used in AERx systems are expected to have the same stability profile as the currently marketed versions of the same drugs. Because of the nature of liquid formulations, the excipients we use are standard and therefore minimize safety concerns.

***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 system. Each disposable packet is comprised of a small blister package of the drug and an adjacent aerosolization nozzle. The AERx device compresses the packet to push the drug through the nozzle and thereby creates the aerosol. No propellants are required since mechanical pressure is used to generate the aerosol. Each packet is used only once to avoid plugging or wearing that would degenerate aerosol quality if reused. Through this technology, we believe we can achieve highly efficient and reproducible aerosols. The AERx device also has the ability to deliver a range of patient selected doses, making it ideal for applications where the dose can change between uses or over time.

***Automated Breath-Controlled Delivery***

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

***Subcutaneous Delivery Background***

While the concept of subcutaneous, needle-free drug delivery has been around for several decades, early systems were powered by large, complex and expensive air compressors and therefore usually reserved for vaccine applications. Only recently have research and advances in technology produced smaller, more patient-friendly configurations and made subcutaneous, needle-free delivery an attractive and viable option. Data from clinical trials conducted using the Intraject system indicate that the needle-free delivery of drugs to the subcutaneous region of the skin allows for a speed of absorption into the bloodstream equivalent to

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subcutaneous needle injections. We believe that effective and convenient needle-free delivery could improve patient compliance with prescribed therapy compared with the same therapy delivered with needle injections.

### **The Aradigm Solution for Needle-Free Subcutaneous Delivery**

#### ***Intraject***

Intraject, a pen-sized, pre-filled, single-use system, is designed to enable patients and healthcare workers to deliver precise measured doses of drug to the subcutaneous layer of the skin without the use of needles. This system has two main parts: the glass drug capsule with a fill volume of 0.5 ml and a compact nitrogen gas power source called the actuator. Intraject uses the actuator to create a high-velocity, fine liquid stream that penetrates the skin to pass into the subcutaneous layer.

The Intraject system uses a pre-filled, fixed dose, a feature that is ideal for those applications where the dose does not change over the short term.

Ease-of-use is an important benefit of the Intraject system. The patient or healthcare worker first snaps the cap off of the system, flips the safety lever, and then presses the Intraject directly to the skin, thereby activating the system. The injection itself is completed in less than 60 milliseconds.

We are developing this system to allow for the subcutaneous needle-free delivery of a wide range of pharmaceuticals and biopharmaceuticals. In clinical trials, patients have preferred Intraject to the standard needle and syringe and were able to self-administer the system.

In December, we announced the completion of production of supplies for our pivotal bioequivalence trial for sumatriptan.

Key features of the Intraject platform include:

Pre-filled and ready to use;

Lightweight and pocket-sized; and

Easy to operate.

Intraject's clinical and regulatory development timelines may be more abbreviated than traditional drug development candidates. In the case of drugs that are already approved for subcutaneous injection, bioequivalence studies are pivotal in obtaining marketing approval. These studies and trials could be conducted in as little as a few months. We believe that this is another attractive feature to potential partners as they address issues such as patent expiration and life cycle management relating to their marketed products.

#### **Our Strategy**

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

##### ***Identify Suitable Drug Delivery Candidates for our Platforms***

We believe the AERx and Intraject platforms will be broadly applicable to drugs intended for either local delivery to the lung or systemic delivery.

Our strategy will be to maximize the number of commercial product opportunities for each of our two systems and increase the interest of potential partners in developing drugs for the AERx and Intraject systems.

##### ***Expand Existing Collaborative Relationships and Develop New Collaborative Relationships***

In order to enhance our commercial opportunities and effectively leverage our core scientific resources, our strategy is to enter into multiple collaborative relationships with pharmaceutical and biotech companies for the development and commercialization of new products utilizing our technologies. In 2005 we continued to see an increased interest in our technology platforms that resulted in initiation of several early-stage

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feasibility studies, progression of a mid-stage program and the signing of a commercial agreement. Through product development collaborations, we seek access to proprietary pharmaceutical compounds as well as to the resources necessary to conduct late-stage clinical programs and obtain regulatory approvals. In addition, we will continue pursuing relationships with companies with established sales forces and distribution channels in our target markets. By establishing such collaborative relationships, we intend to introduce multiple new products while avoiding the need to establish drug discovery research, sales, marketing and large-scale commercialization capabilities.

***Enhance Our Strong Proprietary Position***

We believe that establishing a strong proprietary position in pulmonary and needle-free drug delivery is important in order for us to be competitive in our target markets. We are establishing and intend to protect our strong intellectual property position that includes inventions in the field of pulmonary delivery and our AERx and Intraject systems. We currently hold 211 issued United States and foreign patents and 136 pending worldwide applications. While there can be no assurance that any of our patents will provide us with a significant commercial advantage, these patents are intended to provide protection for important aspects of our technologies and maintenance of trade secrets associated with key elements of our manufacturing technologies.

***Maintain Technological Leadership***

We are making a substantial research and development investment to establish and maintain technological leadership in pulmonary and needle-free drug delivery. This includes research and development programs to design future generations of our pulmonary and needle-free delivery systems. The goal of these programs is to access a wider range of markets, broaden our technology base, achieve manufacturing efficiencies and develop next-generation delivery devices. We have invested in efforts to accelerate development of the Intraject program by creating an *in-vitro/in-vivo* correlation model intended to predict the clinical performance of compounds we are testing. We are supported by our Scientific Advisory Board, whose members are leaders in drug delivery and clinical specialties of key interest to us. We access scientific and medical experts in academia, as needed, to support our scientific advisory board.

**Research and Development Strategy**

We plan to focus our future research and development efforts on the development and commercialization of products on our AERx and Intraject technology platforms, both through self-initiated activities and collaborations with other parties. However, future research and development expenditures cannot be predicted reliably as we depend in part upon continued success and funding levels supported by our existing development collaborations, as well as entering into new collaborative agreements.

**Sales and Marketing Strategy**

We plan to establish additional collaborative relationships to develop and commercialize our AERx and Intraject products. Through these collaborations, we intend to access resources and expertise to conduct late-stage clinical development and to market and commercialize AERx and Intraject products. Ideal development partners will generally have both a commercial presence and a development presence in a given target market and will also have committed 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 drug-delivery technologies.

In some cases, our strategy may be to take a program further in development before securing a partner in order to achieve higher royalties from the commercialization partner.

**Manufacturing/ Commercialization Strategy**

For both our AERx and Intraject platforms we have implemented a Contract Manufacturing Organization ( CMO ) strategy for production. This approach uses best-in-class suppliers from around the world



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whose expertise allows us to minimize risk and costs normally incurred if we were to assume responsibility ourselves. In these cases, we have secured agreements with several of these manufacturers.

As of January 26, 2005, we completed the restructuring of our AERx iDMS program, pursuant to the Restructuring Agreement entered into with Novo Nordisk and NNDT. Under the terms of the Restructuring Agreement, we have transferred our clinical strip manufacturing and our AERx device manufacturing facilities to NNDT, and NNDT has agreed to perform contract manufacturing services for us for at least three years of non-AERx iDMS devices and AERx dosage forms filled with compounds provided by us in support of initial clinical development by us of other AERx products.

We believe that the manufacturing processes for the AERx delivery system are now sufficiently advanced that additional capacity can be replicated using the services of CMOs. Therefore, we do not intend to build any additional facilities for commercial AERx manufacturing, except at the specific request and with funding from our marketing partners.

Our Intraject manufacturing strategy employs a fully integrated third party supply chain, in which outside suppliers are responsible for key components, including final assembly. This approach will use best-in-class suppliers from around the world whose expertise will allow us to minimize risk and costs normally incurred if we were to assume responsibility for manufacture ourselves. We have secured supplier agreements with each of these manufacturers, many of who worked on the Intraject program prior to our acquisition of the Intraject technology. This approach will allow us to focus on establishing core competencies in the area of research and development.

There can be no assurance that we will not encounter unanticipated delays or expenses in establishing high-volume production capacity for AERx devices, AERx disposable drug packets or components related to the Intraject system. 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 on 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 97 issued United States patents as of February 28, 2006, with 18 additional United States patent applications pending. In addition, we have purchased three United States patents covering inventions that are relevant to our inhalation technologies. We have also purchased a portfolio of patents covering the Intraject technology, with 14 issued United States and 4 additional patent applications pending. In total, we have 97 issued foreign patents and 114 foreign patent applications pending.

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 covering what we deem to be important technological developments that might relate to our technologies 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,

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whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated.

Furthermore, patents already issued to us or our pending applications may become subject to dispute, and any disputes could be resolved against us. For example, Eli Lilly brought an action against us seeking to have one or more employees of Eli Lilly named as co-inventors on some of our patents. This case was determined in our favor in 2004, but there can be no assurance that we will not face other similar claims in the future.

In addition, because patent applications in the United States and in certain other countries generally are not published until more than 18 months after they are first filed, and because publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first creator of inventions covered by pending patent applications or that we were the first to file patent applications on such inventions.

Our policy is to require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the relationship shall be kept confidential except in specified circumstances. These agreements also provide that all inventions developed by the individual on behalf of us shall be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets or other proprietary information in the event of unauthorized use or disclosure of such information.

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

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

## **Competition**

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

We believe our technology and integrated pulmonary delivery systems approach provides us with important competitive advantages in the delivery of drugs compared with currently known alternatives. While we believe that the capabilities of our AERx and Intraject systems will provide us with certain important

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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 or Intraject systems.

Several companies have developed or are developing products that will compete with our technology platforms. Some are marketing and developing dry-powder and other devices that could have applications for pulmonary drug delivery, including Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), Alkermes Pharmaceuticals, Inc. and Mannkind Corporation. Two of these companies also have collaborative arrangements with corporate partners for the development of pulmonary delivery systems for insulin. There are also several companies that are marketing and/or developing needle-free injection systems, including Antares Pharma Inc., Bioject Medical Technologies Inc., Biovalve Technologies, Inc., Crossject and Penjet Corporation. 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. The FDA under a series of regulations called the current Good Laboratory Practice regulations regulates Preclinical studies. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be replicated, thus extending time of development.

The pre-clinical 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 begin clinical trials. Once trials have begun, either the FDA or we may place them on clinical hold to stop them, because of concerns, for example, about the conduct of the study or 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. Typically, Phase 1 trials consist of testing the product in a small number of healthy 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 the patient population. Phase 3 trials (also known as pivotal studies) the basis for approval, typically involve additional testing for safety and clinical efficacy in an expanded population at geographically dispersed sites.



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A company seeking FDA approval to market a new drug must file a New Drug Application ( NDA ) 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 NDA includes Chemistry, Manufacturing and Controls ( CMC ) information pertaining to the preparation of the drug substance (active ingredient), analytical methods, drug product formulation, details on the manufacture of finished products and proposed product packaging, labeling and storage. Submission of a new drug application does not assure FDA approval for marketing. Based on the Prescription Drug User Fee Act, review of NDAs should result in an action letter within ten months after filing. However, the application approval 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. The process may take substantially longer if, among other things, the FDA has questions or concerns about the safety, efficacy or CMC of a product. In general, the FDA requires at least two properly conducted, adequate and well-controlled clinical studies demonstrating safety and efficacy with sufficient levels of statistical assurance.

Notwithstanding the submission of safety and efficacy data, the FDA ultimately may decide that the application does not satisfy all of its regulatory criteria for approval. The FDA could also determine that there is insufficient data or experience with chronic administration of drugs delivered via the lung for systemic effect to demonstrate that such chronic administration is safe, and could require further studies. The FDA also may require additional clinical tests (i.e., Phase 4 clinical trials) following new drug application approval to confirm safety and efficacy.

In addition, the FDA may in some circumstances impose restrictions on the use of the drug that may be difficult and expensive to administer. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. The FDA also requires reporting of certain safety and other information that becomes known to a manufacturer of an approved drug. The product testing and approval process is likely to take a substantial number of years and involves expenditure of substantial resources. There is no guarantee that any approval will be granted on a timely basis, or at all. Upon approval, a prescription drug may only be marketed for the approved symptoms in the approved dosage forms and at the approved dosage.

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

Products marketed outside the United States that are manufactured in the United States are subject to certain FDA regulations, as well as regulation by the country in which the products are to be sold. We also would be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are marketed abroad. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries 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;

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fire hazard control; and

disposal of hazardous or potentially hazardous substances.

The United States Drug Enforcement Agency ( DEA ) regulates controlled drug substances, such as morphine and other narcotics. Establishments handling controlled drug substances 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.

**Scientific Advisory Board**

We have assembled a Scientific Advisory Board comprised of scientific and development advisors who 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. We access scientific and medical experts in academia, as needed, to support our scientific advisory board. The 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:

<b>Name</b>	<b>Affiliation</b>	<b>Area of Expertise</b>
Peter R. Byron, Ph.D.	Medical College of Virginia, Virginia Commonwealth University	Aerosol Science/Pharmaceutics
Peter S. Creticos, M.D.	The Johns Hopkins University School of Medicine	Allergy/Immunology/Asthma
Igor Gonda, Ph.D.	AcruX Limited	Drug Delivery
Robert E. Ratner, M.D.	MedStar Research Institute	Endocrinology

**Employees**

As of February 28, 2006, we had 103 employees. Of these, 73 are involved in research and development, product development and commercialization; and 30 are involved in business development, finance and administration. 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 excellent.

**Table of Contents****Corporate History and Website Information**

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

**Directors and Executive Officers**

The directors and executive officers of Aradigm and their ages as of February 28, 2006 are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
V. Bryan Lawlis, Ph.D.	54	President, Chief Executive Officer and Director
Thomas C. Chesterman	46	Senior Vice President and Chief Financial Officer
Steven J. Farr, Ph.D.	47	Senior Vice President, Chief Scientific Officer
Bobba Venkatadri	62	Senior Vice President, Operations
Babatunde A. Otulana, M.D	49	Vice President, Clinical & Regulatory Affairs
John J. Turanin	48	Vice President, Program Management and Corporate Planning
Virgil D. Thompson(2)	66	Director and Chairman of the Board
Frank H. Barker(1)(3)	75	Director
Igor Gonda(2)	58	Director
Stephen O. Jaeger(1)(2)	61	Director
John Nehra(3)(4)	57	Director
Wayne I. Roe(1)(4)	55	Director
Richard P. Thompson(3)(4)	54	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

(4) Not standing for reelection at the May 2006 Annual Shareholders Meeting

*V. Bryan Lawlis, Ph.D.*, has been a director since February 2005 and has served as President and Chief Executive Officer since August 2004. Dr. Lawlis served as President and Operating Officer from June 2003 to August 2004 and as our Chief Operating Officer from November 2001 to June 2003. Previously, Dr. Lawlis founded Covance Biotechnology Services, Inc., a contract biopharmaceutical manufacturing operation, and served as its President and Chief Executive Officer from 1996 to 1999, and as Chairman 1999 to 2001, when it was sold to Diosynth, RTP, Inc., a division of Akzo Nobel, NV. From 1981 to 1996, Dr. Lawlis 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.



