

ARADIGM CORP
Form 10-K
March 30, 2009

Table of Contents

**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, 2008
- 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-known 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 ☐

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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. ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒
(Do not check if a smaller reporting company)

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, 2008 was: \$41,192,879.

The number of shares of the registrant's common stock outstanding as of February 27, 2009 was: 99,968,455

DOCUMENTS INCORPORATED BY REFERENCE

Parts of the Proxy Statement for the Registrant's Annual Meeting of Shareholders to be held in May 2009 are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

	Page
<u>PART I</u>	
<u>Item 1.</u> <u>Business</u>	1
<u>Item 1A.</u> <u>Risk Factors</u>	21
<u>Item 1B.</u> <u>Unresolved Staff Comments</u>	32
<u>Item 2.</u> <u>Properties</u>	32
<u>Item 3.</u> <u>Legal Proceedings</u>	33
<u>Item 4.</u> <u>Submission of Matters to a Vote of Security Holders</u>	33
<u>PART II</u>	
<u>Item 5.</u> <u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	33
<u>Item 6.</u> <u>Selected Financial Data</u>	34
<u>Item 7.</u> <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	35
<u>Item 7A.</u> <u>Quantitative and Qualitative Disclosure About Market Risk</u>	43
<u>Item 8.</u> <u>Financial Statements and Supplementary Data</u>	44
<u>Item 9.</u> <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	72
<u>Item 9A.</u> <u>Controls and Procedures</u>	72
<u>Item 9B.</u> <u>Other Information</u>	72
<u>PART III</u>	
<u>Item 10.</u> <u>Directors, Executive Officers and Corporate Governance</u>	73
<u>Item 11.</u> <u>Executive Compensation</u>	73
<u>Item 12.</u> <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	73
<u>Item 13.</u> <u>Certain Relationships and Related Transactions and Director Independence</u>	73
<u>Item 14.</u> <u>Principal Accountant Fees and Services</u>	73
<u>PART IV</u>	
<u>Item 15.</u> <u>Exhibits and Financial Statement Schedules</u>	74
<u>SIGNATURES</u>	77
<u>EX-23.1</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	

Table of Contents

Forward Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. When used in this Annual Report the words anticipate, objective, may, might, should, could, can, intend, expect, believe, estimate, predict, negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about: our expectations regarding our future expenses, sales and operations; our anticipated cash needs and our estimates regarding our capital requirements and our need for additional financing; the expected development path and timing of our product candidates; our expectations regarding the use of Section 505(b)(2) of the United States Food, Drug and Cosmetic Act and an expedited development and regulatory process; our ability to obtain and derive benefits from orphan drug designation; our ability to anticipate the future needs of our customers; our plans for future products and enhancements of existing products; our growth strategy elements; the anticipated trends and challenges in the markets in which we operate; and our ability to attract customers.

These statements reflect our current views with respect to uncertain future events and are based on imprecise estimates and assumptions and subject to risk and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. While we believe our plans, intentions and expectations reflected in these forward-looking statements are reasonable, these plans, intentions or expectations may not be achieved. Our actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements contained in this Annual Report for a variety of reasons, including those under the heading Risk Factors.

All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the risk factors and other cautionary statements set forth in this Annual Report. Other than as required by applicable securities laws, we are under no obligation, and we do not intend, to update any forward-looking statement, whether as result of new information, future events or otherwise.

PART I

Item 1. Business

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. Over the last decade, we invested a large amount of capital to develop drug delivery technologies, particularly the development of a significant amount of expertise in pulmonary drug delivery. We also invested considerable effort into the generation of a large volume of laboratory and clinical data demonstrating the performance of our AERx® pulmonary drug delivery platform. We have not been profitable since inception and expect to incur additional operating losses over at least the next several years as we expand product development efforts, preclinical testing, clinical trial activities, and possible sales and marketing efforts, and as we secure production capabilities from outside contract manufacturers. To date, we have not had any significant product sales and do not anticipate receiving any revenues from the sale of products in the near term. As of December 31, 2008, we had an accumulated deficit of \$334.7 million. Historically, we have funded our operations primarily through public offerings and private placements of our capital stock, proceeds from equipment lease financings, license fees and milestone payments from collaborators, proceeds from the January 2005 restructuring transaction with Novo Nordisk, borrowings from Novo Nordisk, sale of Intraject related assets and interest earned on investments. In February 2009, we closed the sale of 44,663,071 shares of common stock in a registered direct offering with net proceeds, after expenses, of \$4.1 million.

Over the last three years, our business has focused on opportunities for product development for treatment of severe respiratory diseases that we could develop and commercialize in the United States without a partner, or be able to retain co-marketing rights in the United States for such products. In selecting our proprietary development programs, we primarily seek drugs approved by the United States Food and Drug Administration (FDA) that can be reformulated for both existing and new indications in respiratory disease. Our intent is to use our pulmonary

Table of Contents

delivery methods and formulations to improve their safety, efficacy and convenience of administration to patients. We believe that this strategy will allow us to reduce cost, development time and risk of failure, when compared to the discovery and development of new chemical entities. It is our longer term strategy to commercialize our respiratory product candidates with our own focused sales and marketing force addressing pulmonary specialty doctors in the United States, where we believe that a proprietary sales force will enhance the return to our shareholders. Where our products can benefit a broader population of patients in the United States or in other countries, we may enter into co-development, co-promotion or other marketing arrangements with collaborators, thereby reducing costs and increasing revenues through license fees, milestone payments and royalties. Our lead development candidate in Phase 2 clinical trials is a proprietary liposomal formulation of the antibiotic ciprofloxacin that is delivered by inhalation for the treatment of infections associated with the severe respiratory diseases cystic fibrosis and bronchiectasis. The same formulation could also be potentially used for the prevention and treatment of inhaled anthrax. In the near term given our financial resources, our focus will be on completing a Phase 2b clinical trial of liposomal ciprofloxacin in a single indication.

Historically, our development activities consisted primarily of collaborations and product development agreements with third parties. The most notable collaboration was with Novo Nordisk on the AERx[®] insulin Diabetes Management System (iDMS) for the treatment of Type I and Type II diabetes. This program began in 1998 and included nine Phase 3 clinical trials in Type I and Type II diabetes patients. From 1998 through December 31, 2007, we received approximately \$150 million in product development and milestone payments from Novo Nordisk. On April 30, 2008, Novo Nordisk announced that following recent reports of lung cancer in Type II diabetes patients treated with Exubera*, an inhaled insulin product from Pfizer, the likelihood of achieving a positive benefit/risk ratio for future pulmonary diabetes projects had become more uncertain, and as a result, Novo Nordisk had decided to stop all research and development activities in the field. In May 2008, the July 3, 2006 License Agreement between us and Novo Nordisk was terminated. Pursuant to the License Agreement, on September 25, 2008, Novo Nordisk assigned, at no charge to us, the inhaled insulin-related patents, which Novo Nordisk purchased from us in July 2006, as well as certain related patents that originate from Novo Nordisk. The portfolio includes both U.S. and foreign patents. We assume the responsibility for the maintenance of this portfolio. Novo Nordisk is also providing us with the data from the preclinical and clinical research generated during the collaboration. We do not intend to complete the development of AERx iDMS on our own. We are attempting to out-license or sell the assets associated with inhaled insulin.

Pulmonary delivery by inhalation is already a widely used and well accepted method of administration of a variety of drugs for the treatment of respiratory diseases. Compared to other routes of administration, inhalation provides local delivery of the drug to the respiratory tract, offering a number of potential advantages, including rapid onset of action, less drug required to achieve the desired therapeutic effect, and reduced side effects because the rest of the body has lower exposure to the drug. We believe that there still are significant unmet medical needs in the respiratory disease market, both to replace existing therapies that over prolonged use in patients demonstrate reduced efficacy or increased side effects, as well as to provide novel treatments to patient populations and for disease conditions that are inadequately treated.

In addition to its use in the treatment of respiratory diseases, there is also an increasing awareness of the value of the inhalation route of delivery to administer drugs via the lung for the systemic treatment of disease elsewhere in the body. For many drugs, the large and highly absorptive area of the lung enables bioavailability as a result of pulmonary delivery that could otherwise only be obtained by injection. We believe that the features of our AERx delivery system make it more attractive for many systemic drug applications than alternative methods. We believe particular opportunities exist for the use of our pulmonary delivery technology for the delivery of biologics, including proteins, antibodies and peptides, that today must be delivered by injection, as well as small molecule drugs, where rapid absorption is desirable. We intend to pursue selected opportunities for systemic delivery via inhalation by seeking collaborations that will fund development and commercialization.

We believe that our proprietary formulation and delivery technologies and our experience in the development and management of pulmonary clinical programs uniquely position us to benefit from opportunities in the respiratory disease market as well as other pharmaceutical markets that would benefit from the efficient, non-invasive inhalation delivery of drugs.

