

ARADIGM CORP
Form 424B3
February 09, 2005

Table of Contents

**Filed pursuant to Rule 424(b)(3)
Registration number 333-122223**

PROSPECTUS

10,416,742 Shares

Aradigm Corporation
Common Stock

This prospectus relates to the offer and sale, from time to time, of up to 10,416,742 shares of Aradigm Corporation common stock held by the selling security holders listed on page 12 of this prospectus, including common stock issuable upon exercise of warrants. The selling security holders purchased common stock and common stock warrants from Aradigm in a private placement that closed in December 2004. Aradigm will not receive any proceeds from the sale of the shares by the selling security holders.

For a description of the plan of distribution of the shares, see page 14 of this prospectus.

Our common stock is listed on The Nasdaq National Market under the symbol ARDM. On February 7, 2005, the last reported sale price for our common stock was \$1.70 per share.

Investing in our common stock involves risks. See Risk Factors on page 2.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is February 9, 2005.

TABLE OF CONTENTS

<u>THE COMPANY</u>	2
<u>RISK FACTORS</u>	2
<u>FORWARD-LOOKING STATEMENTS</u>	11
<u>USE OF PROCEEDS</u>	11
<u>SELLING SECURITY HOLDERS</u>	12
<u>PLAN OF DISTRIBUTION</u>	14
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	15
<u>LEGAL MATTERS</u>	16
<u>EXPERTS</u>	16

You should rely only on the information or representations provided in this prospectus or incorporated by reference into this prospectus. We have not authorized anyone to provide you with any different information or to make any different representations in connection with any offering made by this prospectus. This prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, in any state where the offer or sale is prohibited. Neither the delivery of this prospectus, nor any sale made under this prospectus shall, under any

circumstances, imply that the information in this prospectus is correct as of any date after the date of this prospectus.

Aradigm , AERx and Intraject are trademarks of the Company. This prospectus also includes trademarks owned by other parties.

Table of Contents

This prospectus contains forward-looking statements which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors appearing under Risk Factors and elsewhere in this prospectus.

THE COMPANY

The following summary does not contain all the information that may be important to you. You should read the entire prospectus, including the financial statements and other information incorporated by reference in this prospectus, before making an investment decision.

Aradigm Corporation

We are a leading developer of advanced needle-free drug delivery systems for the treatment of lung and systemic diseases. We are developing two technologies designed to deliver drugs and biologics either via the pulmonary or subcutaneous route. Our hand-held AERx platform is being designed for the rapid and reproducible delivery of a wide range of pharmaceutical drugs and biotech compounds via pulmonary delivery or through the lung. Our pen-sized, needle-free subcutaneous Intraject system is designed to comfortably and rapidly deliver drugs to the subcutaneous region of the skin, where they can gain access to the bloodstream. We believe that our non-invasive AERx and Intraject systems, which have been shown in clinical studies to achieve performance equivalent to injection, will be a welcome alternative to injection-based drug delivery. In addition, both of our systems may improve therapeutic efficacy in cases where other existing drug delivery methods, such as pills, transdermal patches or inhalers, are too slow or imprecise.

We were incorporated in California in January 1991. Our principal executive offices are located at 3929 Point Eden Way, Hayward, California 94545, and our telephone number is (510) 265-9000. Our Internet address is www.aradigm.com. The information on our website is not incorporated by reference into this prospectus.

RISK FACTORS

An investment in our common stock involves a high degree of risk. We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. You should carefully consider the factors described below in addition to other information contained in this prospectus or incorporated by reference into this prospectus before purchasing our shares. Additional risks and uncertainties not presently known to us or that we currently see as immaterial may also impair our business operations.

We are an early stage company.

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

We have a history of losses and anticipate future losses.

We have never been profitable, and through September 30, 2004, we have incurred a cumulative deficit of approximately \$239 million. We have not had any material product sales and do not anticipate receiving any revenue from product sales in 2005. We expect to continue to incur substantial losses over at least the next several years as we:

expand our research and development efforts;

2

Table of Contents

expand our preclinical and clinical testing activities;

expand our manufacturing efforts; and

plan and build our commercial production capabilities.