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

*Stephen J. Farr, Ph.D.*, has served as our Senior Vice President, Chief Scientific Officer since April 2003. Since 1995, Dr. Farr served in various positions at Aradigm including as Director, Pharmaceutical Sciences, Senior Director and Vice President, Pharmaceutical Sciences, and Vice President, Research and Development. From September 1985 to December 1994, Dr. Farr was Lecturer and later Senior Lecturer in the Welsh School of Pharmacy, Cardiff University, United Kingdom. Dr. Farr was a founder and director of Cardiff Scintigraphics Ltd., a contract research organization. Dr. Farr holds a B.Sc. in Pharmacy from De Montfort University, and a Ph.D. in pharmaceutics from the University of Wales. Dr. Farr is a Visiting Associate Professor in the Department of Pharmaceutics, School of Pharmacy, Virginia Commonwealth University, Richmond, Virginia.

*Bobba Venkatadri* has served as our Senior Vice President, Operations, since June 2003. Mr. Venkatadri has over 30 years of U.S. and international senior executive leadership experience in pharmaceutical and biotechnology manufacturing. Prior to joining Aradigm, Mr. Venkatadri was Executive Vice President of Operations for Diosynth RTP, Inc., a division of Akzo Nobel AV from January 2001. Mr. Venkatadri served as Chief Executive Officer of Molecular Biosystems, Inc. from 1995 to 2000, and Executive Vice President of Centocor, Inc. from 1992 to 1995. Mr. Venkatadri held multiple positions with Warner-Lambert Company from 1967 to 1992 including, President of Warner-Lambert Indonesia, Vice President of Warner-Lambert Puerto Rico, and Vice President, U.S. Operations of Parke-Davis. Mr. Venkatadri holds a Masters Degree in Pharmacy from Andhra University, India, and an MBA in Finance from Fairleigh Dickinson University.

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

*John J. Turanin* has served as our Vice President, Corporate Planning and Program Management since May 2004. From October 1996 to May 2004, Mr. Turanin held several positions in business development and project management at Aradigm and most recently was Director of Project Management. From August 1987 to September 1996, Mr. Turanin held several positions at Invacare Corporation, a leading manufacturer of home medical equipment, where his last position was Senior General Manager of Respiratory Products for Invacare. Mr. Turanin holds an MBA from the University of Pittsburgh and a B.A. in Business from Indiana University of Pennsylvania.

*Virgil D. Thompson* has been a director since June 1995 and has been Chairman of the Board since January 2005. Since November 2002, Mr. Thompson has been President and Chief Executive Officer of Angstrom Pharmaceuticals Inc., a pharmaceutical company. From September 2000 to November 2002, Mr. Thompson was President, Chief Executive Officer and Director of Chimeric Therapies, Inc., a biotechnology company. From May 1999 until September 2000, Mr. Thompson was the President, Chief Operating Officer and a Director of Bio-Technology General Corp. (now Savient Pharmaceuticals, Inc.) a pharmaceutical company. From January 1996 to April 1999, Mr. Thompson was the President and Chief Executive Officer and a Director of Cytel Corporation, a biopharmaceutical company. From 1994 to 1996, Mr. Thompson was President and Chief Executive Officer of Cibus Pharmaceuticals, Inc., a drug delivery device company. From 1991 to 1993, Mr. Thompson 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

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The George Washington University Law School. Mr. Thompson is also a director of Questcor Pharmaceuticals, Inc. and Savient Pharmaceuticals Inc.

*Frank H. Barker* has been a director since May 1999. From January 1980 to January 1994, Mr. Barker served as a company group chairman of Johnson & Johnson, Inc., a diversified health care company and was Corporate Vice President from January 1989 to January 1996. Mr. Barker holds a B.A. in Business Administration from Rollins College, Winter Park, Florida.

*Igor Gonda, Ph.D.* has been a director since September 2001. Dr. Gonda 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. Dr. Gonda is the Chairman of the Scientific Advisory Board of Aradigm.

*Stephen O. Jaeger* has been a director since March 2004. He has been the Chairman of eBT International, Inc., a former software products and services company since 1999. Mr. Jaeger also held the positions of President and Chief Executive Officer from 1999 to December 2005. Prior to joining eBT, Mr. Jaeger was the Executive Vice President and Chief Financial Officer of Clinical Communications Group, Inc., a provider of educational marketing services to the pharmaceutical and biotech industries, from 1997 to 1998. From 1995 to 1997, Mr. Jaeger served as Vice President, Chief Financial Officer and Treasurer of Applera Corp., formerly know as Perkin Elmer Corporation, an analytical instrument and systems company with a focus on life science and genetic discovery. Prior to 1995, Mr. Jaeger was Chief Financial Officer and a director of Houghton Mifflin Company and held various financial positions with the British Petroleum Company, PLC, Weeks Petroleum Limited and Ernst & Young LLP. Mr. Jaeger holds a B.A. in Psychology from Fairfield University and an MBA in Accounting from Rutgers University and is a Certified Public Accountant. Mr. Jaeger is on the board of Savient Pharmaceuticals Inc. and Arlington Tankers, Ltd. Mr. Jaeger is the Chairman of and the designated financial expert on Aradigm's and Savient's Audit Committees and is the Chairman of Arlington Tankers' Audit Committee.

*John M. Nehra* has been a director since December 2001. Mr. Nehra is a Special Partner of New Enterprise Associates 10 Limited Partnership ( NEA 10 ) and New Enterprise Associates 11, Limited Partnership, both venture capital partnerships, 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 10 and its affiliated venture funds in 1989, Mr. Nehra was Managing Director of Alex Brown & Sons Inc., 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 holds a B.A. from the University of Michigan. Mr. Nehra is a director of Davita Inc. and also serves on the boards of several privately held healthcare companies.

*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. Mr. Roe was Chairman of Covance Health Economics and Outcome 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. Mr. Roe is also a director of Ista Pharmaceuticals Inc. and several privately held companies.

*Richard P. Thompson* has been director since June 1994 and served as our President and Chief Executive Officer from June 1994 to June 2003. He served as Chief Executive Officer from June 2003 through July 2004 and Chairman of the Board from 2000 until January 2005. From 1991 to 1994, Mr. Thompson was President of LifeScan, Inc., a diversified health care subsidiary of Johnson & Johnson Company. He is currently president and CEO of Luminous Medical, a private, medical device company. In 1981, Mr. Thompson co-



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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 University.

**Item 1A. 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. All of our potential products are in an early stage of research or development. Our potential drug delivery products require extensive research, development and pre-clinical and clinical testing. Our potential products also may involve lengthy regulatory reviews before they can be sold. Because none of our products has yet received approval by the FDA, we cannot assure you that our research and development efforts will be successful, any of our potential products will be proven safe and effective or regulatory clearance or approval to sell any of our potential products will be obtained. 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 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, our drug delivery systems and potential applications;

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 believe that our existing cash and cash equivalent balances at December 31, 2005, funding commitments from corporate development partners, and interest earned on our investments should be sufficient to meet our needs for at least the next 12 months. However, there can be no assurances that these sources of funding will be sufficient, that our cash requirements will not change or that funding commitments from our corporate development partners will not be amended or terminated.

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We will need to raise additional capital to fund our capital spending and operations before we become profitable. During 2006, we will be seeking additional funding through collaborations, borrowing arrangements and/ or through public or private equity financing, although additional equity financing will be needed to avoid a shareholders' equity deficit. 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 during the first half of 2006, we will 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, and to reduce personnel related costs.

**We have a history of losses and anticipate future losses.**

We have never been profitable, and through December 31, 2005, we have incurred a cumulative deficit of approximately \$274.8 million and our shareholders' equity is only \$7.2 million. We have not had any product sales and do not anticipate receiving any revenue from product sales in 2006. 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;

pursue additional applications for our existing delivery platforms;

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 platforms. We cannot assure investors that we will generate sufficient product or contract research revenue to become profitable or to sustain profitability.

**We may not be able to develop our products successfully.**

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

Even if our delivery technologies have been successfully developed and are commercially feasible for a range of large and small molecule drugs, we cannot assure you that such applications will be commercially acceptable. For our delivery systems to be commercially viable, we will need to demonstrate that drugs delivered by our 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.

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**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 addition, our development partners could terminate their 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.

The development and commercialization of the AERx iDMS will be delayed if Novo Nordisk fails to conduct these activities in a timely manner or at all.

Under the terms of our current agreements with Novo Nordisk, Novo Nordisk and its affiliates assumed broad control and responsibility with respect to:

development and commercialization of the AERx diabetes management products; and

management and operation of the manufacturing facility for the AERx iDMS.

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 on our AERx and Intraject systems. In addition, our ability to apply our delivery systems 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. We can not assure you that our existing or future corporate partners or collaborators will not pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors. We could have disputes with our existing or future corporate partners or collaborators. Any such disagreements could lead to delays in the research, development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor. If any of our corporate partners or collaborators do not develop or commercialize any product to which it has obtained rights from us, our business could be impaired.

**We have limited manufacturing experience.**

We have validated only a single clinical manufacturing facility for our single dosage forms for our AERx delivery system, and responsibility for and control of this facility has transferred to NNDT. We have limited future access to the NNDT manufacturing facility.

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Either our development partners or we will have to invest significant amounts to attempt to provide for the high-volume manufacturing required for multiple products, and much of this spending will occur before our products are approved. There can be no assurance that:

the design requirements of our pulmonary and subcutaneous systems 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 have limited capacity to manufacture key components of our drug delivery systems. Under the terms of a Contract Manufacturing Agreement we have entered into with NNDT, NNDT agreed to supply devices and dosage forms to us for development of our other AERx systems. This agreement expires at the end of 2007, and there can be no assurance that we will be able to extend this agreement at satisfactory terms or that we will be able to find a replacement supplier at satisfactory terms.

We may decide to invest in additional clinical manufacturing facilities in order to internally produce critical components of our drug delivery systems including the disposable nozzles, assemble the disposable unit-dose packets and fill the drug into the unit-dose packets.

We intend to use contract manufacturers to produce key components, assemblies and subassemblies in the clinical and commercial manufacturing of our delivery 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 rely on a small number of vendors and contract manufacturers to supply us with specialized equipment, tools and components.**

We rely on a small number of vendors and contract manufacturers to supply us with specialized equipment, tools and components for use in our development and manufacturing processes. There can be no assurances that these vendors will continue to supply us with such specialized equipment, tools and components, nor can there be any assurances that we could find alternative sources for such specialized equipment and tools. A delay or interruption in development or manufacturing resulting from our inability to acquire the equipment, tools and components we need could have a material adverse effect on our business.

**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 on 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 system.

In connection with our acquisition of assets from the Weston Medical Group in May 2003, we acquired certain proprietary technologies and other intellectual property relating to the Intraject subcutaneous delivery system. While we have continued to develop the technologies relating to the Intraject system, we cannot assure you that our efforts to protect the proprietary technologies and other intellectual property that we have

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acquired from Weston Medical Group will provide adequate protection or significant commercial advantage. To date we have been unable to secure a partner for commercial-scale production of any application of the Intraject system, and there can be no assurance that we will be able to secure such a partner.

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 needle-free 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. This case was determined in our favor in 2004, but there can be no assurance that we will not face other similar claims in the future. 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.

Sumatriptan is currently marketed under the trade name Imitrex in oral, nasal and injectable forms and the injectable form is covered by a series of patents, the first of which is scheduled to come off patent in 2006 in Europe and 2007 in the United States. There is an additional U.S. patent relating to the injectable form of sumatriptan that does not expire until 2009, though this patent has been challenged by multiple parties and





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may be invalidated. There can be no assurance that this patent will be invalidated, and if not, under certain circumstances we will be unable to enter the U.S. market with Intraject sumatriptan until 2009.

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

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

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

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

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

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

warning letters;

finest;

product recalls or seizures;

injunctions;

refusals to permit products to be imported into or exported out of the United States;

withdrawals of previously approved marketing applications; and

criminal prosecutions.

Manufacturers of drugs also are required to comply with the applicable GMP requirements, which relate to product testing, quality assurance and maintaining records and documentation. We cannot assure you that we will be able to comply with the applicable GMP and other FDA regulatory requirements for manufacturing as we expand our manufacturing operations, which would impair our business.

In addition, to market our products in foreign jurisdictions, Aradigm 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

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jurisdictions or that we will not incur significant costs in obtaining or maintaining any foreign regulatory approvals. If approvals to market our products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our business would be impaired.

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

**The results of preclinical and clinical testing are uncertain.**

Before we can file for regulatory approval for the commercial sale of our potential AERx and Intraject products, the FDA will require extensive preclinical and clinical testing to demonstrate their safety and efficacy. We have tested prototype patient-operated versions of our AERx and Intraject delivery systems on a limited number of individuals in Phase 1 and Phase 2 clinical trials and have initiated a Phase 3 clinical trial for the AERx iDMS. If we do not or cannot complete current trials or progress to more advanced clinical trials, we may not be able to commercialize our AERx or Intraject 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 delivery platforms for the delivery of other compounds. These applications are in early stages of development and we do not yet know the degree of testing and development that will be needed to obtain necessary marketing approvals from the FDA and other regulatory agencies. We cannot assure you that these applications will prove to be viable or that any necessary regulatory approvals will be obtained in a timely manner, if at all.

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

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

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. We are aware of a number of companies such as Alkermes Pharmaceuticals, Inc. and Nektar Therapeutics (formerly Inhale Therapeutic Systems, 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, buccal and colonic absorption systems. Several of these companies may have developed or are developing dry powder devices that could be used for pulmonary delivery. Many of these companies and entities have greater research and development capabilities, experience, manufacturing, marketing, financial and managerial resources than we do and many of these companies may have applications for their delivery platforms that are in a more advanced stage of

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development than our applications. 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. 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. Losing any of these key employees could harm our business and operations.

**We may be exposed to product liability.**

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

Companies often address the exposure of such risk by obtaining product liability insurance. Although we currently have product liability insurance, there can be no assurance that we can maintain such insurance or obtain additional insurance on acceptable terms, in amounts sufficient to protect our business, or at all. A successful claim brought against us in excess of our insurance coverage would have a material adverse effect on our business.

**Third-party reimbursement for our products is uncertain.**

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

**We use hazardous materials.**

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

**Our stock price is likely to remain volatile.**

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

investor perception of us;

analyst recommendations;

fluctuations in our operating results;

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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 our company 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". We have also adopted an Executive Officer Severance Plan and a Form of Change of Control Agreement, both of which may provide for the payment of benefits to our officers in connection with an acquisition. The provisions described above, our poison pill, our severance plan and our change of control agreements, and provisions of the California General Corporation Law may discourage, delay or prevent a third party from acquiring us.

**Item 1B. Unresolved Staff Comments**

None

**Item 2. Properties**

At December 31, 2005, we leased approximately 72,467 square feet of office space in an office park at 3929 Point Eden Way, Hayward, California. The lease for the office space expires in 2016. A portion of this lease expense is offset by a sublease to NNDT of \$10,000 per month through December 2006. Minimum payments under this lease, net of sublease payments, will be approximately \$1.7 million in 2006 and an aggregate of \$22.8 million for the period 2006 through 2016. We believe that our existing facilities are adequate to meet our requirements for the near term.

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There are no material pending legal proceedings.

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

There were no submission of matters to a vote of security holders in the fourth quarter of the year-ended December 31, 2005.

**PART II****Item 5. Market for the Registrant's Common Stock and Related Stockholder Matters and Issuer Purchases of Equity Securities****Market Information**

Our common stock is traded on The Nasdaq National Market under the symbol ARDM. The following table sets forth the intra-day high and low sale prices for our common stock as reported on The Nasdaq National Market for the periods indicated below. On December 12, 2005 we announced that the Board of Directors approved a one-for-five reverse stock split that became effective at 5:00 pm PST on January 4, 2006. The high and low sales prices on the following table are adjusted for the one-for-five reverse stock split.