Table of Contents

Our Strategy

We have been transitioning our business model toward a specialty pharmaceutical company focused on development and commercialization of a portfolio of drugs delivered by inhalation for the treatment of respiratory diseases. We have chosen to focus on respiratory diseases based on the expertise of our management team and the history of our company. We have significant experience in the treatment of respiratory diseases and specifically in the development of inhalation products that are uniquely suited for their treatment. We have a portfolio of proprietary technologies that may potentially address significant unmet medical needs for better products in the global respiratory market. There are five key elements of our strategy:

Develop a proprietary portfolio of products for the treatment of respiratory diseases. We believe our expertise in the development of pulmonary pharmaceutical products should enable us to advance and commercialize respiratory products for a variety of indications. We select for development those products that can benefit from our experience in pulmonary delivery and that we believe are likely to provide a superior therapeutic profile or other valuable benefits to patients when compared to existing products.

Accelerate the regulatory approval process. We believe our management team's expertise in pharmaceutical inhalation products, new indications and reformulations of existing drugs will enable us to pursue the most appropriate regulatory pathway for our product candidates. Because most of our current product candidates incorporate FDA-approved drugs, we believe that the most expedient review and approval pathway for many of these product candidates in the United States will be under Section 505(b)(2) of the Food, Drug and Cosmetic Act, or the FDCA. Section 505(b)(2) permits the FDA to rely on scientific literature or on the FDA's prior findings of safety and/or effectiveness for approved drug products. By choosing to develop new applications or reformulations of FDA-approved drugs, we believe that we can substantially reduce or potentially eliminate the significant time, expenditure and risks associated with preclinical testing of new chemical entities and biologics, as well as utilize knowledge of these approved drugs to reduce the risk, time and cost of the clinical trials needed to obtain drug approval. In addressing niche market opportunities, we intend to pursue orphan drug designation for our products when appropriate. Orphan drug designation may be granted to drugs and biologics that treat rare life-threatening diseases that affect fewer than 200,000 persons in the United States. Such designation provides a company with the possibility of market exclusivity for up to seven years as well as regulatory assistance, reduced filing fees and possible tax credits.

Develop our own sales and marketing capacity for products in niche markets. It is our longer term strategy to develop our own targeted sales and marketing force for those of our products prescribed primarily by the approximately 11,000 pulmonologists, or their subspecialty associates, in the United States. We expect to begin establishing a sales force as we approach commercialization of the first of such products. We believe that by developing a small sales group dedicated to interacting with disease-specific physicians in the respiratory field, we can create greater value from our products for our shareholders. For markets where maximizing sales of the product would depend on marketing to primary healthcare providers that are only addressable with a large sales force, we plan to enter into co-marketing arrangements. We also intend to establish collaborative relationships to commercialize our products in cases where we cannot meet these goals with a small sales force or when we need collaborators with relevant expertise and capabilities, such as the ability to address international markets. Through such collaborations, we may also utilize our collaborators' resources and expertise to conduct large late-stage clinical development.

Exploit the broad applicability of our delivery technology through product development collaborations. We continue to believe that companies can benefit by collaborating with us when our proprietary delivery technologies create new pharmaceutical and biologics products. We intend to continue to exploit the broad applicability of our delivery technologies for systemic applications of our validated technologies in

collaborations with companies that will fund development and commercialization. We intend to continue to out-license technologies and product opportunities that we have already developed to a certain stage and that are outside of our core strategic focus. Collaborations and out-licensing may generate additional revenues while we progress towards the development and potential launch of our own proprietary products.

Table of Contents

Outsource manufacturing activities. We intend to outsource the late stage clinical and commercial scale manufacturing of our products to conserve our capital for product development. We believe that the manufacturing processes for our AERx delivery systems are now sufficiently advanced that the required late stage clinical and commercial manufacturing capacity can be obtained from contract manufacturers. We are also utilizing contract manufacturers to make our liposomal formulations. With this approach, we seek manufacturers whose expertise should allow us to reduce risk and the costs normally incurred if we were to build, operate and maintain large-scale production facilities ourselves.

Product Candidates

Product candidates in development include both our own proprietary products and products under development with collaborators. They consist of approved drugs combined with our inhalation delivery and/or formulation technologies. The following table shows the disease indication and stage of development for each product candidate in our portfolio.

Product Candidate	Indication	Stage of Development
Proprietary Programs Under Development		
ARD-3100 (Liposomal ciprofloxacin)	Cystic Fibrosis	Phase 2
ARD-3150 (Liposomal ciprofloxacin)	Bronchiectasis	Phase 2
ARD-1100 (Liposomal ciprofloxacin)	Inhalation Anthrax	Preclinical
ARD-1600 (Nicotine)	Tobacco Smoking Cessation	Phase 1
Collaborative Programs Under Development		
ARD-1550 (Inhaled treprostinil)	Pulmonary Arterial Hypertension	Phase 1
ARD-1500 (Inhaled liposomal treprostinil)	Pulmonary Arterial Hypertension	Preclinical
ARD-1700 (combination products)	Asthma, COPD	Preclinical

We periodically conduct feasibility studies with other parties in an effort to utilize our expertise and intellectual property for product candidates that could potentially bring us revenues from partners.

Proprietary Programs Under Development***Liposomal Ciprofloxacin***

Ciprofloxacin has been approved by the FDA as an anti-infective agent and is widely used for the treatment of a variety of bacterial infections. Today ciprofloxacin is delivered by oral or intravenous administration. We believe that delivering this potent antibiotic directly to the lung may improve its safety and efficacy in the treatment of pulmonary infections. We believe that our novel sustained release formulation of ciprofloxacin may be able to provide high and prolonged concentrations of the antibiotic within infected lung tissues, while reducing systemic exposure and the resulting side effects seen with currently marketed ciprofloxacin products. To achieve this sustained release, we employ liposomes, which are lipid-based nanoparticles dispersed in water that encapsulate the drug during storage and release the drug gradually upon contact with fluid covering the airways and the lung. In an animal experiment, ciprofloxacin delivered to the lung of mice appeared to be rapidly absorbed into the bloodstream, with no drug detectable four hours after administration. In contrast, the liposomal formulation of ciprofloxacin produced significantly higher levels of ciprofloxacin in the lung at all time points and was still detectable at 12 hours post

dosing. We also believe that for certain respiratory disease indications it may be possible that a liposomal formulation enables better interaction of the drug with the disease target, leading to improved effectiveness over other therapies. We have at present under development three disease indications for this formulation that share much of the laboratory and production development efforts, as well as a common safety data base.

Table of Contents

ARD-3100 Liposomal Ciprofloxacin for the Treatment of Infections in Cystic Fibrosis (CF) Patients

One of our liposomal ciprofloxacin programs is a proprietary program using our liposomal formulation of ciprofloxacin for the treatment and control of respiratory infections common to patients with cystic fibrosis, or CF. CF is a genetic disease that causes thick, sticky mucus to form in the lungs, pancreas and other organs. In the lungs, the mucus tends to block the airways, causing lung damage and making these patients highly susceptible to lung infections. According to the Cystic Fibrosis Foundation, CF affects roughly 30,000 children and adults in the United States and roughly 70,000 children and adults worldwide. According to the American Lung Association, the direct medical care costs for an individual with CF are currently estimated to be in excess of \$40,000 per year.

The inhalation route affords direct administration of the drug to the infected part of the lung, maximizing the dose to the affected site and minimizing the wasteful exposure to the rest of the body where it could cause side effects. Therefore, treatment of CF-related lung infections by direct administration of antibiotics to the lung may improve both the safety and efficacy of treatment compared to systemic administration by other routes, as well as improving patient convenience as compared to injections. Oral and injectable forms of ciprofloxacin are approved for the treatment of *Pseudomonas aeruginosa*, a lung infection to which CF patients are vulnerable. Currently, there is only one inhalation antibiotic approved for the treatment of this infection which is given twice a day by nebulization. We believe that local lung delivery via inhalation of ciprofloxacin in a sustained release formulation could provide a convenient, effective and safe treatment of the debilitating and often life-threatening lung infections that afflict patients with CF. We think that once a day dosing of inhaled liposomal ciprofloxacin could also be a welcome reduction in the burden of therapy for this patient population. We have received orphan drug designations from the FDA for this product for the management of CF.

We believe we have the preclinical development, clinical and regulatory expertise to advance this product through development. We intend to retain marketing or co-marketing rights for the inhaled liposomal ciprofloxacin formulations in the United States.

Development

We initiated preclinical studies for liposomal ciprofloxacin in 2006 and we also continued to work on new innovative formulations for this product with the view to maximize the safety, efficacy and convenience to patients. In October 2007, we completed a Phase 1 clinical trial in 20 healthy volunteers in Australia. This was a safety, tolerability and pharmacokinetic study that included single dose escalation followed by dosing for one week. Administration of the liposomal formulation by inhalation was well tolerated and no serious adverse reactions were reported. The pharmacokinetic profile obtained by measurement of blood levels of ciprofloxacin following the inhalation of the liposomal formulation was consistent with the profile from sustained release of ciprofloxacin from liposomes, supporting once daily dosings; the blood levels of ciprofloxacin were much lower than those that would be observed following administration of therapeutic doses of ciprofloxacin by injection or via the gastrointestinal tract. We believe that this is a desirable pharmacokinetic profile likely to result in reduction of the incidence and severity of systemic side effects of ciprofloxacin and to be less likely to lead to systemic emergence of resistant micro-organisms. Further, we believe that once a day dosing of this product could provide a significant reduction in the burden of therapy for CF patients and their healthcare providers.