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

We may not be able to develop our products successfully.

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

We may not be able to commercialize products successfully.

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

safety;

efficacy;

ease of use; and

price.

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

We depend on collaborative partners and need additional collaborative partners.

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

Under the terms of the collaborative agreement with Novo Nordisk A/S in effect until the closing of the restructuring transaction with Novo Nordisk A/S and Novo Nordisk Delivery Technologies, Inc., Novo Nordisk A/S

Table of Contents

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

Under the terms of the Restructuring Agreement dated as of September 28, 2004 among us, Novo Nordisk A/S and Novo Nordisk Delivery Technologies, Inc., the Novo Nordisk parties have agreed to assume broader 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 insulin Diabetes Management System.

The development and commercialization of the AERx insulin Diabetes Management System will be delayed if Novo Nordisk A/S fails to conduct these activities in a timely manner or at all. In addition, our development partners could terminate these agreements and we have no assurance that we will receive any royalty or other payments. If we do not receive development funds or achieve milestones set forth in the agreements, or if any of our development partners breach or terminate their agreement, our business will be impaired.

Although we have development arrangements with other collaborative partners, in 2004 our arrangement with Novo Nordisk A/S was our only active funded development agreement. For the nine months ended September 30, 2004, this partner-funded program contributed approximately 97.3% of our total contract revenues. In connection with the Restructuring Agreement, we are entering into an Amended and Restated License Agreement that expands the license we have granted to Novo Nordisk A/S to include the right to develop and manufacture AERx iDMS and other licensed products. Novo Nordisk A/S may terminate this agreement at will, for our uncured material breach of various related agreements to which we and Novo Nordisk A/S or Novo Nordisk Delivery Technologies, Inc. are parties, and in connection with certain change in control events. If Novo Nordisk A/S terminates this agreement at will, Novo Nordisk A/S loses all rights to develop or market AERx products (or substantially similar products) but retains non-exclusive, royalty-bearing licenses to develop other pulmonary delivery products.

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

We have limited manufacturing experience.

We have validated only a single clinical manufacturing facility for disposable packets for our various AERx systems, and pursuant to the Restructuring Agreement with Novo Nordisk A/S and Novo Nordisk Delivery Technologies, Inc., responsibility for and control of this facility is being transferred to Novo Nordisk Delivery

Technologies, Inc.

Either we or our development partners 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:

Table of Contents

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.

As a result of the Restructuring Agreement with Novo Nordisk A/S and Novo Nordisk Delivery Technologies, Inc., we have limited capacity to manufacture key components of our drug delivery systems. Under the terms of a Contract Manufacturing Agreement we are entering into with Novo Nordisk Delivery Technologies, Inc. in connection with the restructuring transaction, Novo Nordisk Delivery Technologies, Inc. will supply devices and dosage forms to us for development of our other AERx programs. We may decide to attempt to invest in additional production and 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. Such investment would be significant and we have limited experience in manufacturing disposable unit-dose packets. There can be no assurance that we can successfully do so in high volumes, in a timely manner, at an acceptable cost, or at all.

We intend to use contract manufacturers to produce key components, assemblies and subassemblies in the clinical and commercial manufacturing of our 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 will need additional capital and our ability to find additional funding is uncertain.

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

progress in researching and developing our technology and drug delivery systems;

our ability to establish and maintain favorable collaborative arrangements with others;

progress with preclinical studies and clinical trials;

time and costs to obtain regulatory approvals;

costs of development and the rate at which we expand our production technologies;

costs of preparing, filing, prosecuting, maintaining and enforcing patent claims; and

Table of Contents

our need to acquire licenses or other rights to technology.

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

We anticipate that our existing cash balances at December 31, 2004, together with the proceeds from the sale of certain assets to Novo Nordisk Delivery Technologies, Inc. pursuant to the Restructuring Agreement dated as of September 28, 2004 among us, Novo Nordisk A/S and Novo Nordisk Delivery Technologies, research and development funding commitments from corporate development partners, and projected interest income, will enable us to maintain our current and planned operations at least through the end of 2005. 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.