	High	Low
<b>2004</b>		
First Quarter	\$ 13.70	\$ 9.05
Second Quarter	11.35	4.20
Third Quarter	6.40	3.30
Fourth Quarter	10.00	5.90
<b>2005</b>		
First Quarter	\$ 8.65	\$ 5.60
Second Quarter	5.90	5.00
Third Quarter	6.05	4.95
Fourth Quarter	5.25	3.45
<b>2006</b>		
First Quarter (through Feb. 28, 2006)	\$ 5.04	3.50

On February 28, 2006, there were 146 holders of record of our common stock.

**Dividend Policy**

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

**Table of Contents****Equity Compensation Plan Information**

The following table summarizes our equity compensation plan information as of December 31, 2005. Information is included for the equity compensation plans approved by our stockholders. There are no equity compensation plans not approved by our stockholders.

<b>Plan Category</b>	<b>Common Stock to be Issued Upon Exercise of Outstanding Options and Rights(1) (a)</b>	<b>Weighted-Average Exercise Price of Outstanding Options and Rights (b)</b>	<b>Common Stock Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))(1) (c)</b>
Equity compensation plans approved by Aradigm stockholders	1,729,709	\$ 19.47	919,386

(1) Issued pursuant to the Company's 1996 Equity Incentive Plan, the 1996 Non-Employee Directors' Plan, and the 2005 Equity Incentive Plan. (See Note 6 of the Financial Statements.)



**Table of Contents****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.

	<b>Years Ended December 31,</b>				
	<b>2005(1)</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
<b>Statements of Operations Data:</b>					
Contract and license revenues	\$ 10,507	\$ 28,045	\$ 33,857	\$ 28,967	\$ 28,916
Operating expenses:					
Research and Development	30,174	46,477	49,636	54,680	58,836
General and Administrative	10,895	11,934	10,391	10,394	9,355
 Total Operating Expenses	 41,069	 58,411	 60,027	 65,074	 68,191
Loss from operations	(30,562)	(30,366)	(26,170)	(36,107)	(39,275)
Interest income	1,317	194	338	818	1,324
Other income(2)					6,675
Other income (expenses)	30	(17)	(138)	(642)	(1,081)
Net loss	(29,215)	(30,189)	(25,970)	(35,931)	(32,357)
Deemed dividend(3)					(10,722)
Net loss applicable to common shareholders	\$ (29,215)	\$ (30,189)	\$ (25,970)	\$ (35,931)	\$ (43,079)
Basic and diluted loss per share applicable to common shareholders:	\$ (2.01)	\$ (2.37)	\$ (2.59)	\$ (5.94)	\$ (9.89)
Shares used in computing basic and diluted net loss per share	14,513	12,741	10,039	6,052	4,358
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short term investments	\$ 27,694	\$ 16,763	\$ 29,770	\$ 31,443	\$ 71,164
Working capital	\$ 21,087	\$ 4,122	\$ 19,708	\$ 16,039	\$ 48,308
Total assets	\$ 39,497	\$ 79,741	\$ 95,218	\$ 97,129	\$ 132,100
Noncurrent portion of notes payable and capital lease obligations	\$	\$	\$	\$ 497	\$ 2,427
Redeemable convertible preferred stock	\$ 23,669	\$ 23,669	\$ 23,669	\$ 30,665	\$ 30,735
Accumulated deficit	\$ (274,838)	\$ (245,623)	\$ (215,436)	\$ (189,443)	\$ (153,535)
Total shareholders' equity	\$ 7,171	\$ 35,753	\$ 52,970	\$ 41,410	\$ 71,149

(1) On January 26, 2005, we completed the restructuring of our AERx iDMS program, pursuant to the Restructuring Agreement entered into with Novo Nordisk and NNDT. In accordance with the restructuring transaction, the

Company received \$51.1 million in cash and applied \$4.0 million of deposits from Novo Nordisk in consideration for \$54.3 million of property and equipment at net book value, \$515,000 of inventory and \$317,000 for prepaid and other assets. As a result of the restructuring transaction, our contract revenue from our development agreement with Novo Nordisk ceased in 2005. Of the amount recorded in deferred revenue at December 31, 2004, we recorded \$11.3 million in the first quarter of 2005, consisting of: project development revenue of \$2.1 million, deferred milestone revenue of \$5.2 million, and \$4.0 million as partial payment for the sale of the insulin development program assets in

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accordance with the restructuring agreement. We recorded no material gain or loss was recorded as a result of sales of assets.

- (2) Other income consists of the gain related to forgiveness of outstanding notes and interest by Genentech, previously classified as an extraordinary item. In 2002, the Company early adopted Statement of Financial Accounting Standard ( SFAS ) 145, Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB 13 and Technical Corrections , which requires the reclassification of this type of extraordinary item as a component of operating results.
- (3) This represents the beneficial conversion feature, measured as the difference between the fair market value of Aradigm s common stock and the discounted conversion price. We reported the value of the beneficial conversion feature on the Statements of Operations for the year ended December 31, 2001 as a deemed dividend and included the value in the calculation of net loss applicable to the common shareholders.

**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 and elsewhere in this report. This discussion should be read in conjunction with the financial statements and notes to the financial statements contained in this report.*

**Overview**

Since our inception in 1991, we have been engaged in the development of needle-free drug delivery systems. 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 product sales and do not anticipate receiving any revenue from the sale of products in 2006. As of December 31, 2005 we had an accumulated deficit of \$274.8 million. The sources of working capital have been equity financings, equipment lease financings, contract and license revenues and interest earned on investments.

We have performed initial feasibility work on a number of compounds and have been compensated for expenses incurred while performing this work in several cases pursuant to feasibility study agreements with third parties. Once feasibility is demonstrated with respect to a potential product, we seek to enter into development contracts with pharmaceutical corporate partners.

During 2005, our collaborative agreement with Novo Nordisk and NNDT contributed approximately 76% of our total contract revenues. From the inception of our collaboration in June 1998 through December 31, 2005, we have received from Novo Nordisk approximately \$137.1 million in product development payments, approximately \$13.0 million in milestone payments and \$35.0 million from the purchase of our common stock by Novo Nordisk and its affiliates. All product development and milestone payments received to date have been recognized as revenue.

On January 26, 2005, we completed the restructuring of its AERx iDMS program, pursuant to the Restructuring Agreement entered into with Novo Nordisk and NNDT. In accordance with the restructuring transaction, we received \$51.1 million in cash and applied \$4.0 million of deposits from Novo Nordisk in consideration for \$54.3 million of property and equipment at net book value, \$515,000 of inventory and \$317,000 for prepaid and other assets. In addition, NNDT hired 126 Aradigm employees at the closing of the restructuring transaction. Our expenses related to this transaction for legal and other consulting costs were approximately \$1.1 million. We do not anticipate a material tax liability associated with this transaction.

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In connection with the restructuring transaction we entered into various related agreements with Novo Nordisk and NNDT effective January 26, 2005, including the following:

an amended and restated license agreement amending the Development and License Agreement previously in place with Novo Nordisk, expanding Novo Nordisk's development and manufacturing rights to the AERx iDMS program and providing for royalties to us on future AERx iDMS net sales in lieu of a percentage interest in the gross profits from the commercialization of AERx iDMS;

a three-year agreement under which NNDT agreed to perform contract manufacturing for us of AERx iDMS-identical devices and dosage forms filled with compounds we provide in support of our preclinical and initial clinical development of other AERx products; and

an amendment of the stock purchase agreement in place with Novo Nordisk, Inc. prior to the closing of the restructuring transaction, deleting the provisions whereby we can require Novo Nordisk to purchase certain amounts of common stock, imposing certain restrictions on the ability of Novo Nordisk to sell shares of our common stock previously purchased by Novo Nordisk, and providing Novo Nordisk with certain registration and information rights with respect to these shares.

As a result of this transaction, we recorded our final project development revenue from Novo Nordisk (approximately \$2.1 million for the first 26 days of 2005) and as we were no longer obligated to continue work related to the non-refundable milestone payment from Novo Nordisk related to the commercialization of AERx, we recognized the remaining balance of the deferred revenue associated with the milestone of \$5.2 million as revenue. Also, in 2005 we recorded revenue of approximately \$727,000 from NNDT related to transition and support agreements.

As a result of the restructuring transaction, we were released from our contractual obligations relating to future operating lease payments for the two buildings assigned to NNDT and accordingly reversed the deferred rent liability related to the two buildings of \$1.4 million, resulting in a reduction of operating expenses in 2005.

As of February 28, 2005 Novo Nordisk, together with its affiliates, beneficially owned 1,573,674 shares of our common stock (10% of our total common stock outstanding on a converted basis) and is considered a related party.

In May 2003, we announced the acquisition of selected assets from Weston relating to Weston's Intraject needle-free drug delivery system. Weston developed a proprietary needle-free drug delivery system, successfully moved it through the early-stage development process and signed several commercial agreements. In September 2002, Weston announced that it had encountered certain performance problems associated with the system's configuration and that its program would be delayed until those problems could be resolved. Subsequently, Weston was unable to secure the financing needed to continue its programs and was forced into bankruptcy administration in February 2003. We acquired select Weston assets, including the Intraject technology, related manufacturing equipment with an approximate book value of \$22 million and intellectual property for a total of approximately \$2 million in initial purchase price and approximately an additional \$1 million in subsequent transfer and additional capital costs. The purchase price and additional costs were allocated to the major pieces of purchased commercial equipment for the production of Intraject and were recorded in property and equipment as construction in progress. These assets, along with subsequent additions to the commercial equipment will be depreciated at the time commercial manufacturing begins. No costs or expense were allocated to intellectual property or in process research and development on a pro-rata basis, because of the lack of market information, the stage of development and the immateriality of any allocation to intellectual property or in process research and development based on the substantial value of the tangible assets acquired.

In October 2004, we announced positive results from the Clinical Performance Verification trial of our Intraject needle-free delivery system in which the final design of the system demonstrated an excellent delivery profile. Results showed that the modified delivery system demonstrated successful injection performance reliability and that the current design presented commercially viable delivery parameters. Following the results from the configuration trial, we initiated a pilot pharmacokinetic study comparing



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Intraject with Sumatriptan, a treatment for migraines, to the currently marketed needle-injected product. The trial was a randomized, open-label, single-dose, crossover study evaluating the pharmacokinetics of sumatriptan at three injection sites (abdomen, thigh, and arm) in 18 healthy adult male and female volunteers. Results demonstrated that Intraject was bioequivalent to the currently injectable product. In June 2005, we announced results from a self-injection study comparing Intraject Sumatriptan to the currently marketed subcutaneously injected product. This trial was a randomized, open-label, single-dose, crossover study evaluating the pharmacokinetics of sumatriptan at three injection sites (abdomen, thigh, and arm) in 24 healthy adult male and female volunteers naïve to self-injection with Intraject. The data showed that Intraject Sumatriptan was bioequivalent to the marketed injectable product and that patients were able to self-administer using Intraject.

We have completed manufacture of supplies on commercial equipment for pivotal bioequivalence studies. These bioequivalence studies could be initiated in 2006 pending partnering. There can be no assurance that the Intraject Triptan development program or any other Intraject development program will be successful.

We have additional programs in development with disclosed and undisclosed partners. It is our policy not to disclose the partner and/or the drug until a long-term development agreement has been established; both parties agree to highlight a clinical advancement in the program or under special circumstances in which both parties agree to disclosure. In 2004 we executed a development and licensing agreement with Defense R&D Canada for the development of liposomal ciprofloxacin for the treatment of respiratory infections including biological terrorism-related inhalation anthrax. In 2005, we announced positive data from an early stage trial of AERx and a novel aerosol formulation of Hydroxychloroquine ( HCQ ) as a new class of treatment for asthma and chronic obstructive pulmonary disease.

***Reverse Stock Split***

On January 4, 2006, we filed an amended and restated certificate of incorporation with the California Secretary of State effecting a 1-for-5 reverse split of our common stock. All share and per share amounts have been retroactively restated in the accompanying financial statements, notes to the financial statements and elsewhere in this document for all periods presented.

**Critical Accounting Policies and Estimates**

We consider certain accounting policies related to revenue recognition and impairment of long-lived assets to be critical accounting policies that require the use of significant judgments and estimates relating to matters that are inherently uncertain and may result in materially different results under different assumptions and conditions. The preparation of financial statements in conformity with U.S. 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, warrants and the beneficial conversion feature of preferred stock. Actual results could differ from these estimates.

***Revenue Recognition***

Contract revenues consist of revenue from grants, collaboration agreements and feasibility studies. We recognize revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 104,

Revenue Recognition. Under the agreements, revenue is recognized once costs are incurred and collectibility is reasonably assured. Under some agreements our partners have the right to withhold reimbursement of our costs incurred until the work performed under the relative agreement is mutually agreed upon. For these agreements revenue is recognized upon confirmation from the partner of acceptance of work performed and payment amount. 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

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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 are approximate to or are greater than 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 and accepted.

***Impairment of Long-Lived Assets***

We review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable in accordance with SFAS 144, Accounting for the Impairment or Disposal of Long-Lived Assets. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values and the loss is recognized on the Statements of Operations.

**Results of Operations*****Years Ended December 31, 2005, 2004 and 2003***

**Contract Revenues.** We reported revenues from collaborative contracts of \$10.5 million in 2005, compared to \$28.0 million in 2004 and \$33.9 million in 2003. The 63% decrease in revenue in 2005 compared to 2004 is primarily due to decreases in partner-funded project development revenue from Novo Nordisk, which was \$8.0 million in 2005 compared to \$27.0 million in 2004 and offset by contract revenue from other partner-funded programs, which totaled \$2.5 million in 2005 and \$1.0 million in 2004. The increase in other partner revenue was the result of initiating four new feasibility projects in 2005. Revenue in 2003 consisted of \$33.5 million from partner-funded project development revenue from Novo Nordisk and \$311,000 from other partner-funded project development programs. The \$6.5 million reduction in revenue from partners from 2003 to 2004 is due to the maturation of the project and the subsequent ramping down. Costs associated with contract-research revenue are included in research and development expenses.

As a result of the restructuring of the AERx iDMS program, which was completed on January 26, 2005, our iDMS contract revenue from our development agreement with Novo Nordisk ended in 2005. We recorded project development revenue from Novo Nordisk for the first 26 days of 2005 of approximately \$2.1 million. As a result of the restructuring transaction we are no longer obligated to continue work related to the non-refundable milestone payment from Novo Nordisk related to the commercialization of AERx and recognized \$5.2 million, the remaining balance of the deferred revenue associated with a previously received milestone payment of \$13.0 million, as revenue in the first quarter of 2005. Subsequently, in 2005 we recorded revenue of \$727,000 from NNDDT related to transition and support agreements entered into in connection with the restructuring transaction.

**Research and Development Expenses.** Research and development expenses decreased in 2005 compared to 2004 and 2003. These expenses were \$30.2 million in 2005 compared to \$46.5 million in 2004 and \$49.6 million in 2003.