In June 2008, we completed a multi-center 14-day treatment Phase 2a trial in Australia and New Zealand in 21 CF patients to investigate safety, efficacy and pharmacokinetics of once daily inhaled liposomal ciprofloxacin. The primary efficacy endpoint in this Phase 2a study was the change from baseline in the sputum *Pseudomonas aeruginosa* colony forming units (CFU), an objective measure of the reduction in pulmonary bacterial load. Data analysis in 21 patients who completed the study demonstrated that the CFUs decreased by a mean 1.43 log over the 14-day treatment period ($p < 0.0001$). Evaluation one week after study treatment was discontinued showed that the

Pseudomonas bacterial density in the lung was still reduced from the baseline without additional antibiotic use. Pulmonary function testing as measured by the forced expiratory volume in one second (FEV1) showed a significant mean increase of 6.86% from baseline after 14 days of treatment ($p=0.04$). The study drug was well tolerated, and there were no serious adverse events reported during the trial.

Table of Contents

In order to expedite anticipated time to market and increase market acceptance, we have elected to deliver our formulation via nebulizer, as most CF patients already own a nebulizer and are familiar with this method of drug delivery. We intend to examine the potential for delivery of ciprofloxacin via our AERx delivery system as well.

ARD 3150 Liposomal Ciprofloxacin for the Treatment of Infections in Non-Cystic Fibrosis Bronchiectasis (BE) Patients

Bronchiectasis is a chronic condition characterized by abnormal dilatation of the bronchi and bronchioles associated with chronic infection. It is frequently observed in patients with CF. However, it is a condition that affects about 110,000 people without CF in the United States and many more in other countries, and results from a cycle of inflammation, recurrent infection, and bronchial wall damage. There is currently no drug specifically approved for the treatment of non-CF bronchiectasis in the US. We were granted orphan-drug designation in the US for the management of this condition with inhaled liposomal ciprofloxacin. We believe we have the preclinical development, clinical and regulatory expertise to advance this product through development. We intend to retain marketing or co-marketing rights for the inhaled liposomal ciprofloxacin formulations in the United States.

Development

Pre-clinical and Phase 1 clinical activities described above for ARD-3100 are also utilized by the ARD-3150 program.

In December 2008, we completed an open-label, four week treatment study of efficacy, safety and tolerability of once daily inhaled liposomal ciprofloxacin in patients with non-CF bronchiectasis. The study was conducted at eight leading centers in the United Kingdom and enrolled a total of 36 patients. The patients were randomized into two equal size groups, one receiving 3 mL of inhaled liposomal ciprofloxacin and the other receiving 6 mL of inhaled liposomal ciprofloxacin, once-a-day for the four-week treatment period. The primary efficacy endpoint was the change from baseline in the sputum *Pseudomonas aeruginosa* CFU, the standard objective measure of the reduction in pulmonary bacterial load. The 3 mL and 6 mL doses of inhaled liposomal ciprofloxacin in the evaluable patient population demonstrated significant mean decreases against baseline in the *Pseudomonas aeruginosa* CFUs over the 28-day treatment period of 3.5 log ($p < 0.001$) and 4.0 log ($p < 0.001$) units, respectively.

With regard to safety, there were no statistically significant changes in lung function for the evaluable patient population at the end of treatment as measured by the normalized forced expiratory volume in one second (FEV1% predicted). Inhaled liposomal ciprofloxacin was well tolerated: no bronchodilator use was mandated or needed before administration of the study drug. In the 3 mL group, respiratory drug-related adverse reactions were only mild. Three serious adverse events (SAEs) were observed in each dose group, with only one of the six classified as possibly drug-related in the 6 mL group. This particular patient suffered from a recurrent episode of a viral infection (shingles) early in the treatment period that might have been a confounding factor leading ultimately to a respiratory exacerbation requiring hospitalization.

In order to expedite anticipated time to market and increase market acceptance, we have elected to deliver our formulation via nebulizer. We intend to examine the potential for delivery of ciprofloxacin via our AERx delivery system as well.

The CF and BE programs incorporate formulation and manufacturing processes and the early preclinical safety data developed for our inhalation anthrax program discussed below. We believe our inhaled liposomal ciprofloxacin could be explored also for the treatment of other serious respiratory infections, such as those occurring in severe COPD patients.

We intend to finalize development plans and budgets for the CF and BE programs in conjunction with discussions with the FDA. We are seeking partnerships for these programs in order to reduce the overall cost to us of development and to bring additional expertise for the global development and commercialization of inhaled liposomal ciprofloxacin for multiple indications.

Table of Contents

ARD-1100 Liposomal Ciprofloxacin for the Treatment of Inhalation Anthrax

The third of our liposomal ciprofloxacin programs is for the prevention and treatment of pulmonary anthrax infections. Anthrax spores are naturally occurring in soil throughout the world. Anthrax infections are most commonly acquired through skin contact with infected animals and animal products or, less frequently, by inhalation or ingestion of spores. With inhalation anthrax, once symptoms appear, fatality rates are high even with the initiation of antibiotic and supportive therapy. Further, a portion of the anthrax spores, once inhaled, may remain dormant in the lung for several months and germinate. Anthrax has been identified by the Centers for Disease Control as a likely potential agent of bioterrorism. In the fall of 2001, when anthrax-contaminated mail was deliberately sent through the United States Postal Service to government officials and members of the media, five people died and many more became sick. These attacks highlighted the concern that inhalation anthrax and similar types of inhaled bacterial (e.g. tularemia) bioterror agents represents a real and current threat.

Ciprofloxacin has been approved by the FDA for use orally and via injection for the treatment of inhalation anthrax (post-exposure) since 2000. Our ARD-1100 research and development program has been funded by Defence Research and Development Canada, or DRDC, a division of the Canadian Department of National Defence. We believe that our product candidate may potentially be able to deliver a long-acting formulation of ciprofloxacin directly into the lung and could have fewer side effects and be more effective to prevent and treat inhalation anthrax than currently available therapies.

Development

We began our research into liposomal ciprofloxacin for the treatment of inhalation anthrax under a technology demonstration program funded by the DRDC as part of their interest in developing products to counter bioterrorism. The DRDC had already demonstrated the feasibility of inhaled liposomal ciprofloxacin for post-exposure prophylaxis of *Francisella tularensis*, a potential bioterrorism agent similar to anthrax. Mice were exposed to a lethal dose of *F. tularensis* and then 24 hours later were exposed via inhalation to a single dose of free ciprofloxacin, liposomal ciprofloxacin or saline. All the mice in the control group and the free ciprofloxacin group were dead within 11 days post-infection; in contrast, all the mice in the liposomal ciprofloxacin group were alive 14 days post-infection. The same results were obtained when the mice received the single inhaled treatment as late as 48 or 72 hours post-infection. The DRDC has funded our development efforts to date and additional development of this program is dependent on negotiating for and obtaining additional funding from DRDC or on identifying other collaborators or sources of funding. We plan to use our preclinical and clinical safety data from our CF program to supplement the data needed to have this product candidate considered for approval for use in treating inhalation anthrax and possibly other inhaled life-threatening bioterrorism infections.

If we can obtain sufficient additional funding, we would anticipate developing this drug for approval under FDA regulations relating to the approval of new drugs or biologics for potentially fatal diseases where human studies cannot be conducted ethically or practically. Unlike most drugs, which require large, well controlled Phase 3 clinical trials in patients with the disease or condition being targeted, these regulations allow for a drug to be evaluated and approved by the FDA on the basis of demonstrated safety in humans combined with studies in animal models to show effectiveness.

Smoking Cessation Therapy

ARD-1600 (Nicotine) Tobacco Smoking Cessation Therapy

According to the National Center for Health Statistics (NCHS), 21% of the U.S. population age 18 and above currently smoke cigarettes. The World Health Organization's (WHO) recent report states that tobacco smoking is the

single most preventable cause of death in the world today. Already tobacco kills more than five million people per year more than tuberculosis, HIV/AIDS and malaria combined. WHO warns that by 2030, the death toll could exceed eight million a year. Unless urgent action is taken, tobacco could kill one billion people during this century. According to the National Institute on Drug Abuse, more than \$75 billion of total U.S. healthcare costs each year is attributable directly to smoking. However, this cost is well below the total cost to society because it does not include burn care from smoking-related fires, perinatal care for low birth-weight infants of mothers who smoke, and medical care costs associated with disease caused by secondhand smoke. In addition to healthcare costs, the costs of

Table of Contents

lost productivity due to smoking effects are estimated at \$82 billion per year, bringing a conservative estimate of the economic burden of smoking to more than \$150 billion per year.

NCHS indicates that nicotine dependence is the most common form of chemical dependence in this country. Quitting tobacco use is difficult and often requires multiple attempts, as users often relapse because of withdrawal symptoms. Our goal is to develop an inhaled nicotine product that would address effectively the acute craving for cigarettes and, through gradual reduction of the peak nicotine levels, wean-off the patients from cigarette smoking and from the nicotine addiction.

Development

The initial laboratory work on this program was partly funded under grants from the National Institutes of Health.