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

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

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

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. In addition,

Table of Contents

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

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

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

We may incur substantial costs if we are required to defend ourselves in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process and we cannot assure you that any license required under any such patent would be made available to us on acceptable terms, if at all. Litigation may also be necessary to enforce our patents against others or to protect our know-how or trade secrets. Such litigation could result in substantial expense, and we cannot assure you that any litigation would be resolved in our favor.

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

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

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

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

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

disperse sites. All of the phases of clinical studies must be conducted in conformance with FDA's bioresearch monitoring regulations.

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

Table of Contents

warning letters;

fines;

product recalls or seizures;

injunctions;

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

withdrawals of previously approved marketing applications; and

criminal prosecutions.

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

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

Because certain of our clinical studies involve narcotics, we are registered with the Drug Enforcement Agency (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. To date, we have tested prototype patient-operated versions of our AERx systems with morphine, insulin and dornase alfa on a limited number of individuals in Phase 1 and Phase 2 clinical trials and have initiated a Phase 3 clinical trial for our AERx insulin Diabetes Management System. In addition, we have completed a clinical performance verification trial of our Intraject subcutaneous delivery system. If we do not or cannot complete trials that we have initiated 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

Table of Contents

will be needed to obtain necessary marketing approvals from the FDA and other regulatory agencies. We cannot assure you that these applications will prove to be viable or that any necessary regulatory approvals will be obtained in a timely manner, if at all.

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

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

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of alternative drug delivery systems or new drug research and testing, as well as with entities producing and developing injectable drugs. We are aware of a number of companies such as Alkermes Pharmaceuticals, Inc. and Nektar Therapeutics (formerly Inhale Therapeutic Systems) that are currently seeking to develop new products and non-invasive alternatives to injectable drug delivery, including oral delivery systems, intranasal delivery systems, transdermal systems, buccal and colonic absorption systems. These companies and others may have developed or are developing dry powder devices that could be used for pulmonary delivery and needle-free injection 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 FDA approval for products or gaining market acceptance more rapidly than we can.

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

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

We may be exposed to product liability.

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

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

Third-party reimbursement for our products is uncertain.

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

you that our products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement.

We use hazardous materials.

Our operations involve use of hazardous and toxic materials, chemicals and various radioactive compounds that generate hazardous, toxic and radioactive wastes. Although we believe that our safety procedures for handling and

Table of Contents

disposing of such materials comply with all state and federal regulations and standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any damages that result and such liability could exceed the resources of our business.

Our stock price is likely to remain volatile.

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

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

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

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

At various times during 2004, our common stock traded below \$1.00. The Nasdaq has a \$1.00 per share minimum bid requirement, pursuant to which our common stock could be de-listed from the Nasdaq National Market if it trades below \$1.00 for 30 consecutive trading days and does not subsequently trade above \$1.00 for 10 consecutive days. If

we are unable to meet the Nasdaq requirements to maintain listing on the Nasdaq National Market our common stock could trade on the OTC Bulletin Board or in the pink sheets maintained by the National Quotation Bureau, Inc. Such alternatives are generally considered to be less efficient markets, and our stock price, as well as the liquidity of our common stock, will be adversely impacted as a result. Any reverse stock split we may implement in order to increase the price at which our common stock is traded may not raise such price in proportion to the magnitude of the reverse stock split.

We have implemented certain anti-takeover provisions.

Table of Contents

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

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

FORWARD-LOOKING STATEMENTS

This prospectus contains forward looking statements, which include statements based on our current expectations, assumptions, estimates and projections about us and our industry, including statements about:

the timing and results of clinical trials;

regulatory approval;

the establishment of corporate partnering arrangements;

the anticipated commercial introduction of our products; and

projected capital expenditures and the timing of our cash requirements.