Spending for collaborative and self-initiated research and development projects was as follows (in millions of dollars):

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Research and Development Expenses:</b>			
Collaborative	\$ 6.0	\$ 28.2	\$ 33.5
Self-Initiated	24.2	18.3	16.1
Total research and development expense	\$ 30.2	\$ 46.5	\$ 49.6





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Research and development expenses in 2005 decreased by \$16.3 million, or 35%, compared to 2004. The decrease in research and development expenses is primarily due to a reduction in headcount and facility costs associated with the restructuring transaction with Novo Nordisk and cost reduction programs. This was offset by the \$5.9 million increase in self-initiated development efforts primarily relating to Intraject. Research and development expenses in 2004 decreased by \$3.2 million, or 6%, compared to 2003. The decrease in research and development expenses is primarily due to cost reduction programs, including a reduction in force implemented in July 2003 in order to align our costs with the reduced revenue from partners offset by a net increased self-initiated program costs. A reduction in pulmonary delivery development efforts was more than offset by increased spending on the Intraject program. The reduced head count affected six months of 2003 and all of 2004.

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 have other on-going partner-funded and self-initiated programs under development. In 2006 we expect research and development expense to increase from 2005, however, 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 \$10.9 million in 2005 compared to \$11.9 million in 2004 and \$10.4 million in 2003. General and administrative expenses decreased in 2005 over 2004 by \$1.0 million, or 8.0%, and increased in 2004 over 2003 by \$1.5 million, or 14.0%, resulting primarily from legal and consulting costs incurred in 2004 associated with the restructuring transaction with Novo Nordisk, which closed on January 26, 2005. Other than the restructuring transaction, there were no significant corporate transactions in 2005, 2004 and 2003. In 2006 we expect general and administrative expenses to remain consistent with 2005.

*Interest Income.* Interest income was approximately \$1.3 million in 2005 compared to \$194,000 in 2004 and \$338,000 in 2003. The increase in interest income in 2005 compared to 2004 of \$1.1 million is due to an increase in interest rates earned and higher average invested balances in 2005. The average cash and investment balances were higher in 2005 primarily due to receipt of net proceeds of approximately \$11.7 million from a private placement of common stock in December 2004 and net proceeds of approximately \$51.1 million from the closing of the restructuring transaction with Novo Nordisk in January 2005. The decrease in interest income in 2004 compared to 2003 by \$150,000 was primarily due to lower average cash and investment balances in 2004 and to a lesser extent a decrease in interest rates earned on invested cash balances.

*Other Income (Expense):* Other income (expense) was approximately \$30,000 in 2005 compared to (\$17,000) in 2004 and (\$138,000) in 2003. The increase in other income (expenses) in 2005 compared to 2004 is due primarily to the \$49,000 net gain on the sale of assets off-set by \$12,000 loss on foreign exchange translation and \$6,000 interest on a loan associated with a copier lease. The decrease in other expense in 2004 compared to 2003 is primarily due to lower outstanding capital lease and equipment loan balances under various equipment and lease lines of credit which were completely paid off during 2004.

**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, proceeds from the sale of assets to Novo Nordisk in connection with the restructuring transaction and interest earned on investments. As of December 31, 2005, we had cash and cash equivalents of approximately \$27.7 million.

Net cash used in operating activities in 2005 was \$34.6 million compared to \$23.1 million in 2004 and \$24.7 million in 2003. The \$11.5 million increase in net cash used in 2005 compared to 2004 was primarily the result of a slightly lower net loss in 2005 compared to 2004, down \$974,000, offset by lower depreciation expense incurred in the 2005, down \$2.4 million from 2004 and changes in deferred revenue activity of

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\$5.8 million and deferred rent activity of \$1.8 million. The reduction in depreciation expense, the change in deferred revenue and the change in deferred rent were primarily due to the restructuring agreement with Novo Nordisk and NNDT. In 2005 we recognized less depreciation expense due to the sale of AERx iDMS program-related assets to Novo Nordisk pursuant to the restructuring transaction, recognized AERx iDMS program related funding and milestone payments received in prior years as revenue and recorded the reversal of deferred rent liability for lease obligations associated with the AERx iDMS program to the statement of operations as a credit to rent expense. Additionally, 2005 activity in accounts payable and accrued liabilities reflects a \$2.0 million of operating cash used when compared to 2004 activity. The smaller increase in accounts payable results primarily from liabilities for expenses associated with the private placement of equity in December 2004, the restructuring transaction with Novo Nordisk, and capital expenditures recorded at 2004 year-end.

The decrease in net cash used in operating activities in 2004 when compared to 2003 was the result of a higher net loss in 2004 compared to 2003 which was offset by changes in working capital that resulted in decreased use of cash: a decrease in other current assets, and increases in accounts payable, deferred revenue and accrued compensation. The timing of rent payments from end of month to first of month reduced prepayments within other current assets. The increase in accounts payable results primarily from liabilities for expenses associated with the December 2004 private placement of equity, the restructuring transaction with Novo Nordisk, and capital expenditures. The smaller decrease in deferred revenue compared to the prior year is due to our partners' funding future development at a lower level and the reduced rate of amortization of past milestone payments. The increase in accrued compensation was the result of the timing of the last payroll of the year.

Net cash provided by investing activities in 2005 was \$47.4 million compared to \$6.5 million in 2004 and cash used of \$8.3 million in 2003. The 2005 increase in cash provided from investing compared to 2004 is primarily due to \$50.3 million provided from the sale of assets to NNDT in connection with the restructuring transaction with Novo Nordisk that closed in January 2005, off-set by \$3.0 million increase in capital expenditures primarily related to Intraject and \$6.6 million decrease in proceeds from sales and maturities of available-for-sale investments, net of purchases.

The majority of the \$14.9 million increase in cash provided by investing activities in 2004 compared to 2003 was due to liquidating available-for-sale investments. Short-term investments at the end of 2004 were \$2.5 million compared to \$11.4 at the end of 2003, reflecting an \$8.9 million transfer from short-term investments to cash and cash equivalents. In addition, capital expenditures during 2004 of \$2.3 million for the acquisition of Intraject assets were \$3.1 million less than total capital expenditures in 2003.

Net cash provided by financing activities in 2005 was \$592,000 compared to \$12.6 million in 2004 and \$28.5 million in 2003. Cash provided by financing activities in 2005 was from the issuance of common stock upon exercise of stock options and purchase of common stock under the employee stock purchase plan, \$500,000 and repayment of notes receivable from officers and employees of \$92,000. Financing activities in 2004 included the sale of common stock through private placements in December 2004, which raised net proceeds of approximately \$11.7 million. In addition, net proceeds received from the issuance of common stock upon exercise of stock options and purchase of common stock under the employee stock purchase plan was \$911,000. The proceeds were offset by \$427,000 of cash used for capital lease obligations. Financing activities in 2003 included the sale of common stock through private placements in March and November 2003, which raised net proceeds of approximately \$27.3 million. In addition, net proceeds received from the issuance of common stock upon exercise of warrants and stock options, and under the employee stock purchase plan was \$3.1 million. The proceeds were offset by \$1.8 million of cash used for capital lease obligations.

Our research and development efforts have and will continue to require a commitment of substantial funds to conduct the costly and time-consuming research and preclinical and clinical testing activities necessary to develop and refine such technology and proposed products and to bring any such products to market. Our future capital requirements will depend on many factors, including continued progress and the results of the research and development of our technology and drug delivery systems, our ability to establish



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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 2006, and beyond. We particularly focus on capital spending requirements to ensure that capital outlays are not expended sooner than necessary. If we make good progress in our development programs, we would expect our cash requirements for capital spending and operations to increase in future periods. We currently expect our total capital outlays for 2006 will be approximately \$7.9 million. The majority of these outlays will be associated with completing the commercial scale-up of the Intraject production processes. These outlays, however, are contingent on our having partnered the Intraject technology and our partner sharing some or all of the capital costs.

We have incurred significant operating losses and negative cash flows from operations since our inception. At December 31, 2005, we have an accumulated deficit of \$274.8 million, working capital of \$21.1 million, and shareholders' equity of \$7.2 million. Management believes that cash and cash equivalents on hand at December 31, 2005 together with expected funding to be received under additional collaborative arrangements, or equity or debt financing(s) will be sufficient to enable us to meet our obligations through at least January 1, 2007. If such additional expected funds are not available during the first half of 2006, we will be required to delay, reduce the scope of, or eliminate one or more of our development programs or obtain funds through collaborative arrangements with others that may require us to relinquish rights of certain of our technologies, or programs that we would otherwise seek to develop or commercialize ourselves, and to reduce personnel related costs. The Company has developed contingency plans to make these needed costs reductions upon determination that funds will not be available in a timely matter. Management plans to continue to fund the Company with funds obtained through collaborative arrangements, equity issuances and or debt arrangements, although our shareholders' equity will become negative absent additional equity financing.

**Off-Balance Sheet Financings and Liabilities**

Other than contractual obligations incurred in the normal course of business, we do not have any off-balance sheet financing arrangements or liabilities, guarantee contracts, retained or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity. We do not have any majority-owned subsidiaries.

**Contractual Obligations**

The following summarizes our contractual obligations at December 31, 2005, and the effect such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

Contractual Obligations	Total	Payment Due by Period			
		Less than 1 Year	1-3 Years	3-5 Years	After 5 Years
Unconditional purchase obligations	\$ 2,113	\$ 2,113	\$	\$	\$
Unconditional capital purchase obligations	1,015	1,015			
Operating lease obligations(a)	22,811	1,660	4,677	4,541	11,933
Total contractual commitments	\$ 25,939	\$ 4,788	\$ 4,677	\$ 4,541	\$ 11,933

(a) We have future commitments under one building lease. The lease is for a building containing office, laboratory and manufacturing facilities, and expires in 2016. A portion of operating lease obligation is offset by a sublease

to NNDT of \$10,000 per month for 24 months that commenced in January 2005 and expires in December 2006. We were committed to a second lease for a warehouse that expired December 31, 2005 and is not included above. Additionally, we entered into a new copier lease agreement in July 2005 for \$5,030 per month for 60 months.

**Table of Contents****Recent Accounting Pronouncements**

The Financial Accounting Standards Board ( FASB ) issued SFAS No. 123R (revised 2004), *Share-Based Payment* ( SFAS 123R ) on December 16, 2004, which is a revision of FASB Statement No. 123 ( SFAS 123 ), *Accounting for Stock Issued to Employees*, that requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. SFAS 123R supersedes Accounting Principles Board ( APB ) No. 25, *Accounting for Stock Issued to Employees*, ( APB 25 ) and amends SFAS No. 95, *Statement of Cash Flows* .

Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. Under SFAS 123R, share-based payments to employees result in a cost that will be measured at fair value on the awards grant date, based on the estimated number of awards that are expected to vest. Compensation cost for awards that vest would not be reversed if the awards expire without being exercised. When measuring fair value, companies can choose an option-pricing model (e.g., Black-Scholes or binomial models) that appropriately reflects their specific circumstances and the economics of their transactions. Upon adoption of SFAS 123R public companies are allowed to select from alternative transition methods, each having different reporting implications. SFAS 123R is effective for the fiscal year beginning after June 15, 2005, and applies to all outstanding and unvested share-based payments as of the adoption date.

SFAS 123R permits public companies to adopt its requirements using one of two methods: modified prospective method or modified retrospective method. We adopted FAS 123R using the modified prospective basis on January 1, 2006, and will continue to use the Black-Scholes option pricing model to calculate the fair value of the awards. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date. We will recognize in our results of operations the compensation cost on a straight-line basis over the requisite service period for the entire award for both stock-based awards issued after December 31, 2005 and prior to January 1, 2006.

As permitted by SFAS 123, we currently account for share-based payments to employees using APB 25 intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. The adoption of the SFAS 123R fair value method will have a significant adverse impact on our reported results of operations because the stock-based compensation expense will be charged directly to our statement of operations. At December 31, 2005 there are 636,869 unvested stock options currently outstanding. Our adoption of FAS 123R is expected to result in compensation expense that will increase basic net loss by approximately \$1.1 million to \$1.5 million for 2006. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase, or cancel any remaining unearned stock-based compensation expense. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors.

SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current standard. This requirement will likely reduce net operating cash flow and increase net financing cash flows in periods after adoption.

In October 2005, the FASB issued FSP FAS 123R-2, *Practical Accommodation to the Application of Grant Date*. The FSP provides an exception (that should not be analogized to) to the application of the concept of mutual understanding in the determination of whether a grant date (and, for an equity award, a measurement date) has occurred. The exception permits companies to measure compensation cost for equity awards to employees on the Board approval date if certain conditions are met, provided that the communication to the employee occurs within a relatively short period of time from the approval date. The guidance in this FSP is to be applied upon initial adoption of Statement 123(R). An entity that adopted Statement 123(R) prior to the



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issuance of this FSP and did not apply the provisions of this FSP should apply the guidance in this FSP to the first reporting period after October 18, 2005, for which financial statements or interim reports have not been issued.

In November 2005, the FASB issued FSP FAS 123R-3, *Transition Election and Accounting for Tax Effects*. The guidance provides a simplified method to calculate the Additional Paid-In Capital ( APIC ) pool for the beginning balance of excess tax benefits and the method of determining the subsequent impact on the pool of option awards that are outstanding and fully or partially vested upon the adoption of SFAS No. 123R, *Share-Based Payment*, beginning on January 1, 2006. In addition, this FSP addresses that when the alternative APIC pool calculation is used, tax benefits related to certain employee awards should be included as a cash flow from financing activities and a cash outflow from operating activities within the statements of cash flows. The FSP allows companies up to one year from the later of the adoption date of SFAS 123R or November 10, 2005 to evaluate the available transition alternatives and make a one-time election. We are in the process of evaluating the impact of the new method provided by this guidance.

**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, 2005 and 2004, we had cash, cash equivalents and short-term investments of \$27.7 million and \$16.8 million, respectively, consisting of cash and highly liquid, short-term investments. As of December 31, 2005 all cash equivalents were invested in commercial paper maturing in less than 90 days. The market value of our short-term investments will decline by an immaterial amount if market interest rates increase, and therefore, our exposure to interest rate changes has been immaterial. Declines of interest rates over time will, however, reduce our interest income from our short-term investments.



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**Item 8. *Financial Statements and Supplementary Data***

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of Aradigm Corporation

We have audited the accompanying balance sheets of Aradigm Corporation as of December 31, 2005 and 2004, 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, 2005. 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 the standards of the Public Company Accounting Oversight Board (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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aradigm Corporation at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Palo Alto, California  
March 10, 2006

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BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
	<b>(In thousands, except share data)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 27,694	\$ 14,308
Short-term investments		2,455
Receivables	400	99
Current portion of notes receivable from officers and employees	62	67
Prepaid and other current assets	874	1,602
Total current assets	29,030	18,531
Property and equipment, net	9,875	60,555
Noncurrent portion of notes receivable from officers and employees	129	216
Other assets	463	439
Total assets	\$ 39,497	\$ 79,741
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,034	\$ 2,469
Accrued clinical and cost of other studies	398	293
Accrued compensation	3,814	2,984
Deferred revenue	222	7,525
Other accrued liabilities	475	1,138
Total current liabilities	7,943	14,409
Noncurrent portion of deferred revenue		3,966
Noncurrent portion of deferred rent	714	1,943
Commitments and contingencies		
Redeemable convertible preferred stock, no par value; 5,000,000 shares authorized; issued and outstanding shares: 1,544,626 in 2005 and 2004; liquidation preference of \$41,866 in 2005 and 2004	23,669	23,669
Shareholders equity:		
Common stock, no par value, 100,000,000 shares authorized; issued and outstanding shares: 14,562,809 in 2005; 14,459,145 in 2004	282,004	281,387
Accumulated other comprehensive income (loss)	5	(10)
Accumulated deficit	(274,838)	(245,623)
Total shareholders equity	7,171	35,754

Total liabilities, redeemable convertible preferred stock and shareholders' equity	\$ 39,497	\$ 79,741
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See accompanying Notes to Financial Statements.