We have encouraging data from our first human clinical trial delivering aqueous solutions of nicotine using the palm-size AERx Essence system. Our randomized, open-label, single-site Phase 1 trial evaluated arterial plasma pharmacokinetics and subjective acute cigarette craving when one of three nicotine doses was administered to 18 adult male smokers. Blood levels of nicotine rose much more rapidly following a single-breath inhalation compared to published data on other approved nicotine delivery systems. Cravings for cigarettes were measured on a scale from 0-10 before and after dosing for up to four hours. Prior to dosing, mean craving scores were 5.5, 5.5 and 5.0, respectively, for the three doses. At five minutes following inhalation of the nicotine solution through the AERx Essence device, craving scores were reduced to 1.3, 1.7 and 1.3, respectively, and did not return to pre-dose baseline during the four hours of monitoring. Nearly all subjects reported an acute reduction in craving or an absence of craving immediately following dosing. No serious adverse reactions were reported in the study.

We believe these results provide the foundation for further research with the AERx Essence device as a means toward smoking cessation. We are seeking collaborations with government and non-government organizations to further develop this product.

Collaborative Programs Under Development:

ARD-1550 and 1500 Treprostinil for the Treatment of Pulmonary Arterial Hypertension

The ARD-1550 program is a collaboration with Lung Rx, Inc. (Lung Rx) a wholly owned subsidiary of United Therapeutics Corporation (United Therapeutics), and is investigating an inhaled aqueous formulation of a prostacyclin analogue, treprostinil, for administration using our AERx delivery system for the treatment of pulmonary arterial hypertension, or PAH. PAH is a rare disease that results in the progressive narrowing of the arteries of the lungs, causing continuous high blood pressure in the pulmonary artery and eventually leading to heart failure. According to Datamonitor, in 2005 the more than 146,000 people worldwide affected by PAH purchased over \$800 million of PAH-related medical treatments, and sales are expected to reach \$2.0 billion per year by 2015.

Prostacyclin analogues are an important class of drugs used for the treatment of PAH. However, the current methods of administration of these drugs are burdensome on patients. Treprostinil is marketed by United Therapeutics under the name Remodulin* and is administered by intravenous or subcutaneous infusion. Remodulin accounted for approximately \$270 million of United Therapeutics revenue in 2008. We believe that the ARD-1550 product candidate could offer a non-invasive, more direct and patient-friendly approach compared to currently available treatments. Actelion Pharmaceuticals Ltd. markets in the United States another prostacyclin analogue, iloprost, under the name Ventavis* that is administered six to nine times per day using a nebulizer, with each treatment lasting four to ten minutes. We believe administration of treprostinil by inhalation using our convenient palm-sized AERx delivery system may be able to deliver an adequate dose for the treatment of PAH in a small number of breaths. Based on our

previous work with United Therapeutics, we also believe that in the future our sustained release formulation (ARD-1500) may lead to a reduction in the number of daily administrations that are needed to be effective when compared to existing inhaled therapies.

Table of Contents

Development

We conducted two collaborative research projects with United Therapeutics on inhaled treprostinil using our AERx Essence delivery system. The first project was with an aqueous formulation of treprostinil. The second project involved development of a slow-acting liposomal formulation of treprostinil (ARD-1500), with the view to achieve once-a-day dosing. On August 30, 2007, we signed an Exclusive License, Development and Commercialization Agreement with Lung Rx (Lung Rx License Agreement) pursuant to which we granted Lung Rx a license, which could become exclusive upon the payment of specified sums, to develop and commercialize inhaled treprostinil using our AERx Essence technology for the treatment of PAH and other potential therapeutic indications. As a part of this collaboration, we initiated with Lung Rx in April 2008 a clinical trial to evaluate lung distribution, pharmacokinetics and safety of inhaled treprostinil delivered by the AERx Essence system versus delivery with the Nebu-Tec OPTINEB(1)-ir nebulizer. Lung Rx used the latter device in its Phase 3 TRIUMPH (TReprostinil Sodium Inhalation Used in the Management of Pulmonary Arterial Hypertension) study of inhaled treprostinil in patients with PAH.

In November 2008, we announced data from the clinical trial, which showed that the AERx Essence delivery system efficiently delivered aerosolized treprostinil deeper into the lung than delivery by the OPTINEB nebulizer. Inhaled treprostinil was well tolerated from both delivery systems, and no serious adverse events were reported in the study. The AERx Essence delivery system is expected to deliver medication to the patient in 2 to 4 breaths, significantly reducing the burden of therapy for PAH patients.

We are now in discussions with Lung Rx regarding the next steps required on the clinical, manufacturing and regulatory paths toward the approval and launch of this product. Lung Rx will be responsible for funding the remainder of the development of treprostinil in the AERx delivery system through registration and commercial launch.

Under the terms of the Lung Rx License Agreement, we received an upfront fee of \$440,000 and an additional fee of \$440,000 four months after the signing date. These fees are nonrefundable and were included in deferred revenue in the balance sheet at December 31, 2007. Under the terms of the Lung Rx License Agreement, we were responsible for conducting and funding the feasibility study. In November 2008, we announced the results of the study and the receipt of \$2.75 million from Lung Rx which included the first milestone of \$2 million and development costs. We could receive additional milestone payments of up to \$7 million. Following commercialization of the product, we would receive royalties from Lung Rx on a tiered basis of up to 10% of net sales for any licensed products that deliver treprostinil using our AERx technology.

Lung Rx was to pay a \$650,000 license fee for an exclusive license and had the right under the Lung Rx Agreement to purchase \$3.47 million of our common stock at an average closing price over a certain trailing period within 15 days of Lung Rx's determination that the feasibility study was successful. Lung Rx determined that while the results of the clinical trial warranted continuation of the development of AERx Essence technology with treprostinil, the performance of the AERx Essence inhaler in the clinical study was different from the nebulizer. As such, they did not pay the license fee or purchase our stock.

ARD-1700 (Combination Products) and Other Prior and Potential Applications

We have demonstrated in human clinical trials to date effective deposition and, where required, systemic absorption of a wide variety of drugs, including small molecules, peptides and proteins, using our AERx delivery system. We intend to identify additional pharmaceutical product opportunities that could potentially utilize our proprietary delivery systems for the pulmonary delivery of various drug types, including proteins, peptides, oligonucleotides, gene products and small molecules. We have demonstrated in the past our ability to successfully enter into collaborative arrangements for our programs, and we believe additional opportunities for collaborative arrangements exist outside

of our core respiratory disease focus, for some of which we have data as well as intellectual property positions.

In August 2006, we sold all of our assets related to the Intraject needle-free injector technology platform and products, including 12 United States patents along with foreign counterparts, to Zogenix, Inc., a private company. Zogenix is responsible for further development and commercialization efforts of Intraject (now rebranded under the

Table of Contents

name DosePro™). We received a \$4 million initial payment from Zogenix, and we will be entitled to a milestone payment upon initial commercialization, and royalty payments upon any commercialization of products in the US and other countries, including the European Union, that may be developed and sold using the DosePro technology. In December 2007, Zogenix submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the migraine drug sumatriptan using the needle-free injector DosePro (Sumavel DosePro). Zogenix stated that it is their intention to launch Sumavel DosePro following FDA approval in the second half of 2009.

The following are descriptions of two potential opportunities:

Cyclodextrin Combination Products for Asthma, Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD). Asthma is a common chronic disorder of the lungs characterized by airway inflammation, airway hyper-responsiveness or airway narrowing due to certain stimuli. Despite several treatment options, asthma remains a major medical problem associated with high morbidity and large economic costs to society. According to the American Lung Association, asthma accounted for \$11.5 billion in direct healthcare costs annually in the United States, of which the largest single expenditure, at \$5 billion, was prescription drugs. Primary symptoms of asthma include coughing, wheezing, shortness of breath and tightness of the chest with symptoms varying in frequency and degree. According to Datamonitor, in 2005 asthma affected 41.5 million people in developed countries, with 9.5 million of those affected being children. The highest prevalence of asthma occurs in the United States and the United Kingdom. According to the American Lung Association, non-asthma COPD was the fourth leading cause of death in America, claiming the lives of 118,171 Americans in 2004. In 2005, an estimated 8.9 million Americans reported a physician diagnosis of chronic bronchitis, an obstructive disease of the lung. In August 2007, we and CyDex Pharmaceuticals, Inc. (CyDex) began to collaborate on the development and commercialization of products that utilize our AERx pulmonary delivery technology and CyDex's solubilization and stabilization technologies to deliver inhaled corticosteroids, anticholinergics and beta-2 agonists for the treatment of asthma and COPD.

Pain Management System. Based on our internal work and a currently dormant collaboration with GlaxoSmithKline, we have developed a significant body of preclinical and Phase 1 clinical data on the use of inhaled morphine and fentanyl, and Phase 2 clinical data on inhaled morphine, with our proprietary AERx delivery system for the treatment of breakthrough pain in cancer and postsurgical patients.

We are regularly examining our previously conducted preclinical and clinical programs to identify product candidates that may be suitable for further development consistent with our current business strategy. We previously demonstrated the feasibility of delivering a variety of small molecules, peptides, proteins and gene therapies via our proprietary AERx delivery system but we have not been able to continue their development due to a variety of reasons, most notably the lack of funding provided from collaborators. We seek to identify partners who may wish to license or buy these assets.