We use words such as believes, anticipates, expects, intends, plans and similar expressions to identify forward-looking statements, but these are not the exclusive means of identifying these statements. Actual results could differ materially from those projected in any forward-looking statements for the reasons detailed in Risk Factors or elsewhere in this prospectus. Before you decide to invest in our common stock, you should be aware that if any of the events described in the Risk Factors section and elsewhere in this prospectus occur, they could have an adverse affect on our business. We assume no obligation to update any forward-looking statement.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares by the selling security holders. All proceeds from the sale of the shares will be for the accounts of the selling security holders.

Table of Contents**SELLING SECURITY HOLDERS**

We are registering for resale shares of our common stock which have been sold to the selling security holders identified below or that may be issued upon exercise of the warrants to permit the selling security holders to resell the shares underlying the warrants. Pursuant to a securities purchase agreement dated as of December 17, 2004 among us and the selling security holders, we issued and sold, for an aggregate purchase price approximately of \$12,500,000:

an aggregate of 8,333,395 shares of our Common Stock; and

warrants to purchase an aggregate of 2,083,347 shares of our common stock at an exercise price of \$2.10 per share, which warrants are exercisable at the election of the selling security holders on or prior to December 22, 2008.

The table below presents information as of the date of this prospectus regarding the selling security holders and the shares that they may offer and sell from time to time under this prospectus. The shares of common stock covered, as to their resale, under this prospectus include shares of common stock sold at the financing and issuable upon exercise of warrants.

This table is prepared based in part on information supplied to us by the listed selling security holders prior to the date of this prospectus. The table assumes that the selling security holders sell all of the shares offered under this prospectus. However, because the selling security holders may offer from time to time all or some of their shares under this prospectus, or in another permitted manner, we cannot assure you as to the actual number of shares that will be sold by the selling security holders or that will be held by the selling security holders after completion of the sales. Information concerning the security holders may change from time to time and changed information will be presented in a supplement to this prospectus if and when necessary and required.

Security Holders	Shares Owned Prior to Offering		Number of Shares Being Offered	Shares Owned After Offering	
	Number (1)	Percent (1)		Number(1)	Percent (1)
BayStar Capital II LP (2)	902,777	1.2	625,000	277,777	*
Biotechnology Value Fund II, L.P. (3)	475,000	*	475,000		
Biotechnology Value Fund, L.P. (4)	750,000	1.0	750,000		
BVF Investments, LLC (5)	1,150,000	1.6	1,150,000		
Capital Ventures International (6)	1,144,197	1.6	625,000	519,197	*
Castle Creek Healthcare Partners LLC (7)	931,830	1.3	416,667	515,163	*
Catalytix Life Science Hedge (8)	83,332	*	83,332		
Catalytix, LDC (9)	83,333	*	83,333		
CC Lifescience Ltd. (10)	931,829	1.3	416,666	515,163	*
Investment 10, L.L.C. (11)	125,000	*	125,000		
Penn Footwear Co. (12)	1,034,472	1.4	843,500	190,972	*
ProMed Offshore Fund II, Ltd. (13)	441,500	*	441,500		
ProMed Offshore Fund, Ltd. (14)	72,250	*	72,250		
ProMed Partners II, L.P. (15)	107,750	*	107,750		
ProMed Partners, L.P. (16)	451,750	*	451,750		
SF Capital Partners Ltd. (17)	625,000	*	625,000		
Silverback Life Sciences Master Fund, Ltd. (18)	625,000	*	625,000		
Straus GEPT Partners, LP (19)	451,600	*	375,000	76,600	*

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Straus Partners, LP (20)	573,132	*	458,332	114,800	*
UBS O Connor LLC F/B/O O Connor PIPES Corporate Strategies Master Limited (21)	416,662	*	416,662		
Ursus Capital LP (22)	455,625	*	455,625	415,487	*
Ursus Offshore Ltd. (23)	169,375	*	169,375	279,512	*
Walker Smith Capital (QP), L.P. (24)	166,666	*	166,666		
Walker Smith Capital, L.P. (25)	33,333	*	33,333		
Walker Smith International Fund, Ltd. (26)	216,667	*	216,667		
WS Opportunity Fund (QP), L.P. (27)	70,834	*	70,834		
WS Opportunity Fund International, Ltd. (28)	79,166	*	79,166		
WS Opportunity Fund, L.P. (29)	58,334	*	58,334		