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**ARADIGM CORPORATION**  
**STATEMENTS OF OPERATIONS**

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>(In thousands, except per share data)</b>		
<b>Contract and license revenues:</b>			
Related parties	\$ 8,013	\$ 26,999	\$ 33,546
Unrelated parties	2,494	1,046	311
Total revenues	10,507	28,045	33,857
Research and development	30,174	46,477	49,636
General and administrative	10,895	11,934	10,391
Total expenses	41,069	58,411	60,027
Loss from operations	(30,562)	(30,366)	(26,170)
Interest income	1,317	194	338
Other income (expense)	30	(17)	(138)
Net loss	\$ (29,215)	\$ (30,189)	\$ (25,970)
Basic and diluted net loss per common share	\$ (2.01)	\$ (2.37)	\$ (2.59)
Shares used in computing basic and diluted net loss per common share	14,513	12,741	10,039

See accompanying Notes to Financial Statements.

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**ARADIGM CORPORATION**  
**STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK**  
**AND SHAREHOLDERS EQUITY**

	Redeemable Convertible		Common Stock		Accumulated Other Comprehensive Income/ Deficit		Total Shareholders Equity
	Shares	Amount	Shares	Amount	Deficit	Income/ (Loss)	
(In thousands, except share data)							
Balances at December 31, 2002	2,001,236	\$ 30,665	6,231,522	\$ 230,853	\$	\$ 21	\$ (189,464) \$ 41,410
Issuance of common stock for cash, net of issuance costs of \$7,353 including warrants valued at \$5,657			5,354,588	27,312			27,312
Issuance of common stock through conversion of Series A preferred stock	(456,610)	(6,996)	365,288	6,996			6,996
Issuance of common stock under the employee stock purchase plan			110,606	596			596
Issuance of common stock upon exercise of stock options			5,425	11			11
Issuance of common stock upon exercise of warrants			482,810	2,522			2,522
Issuance of options and warrants to purchase common stock for services				116			116
Comprehensive loss:							
Net loss							(25,970) (25,970)
Net change in unrealized loss on available-for-sale investments:						(23)	(23)

Total comprehensive loss							(25,993)
Balances at December 31, 2003	1,544,626	23,669	12,550,239	268,406	(2)	(215,434)	52,970
Issuance of common stock for cash, net of issuance costs of \$817 including warrants valued at \$2,278			1,666,679	11,683			11,683
Issuance of common stock under the employee stock purchase plan			167,946	911			911
Issuance of common stock upon exercise of stock options			81	1			1
Issuance of common stock upon exercise of warrants			74,200	304			304
Issuance of options and warrants to purchase common stock for services				82			82
Comprehensive loss:							
Net loss						(30,189)	(30,189)
Net change in unrealized loss on available-for-sale investments					(8)		(8)
Total comprehensive loss							(30,197)
Balances at December 31, 2004	1,544,626	23,669	14,459,145	281,387	(10)	(245,623)	35,754

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	Redeemable Convertible		Common Stock		Accumulated Other		Total
	Preferred Stock		Common Stock		Deferred	Comprehensive	
	Shares	Amount	Shares	Amount	Compensation	Income/ (Loss)	Equity
(In thousands, except share data)							
Issuance of common stock under the employee stock purchase plan			93,662	458			458
Issuance of common stock upon exercise of stock options			10,077	42			42
Adjustment to common stock shares for rounding of partial shares from the reverse split			(75)				
Warrant revaluation				90			90
Issuance of options for services				27	(21)		6
Amortization of deferred compensation					21		21
Comprehensive loss:							
Net loss							(29,215)
Net change in unrealized loss on available-for-sale investments						15	15
Total comprehensive loss							(29,200)
Balances at December 31, 2005	1,544,626	\$ 23,669	14,562,809	\$ 282,004	\$	\$ 5	\$ (274,838)
							\$ 7,171

See accompanying Notes to Financial Statements.

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**ARADIGM CORPORATION**  
**STATEMENTS OF CASH FLOWS**

	Years Ended December 31,		
	2005	2004	2003
	(In thousands)		
<b>Cash flows from operating activities:</b>			
Net loss	\$ (29,215)	\$ (30,189)	\$ (25,970)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Amortization and accretion of investments	50	166	83
Depreciation and amortization	1,412	3,813	5,983
Loss on impairment and sale of property and equipment	268	544	
Cost of warrants and common stock options for services	117	82	116
<b>Changes in operating assets and liabilities:</b>			
Receivables	(301)	41	142
Prepaid and other current assets	728	308	(454)
Other assets	(24)	(51)	21
Accounts payable	565	1,584	(1,066)
Accrued compensation	830	963	(174)
Accrued liabilities	(558)	439	294
Deferred rent	(1,229)	620	215
Deferred revenue	(7,250)	(1,440)	(3,921)
<b>Net cash used in operating activities</b>	<b>(34,607)</b>	<b>(23,120)</b>	<b>(24,731)</b>
<b>Cash flows from investing activities:</b>			
Capital expenditures	(5,311)	(2,300)	(5,362)
Proceeds from sale of property and equipment to Novo Nordisk Delivery Technologies, Inc., a related party	50,292		
Purchases of available-for-sale investments	(5,330)	(6,376)	(9,962)
Proceeds from sales and maturities of available-for-sale investments	7,750	15,190	7,056
<b>Net cash provided by (used) in investing activities</b>	<b>47,401</b>	<b>6,514</b>	<b>(8,268)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock, net	500	12,899	30,441
Forgiveness of (cash used in issuance of) notes receivable with officers and employees	92	115	(93)
Payments on capital lease obligations and equipment loans		(427)	(1,822)
<b>Net cash provided by financing activities</b>	<b>592</b>	<b>12,587</b>	<b>28,526</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>13,386</b>	<b>(4,019)</b>	<b>(4,473)</b>
Cash and cash equivalents at beginning of year	14,308	18,327	22,800
<b>Cash and cash equivalents at end of year</b>	<b>\$ 27,694</b>	<b>\$ 14,308</b>	<b>\$ 18,327</b>



Supplemental disclosure of cash flow information:

Cash paid for interest	\$	6	\$	16	\$	126
Non-cash investing and financing activities:						
Issuance of options and warrants to purchase common stock for services	\$	117	\$	82	\$	116
Issuance of common stock through conversion of Series A preferred stock	\$		\$		\$	6,996
Issuance of warrants in conjunction with private placement of common stock	\$		\$	2,278	\$	5,657

See accompanying Notes to Financial Statements.

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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS**

**1. Summary of Significant Accounting Policies*****Organization and Basis of Presentation***

Aradigm Corporation (the Company) is a California corporation engaged in the development and commercialization of non-invasive drug delivery systems. 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. The Company does not anticipate receiving any revenue from the sale of products in the upcoming year. The Company has incurred significant operating losses and negative cash flows from operations since its inception. At December 31, 2005, the Company has an accumulated deficit of \$274.8 million and working capital of \$21.1 million and shareholders' equity of \$7.2 million. Management believes that cash and cash equivalents on hand at December 31, 2005 together with expected funding to be received under additional collaborative arrangements or equity or debt financing(s) will be sufficient to enable the Company to meet its obligations through at least January 1, 2007. If such additional expected funds are not available during the first half of 2006, the Company will be required to delay, reduce the scope of, or eliminate one or more of its development programs or obtain funds through collaborative arrangements with others that may require the Company to relinquish rights of certain of its technologies, or programs that the Company would otherwise seek to develop or commercialize itself, and to reduce personnel related costs. The Company has developed contingency plans to make these needed cost reductions upon determination that funds will not be available in a timely manner. Management plans to continue to fund the Company with funds obtained through collaborative arrangements, equity issuances and or debt arrangements although our shareholders' equity will become negative absent additional equity financing.

The Company operates as a single operating segment.

***Use of Estimates***

The preparation of financial statements in conformity with U.S. 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, and warrants. Actual results could differ from these estimates.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments purchased with a maturity of three months or less from purchase date to be cash equivalents. The Company places its cash and cash equivalents in money market funds, commercial paper and corporate notes.

***Investments***

Management determines the appropriate classification of the Company's marketable securities, which consist solely of debt securities, at the time of purchase and re-evaluates such designation at each balance sheet date. All marketable securities are classified as available-for-sale, carried at estimated fair value and reported in either cash equivalents or short-term investments. Unrealized gains and losses on available-for-sale securities are excluded from earnings and reported as 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. Interest income is recognized when earned and includes interest, dividends, amortization of purchase premiums and discounts, and realized gains and losses on sales of securities. The cost of securities sold is based on the specific identification method. The Company regularly

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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

reviews all of its investments for other-than-temporary declines in fair value. When we determine that the decline in fair value of an investment below our accounting basis is other-than-temporary, the Company reduces the carrying value of the securities held and records a loss in the amount of any such decline. No such reductions have been required during any of the periods presented.

**Notes Receivable**

Notes receivable are related to advances granted to employees for relocation. All amounts classified as current are due within 12 months. All amounts classified as long-term are due no later than April 2008. All balances are believed to be collectible and are stated at approximate fair value at December 31, 2005.

**Property and Equipment**

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. Machinery and equipment includes external costs incurred for validation of the equipment. The Company does not capitalize internal validation expense. Computer equipment and software includes capitalized computer software. All of the Company's capitalized software is purchased; the Company has not internally developed computer software. Leasehold improvements are depreciated 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**

In accordance with Statement of Financial Accounting Standards ( SFAS ) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, the Company reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values and the loss is recognized in the Statements of Operations.

**Revenue Recognition**

Contract revenues consist of revenue from grants, collaboration agreements and feasibility studies. We recognize revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 104,

Revenue Recognition. Under the agreements, revenue is recognized once costs are incurred and collectibility is reasonably assured. Under some agreements our partners have the right to withhold reimbursement of our costs incurred until the work performed under the relative agreement is mutually agreed upon. For these agreements revenue is recognized upon confirmation from the partner of acceptance of work performed and payment amount. 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

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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

expended over the remaining term of the agreements when payments precede the required efforts. Costs of contract revenues are approximate to or are greater than 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 and accepted.

**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.

**Advertising**

Advertising costs are charged to general and administrative expense as incurred. Advertising expenses for the years ended December 31, 2005, 2004 and 2003 were \$265,000, \$223,000 and \$199,000, respectively.

**Stock Based Compensation**

The Company has elected to follow Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issued to Employees ( APB 25 ), and related interpretations in accounting for its employee stock options. Compensation expense is based on the difference, if any, between the fair value of the Company's common stock and the exercise price of the option or share right on the measurement date, which is typically the date of grant. In accordance with SFAS 123, Accounting for Stock-Based Compensation, as amended by SFAS 148, Accounting for Stock-Based Compensation Transition and Disclosure, the Company has provided, below, the pro forma disclosures of the effect on net loss and loss per share as if SFAS 123 had been applied in measuring compensation expense for all periods presented (in thousands, except per share data).

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss as reported	\$ (29,215)	\$ (30,189)	\$ (25,970)
Add:			
Stock-based employee compensation expense included in reported net loss	21		
Less:			
Total stock-based employee compensation expense determined under fair value based method for all awards	(3,066)	(4,585)	(5,400)
Pro forma net loss	\$ (32,260)	\$ (34,774)	\$ (31,370)
Basic and diluted net loss per common share:			
As reported	\$ (2.01)	\$ (2.37)	\$ (2.59)
Pro forma	\$ (2.22)	\$ (2.73)	\$ (3.12)

Pro forma information regarding net loss and basic and diluted net loss per common 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 using the fair value method prescribed by this statement. The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions: a risk-free interest rate of 3.8%, 3.1%, and 2.5% for the years ended December 31, 2005, 2004 and 2003,

respectively; a dividend yield of 0.0%; the annual volatility factor of the  
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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

expected market price of the Company's common stock for 2005, 2004 and 2003 are 97.6%, 98.0%, and 98.0% respectively; and a weighted average expected option life of four years. The weighted average fair value of options granted during 2005, 2004 and 2003 with an exercise price equal to the fair value of the Company's common stock on the date of grant was \$4.08, \$5.50 and \$3.75, respectively. Additionally, the weighted average fair value of options granted during 2005 with an exercise price greater than the fair value of the Company's common stock on the day of grant was \$3.82.

The Company accounts for options and warrants issued to non-employees under SFAS 123 and Emerging Issues Task Force Issue No. ( EITF ) 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, using the Black-Scholes option pricing model. The value of such non-employee options and warrants are periodically re-measured over their vesting terms. The fair value of options and warrants was remeasured at period end using the Black-Scholes option pricing model with the following assumptions: a risk-free interest rate of 2.0% to 4.0%; using applicable U.S. Treasury rates; a dividend yield of 0.0%; the annual volatility factor of 87% to 98%; and an average expected life based on the terms of the option grant or contractual term of the warrant of 1 to 4 years. Expense recognized related to options and warrants issued to non-employees was \$117,000, \$82,000, and \$116,000 during the years ended December 31, 2005, 2004, and 2003, respectively.

***Income Taxes***

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

***Net Loss Per Share***

Basic net loss per share on a historical basis is computed using the weighted-average number of shares of common stock outstanding less the weighted-average number of shares subject to repurchase. There were no shares subject to repurchase in the years ended December 31, 2005, 2004 and 2003. No separate 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, 2005, 2004 and 2003, the total number of shares excluded, based on the treasury stock method, from diluted loss per share relating to these securities was 1,241,936, 1,650,082, and 1,658,377 shares, respectively.

***Significant Concentrations***

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. Risks associated with these instruments are mitigated by banking with and only purchasing commercial paper from creditworthy institutions. The maximum amount of loss due to credit risk associated with these financial instruments is their respective fair values as stated in the Balance Sheet.

The Company has development arrangements with various collaborative partners. For the years ended December 31, 2005, 2004 and 2003, the Novo Nordisk AERx iDMS program contributed approximately 76%, 96% and 99% of total contract revenues, respectively. In January 2005, the Company completed the restructuring of the AERx iDMS program, pursuant to the Restructuring Agreement entered into with Novo Nordisk A/S ( Novo Nordisk ) and Novo Nordisk Delivery Technologies, Inc. ( NNDT ) in September 2004. Under our current agreements with Novo Nordisk, Novo Nordisk has assumed responsibility of the completion of development, manufacturing and commercialization of the AERx insulin product. We will be entitled to receive royalties on future sales of the commercialized product. Novo Nordisk, a publicly traded

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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

Danish company, is considered to be a related party due to its ownership interest in the Company. Novo Nordisk owned approximately 10% of the Company's common stock on an as converted basis as of December 31, 2005.

***Comprehensive Income (Loss)***

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

***Recent Accounting Pronouncements***

The Financial Accounting Standards Board (FASB) issued SFAS No. 123R (revised 2004), Share-Based Payment (SFAS 123R) on December 16, 2004, which is a revision of FASB Statement No. 123 (SFAS 123), *Accounting for Stock Issued to Employees*, that requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Pro forma disclosure is no longer an alternative. SFAS 123R supersedes Accounting Principles Board (APB) No. 25, *Accounting for Stock Issued to Employees*, (APB 25) and amends SFAS No. 95, *Statement of Cash Flows*.

Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. Under SFAS 123R, share-based payments to employees result in a cost that will be measured at fair value on the awards' grant date, based on the estimated number of awards that are expected to vest. Compensation cost for awards that vest would not be reversed if the awards expire without being exercised. When measuring fair value, companies can choose an option-pricing model (e.g., Black-Scholes or binomial models) that appropriately reflects their specific circumstances and the economics of their transactions. Upon adoption of SFAS 123R public companies are allowed to select from alternative transition methods, each having different reporting implications. SFAS 123R is effective for the fiscal year beginning after June 15, 2005, and applies to all outstanding and unvested share-based payments as of the adoption date.

SFAS 123R permits public companies to adopt its requirements using one of two methods: modified prospective method or modified retrospective method. The Company adopted FAS 123R using the modified prospective basis on January 1, 2006, and will continue to use the Black-Scholes option pricing model to calculate the fair value of the awards. Under the modified prospective method, compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date. We will recognize in our results of operations the compensation cost for stock-based awards issued after December 31, 2005 on a straight-line basis over the requisite service period for the entire award. For stock-based awards issued prior to January 1, 2006, we amortize the related compensation costs using the straight-line method.

As permitted by SFAS 123, we currently account for share-based payments to employees using APB 25 intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. The adoption of the SFAS 123R fair value method will have a significant adverse impact on our reported results of operations because the stock-based compensation expense will be charged directly to our statement of operations. At December 31, 2005 there are 636,869 unvested stock options currently outstanding. Our adoption of FAS 123R is expected to result in compensation expense that will increase net loss by approximately \$1.1 million to \$1.5 million for 2006. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase, or cancel any remaining unearned stock-based compensation expense. However, our estimate of future stock-based compensation expense is

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**NOTES TO FINANCIAL STATEMENTS (Continued)**

affected by our stock price, the number of stock-based awards our board of directors may grant in 2006, as well as a number of complex and subjective valuation assumptions. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercise behaviors.

SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current standard. This requirement will likely reduce net operating cash flow and increase net financing cash flows in periods after adoption.

In October 2005, the FASB issued FSP FAS 123R-2, *Practical Accommodation to the Application of Grant Date*. The FSP provides an exception (that should not be analogized to) to the application of the concept of mutual understanding in the determination of whether a grant date (and, for an equity award, a measurement date) has occurred. The exception permits companies to measure compensation cost for equity awards to employees on the Board approval date if certain conditions are met, provided that the communication to the employee occurs within a relatively short period of time from the approval date. The guidance in this FSP is to be applied upon initial adoption of Statement 123(R). An entity that adopted Statement 123(R) prior to the issuance of this FSP and did not apply the provisions of this FSP should apply the guidance in this FSP to the first reporting period after October 18, 2005, for which financial statements or interim reports have not been issued.

In November 2005, the FASB issued FSP FAS 123R-3, *Transition Election and Accounting for Tax Effects*. The guidance provides a simplified method to calculate the Additional Paid-In Capital ( APIC ) pool for the beginning balance of excess tax benefits and the method of determining the subsequent impact on the pool of option awards that are outstanding and fully or partially vested upon the adoption of SFAS No. 123R, *Share-Based Payment*, beginning on January 1, 2006. In addition, this FSP addresses that when the alternative APIC pool calculation is used, tax benefits related to certain employee awards should be included as a cash flow from financing activities and a cash outflow from operating activities within the statements of cash flows. The FSP allows companies up to one year from the later of the adoption date of SFAS 123R or November 10, 2005 to evaluate the available transition alternatives and make a one-time election. We are in the process of evaluating the impact of the new method provided by this guidance.

***Reclassifications***

Certain reclassifications of prior year amounts have been made to conform to current-year presentation. We reclassified amounts from investing activity to operating activity in order to separately disclose amortization and accretion of investments on the Statement of Cash Flows. We made clarification in regards to the liquidation preference of preferred stock to include the accumulated undeclared dividends of 6% in note 6 and on the Balance Sheet.



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**2. Financial Instruments*****Cash and Cash Equivalents and Investments***

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

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Cash equivalents:</b>		
Money market fund	\$ 1,321	\$ 800
Commercial paper	26,373	13,508
	\$ 27,694	\$ 14,308
<b>Short-term investments:</b>		
Commercial paper	\$	
Corporate and Government notes		\$ 2,455
	\$	\$ 2,455

All short-term investments at December 31, 2004 mature in less than one year.

As of December 31, 2005 and 2004, the difference between the fair value and the amortized cost of available-for-sale securities was \$5,000 gain and \$10,000 loss, respectively. The individual gross unrealized gains and individual gross unrealized losses for 2005 and 2004 were immaterial.

**3. Property and Equipment**

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

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Machinery and equipment	\$ 4,505	\$ 14,364
Furniture and fixtures	1,150	1,917
Lab equipment	2,539	4,086
Computer equipment and software	3,790	6,256
Leasehold improvements	1,564	12,225
Property and Equipment at cost	13,548	38,848
Less accumulated depreciation and amortization	(10,201)	(27,740)
Net depreciable assets	3,347	11,108
Construction in progress	6,528	49,447
Property and equipment, net	\$ 9,875	\$ 60,555

Depreciation expense was \$1.4 million, \$3.8 million, and \$6.0 million in 2005, 2004, and 2003, respectively.

On January 26, 2005, the Company completed the restructuring of its AERx iDMS program, pursuant to the Restructuring Agreement entered into with Novo Nordisk and NNDT. In accordance with the restructuring transaction, the Company received \$51.1 million in cash and applied \$4.0 million of deposits

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from Novo Nordisk in consideration for \$54.3 million of property and equipment at net book value, \$515,000 of inventory and \$317,000 for prepaid and other assets.

**4. Leases, Commitments and Contingencies**

Subsequent to completion in January 2005 of the restructuring transaction between the Company and Novo Nordisk, the Company had commitments under two leases. The first lease is for a building containing office, laboratory and manufacturing facilities, and expires in 2016. A minor portion of this lease expense is offset by a sublease to NNDT of \$10,000 per month through December 2006. The second lease, which expired in December 2005, is for a warehouse. Additionally, the Company entered into a new copier lease agreement in July 2005 for \$5,030 per month for 60 months. Future minimum lease payments non-cancelable at December 31, 2005 for the remaining lease agreements are as follows (amounts in thousands):

	<b>Operating Leases</b>
Year ending December 31:	
2006	\$ 1,660
2007	2,306
2008	2,371
2009	2,318
2010	2,223
2011 and thereafter	11,933
 Total minimum lease payments	 \$ 22,811

The Company's operating lease has a rent escalation clause and accordingly, the Company recognizes rent expense on a straight-line basis. At December 31, 2005 and 2004, the Company had \$714,000 and \$1.9 million of deferred rent, respectively. The overall reduction in deferred rent is due to reversing of \$1.4 million expense associated with the deferred rent on two buildings transferred to NNDT as part of the restructuring agreement. A portion of the lease commitment for 2006 is offset by a sublease to NNDT of \$10,000 per month through December 2006.

For the years ended December 31, 2005, 2004 and 2003, building rent expense, net of sublease income, under operating leases totaled \$1.3 million, \$5.5 million, and \$5.4 million, respectively.

At December 31, 2005, the Company had contractual non-cancelable purchase commitments for capital equipment purchases, \$1.0 million, and services, \$2.1 million.

**Indemnification**

The Company from time to time enters into contracts that contingently require the Company to indemnify parties against third party claims. These contracts primarily relate to: (i) real estate leases, under which the Company may be required to indemnify property owners for environmental and other liabilities, and other claims arising from the Company's use of the applicable premises, and (ii) agreements with the Company's officers, directors and employees, under which the Company may be required to indemnify such persons from certain liabilities arising out of such persons' relationships with the company. To date, the Company has made no payments related to such indemnifications and no liabilities have been recorded for these obligations on the balance sheets as of December 31, 2005 or 2004.

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**NOTES TO FINANCIAL STATEMENTS (Continued)**

***Legal Matters***

From time to time, the Company is involved in litigation arising out of the ordinary course of its business. Currently there are no known claims or pending litigation expected to have a material effect on the Company's overall financial position, results of operations, or liquidity.

**5. Redeemable Convertible Preferred Stock and Common Stock Warrants**

The Company completed a \$48.4 million preferred stock financing in December 2001. Under the terms of the financing the Company sold to a group of investors 2,001,236 shares of Series A redeemable convertible preferred stock ( preferred stock ) at a purchase price of \$24.20 per share. Each share of preferred stock, together with accrued and unpaid dividends, is convertible at the option of the holder into 0.8 shares of common stock. The Company also issued warrants to the investors to purchase approximately 1,040,642 shares of common stock at an exercise price of \$34.85 per share. Issuance costs of approximately \$3.0 million were accounted for as a reduction to proceeds from the preferred stock financing. The warrants are exercisable through December 2006.

In March, June and July 2003, certain holders of shares of the Company's preferred stock elected to convert an aggregate of 456,610 shares of preferred stock to common stock. The Company issued 365,288 shares of common stock in connection with the conversion.

During the two year period following the original issue dates holders of preferred stock are entitled to dividends, at an annual rate of 6%, payable only when and if declared by the Board of Directors. Such dividends are cumulative and accrue whether or not they are declared. 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, 2005 or 2004.

The conversion rate of the preferred stock 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 \$52.9375 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 holders of preferred stock. 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. At December 31, 2005 the total liquidation preference of all outstanding preferred stock, consisting of the original issue price plus accrued dividends, was approximately \$41.9 million.

***Summary of Preferred Stock Accounting***

The preferred stock agreement provides that a mandatory redemption is triggered if a change in control occurs. Accordingly, in accordance with EITF D-98, Classification and Measurement of Redeemable Securities, which clarifies Rule #5-02.28 of Regulation S-X previously adopted in accounting series Release

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No. 268, Presentation in Financial Statements of Redeemable Preferred Stock, the Company has classified the preferred stock outside of permanent equity.

**6. Shareholders Equity**

In a private placement in December 2004, the Company issued 1,666,679 shares of common stock at a price of \$7.50 per share and warrants to purchase 416,669 shares of common stock at \$10.50 per share, for aggregate consideration of approximately \$12.5 million. The warrants are exercisable at the election of the warrant holders for a four-year term. The Company valued the warrants as of December 2004, the date of financing, using the Black-Scholes option pricing model using the following assumptions: estimated volatility of 88%, risk-free interest rate of 3.6%, no dividend yield, and an expected life of four years, and recorded approximately \$2.3 million as issuance costs related to the private placement. These warrants are exercisable through December 2008.

In November 2003 the Company issued 1,556,110 shares of common stock at \$9.00 per share and warrants to purchase 389,027 shares of common stock at \$12.50 per share to certain investors for an aggregate purchase price of approximately \$14.0 million in a private placement. The warrants are exercisable at the election of the warrant holders for a four-year term. The Company valued the warrants as of November 2003, the date of financing, using the Black-Scholes option pricing model using the following assumptions: estimated volatility of 88%, risk-free interest rate of 2.5%, no dividend yield, and an expected life of four years, and recorded approximately \$2.6 million as issuance costs related to the private placement. These warrants are exercisable through November 2007.

In March 2003, the Company issued 3,798,478 shares of common stock at \$3.95 per share and warrants to purchase 854,654 shares of the common stock at \$5.35 per share to certain investors for an aggregate purchase price of approximately \$15.0 million in a private placement. The warrants are exercisable at the election of the warrant holders for a four-year term. The Company valued the warrants as of March 2003, the date of financing, using the Black-Scholes option pricing model using the following assumptions: estimated volatility of 84%, risk-free interest rate of 2.5%, no dividend yield, and an expected life of four years, and recorded approximately \$1.9 million as issuance costs related to the private placement. In addition, in connection with this private placement, the Company issued warrants ( replacement warrants ) to purchase an aggregate of 803,205 shares of its common stock at \$5.60 per share to certain of the investors in the private placement in exchange for the cancellation of an equal number of warrants to purchase shares of the common stock at \$34.85 per share, held by the same investors. The Company valued the replacement warrants as of March 2003, the date of the replacement, using the Black-Scholes option pricing model using the following assumptions: estimated volatility of 84%, risk-free interest rate of 2.5%, no dividend yield, and an expected life of 3.8 years, and recorded an additional \$1.1 million as issuance costs related to the private placement. These warrants are exercisable through March 2007.

In June 2004, the Company filed a Certificate of Amendment to the Company's amended and restated Articles of Incorporation with the Secretary of State of the State of California to increase the Company's authorized number of shares of common stock from 100,000,000 to 150,000,000 shares. The additional shares of common stock authorized by the amendment have rights identical to the common stock of the Company outstanding immediately before the filing of the amendment. Issuances of common stock from the additional authorized shares do not affect the rights of the holders of the Company's common stock and preferred stock outstanding immediately before the filing of the amendment, except for effects that may be incidental to increasing the number of shares of the Company's common stock outstanding, such as dilution of the earnings per share and voting rights of holders of other common stock.

In January 2006, the Company filed a Certificate of Amendment to the Company's amended and restated Articles of Incorporation with the Secretary of State of the State of California to decrease the Company's authorized number of shares of common stock from 150,000,000 to 100,000,000 shares.

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***Reverse Stock Split***

On January 4, 2006, the Company filed an amended and restated certificate of incorporation with the California Secretary of State affecting a 1-for-5 reverse split of the Company's common stock. All share and per share amounts have been retroactively restated in the financial statements and these accompanying notes for all periods presented.

***Reserved Shares***

At December 31, 2005, the Company had 2,119,766 shares of its common stock reserved for issuance upon exercise of common stock warrants, 2,649,095 shares reserved for issuance upon exercise of options under all plans, 1,235,701 shares reserved for issuance upon conversion of preferred stock and 452,400 available authorized shares under the Employee Stock Purchase Plan.

***Other Common Stock Warrants***

During 2004 the Company received net proceeds of approximately \$304,000 and issued an aggregate of 74,200 shares of common stock in connection with the exercise of warrants.

In January 2004, the Company amended the payment terms of the operating lease for its primary offices. In consideration for the amended lease agreement, Aradigm replaced common stock warrants to purchase 27,000 shares of common stock at \$50.80 - \$108.60 per share with new common stock warrants with an exercise price equal to \$8.55 per share. The \$88,000 incremental fair value of the replacement warrants, as defined as the fair value of the new warrant less the fair value of the old warrant on date of replacement, is being amortized to operating expenses on a straight-line basis over the remaining life of the lease. The fair value of the warrants was measured as of January 2004, the date of the amendment, using the Black-Scholes option pricing model with the following assumptions: risk-free interest rates between 1.3% and 2.4%; a dividend yield of 0.0%; annual volatility factor of 88%; and a weighted average expected life based on the terms on the contractual term of the warrants from 1 to 3.5 years.

During 2003 the Company received net proceeds of approximately \$2.5 million and issued an aggregate of 482,810 shares of common stock in connection with the exercise of warrants.

In March 2003, the Company issued warrants in connection with a financial relations service agreement that entitles the holder to purchase 5,000 shares of common stock which are exercisable at \$6.55 per share and vests over the 48 month service period of which 938 shares vested during the year ended December 31, 2003. In 2004, the Company terminated the financial service relationship and accelerated the vesting schedule for all remaining 4,062 shares. The Company valued the warrants as of March 2003, the date of agreement, using the Black-Scholes option pricing model using the following assumptions: estimated volatility of 88%, risk-free interest rate of 2.0%, no dividend yield, and an expected life of four years. The fair value of these warrants is re-measured as the underlying warrants vest and is being expensed over the vesting period of the warrants. For the year ended December 31, 2004 the Company recorded \$22,000 of expense in connection with these warrants. These warrants are exercisable through March 2008.