Pulmonary Drug Delivery Background

Pulmonary delivery describes the delivery of drugs by inhalation and is a common method of treatment of many respiratory diseases, including asthma, chronic bronchitis, cystic fibrosis and bronchiectasis. The current global market for inhalation products includes delivery through metered-dose inhalers, dry powder inhalers and nebulizers. The advantage of inhalation delivery for the diagnosis, prevention and treatment of lung disease is that the active agent is delivered in high concentration directly to the desired targets in the respiratory tract while keeping the body's exposure to the rest of the drug, and resulting side effects, at a minimum. Over the last two decades, there has also been increased interest in the use of the inhalation route for systemic delivery of drugs throughout the body, either for the purpose of rapid onset of action or to enable noninvasive delivery of drugs that are not orally bioavailable.

Table of Contents

The efficacy, safety and efficient delivery of any inhaled drug depend on delivering the dose of the drug to the specified area of the respiratory tract. To achieve reproducible delivery of the dose, it is essential to control three factors:

emitted dose;

particle size distribution; and

breathing maneuver.

Breathing maneuver includes synchronization of the dose administration with the inhalation, inspiratory flow rate and the amount of air that the patient inhales at the time of dose the lung volume.

Lack of control of any of these factors may impair patient safety and therapeutic benefits. Further, the efficiency of delivery has economic implications, especially for drugs whose inherent production costs are high, such as biologics.

Traditional inhalation delivery systems, such as inhalers, have been designed and used primarily for delivery of drugs to the respiratory airways, not to the deep lung. 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 deep lung tissues. In order for an aerosol to be delivered to the deep lung where there is a large absorptive area suitable for effective systemic absorption, the medication needs to be delivered into the airstream early during inhalation. This is best achieved with systems that are breath-actuated, *i.e.*, the dose delivery is automatically started at the beginning of inhalation. Further, the drug formulation must be transformed into very fine particles or droplets (typically one to three microns in diameter). In addition, the velocity of these particles must be low as they pass through the airways into the deep lung. The particle velocity is determined by the particle generator and the inspiratory flow rate of the patient. Large or fast-moving particles typically get deposited in the mouth and upper airways, where they may not be absorbed and could cause side effects. Most of the traditional drug inhalation delivery systems have difficulty in generating appropriate drug particle sizes or consistent emitted doses, and they also rely heavily on proper patient breathing technique to ensure adequate and reproducible lung delivery. To achieve appropriate drug particle sizes and consistent emitted doses, most traditional inhalation systems require the use of various additives such as powder carrier materials, detergents, lubricants, propellants, stabilizers and solvents, which may potentially cause toxicity or allergic reactions. It is also well documented that the typical patient frequently strays from proper inhalation technique after training and may not be able to maintain a consistent approach over even moderate periods of time. Since precise and reproducible dosing with medications is necessary to ensure safety and therapeutic efficacy, any variability in breathing technique among patients or from dose to dose may negatively impact the therapeutic benefits to the patient. We believe high efficiency and reproducibility of lung delivery will be required in order for inhalation to successfully replace certain injectable products.

The rate of absorption of drug molecules such as insulin from the lung has been shown to depend also on the lung volume following the deposition of the drug in the lung. In order to achieve safety and efficacy comparable to injections, this absorption step also needs to be highly reproducible. We therefore believe that an inhalation system that will coach the patient to breathe reproducibly to the same lung volume will be required to assure adequate safety and reproducibility of delivery of certain drugs delivered systemically via the lung.

The AERx Delivery Technology

The AERx delivery technology provides an efficient and reproducible means of targeting drugs to the diseased parts of the lung, or to the lung for systemic absorption, through a combination of fine mist generation technology and breath control mechanisms. Similar to nebulizers, the AERx delivery technology is capable of generating aerosols

from simple liquid drug formulations, avoiding the need to develop complex dry powder or other formulations. However, in contrast to nebulizers, AERx is a hand-held unit that can deliver the required dosage typically in one or two breaths in a matter of seconds due to its enhanced efficiency compared to nebulization treatments, which commonly last about 15 minutes. We believe the ability to make small micron-size droplets from a hand-held device that incorporates breath control will be the preferred method of delivery for many medications.

Table of Contents

We have demonstrated in the laboratory and in many human clinical trials that our AERx delivery system enables pulmonary delivery of a wide range of pharmaceuticals in liquid formulations for local or systemic effects. Our proprietary 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, engineering and pharmaceutical sciences. The key features of the AERx delivery system include the following:

Liquid Formulation. Most drugs being considered by us for pulmonary delivery, especially biologics, are currently marketed in stable water formulations for parenteral delivery. The AERx delivery 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 delivery system allows us to use conventional, sterile pharmaceutical manufacturing techniques. The liquid drug formulations used in the AERx delivery system are expected to have the similar stability profile as the currently marketed parenteral versions of the same drugs. Because of the nature of liquid formulations, the additives 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. The AERx delivery system aerosolizes liquid drug formulations from pre-packaged, single-use, disposable packets. Each disposable packet comprises 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 could 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 must be changed between uses or over time.

Breath-Control Technology and 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 typical problems are associated with the inability to coordinate the start of inhalation with the activation of the dose delivery, inappropriate inspiratory flow rate and inhaled volume of air with the medication. The AERx inhalation delivery devices employ breath control methods and technologies to guide the patient into the proper breathing maneuver. As a result, a high degree of consistency of the dose of medication delivered each time to the patient was demonstrated in several clinical trials. The characteristics of the breath control can be customized for different patient groups, such as young children or other patients with small lung volumes.

The AERx delivery system offers additional patented features that we believe provide an advantage over competitive pulmonary products for certain important indications. For example, we believe our adjustable dosing feature may provide an advantage in certain types of disease management where precise dosing adjustment is critical. The electronic version of the AERx delivery system can also be designed to incorporate the ability for a physician to monitor and download a patient's dosing regimen, which we believe will aid in patient care and assist physicians in addressing potential issues of non-compliance. We have also developed a lockout feature for the AERx delivery system, which can be used to prevent use of the system by anyone other than the prescribed patient, and to prevent excessive dosing in any given time frame. These features of our AERx delivery system are protected by our intellectual property estate that includes patent claims directed toward the design, manufacture and testing of the AERx Strip® dosage forms and the various AERx pulmonary drug delivery systems.

The various forms of our AERx technology have been extensively tested in the laboratory and in over 50 human clinical trials with 19 different small molecules, peptides and proteins. We also conducted two human clinical trials (with treprostinil and with nicotine) with the latest version of our inhalation technology, the AERx Essence system. This system retains the key features of breath control and aerosol quality of the previous generations of the AERx technology, but the patient is provided with a much smaller, palm-sized device. The device is easy to use and maintain and it does not require any batteries or external electrical power.

Table of Contents

Formulation Technologies

We have a number of formulation technologies for drugs delivered by inhalation. We have proprietary knowledge and trade secrets relating to the formulation of drugs to achieve products with adequate stability and safety, and for the manufacture and testing of inhaled drug formulations. We have been exploring the use of liposomal formulations of drugs that may be used for the prevention and treatment of respiratory diseases. Liposomes are lipid-based nanoparticles dispersed in water that encapsulate the drug during storage, and release the drug slowly upon contact with fluid covering the airways and the lung. We are developing liposomal formulations specifically for those drugs that currently need to be dosed several times a day, or when the slow release of the drug is likely to improve the efficacy and safety profile. We believe a liposomal formulation will provide extended duration of protection and treatment against lung infection, greater convenience for the patient and reduced systemic levels of the drug. The formulation may also enable better interaction of the drug with the disease target, potentially leading to greater efficacy. We have applied this technology to ciprofloxacin and treprostinil. We are also examining other potential applications of this formulation technology for respiratory therapies.

Intellectual Property and Other Proprietary Rights

Our success will depend, to a significant extent, on our ability to obtain, expand and protect our intellectual property estate, enforce patents, maintain trade secret protection and operate without infringing the proprietary rights of other parties. As of February 28, 2009, we had 98 issued United States patents, with 36 additional United States patent applications pending. In addition, we had 128 issued foreign patents and additional 63 foreign patent applications pending. The bulk of our patents and patent applications contain claims directed toward our proprietary delivery technologies, 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 have purchased three United States patents containing claims that are relevant to our inhalation technologies. The bulk of our patents, including fundamental patents directed toward our proprietary AERx delivery technology, expire between 2013 and 2023. For certain of our formulation technologies we have in-licensed some technology and will seek to supplement such intellectual property rights with complementary proprietary processes, methods and formulation technologies, including through patent applications and trade secret protection. 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.

In December 2004, as part of our research and development efforts funded by the DRDC for the development of liposomal ciprofloxacin for the treatment of biological terrorism-related inhalation anthrax, we obtained worldwide exclusive rights to a patented liposomal formulation technology for the pulmonary delivery of ciprofloxacin from Tekmira Pharmaceuticals Corporation, formerly known as Inex Pharmaceuticals Corporation, and may have the ability to expand the exclusive license to other fields. We do not use Tekmira's liposomal formulation technology and developed our own proprietary technology for our liposomal ciprofloxacin program.