* Less than one percent (1%)

Table of Contents

- (1) Shares owned equals the sum of (a) shares of common stock and (b) shares of common stock issuable upon exercise of warrants. Percentages are based on 72,295,730 shares of our common stock that were outstanding (on an as-converted to common stock basis) on December 22, 2004. In calculating the percentage for each selling security holder, the shares represented by item (b) above are treated as shares outstanding for that selling security holder but are not treated as outstanding for any other person.
- (2) Includes 402,777 shares of common stock issuable upon exercise of warrants (including a warrant to purchase 125,000 shares of common stock received in connection with the December 17, 2004 Agreement).
- (3) Includes 95,000 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (4) Includes 150,000 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (5) Includes 230,000 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (6) Includes 644,197 shares of common stock issuable upon exercise of warrants (including a warrant to purchase 125,000 shares of common stock received in connection with the December 17, 2004 Agreement).
- (7) Includes 598,496 shares of common stock issuable upon exercise of warrants (including a warrant to purchase 83,333 shares of common stock received in connection with the December 17, 2004 Agreement).
- (8) Includes 16,666 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (9) Includes 16,667 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (10) Includes 598,496 shares of common stock issuable upon exercise of warrants (including a warrant to purchase 83,333 shares of common stock received in connection with the December 17, 2004 Agreement).
- (11) Includes 25,000 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (12) Includes 359,672 shares of common stock issuable upon exercise of warrants (including a warrant to purchase 168,700 shares of common stock received in connection with the December 17, 2004 Agreement).
- (13) Includes 88,300 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (14) Includes 14,450 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (15) Includes 21,550 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (16)

Includes 90,350 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.

- (17) Includes 125,000 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (18) Includes 125,000 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (19) Includes 75,000 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (20) Includes 91,666 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (21) Includes 83,332 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (22) Includes 153,112 shares of common stock issuable upon exercise of warrants (including a warrant to purchase 91,125 shares of common stock received in connection with the December 17, 2004 Agreement).
- (23) Includes 106,887 shares of common stock issuable upon exercise of warrants (including a warrant to purchase 33,875 shares of common stock received in connection with the December 17, 2004 Agreement).
- (24) Includes 33,333 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.

Table of Contents

- (25) Includes 6,667 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (26) Includes 43,333 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (27) Includes 14,167 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (28) Includes 15,833 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.
- (29) Includes 11,667 shares of common stock issuable upon exercise of warrants received in connection with the December 17, 2004 Agreement.

PLAN OF DISTRIBUTION

The shares may be sold or distributed from time to time by the selling security holders or by pledgees, donees, transferees or other successors-in-interest selling shares received from a named selling security holder as a gift, partnership distribution or other non-sale-related transfer after the date of this prospectus. The selling security holders will act independently of us in making decisions with respect to the timing, manner and size of each sale of the common stock covered in this prospectus. The shares will be offered on the Nasdaq National Market System or in privately negotiated transactions. The selling security holders may sell the shares registered here in one or more of the following methods:

cross trades or block trades in which the broker or dealer so engaged will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker or dealer as principal and resale by a broker or dealer for its own account under this prospectus;

at the market to or through market makers or into an existing market for the shares;

ordinary brokerage transactions and transactions in which the broker solicits purchasers, which may include long sales or short sales effected after the effective date of the registration statement of which this prospectus is a part;

in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;

through transactions in options, swaps or other derivatives (whether exchange-listed or otherwise); or

any combination of the foregoing, or by any other legally available means.

The selling security holders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In these transactions, broker-dealers may engage in short sales of the shares in the course of hedging the positions they assume with the selling security holders, provided that they hold an offsetting long position in the shares. The selling security holders also may sell shares short, provided that they hold an offsetting long position in the shares, and redeliver the shares to close out short positions. The selling security holders may also enter into option or other transactions with brokers or dealers that require the delivery by these brokers or dealers of the shares, which shares may be resold thereafter pursuant to this prospectus. In addition, a selling security

holder may pledge its shares to brokers or dealers or other financial institutions. Upon a default by a selling security holder, the brokers, dealers or financial institutions may offer and sell the pledged shares.