In October 2002, the Company issued warrants in connection with a financial relations service agreement that entitles the holder to purchase 15,000 shares of common stock, 5,000 of which are exercisable at \$9.95 per share, 5,000 shares of which are exercisable at \$11.95 per share and 5,000 shares of which are exercisable at \$13.95 per share. At the execution of the agreement 3,000 shares immediately vested and the remaining shares shall vest based on the achievement of various performance benchmarks set forth in the agreement: all benchmarks were achieved as of March 2004. The Company valued the warrants as of October 2002, the date of agreement, using the Black-Scholes option pricing model using the following assumptions: estimated volatility of 88%, risk-free interest rate of 2.0%, no dividend yield, and an expected life of four years. The fair value of these warrants is re-measured as the underlying warrants vest and is being expensed over the vesting

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period of the warrants. For the year ended December 31, 2003 the Company recognized \$77,000 of expense associated with these warrants. In the year ended December 31, 2004, due to all benchmarks being achieved during the year, the Company reversed previously recognized expense of \$48,000. The warrants are exercisable through October 2007.

***1996 Equity Incentive Plan, 2005 Equity Incentive Plan and 1996 Non-Employee Directors Plan***

In April 1996, the Company's Board of Directors adopted and the Company's shareholders approved the 1996 Equity Incentive Plan (the "1996 Plan"), which amended and restated on earlier Stock Option Plan. The original plan reserved 960,000 shares for future grants. During May 2001, the Company's shareholders approved an amendment to the Plan to include an evergreen provision. In 2003, the 1996 Plan was amended, to increase the maximum number of shares available for issuance under the evergreen feature of the 1996 Plan by 400,000 shares to 2.0 million. The evergreen provision automatically increased the number of shares reserved under the 1996 Plan, subject to certain limitations, by 6% of the issued and outstanding Common Stock of the Company or such lesser number of shares as determined by the Board of Directors on the date of the annual meeting of shareholders of each fiscal year beginning 2001 and ending 2005. The aggregate reserved for grants was 2.96 million shares.

Options granted under the 1996 Plan may be immediately exercisable if permitted in the specific grant approved by the Board of Directors and, if exercised early, the issued shares may be subject to repurchase provisions. The shares acquired generally vest over a period of four years from the date of grant. The 1996 Plan also provides for a transition from employee to consultant status without termination of the vesting period as a result of such transition. Any unvested stock issued is subject to repurchase agreements whereby the Company has the option to repurchase unvested shares upon termination of employment at the original issue price. The common stock has voting rights but does not have resale rights prior to vesting. The Company has repurchased a total of 7,658 shares in accordance with these agreements through December 31, 1998. Subsequently, no grants with early exercise provision have been made under the 1996 Plan and no shares have been repurchased. During 2005, the Company granted options to purchase 279,420 shares of common stock under the 1996 Plan, none of which included an early exercise provision. As of December 31, 2005, the Company had 1,662,883 options outstanding under the 1996 Plan.

In March 2005, the Company's Board of Directors adopted and in May 2005 the Company's shareholders approved the 2005 Equity Incentive Plan (the "2005 Plan"), which amended, restated and retitled the 1996 Plan. All outstanding awards granted under the 1996 Plan remain subject to the terms of the 1996 Plan. All stock awards granted on or after the adoption date are subject to the terms of the 2005 Plan. No shares were added to the share reserve under the 2005 Plan other than the shares available for future issuance under the 1996 Plan. As of March 21, 2005, the Company had 2,918,638 shares of common stock authorized for issuance under the 1996 Plan. Options (net of canceled or expired options) covering an aggregate of 1,999,252 shares of the Company's Common Stock had been granted under the 1996 Plan, and the remaining 965,026 shares available for future grant under the 1996 Plan became available for future grant under to the 2005 Plan.

As of December 31, 2005, the Company had 965,026 shares of common stock authorized for issuance under the 2005 Plan. Options granted under the 2005 Plan expire no later than 10 years from the date of grant. Options granted under the 2005 Plan may be either incentive or non-statutory stock options. 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.

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Options granted under the 2005 Plan may be immediately exercisable based if permitted in the specific grant approved by the Board of Directors and, if exercised early may be subject to repurchase provisions. The shares acquired generally vest over a period of four years from the date of grant. The 2005 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 2005 Plan, employees may exercise options in exchange for a note payable to the Company, if permitted under the applicable grant. As of December 31, 2005 there were no outstanding notes receivable from shareholders. Any unvested stock issued is subject to repurchase agreements whereby the Company has the option to repurchase unvested shares upon termination of employment at the original issue price. The common stock has voting rights but cannot be resold prior to vesting. No grants with early exercise provisions have been made under the 2005 Plan and no shares have been repurchased. During 2005, the Company granted options to purchase 46,040 shares of common stock under the 2005 Plan.

The 1996 Non-Employee Directors Stock Option Plan (the Directors Plan ) had 45,000 shares of common stock authorized for issuance. Options granted under the Directors Plan expire no later than 10 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. There was no activity in the Directors Plan during the year ended December 31 2005 and as of December 31, 2005, 21,186 outstanding options with exercise prices ranging from \$41.25 - \$120.63 remained with no additional shares available for grant.

The following is a summary of activity under the 1996 Plan, the 2005 Plan and the Directors Plan:

	<b>Options Outstanding</b>				
	<b>Shares Available for Grant of Options</b>	<b>Number of Shares</b>	<b>Price Per Share</b>		<b>Weighted Average Exercise Price</b>
Balance at December 31, 2002	117,619	1,175,752	\$1.65	\$120.65	\$ 40.25
Options authorized	608,524				
Options granted	(362,550)	362,550	\$4.55	\$ 10.80	\$ 6.45
Options exercised		(5,426)	\$1.65	\$ 4.75	\$ 2.10
Options cancelled	236,111	(236,111)	\$4.75	\$116.90	\$ 39.15
Balance at December 31, 2003	599,704	1,296,765	\$1.85	\$120.65	\$ 31.15
Options authorized	762,774				
Options granted	(697,760)	697,760	\$3.80	\$ 12.00	\$ 7.75
Options exercised		(81)	\$4.75	\$ 7.10	\$ 6.20
Options cancelled	111,274	(111,274)	\$1.85	\$117.85	\$ 31.60
Balance at December 31, 2004	775,992	1,883,170	\$2.15	\$120.65	\$ 22.20
Options authorized					
Options granted	(325,460)	325,460	\$4.30	\$ 7.95	\$ 5.97
Options exercised		(10,077)	\$2.17	\$ 4.75	\$ 4.39
Adjustment for rounding of reverse split		10			



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Options cancelled	468,854	(468,854)	\$2.83	\$120.63	\$	21.84
Balance at December 31, 2005	919,386	1,729,709	\$2.83	\$120.63	\$	19.47

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**NOTES TO FINANCIAL STATEMENTS (Continued)**

		Options Outstanding			Options Exercisable		
Exercise Price Range		Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
\$ 2.83	\$ 5.30	349,385	\$ 5.02	8.0	197,911	\$ 4.98	7.8
\$ 5.35	\$ 6.25	350,700	\$ 5.89	8.9	55,727	\$ 5.90	8.5
\$ 6.50	\$ 12.00	364,370	\$ 10.48	8.1	194,103	\$ 9.97	8.0
\$13.00	\$ 24.10	349,410	\$ 20.66	6.1	329,255	\$ 20.76	6.1
\$25.55	\$120.63	315,844	\$ 59.56	3.7	315,844	\$ 59.56	3.7
		1,729,709	\$ 19.47	7.1	1,092,840	\$ 26.44	6.2

The Company recorded deferred compensation of approximately \$21,000 for the difference between the grant price and the fair value of certain of the Company's common stock options granted in 2005. Deferred compensation was fully amortized as of December 31, 2005.

***Employee Stock Purchase Plan***

Employees generally are eligible to participate in the Purchase Plan if they have been continuously employed by the Company for at least 10 days prior to the first day of the offering period and are customarily employed at least 20 hours per week and at least five months per calendar year and are not a 5% or greater stockholder. Shares may be purchased under the Purchase Plan at 85% of the lesser of the fair market value of the common stock on the grant date or purchase date. Employee contributions, through payroll deductions, are limited to the lesser of fifteen percent of earnings or \$25,000.

As of December 31, 2005 a total of 597,600 shares have been issued under the Purchase Plan, leaving a balance of 452,400 available authorized shares. Under SFAS No. 123, pro forma compensation cost is reported for the fair value of the employees' purchase rights, which was estimated using the Black-Scholes model and the following assumptions for 2005; expected volatility of 87.1%; risk-free interest rates of 3.57%; an average expected life of 1.16 years and a dividend yield of 0.0%. The weighted-average fair value of the purchase rights granted was \$2.90 per share in 2005 and in 2004 and \$2.80 in 2003. Pro-forma compensation expense of \$485,000, \$623,000, and \$245,000 for the years ended December 31, 2005, 2004, and 2003 respectively, associated with shares granted under the Employee Stock Purchase Plan has been included in the disclosure entitled *Stock Based Compensation* in Note 1.

**7. Employee Benefit Plans**

The Company has a 401(k) Plan which stipulates that all full-time employees with at least 30-days of employment can elect to contribute to the 401(k) Plan, subject to certain limitations, up to \$14,000 annually on a pretax basis. Subject to a maximum dollar match contribution of \$7,000 per year, the Company will match 50% of the first 6% of the employee's contribution on a pretax basis. The Company expensed total employer matching contributions of \$283,000, \$461,000, and \$483,000 in 2005, 2004 and 2003, respectively.

**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.

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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

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.

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 \$5.0 million through the sale of common stock to Novo Nordisk at the fair market price. In October 2001, the Company entered into a new common stock purchase agreement with Novo Nordisk Pharmaceuticals. Under the new agreement, Novo Nordisk Pharmaceuticals committed to purchase up to \$45.0 million of the Company's common stock at fair market value specified in the agreement, of which \$20.0 million was invested initially. In July 2002, the Company raised \$5.0 million through the sale of common stock to Novo Nordisk Pharmaceuticals under the terms of the agreement. Under the terms of the development agreement in place between the Company and Novo Nordisk before completion of the restructuring transaction, noted below, Novo Nordisk was to fund all product development costs incurred by the Company under the terms of the agreement, while Novo Nordisk and the Company agreed to co-fund final development of the AERx device. The Company was to be the initial manufacturer of all the products covered by the agreement and was to receive a share of the overall gross profits resulting from Novo Nordisk's sales of the products.

On January 26, 2005, the Company completed the restructuring of its AERx iDMS program, pursuant to the Restructuring Agreement entered into with Novo Nordisk and NNDT. In accordance with the restructuring transaction, the Company received \$51.1 million in cash and applied \$4.0 million of deposits from Novo Nordisk in consideration for \$54.3 million of property and equipment at net book value, \$515,000 of inventory and \$317,000 for prepaid and other assets. In addition, NNDT hired 126 Aradigm employees at the closing of the restructuring transaction. The Company's expenses related to this transaction for legal and other consulting costs were approximately \$1.1 million.

In connection with the restructuring transaction, the Company entered into various related agreements with Novo Nordisk and NNDT, effective January 26, 2005, including the following:

an amended and restated license agreement amending the Development and License Agreement previously in place with Novo Nordisk, expanding Novo Nordisk's development and manufacturing rights to the AERx iDMS program and providing for royalties to the Company on future AERx iDMS net sales and

a three-year agreement under which NNDT will perform contract manufacturing for the Company of AERx iDMS-identical devices and dosage forms filled with compounds provided by the Company in support of preclinical and initial clinical development by the Company of other AERx products.

Through December 31, 2005, the Company received from Novo Nordisk approximately \$150.1 million in product development and milestone payments and, the Company has recognized the total amount as contract revenue.

For the years ended December 31, 2005, 2004 and 2003, the Company recognized contract revenues of \$8.0 million, \$27.0 million, and \$33.5 million, respectively.

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):

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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

	December 31,		
	2005	2004	2003
Deferred revenue beginning balance	\$ 11,491	\$ 12,931	\$ 16,852
Partner payments:			
Novo Nordisk	727	25,373	29,625
Other partner-funded programs	2,530	1,232	311
<b>Total partner payments</b>	<b>3,257</b>	<b>26,605</b>	<b>29,936</b>
Contract revenue recognized:			
Novo Nordisk	8,013	26,999	33,546
Other partner-funded programs	2,494	1,046	311
<b>Total contract revenue recognized</b>	<b>10,507</b>	<b>28,045</b>	<b>33,857</b>
Deferred revenue at December 31, 2004 recognized on January 26, 2005 as payment for assets pursuant to the restructuring agreement with Novo Nordisk,	4,019		
Deferred revenue ending balance	222	11,491	12,931
Less: Noncurrent portion of deferred revenue		(3,966)	(5,040)
<b>Current portion of deferred revenue</b>	<b>\$ 222</b>	<b>\$ 7,525</b>	<b>\$ 7,891</b>

As a result of the restructuring transaction, the Company's contract revenue from its development agreement with Novo Nordisk ceased in 2005. Of the amount recorded in deferred revenue at December 31, 2004, the Company recorded \$11.3 million in the first quarter of 2005 as: project development revenue of \$2.1 million, deferred milestone revenue of \$5.2, and \$4.0 million partial payment for the sale of the insulin development program assets in accordance with the restructuring agreement.

## 9. Related Party Transactions

Novo Nordisk and its affiliate, Novo Nordisk Pharmaceuticals, Inc., are considered related parties and at December 31, 2005 own 1,573,674 shares of our common stock representing approximately 10.8% of the Company's total outstanding common stock (10% on an as-converted basis).

### *Development and License Agreement*

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. 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, 2005, the Company received from Novo Nordisk approximately \$150.1 million in product development and milestone payments and, of this amount, the Company has recognized all of these funds as contract revenue. Novo Nordisk was funding all product development costs incurred by the Company under the terms of the agreement, while Novo Nordisk and the Company were co-funding final development of the AERx device. Under its agreements with Novo Nordisk in effect at December 31, 2004, the

Company was to have been the initial manufacturer of all the products covered by the agreement and was to receive a share of the overall gross profits resulting from Novo Nordisk's sales of the products.

On January 26, 2005, the Company completed the restructuring of our AERx iDMS program, pursuant to the Restructuring Agreement entered into with Novo Nordisk and NNDT, a newly created wholly owned subsidiary of Novo Nordisk. Under the terms of the Restructuring Agreement we sold certain equipment,

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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

leasehold improvements and other tangible assets currently utilized in the AERx iDMS program to NNDT for a cash payment of approximately \$55.3 million in which we received net proceeds of \$51.3 million after applying a refund of cost advances of approximately \$4.0 million previously made by Novo Nordisk. In addition, NNDT hired 126 Aradigm employees at the closing of the restructuring transaction. Our expenses related to this transaction for legal and other consulting costs were approximately \$1.1 million. In connection with the restructuring transaction, we entered into various related agreements with Novo Nordisk and NNDT, effective January 26, 2005, including the following:

an amended and restated license agreement amending the Development and License Agreement previously in place with Novo Nordisk, expanding Novo Nordisk's development and manufacturing rights to the AERx iDMS program and providing for royalties to us on future AERx iDMS net sales and

a three-year agreement under which NNDT agreed to perform contract manufacturing for us of AERx iDMS-identical devices and dosage forms filled with compounds provided by us in support of preclinical and initial clinical development by us of other AERx products.