We seek to protect our proprietary position by protecting inventions that we determine are or may be important to our business. We do this, when we are able, through the filing of patent applications with claims directed toward the devices, methods and technologies we develop. Our ability to compete effectively will depend to a significant extent on our ability and the ability of our collaborators to obtain and enforce patents and maintain trade secret protection over our proprietary technologies. The coverage claimed in a patent application typically is significantly reduced before a patent is issued, either in the United States or abroad. Consequently, any of our pending or future patent applications may not result in the issuance of patents or, to the extent patents have been issued or will be issued, these patents may be subjected to further proceedings limiting their scope and may in any event not contain claims broad enough to provide meaningful protection. Patents that are issued to us or our collaborators may not provide significant proprietary protection or competitive advantage, and may be circumvented or invalidated.

We also rely on our trade secrets and the know-how of our officers, employees, consultants and other service providers. Our policy is to require our officers, employees, consultants and advisors to execute proprietary information and invention 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

Table of Contents

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 for the invention if we wish to pursue such protection. These agreements may not 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 or proprietary information to other projects, and any such disputes may not be resolved in our favor. Even if resolved in our favor, such disputes could result in substantial expense and diversion of management attention.

In addition to protecting our own intellectual property rights, we must be able to develop products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to compositions of matter, methods of use, methods of delivery and products in those markets, it may be difficult for us to develop products without infringing the proprietary rights of others.

We would incur substantial costs if we are required to defend ourselves in suits, regardless of their merit. These legal actions could seek damages and seek to enjoin development, testing, manufacturing and marketing of the allegedly infringing product. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the allegedly infringing product and any license required under any such patent may not be available to us on acceptable terms, if at all.

We may determine that litigation is necessary to enforce our proprietary rights against others. Such litigation could result in substantial expense and diversion of management attention, regardless of its outcome and any litigation may not be resolved in our favor.

Competition

We are in a highly competitive industry. We are in competition with pharmaceutical and biotechnology companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of drugs and other therapies for the respiratory disease indications we are targeting. Our competitors may succeed, and many have already succeeded, in developing competing products, obtaining FDA approval for products or gaining patient and physician acceptance of products before us for the same markets and indications that we are targeting. Many of these companies, and large pharmaceutical companies in particular, have greater research and development, regulatory, manufacturing, marketing, financial and managerial resources and experience than we have and many of these companies may have products and product candidates that are in a more advanced stage of development than our product candidates. If we are not first to market for a particular indication, it may be more difficult for us or our collaborators to enter markets unless we can demonstrate our products are clearly superior to existing therapies.

Examples of competitive therapies include:

ARD-3100. Currently marketed products include TOBI* marketed by Novartis, Pulmozyme* marketed by Genentech, Levaquin* marketed by Ortho-McNeil-Janssen Pharmaceuticals, Doribax* marketed by Johnson & Johnson and Cipro* marketed by Bayer. Products under development to treat respiratory infections in diseases such as CF and non-CF BE include inhaled aztreonam* under development by Gilead, inhaled liposomal amikacin under development by Transave, inhaled levofloxacin by Mpex Pharmaceuticals and inhaled ciprofloxacin under development by Bayer. Bayer was granted orphan drug designation for an inhaled ciprofloxacin product for the treatment of cystic fibrosis in Europe.

ARD-1100. Current anthrax treatment products include various oral generic and branded antibiotics, such as ciprofloxacin marketed by Bayer.

ARD-1300. Currently marketed products include Advair* marketed by GlaxoSmithKline, Xolair* marketed by Novartis in collaboration with Genentech, Singulair* marketed by Merck, Symbicort* marketed by

Table of Contents

AstraZeneca, Alvesco* marketed by Sepracor, Asmanex* marketed by Schering-Plough and Pulmicort* marketed by AstraZeneca International.

ARD-1550. Currently marketed products include intravenous delivery and subcutaneous infusion of prostacyclins, such as Remodulin* marketed by United Therapeutics, and inhaled prostacyclins, such as Ventavis*, marketed by Schering AG and CoTherix, (acquired by Actelion Pharmaceuticals Ltd. in 2007).

Many of these products have substantial current sales and long histories of effective and safe use. In addition, we believe there are a number of additional drug candidates in various stages of development that, if approved, would compete with any future products we may develop. Moreover, one or more of our competitors that have developed or are developing pulmonary drug delivery technologies, such as Alkermes,, MAP, Mannkind or Alexza Pharmaceuticals, or other competitors with alternative drug delivery methods, may negatively impact our potential competitive position.

We believe that our respiratory expertise and pulmonary delivery and formulation technologies provide us with an important competitive advantage for our potential products. We intend to compete by developing products that are safer, more efficacious, more convenient, less costly, earlier to market, marketed with smaller sales forces or cheaper to develop than existing products, or any combination of the foregoing.

Government Regulation

United States

The research, development, testing, manufacturing, labeling, advertising, promotion, distribution, marketing and export, among other things, of any products we develop are subject to extensive regulation by governmental authorities in the United States and other countries. The FDA regulates drugs in the United States under the FDCA and implementing regulations thereunder.

If we, or our product development collaborators, fail to comply with the FDCA or FDA regulations, we, our collaborators, and our products could be subject to regulatory actions. These may include delay in approval or refusal by the FDA to approve pending applications, injunctions ordering us to stop sale of any products we develop, seizure of our products, warning letters, imposition of civil penalties or other monetary payments, criminal prosecution, and recall of our products. Any such events would harm our reputation and our results of operations.

Before one of our drugs may be marketed in the United States, it must be approved by the FDA. None of our product candidates has received such approval. We believe that our products currently in development will be regulated by the FDA as drugs.

The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory and animal tests, and formulation studies;

- the submission to the FDA of an Investigational New Drug application, or IND, for human clinical testing that must become effective before human clinical trials may begin;

- adequate and well controlled human clinical trials to establish the safety and efficacy of the product candidate for each indication for which approval is sought;

- the submission to the FDA of a New Drug Application, or NDA, and FDA's acceptance of the NDA for filing;

satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is to be produced to assess compliance with the FDA's Good Manufacturing Practices, or GMP; and

FDA review and approval of the NDA.

In September 2007, the President of the United States signed the Food and Drug Administration Amendments Act of 2007, or FDAAA. The new legislation grants significant new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information, and require risk evaluation and mitigation strategies for certain drugs, including certain

Table of Contents

currently approved drugs. In addition, it significantly expands the Federal Government's clinical trial registry and results databank and creates new restrictions on the advertising and promotion of drug products. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

Although we expect these and other provisions of the FDAAA to have a substantial effect on the pharmaceutical industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new pharmaceutical products and to produce, market and distribute existing products.

Preclinical Testing

The testing and approval process requires substantial time, effort, and financial resources, and the receipt and timing of approval, if any, is highly uncertain. Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the proposed clinical trials as outlined in the IND prior to that time. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in FDA authorization to commence clinical trials. Once an IND is in effect, the protocol for each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

Clinical Trials

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators and healthcare personnel. Clinical trials are conducted under protocols detailing, for example, the parameters to be used in monitoring patient safety and the safety and effectiveness criteria, or end points, to be evaluated. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent institutional review board overseeing the institution conducting the trial before it can begin.

These phases generally include the following:

Phase 1. Phase 1 clinical trials usually involve the initial introduction of the drug into human subjects, frequently healthy volunteers. In Phase 1, the drug is usually evaluated for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.

Phase 2. Phase 2 usually involves studies in a limited patient population with the disease or condition for which the drug is being developed to (1) preliminarily evaluate the efficacy of the drug for specific, targeted indications; (2) determine dosage tolerance and appropriate dosage; and (3) identify possible adverse effects and safety risks.

Phase 3. If a drug is found to be potentially effective and to have an acceptable safety profile in Phase 2 studies, the clinical trial program will be expanded, usually to further evaluate clinical efficacy and safety by administering the drug in its final form to an expanded patient population at geographically dispersed clinical trial sites. Phase 3 studies usually include several hundred to several thousand patients.

Phase 1, Phase 2, or Phase 3 clinical trials may not be completed successfully within any specified period of time, if at all. Further, we, our product development collaborators, or the FDA may suspend clinical trials at any time on various

grounds, including a finding that the patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or facilities at which the product is manufactured,

Table of Contents

and will not approve the product unless continuing GMP compliance is satisfactory. If the FDA determines the NDA is not acceptable, the FDA may outline the deficiencies in the NDA and often will request additional information or additional clinical trials. Notwithstanding the submission of any requested additional testing or information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If regulatory approval of a product is granted, such approval will usually entail limitations on the indicated uses for which such product may be marketed. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory requirements and conditions of approvals are not maintained, if GMP compliance is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies.

After approval, certain changes to the approved product, such as adding new indications, certain manufacturing changes, or additional labeling claims are subject to further FDA review and approval. Post-approval marketing of products can lead to new findings about the safety or efficacy of the products. This information can lead to a product sponsor making, or the FDA requiring, changes in the labeling of the product or even the withdrawal of the product from the market.