Underwriters, broker-dealers and agents that participate in the distribution of shares may be deemed to be underwriters and any discounts or commissions received by them from the selling security holders and any profit on the resale of shares by them may be deemed to be underwriting discounts and commissions under the Securities Act. In addition, selling security holders that are affiliates of broker-dealers may be deemed to be underwriters. At such time that the selling security holders elect to make an offer of shares, a prospectus supplement, if required, will be distributed that will identify any underwriters, dealers or agents and any discounts, commissions and other terms constituting compensation from such selling security holders and any other required information.

Table of Contents

Under agreements which may be entered into by the selling security holders, underwriters who participate in the distribution of shares may be entitled to indemnification by the selling security holders against certain liabilities, including liabilities under the Securities Act. We have also agreed to indemnify, in certain circumstances, the selling security holders and certain control and other persons related to the foregoing persons against certain liabilities, including liabilities under the Securities Act. The selling security holders have agreed to indemnify us in certain circumstances, as well as certain related persons, against certain liabilities, including liabilities under the Securities Act.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling security holders will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of shares of our common stock by the selling security holders. We will make copies of this prospectus available to the selling security holders and have informed the selling security holders of the need to deliver copies of this prospectus to purchasers at or prior to the time of any sale of the shares.

Some of the underwriters or agents and their associates may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

The selling security holders are not obligated to, and there is no assurance that the selling security holders will, sell any or all of the shares.

We will bear all costs, expenses and fees in connection with the registration of the shares. The selling security holders will pay all commissions and discounts, if any, associated with the sale of the shares.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement on Form S-3 we filed with the Securities and Exchange Commission. You should rely only on the information contained in this prospectus or incorporated by reference. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of common stock.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and in accordance therewith, file reports, proxy statements and other information with the Securities and Exchange Commission. Such reports, proxy statements and other information filed by us may be inspected and copied at the Commission's Public Reference Section located at 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such material also can be obtained from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. Please call the Commission at 1-800-SEC-0330 for more information about the operation of the public reference rooms. The Commission also makes electronic filings publicly available on the Internet. The Commission's Internet address is <http://www.sec.gov>. The Commission's web site also contains reports, proxy and information statements and other information regarding us that has been filed with the Commission. Our common stock is quoted on the Nasdaq National Market. Reports, proxy statements and other information concerning us may be inspected at the National Association of Securities Dealers, Inc. at 1735 K Street, N.W., Washington, D.C. 20006.

This prospectus does not contain all of the information set forth in the registration statement.

The Commission allows us to incorporate by reference information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the Commission will automatically update and supersede this information. Further, all filings we make under the Securities Exchange Act of 1934 after the date of the initial registration statement and prior to effectiveness of the registration statement shall be deemed to be incorporated by reference into this prospectus. We incorporate by reference the documents

Table of Contents

listed below and any future filings we will make with the Commission under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934:

- (i) Our Annual Report on Form 10-K for the fiscal year ended December 31, 2003, including all material incorporated by reference therein;
- (ii) Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2004, June 30, 2004 and September 30, 2004;
- (iii) Our Current Reports on Form 8-K dated September 28, 2004, December 17, 2004, January 26, 2005 and February 2, 2005;
- (iv) Pages 9, 10, 18 and 33-44 of our definitive proxy statement filed with the SEC on Schedule 14A on December 22, 2004, relating to the Special Meeting of Shareholders held on January 21, 2005; and
- (v) The description of the common stock contained in our Registration Statement on Form 8-A.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request of such person, a copy of any and all of the documents that have been incorporated by reference in this prospectus (not including exhibits to such documents, unless such exhibits are specifically incorporated by reference in this prospectus or into such documents). Such request may be directed to: Investor Relations Department, Aradigm Corporation, 3929 Point Eden Way, Hayward, California 94545, telephone (510) 265-9000.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon by Cooley Godward LLP, San Francisco, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, have audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2003, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.