For the years ended December 31, 2005, 2004 and 2003, the Company recognized contract revenues of \$8.0 million, \$27.0 million, and \$33.5 million, respectively. Receivables in the amount of \$126,000 were due to the Company from Novo Nordisk at December 31, 2005. Payables in the amount of \$237,000 were due to Novo Nordisk from the Company at December 31, 2005. No amounts were due to the Company from Novo Nordisk at December 31, 2004.

***Securities Purchase Agreements***

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 \$5.0 million through the sale of common stock to Novo Nordisk at the fair market price. In October 2001, the Company entered into a new common stock purchase agreement with Novo Nordisk Pharmaceuticals. Under the new agreement, Novo Nordisk Pharmaceuticals committed to purchase up to \$45.0 million of the Company's common stock at fair market value specified in the agreement, of which \$20.0 million was invested initially. In July 2002, the Company raised \$5.0 million through the sale of common stock to Novo Nordisk Pharmaceuticals under the terms of the agreement. Since the inception of the collaboration in June 1998 through December 31, 2005, the Company raised \$35.0 million through the sale of common stock to Novo Nordisk.

In connection with the restructuring transaction, the Company entered into an amendment of the common stock purchase agreement in place with Novo Nordisk, Inc. deleting the provisions whereby we can require Novo Nordisk to purchase certain amounts of common stock and imposing certain restriction on the ability of Novo Nordisk to sell shares of our common stock that it holds.

**10. Income Taxes**

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

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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

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

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Net operating loss carry forward	\$ 91,800	\$ 73,900
Deferred revenue	100	4,600
Research and development credits	14,400	14,400
Capitalized research and development	3,100	7,100
Other	1,300	1,800
<b>Total deferred tax assets</b>	<b>110,700</b>	<b>101,800</b>
Valuation allowance	(110,700)	(101,800)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Management believes that, based on a number of factors, it is more likely than not that the deferred tax asset will not be realized. Accordingly, a full valuation allowance has been recorded for all deferred tax assets at December 31, 2005, 2004, and 2003. The valuation allowance increased for each of the years ended December 31 by \$8.9 million for 2005, \$13.2 million for 2004, and \$14.6 million for 2003.

As of December 31, 2005, the Company had federal net operating loss carry forwards of approximately \$238.0 million and federal research and development tax credits of approximately \$9.8 million, which expire in the years 2006 through 2025.

As of December 31, 2005, the Company had California net operating loss carry forwards of approximately \$148.2 million, which expire in the years 2006 through 2015, and California research and development tax credits of approximately \$6.3 million, which do not expire and California Manufacturer's Investment Credit of approximately \$700,000, which expire in the years 2006 through 2013.

The Tax Reform Act of 1986 limits the annual use of net operating loss and tax credit carry forwards in certain situations where changes occur in stock ownership of a company. In the event the Company has a change in ownership, as defined, the annual utilization of such carry forwards could be limited.



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**ARADIGM CORPORATION**  
**NOTES TO FINANCIAL STATEMENTS (Continued)**

**12. Quarterly Results of Operations (Unaudited)**

Following is a summary of the quarterly results of operations for the years ended December 31, 2005 and 2004 (amounts in thousands):

	<b>March 31, 2005</b>	<b>June 30, 2005</b>	<b>September 30, 2005</b>	<b>December 31, 2005</b>
Contract and license revenues	\$ 7,714	\$ 1,212	\$ 719	\$ 862
Operating expenses:				
Research and development	7,070	7,317	6,471	9,316
General and administrative	3,235	2,713	2,326	2,621
Total expenses	10,305	10,030	8,797	11,937
Loss from operations	(2,591)	(8,818)	(8,078)	(11,075)
Interest income	288	350	342	337
Other income and expense	(37)	(8)	8	67
Net loss	(2,340)	(8,476)	(7,728)	(10,671)
Basic and diluted net loss per common share	\$ (0.16)	\$ (0.58)	\$ (0.53)	\$ (0.73)
Shares used in computing basic and diluted net loss per common share	14,459	14,512	14,518	14,563

	<b>March 31, 2004</b>	<b>June 30, 2004</b>	<b>September 30, 2004</b>	<b>December 31, 2004</b>
Contract and license revenues	\$ 6,643	\$ 7,078	\$ 6,352	\$ 7,972
Operating expenses:				
Research and development	11,887	11,412	11,407	11,771
General and administrative	2,536	3,167	3,217	3,014
Total expenses	14,423	14,579	14,624	14,785
Loss from operations	(7,780)	(7,501)	(8,272)	(6,813)
Interest income	66	49	45	34
Interest expense	(10)	(5)	(3)	1
Net loss	\$ (7,724)	(7,457)	(8,230)	(6,778)
Basic and diluted net loss per common share	\$ (0.61)	\$ (0.59)	\$ (0.65)	\$ (0.52)

Shares used in computing basic and diluted net loss per common share	12,588	12,706	12,713	12,955
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**ARADIGM CORPORATION  
NOTES TO FINANCIAL STATEMENTS (Continued)**

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

Not applicable.

**Item 9A. *Controls and Procedures***

*Evaluation of disclosure controls and procedures:* Based on their evaluation of our disclosure controls and procedures (as defined in the rules promulgated under the Securities Exchange Act of 1934, as amended, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our chief executive officer and our chief financial officer have concluded that these controls and procedures are effective at the reasonable assurance level.

*Changes in internal controls:* There were no significant changes in our internal controls over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. *Other Information***

None

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**PART III**

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

**Identification of Directors; Audit Committee Information; Code of Ethics**

The information required by this Item concerning (i) the Company's directors, (ii) the identification of the members of the Company's audit committee, (iii) the identification of the Audit Committee Financial Expert and (iv) the Company's Code of Ethics 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 18, 2006, 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 sections captioned "Compensation of Executive Officers," "Compensation of Directors," "Compensation Committee Interlocks and Insider Participation," the Report of the Compensation Committee and the Proxy Graph contained in the Proxy Statement.

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

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

**Item 13. *Certain Relationships and Related Transactions***

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

**Item 14. *Principal Accountant Fees and Services***

The information required by this item is incorporated by reference from the section captioned "Proposal 3: Ratification of Selection of Independent Registered Public Accounting Firm" in the Proxy Statement.

**PART IV****Item 15. Exhibits and Financial Statements Schedules****(a)(1) Financial Statements.**

Included in Part II of this Report:

	<b>Page in Form 10-K</b>
<u>Report of Independent Registered Public Accounting Firm</u>	42
<u>Balance Sheets December 31, 2005 and 2004</u>	43
<u>Statements of Operations Years ended December 31, 2005, 2004 and 2003</u>	44
<u>Statements of Redeemable Convertible Preferred Stock and Shareholders Equity Years ended December 31, 2005, 2004 and 2003</u>	45
<u>Statements of Cash Flows Years ended December 31, 2005, 2004 and 2003</u>	47
<u>Notes to Financial Statements</u>	48

**(2) Financial Statement Schedules.**

All schedules have been omitted because they are not required.

**(3) Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
3.1(1)	Amended and Restated Articles of Incorporation of the Company.
3.2(4)	Bylaws of the Company, as amended.
3.3(10)	Certificate of Determination of Series A Junior Participating Preferred Stock.
3.4(9)	Certificate of Determination and Preferences of Series A Convertible Preferred Stock.
3.5(10)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.6(10)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.7(15)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.8(15)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.9	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7 and 3.8.
4.2(1)	Specimen common stock certificate.
10.1(1)+	Form of Indemnity Agreement between the Registrant and each of its directors and officers.
10.2(18)+	Equity Incentive Plan.
10.3(1)+	Form of the Company's Incentive Stock Option Agreement under the Equity Incentive Plan.
10.4(1)+	Form of the Company's Non-statutory Stock Option Agreement under the Equity Incentive Plan.
10.5(1)+	Non-Employee Directors' Stock Option Plan.
10.6(1)+	Form of the Company's Non-statutory Stock Option Agreement under the Non-Employee Directors' Stock Option Plan.

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10.7(14)+  
10.8(1)+  
10.10(2)\*

Employee Stock Purchase Plan, as amended.  
Form of the Company's Employee Stock Purchase Plan Offering Document.  
Product Development and Commercialization Agreement between the Company and  
SmithKline Beecham PLC.

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<b>Exhibit No.</b>	<b>Description</b>
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)	Rights Agreement, dated as of August 31, 1998, between the Company and Bank Boston, N.A.
10.13a(10)	Amendment to Rights Agreement, dated as of October 22, 2001, by and between the Company and Fleet National Bank.
10.13b(10)	Amendment to Rights Agreement, dated as of December 6, 2001, by and between the Company and EquiServe Trust Company.
10.16(7)*	Amendment to GlaxoSmithKline agreement executed in December 2000.
10.17(11)	Securities Purchase Agreement, dated as of February 10, 2003, by and among the Company and the purchasers named therein.
10.18(11)	Warrant Repricing Agreement, dated as of February 10, 2003, by and between the Company and the persons listed on Exhibit A thereto.
10.19(12)	Securities Purchase Agreement, dated as of November 7, 2003, by and among the Company and the purchasers named therein.
10.20(13)	Securities Purchase Agreement, dated as of November 14, 2003, by and among the Company and the purchasers named therein.
10.21(16)#	Restructuring Agreement, dated as of September 18, 2004, by and among the Company, Novo Nordisk and Novo Nordisk Delivery Technologies, Inc.
10.22(17)	Securities Purchase Agreement, dated as of December 17, 2004, by and among the Company and the purchasers named therein.
10.23(19)+	Form of Change of Control Agreement to be entered into between the Company and certain of the Company's senior officers.
10.24(19)+	Executive Officer Severance Benefit Plan.
10.25+	Form of the Company's Restricted Share Bonus Agreement under the Equity Incentive Plan
10.26#	Amended and Restated License Agreement, dated as of January 26, 2005, by and between the Company and Novo Nordisk A/S
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page.
31.1	Section 302 Certification of the Chief Executive Officer.
31.2	Section 302 Certification of the Chief Financial Officer.
32.1	Section 906 Certification of the Chief Executive Officer and the Chief Financial Officer.

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

+ Represents a management contract or compensatory plan or arrangement.

# The Commission has granted the Company's request for confidential treatment with respect to portions of this exhibit.

(1) Incorporated by reference to the Company's Form S-1 (No. 333-4236), as amended.

(2) Incorporated by reference to the Company's Form 8-K filed on November 7, 1997.

- (3) Incorporated by reference to the Company's Form 10-K filed on March 24, 1998, as amended.
- (4) Incorporated by reference to the Company's Form 10-Q filed on August 14, 1998.
- (5) Incorporated by reference to the Company's 8-K filed on September 2, 1998.
- (7) Incorporated by reference to the Company's Form 10-K filed for the year ended December 31, 2000.
- (9) Incorporated by reference to the Company's Form S-3 (No. 333-76584).
- (10) Incorporated by reference to the Company's Form 10-K filed for the year ended December 31, 2001.
- (11) Incorporated by reference to the Company's Form 10-Q filed on May 13, 2003.



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- (12) Incorporated by reference to the Company's Form 8-K filed on November 12, 2003.
- (13) Incorporated by reference to the Company's Form 8-K filed on November 20, 2003.
- (14) Incorporated by reference to the Company's definitive proxy statement filed on April 2, 2004
- (15) Incorporated by reference to the Company's Form 10-Q filed on August 13, 2004.
- (16) Incorporated by reference to the Company's Form 10-Q filed on November 15, 2004
- (17) Incorporated by reference to the Company's Form 8-K filed on December 23, 2004.
- (18) Incorporated by reference to the Company's definitive proxy statement filed on April 7, 2005.
- (19) Incorporated by reference to the Company's Form 8-K filed on October 13, 2005.

**(b) Index to Exhibits.**

See Exhibits listed under Item 15(a)(3).

**(c) Financial Statement Schedules.**

All schedules have been omitted because they are not required.

**Table of Contents****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 30th day of March 2006.

ARADIGM CORPORATION

By: /s/ V. Bryan Lawlis

V. Bryan Lawlis

*President and Chief Executive Officer*

KNOWN ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, jointly and severally, V. Bryan Lawlis and Thomas C. Chesterman, 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
<u>/s/ V. Bryan Lawlis</u> V. Bryan Lawlis	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 30, 2006
<u>/s/ Thomas C. Chesterman</u> Thomas C. Chesterman	Sr. VP and Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2006
<u>/s/ Virgil D. Thompson</u> Virgil D. Thompson	Chairman of the Board and Director	March 30, 2006
<u>/s/ Frank H. Barker</u> Frank H. Barker	Director	March 30, 2006
<u>/s/ Igor Gonda</u> Igor Gonda	Director	March 30, 2006
<u>/s/ Stephen O. Jaeger</u> Stephen O. Jaeger	Director	March 30, 2006
<u>/s/ John M. Nehra</u>	Director	

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John M. Nehra		March 30, 2006
/s/ Wayne L. Roe	Director	March 30, 2006
Wayne L. Roe		
/s/ Richard P. Thompson	Director	March 30, 2006
Richard P. Thompson		

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**Table of Contents****EXHIBIT INDEX**

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10.19(12)	

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	Securities Purchase Agreement, dated as of November 7, 2003, by and among the Company and the purchasers named therein.
10.20(13)	Securities Purchase Agreement, dated as of November 14, 2003, by and among the Company and the purchasers named therein.
10.21(16)#	Restructuring Agreement, dated as of September 18, 2004, by and among the Company, Novo Nordisk and Novo Nordisk Delivery Technologies, Inc.
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32.1	Section 906 Certification of the Chief Executive Officer and the Chief Financial Officer.

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

+ Represents a management contract or compensatory plan or arrangement.

# The Commission has granted the Company's request for confidential treatment with respect to portions of this exhibit.

- (1) Incorporated by reference to the Company's Form S-1 (No. 333-4236), as amended.
- (2) Incorporated by reference to the Company's Form 8-K filed on November 7, 1997.
- (3) Incorporated by reference to the Company's Form 10-K filed on March 24, 1998, as amended.
- (4) Incorporated by reference to the Company's Form 10-Q filed on August 14, 1998.
- (5) Incorporated by reference to the Company's 8-K filed on September 2, 1998.
- (7) Incorporated by reference to the Company's Form 10-K filed for the year ended December 31, 2000.
- (9) Incorporated by reference to the Company's Form S-3 (No. 333-76584).
- (10) Incorporated by reference to the Company's Form 10-K filed for the year ended December 31, 2001.
- (11) Incorporated by reference to the Company's Form 10-Q filed on May 13, 2003.
- (12) Incorporated by reference to the Company's Form 8-K filed on November 12, 2003.
- (13) Incorporated by reference to the Company's Form 8-K filed on November 20, 2003.
- (14) Incorporated by reference to the Company's definitive proxy statement filed on April 2, 2004
- (15) Incorporated by reference to the Company's Form 10-Q filed on August 13, 2004.

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- (16) Incorporated by reference to the Company's Form 10-Q filed on November 15, 2004
- (17) Incorporated by reference to the Company's Form 8-K filed on December 23, 2004.
- (18) Incorporated by reference to the Company's definitive proxy statement filed on April 7, 2005.
- (19) Incorporated by reference to the Company's Form 8-K filed on October 13, 2005.

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