Section 505(b)(2) Applications

Some of our product candidates may be eligible for submission of applications for approval under the FDA's Section 505(b)(2) approval process, which requires less information than the NDAs described above. Section 505(b)(2) applications may be submitted for drug products that represent a modification (*e.g.*, a new indication or new dosage form) of an eligible approved drug and for which investigations other than bioavailability or bioequivalence studies are essential to the drug's approval. Section 505(b)(2) applications may rely on the FDA's previous findings for the safety and effectiveness of the listed drug, scientific literature, and information obtained by the 505(b)(2) applicant needed to support the modification of the listed drug. For this reason, preparing Section 505(b)(2) applications is generally less costly and time-consuming than preparing an NDA based entirely on new data and information from a full set of clinical trials. The law governing Section 505(b)(2) or FDA's current policies may change in such a way as to adversely affect our applications for approval that seek to utilize the Section 505(b)(2) approach. Such changes could result in additional costs associated with additional studies or clinical trials and delays.

The FDCA provides that reviews and/or approvals of applications submitted under Section 505(b)(2) may be delayed in various circumstances. For example, the holder of the NDA for the listed drug may be entitled to a period of market exclusivity, during which the FDA will not approve, and may not even review a Section 505(b)(2) application from other sponsors. If the listed drug is claimed by a patent that the NDA holder has listed with the FDA, the Section 505(b)(2) applicant must submit a patent certification. If the 505(b)(2) applicant certifies that the patent is invalid, unenforceable, or not infringed by the product that is the subject of the Section 505(b)(2), and the 505(b)(2) applicant is sued within 45 days of its notice to the entity that holds the approval for the listed drug and the patent holder, the FDA will not approve the Section 505(b)(2) application until the earlier of a court decision favorable to the Section 505(b)(2) applicant or the expiration of 30 months. The regulations governing marketing exclusivity and patent protection are complex, and it is often unclear how they will be applied in particular circumstances.

In addition, both before and after approval is sought, we and our collaborators are required to comply with a number of FDA requirements. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain limitations and other requirements concerning advertising and promotion for our products. Also, quality control and manufacturing procedures must continue to conform to continuing GMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with continuing GMP.

In addition, discovery of problems, such as safety problems, may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

Table of Contents

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. A sponsor may request orphan drug designation of a previously unapproved drug, or of a new indication for an already marketed drug. Orphan drug designation must be requested before an NDA is submitted. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan status are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a drug which has orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the drug is entitled to orphan drug exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, unless the subsequent application is able to demonstrate clinical superiority in efficacy or safety. Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication, or the same drug for other indications.

We have obtained orphan drug designation from the FDA for inhaled liposomal ciprofloxacin for the management of cystic fibrosis and non-cystic fibrosis bronchiectasis. We may seek orphan drug designation for other eligible product candidates we develop. However, our liposomal ciprofloxacin may not receive orphan drug marketing exclusivity. Also, it is possible that our competitors could obtain approval, and attendant orphan drug designation or exclusivity, for products that would preclude us from marketing our liposomal ciprofloxacin for this indication for some time.

International Regulation

We are also subject to foreign regulatory requirements governing clinical trials, product manufacturing, marketing and product sales. Our ability to market and sell our products in countries outside the United States will depend upon receiving marketing authorization(s) from appropriate regulatory authorities. We will only be permitted to commercialize our products in a foreign country if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. 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 commencement of marketing of the product in those countries. Approval of a product by the FDA does not assure approval by foreign regulators. Regulatory requirements, and the approval process, vary widely from country to country, and the time, cost and data needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with the FDA process described above.

Scientific Advisory Board

We have assembled a scientific advisory board comprised of scientific and product development advisors who provide expertise, on a consulting basis from time to time, in the areas of respiratory diseases, allergy and immunology, pharmaceutical development and drug delivery, including pulmonary 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

Table of Contents

advisory board assists us on issues related to potential product applications, product development and clinical testing. Its members, and their affiliations and areas of expertise, include:

Name	Affiliation	Area of Expertise
Peter 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
Stephen J. Farr, Ph.D.	Zogenix, Inc.	Pulmonary Delivery/Pharmaceutics
Michael Konstan, M.D.	Rainbow Babies and Children's Hospital	Pulmonary Diseases/Cystic Fibrosis
Babatunde Otulana, M.D.	Aerovance, Inc.	Pulmonary Diseases/Cystic Fibrosis/Regulatory
Adam Wanner, M.D.	University of Miami	Chronic Obstructive Pulmonary Diseases (COPD)
Martin Wasserman, Ph.D.	Roche, AtheroGenics (retired)	Asthma

In addition to our scientific advisory board, for certain indications and programs we assemble groups of experts to assist us on issues specific to such indications and programs.

Employees

As of December 31, 2008, we had 38 full-time and part-time employees, 6 of whom have advanced degrees. Of these, 28 are involved in research and development, product development and commercialization; and 10 are involved in finance and administration. Our employees are not represented by any collective bargaining agreement.

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 or SEC. The public may read and copy any material we file with the SEC at the SEC's Public Reference Room at 100 F 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. If we amend or waive a provision of our Code of Business Conduct and Ethics, we would post such amendment or waiver on our website, as required by applicable rules.

Table of Contents**Executive Officers and Directors**

Our directors and executive officers and their ages as of February 28, 2009 are as follows:

Name	Age	Position
Igor Gonda, Ph.D.	61	President, Chief Executive Officer and Director
Nancy E. Pecota	49	Vice President, Finance and Chief Financial Officer
D. Jeffery Grimes	45	Vice President, Legal Affairs, General Counsel
Frank H. Barker(1)(2)(3)	78	Director
John M. Siebert, Ph.D.(1)(2)(3)	68	Director
Virgil D. Thompson(1)(2)(3)	69	Chairman of the Board and Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

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

Igor Gonda, Ph.D. has served as our President and Chief Executive Officer since August 2006, and as a director since September 2001. From December 2001 to August 2006, Dr. Gonda was the Chief Executive Officer and Managing Director of Acrux Limited, a publicly traded specialty pharmaceutical company located in Melbourne, Australia. From July 2001 to December 2001, Dr. Gonda was our Chief Scientific Officer and, from October 1995 to July 2001, was our Vice President, Research and Development. From February 1992 to September 1995, Dr. Gonda was a Senior Scientist and Group Leader at Genentech, Inc. His key responsibilities at Genentech were the development of the inhalation delivery of rhDNase (Pulmozyme) for the treatment of cystic fibrosis and non-parenteral methods of delivery of biologics. Prior to that, Dr. Gonda held academic positions at the University of Aston in Birmingham, United Kingdom, and the University of Sydney, Australia. Dr. Gonda holds a B.Sc. in Chemistry and a Ph.D. in Physical Chemistry from Leeds University, United Kingdom. Dr. Gonda was the Chairman of our Scientific Advisory Board until August 2006.

Nancy E. Pecota has served as our Vice President, Finance and Chief Financial Officer since September 2008. From October 2005 to July 2008, Ms. Pecota was the Chief Financial Officer for NuGEN Technologies, Inc., a privately held life sciences tools company. From August 2003 to September 2005, Ms. Pecota was a consultant for early to mid-stage biopharmaceutical companies assisting them in developing fundable business models and assessing and improving internal financial preparation and reporting processes. From March 2001 to April 2003, she was Vice President, Finance and Administration at Signature BioScience, Inc., a privately held biopharmaceutical company. Prior to that, she was Director, Finance and Accounting for ACLARA BioSciences, Inc., a publicly traded biotechnology company. Ms. Pecota holds a B.S. in Economics from San Jose State University.

D. Jeffery Grimes has served as our Vice President, Legal Affairs, General Counsel and Secretary since June 2007. From May 2005 to June 2007, Mr. Grimes was an attorney in the Trademark & Brands department at Intel. From May 2002 to January 2005, Mr. Grimes was Assistant General Counsel at Connetics Corporation, a publicly-traded specialty pharmaceutical company focused on dermatology. From February 2000 to April, 2002, he was Vice President, Corporate Counsel & Secretary of GN ReSound, Inc. and Beltone Electronics Corporation, both subsidiaries of a Danish-based multinational leading medical device company for hearing devices. Prior to becoming in-house counsel, Mr. Grimes was a commercial litigator for seven years. Mr. Grimes holds J.D./M.B.A. degrees and

a B.S. in Finance from University of Colorado, Boulder. Mr. Grimes is a member of the Biotechnology Industry Organization General Counsel Committee.

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 retired from Johnson & Johnson, Inc. in January 1996. Mr. Barker holds a B.A. in Business Administration from Rollins College, Winter Park, Florida. Mr. Barker is a director of Jenex Corporation, a Canadian medical devices company.

John M. Siebert, Ph.D. has been a director since November 2006. From May 2003 to October 2008, Dr. Siebert was the Chairman and Chief Executive Officer of CyDex, Inc., a privately held specialty pharmaceutical company.

Table of Contents

From September 1995 to April 2003, he was President and Chief Executive Officer of CIMA Labs Inc., a publicly traded drug delivery company, and from July 1995 to September 1995 he was President and Chief Operating Officer of CIMA Labs. From 1992 to 1995, Dr. Siebert was Vice President, Technical Affairs at Dey Laboratories, Inc., a privately held pharmaceutical company. From 1988 to 1992, he worked at Bayer Corporation. Prior to that, Dr. Siebert was employed by E.R. Squibb & Sons, Inc., G.D. Searle & Co. and The Procter & Gamble Company. Dr. Siebert holds a B.S. in Chemistry from Illinois Benedictine University, an M.S. in Organic Chemistry from Wichita State University and a Ph.D. in Organic Chemistry from the University of Missouri. Dr. Siebert is the Chairman of our audit committee and the designated audit committee financial expert .

Virgil D. Thompson has been a director since June 1995 and has been Chairman of the Board since January 2005. From November 2002 until June 2007, Mr. Thompson served as President and Chief Executive Officer of Angstrom Pharmaceuticals, Inc., a privately held pharmaceutical company, where he continues as a director. From September 2000 to November 2002, Mr. Thompson was President, Chief Executive Officer and a director of Chimeric Therapies, Inc., a privately held biotechnology company. From May 1999 until September 2000, Mr. Thompson was the President, Chief Operating Officer and a director of Savient Pharmaceuticals, a publicly traded specialty pharmaceutical company. From January 1996 to April 1999, Mr. Thompson was the President and Chief Executive Officer and a director of Cytel Corporation, a publicly traded biopharmaceutical company that was subsequently acquired by IDM Pharma, Inc. From 1994 to 1996, Mr. Thompson was President and Chief Executive Officer of Cibus Pharmaceuticals, Inc., a privately held drug delivery device company. From 1991 to 1993, Mr. Thompson was President of Syntex Laboratories, Inc., a U.S. subsidiary of Syntex Corporation, a publicly traded pharmaceutical company. Mr. Thompson holds a B.S. in Pharmacy from Kansas University and a J.D. from The George Washington University Law School. Mr. Thompson is a director and chairman of the board of Questcor Pharmaceuticals, Inc., a publicly traded pharmaceutical company, and a director of Savient Pharmaceuticals.

Item 1A. Risk Factors

Except for historical information contained herein, the discussion in this Annual 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.

Risks Related to Our Business

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 product candidates 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. We may abandon the development of some or all of our product candidates at any time and without prior notice. We must incur substantial up-front expenses to develop and commercialize products and failure to achieve commercial feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or successfully manufacture and market products will negatively impact our business.

Table of Contents

We changed our product development strategy, and if we do not successfully implement this strategy our business and reputation will be damaged.

Since our inception in 1991, we have focused on developing drug delivery technologies to be partnered with other companies. In May 2006, we began transitioning our business focus from development of delivery technologies to the application of our pulmonary drug delivery technologies and expertise to development of novel drug products to treat or prevent respiratory diseases. As part of this transition we have implemented workforce reductions in an effort to reduce our expenses and improve our cash flows. We continue to implement various aspects of our strategy, and we may not be successful in implementing our strategy. Even if we are able to implement the various aspects of our strategy, it may not be successful.

We will need additional capital, and we may not be able to obtain it.

We will need to commit substantial funds to develop our product candidates and we may not be able to obtain sufficient funds on acceptable terms or at all. Our operations to date have consumed substantial amounts of cash and have generated no product revenues. We expect negative operating cash flows to continue for at least the foreseeable future. Our future capital requirements will depend on many factors, including:

our progress in the application of our delivery and formulation technologies, which may require further refinement of these technologies;

the number of product development programs we pursue and the pace of each program;

our progress with formulation development;

the scope, rate of progress, results and costs of preclinical testing and clinical trials;

the time and costs associated with seeking regulatory approvals;

our ability to outsource the manufacture of our product candidates and the costs of doing so;

the time and costs associated with establishing in-house resources to market and sell certain of our products;

our ability to establish and maintain collaborative arrangements with others and the terms of those arrangements;

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

our need to acquire licenses, or other rights for our product candidates.

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 cash and cash equivalents at December 31, 2008 combined with the proceeds of our February 2009 offering will be sufficient to fund operations at least through the first quarter of 2010. We will need to obtain substantial additional funds before we would be able to bring any of our product candidates to market. Our estimates of future capital use are uncertain, and changing circumstances, including those related to implementation of, or further changes to, our development strategy, could cause us to consume capital significantly faster than currently expected, and our expected sources of funding may not be sufficient. If adequate funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our product development programs and reduce

personnel-related costs, or to obtain funds through arrangements with collaborators or other sources that may require us to relinquish rights to or sell certain of our technologies or products that we would not otherwise relinquish or sell. If we are able to obtain funds through the issuance of debt securities or borrowing, the terms may significantly restrict our operations. If we are able to obtain funds through the issuance of equity securities, our shareholders may suffer significant dilution and our stock price may drop.

We have a history of losses, we expect to incur losses for at least the foreseeable future, and we may never attain or maintain profitability.

We have never been profitable and have incurred significant losses in each year since our inception. As of December 31, 2008, we have an accumulated deficit of \$334.7 million. We have not had any product sales and do

Table of Contents

not anticipate receiving any revenues from product sales for at least the next few years, if ever. While our recent shift in development strategy may result in reduced capital expenditures, we expect to continue to incur substantial losses over at least the next several years as we:

expand drug product development efforts;

conduct preclinical testing and clinical trials;

pursue additional applications for our existing delivery technologies;

outsource the commercial-scale production of our products; and

establish a sales and marketing force to commercialize certain of our proprietary products if these products obtain regulatory approval.

To achieve and sustain profitability, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, market and sell our products. We expect to incur substantial expenses in our efforts to develop and commercialize products and we may never generate sufficient product or contract research revenues to become profitable or to sustain profitability.

Our dependence on collaborators and other contracting parties may delay or terminate certain of our programs, and any such delay or termination would harm our business prospects and stock price.

Our commercialization strategy for certain of our product candidates depends on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates. Collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our existing collaborators could delay or terminate their agreements, and our products subject to collaborative arrangements may never be successfully commercialized. For example, Novo Nordisk had control over and responsibility for development and commercialization of the AERx insulin Diabetes Management System (iDMS) inhaled meal-time insulin program. In January 2008, Novo Nordisk announced that it was terminating the AERx iDMS program and gave us a 120-day notice terminating the July 3, 2006 License Agreement between the companies. In May 2008, this termination became effective, ending our collaboration with Novo Nordisk for the AERx iDMS program. Identifying new collaborators for the further development and potential commercialization of the AERx iDMS program may take a significant amount of time and resources and ultimately may not be successful. Lung Rx, Inc. (Lung Rx) may also elect to terminate our collaboration agreement. Further, some portion of the money we received from Lung Rx for development costs is pre-payment for future costs. If Lung Rx terminates our agreement we may have to remit to Lung Rx a portion of that pre-payment. If, due to delays or otherwise, we do not receive development funds or achieve milestones set forth in the agreements governing our collaborations, if we cannot timely find replacement collaborators, or if any of our collaborators breach or terminate their collaborative agreements or do not devote sufficient resources or priority to our programs, our business prospects and our stock price would suffer. For example, Zogenix may not receive approval or launch their migraine drug sumatriptan using the DosePro needle-free delivery system, in which case we may not receive a milestone payment and/or receive royalty payments. Any delay in, or failure to receive, milestone payments or royalties could also adversely affect our financial position and we may not be able to find another source of cash to continue our operations.

Further, our existing or future collaborators may pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators

may shift such that our programs receive less attention or resources than we would like. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our existing or future collaborators regarding, for example, the interpretation of terms in our agreements. Any such disagreements could lead to delays in the 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.

Table of Contents

Even with respect to certain other programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary drugs will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such drugs. We may not be able to establish such arrangements on favorable terms or at all, and our existing or future collaborative arrangements may not be successful.

The results of later stage clinical trials of our product candidates may not be as favorable as earlier trials and that could result in additional costs and delay or prevent commercialization of our products.

Although we believe the limited and preliminary data we have regarding our potential products are encouraging, the results of initial preclinical testing and clinical trials do not necessarily predict the results that we will get from subsequent or more extensive preclinical testing and clinical trials. Clinical trials of our product candidates may not demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after receiving promising results in earlier trials. If we cannot adequately demonstrate through the clinical trial process that a therapeutic product we are developing is safe and effective, regulatory approval of that product would be delayed or prevented, which would impair our reputation, increase our costs and prevent us from earning revenues. For example, while our Phase 2a clinical trials with inhaled liposomal ciprofloxacin showed promising initial efficacy and safety results both in patients with cystic fibrosis and non-cystic fibrosis bronchiectasis, there is no guarantee that longer term studies in larger patient populations will confirm these results or that we will satisfy all efficacy and safety endpoints required by the regulatory authorities.

If our clinical trials are delayed because of patient enrollment or other problems, we would incur additional costs and postpone the potential receipt of revenues.

Before we or our collaborators can file for regulatory approval for the commercial sale of our potential products, the FDA will require extensive preclinical safety testing and clinical trials to demonstrate their safety and efficacy. Completing clinical trials in a timely manner depends on, among other factors, the timely enrollment of patients. Our collaborators' and 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 competing clinical trials. Delays in planned patient enrollment in our current or future clinical trials may result in increased costs, program delays, or both, and the loss of potential revenues.

We are subject to extensive regulation, including the requirement of approval before any of our product candidates can be marketed. We may not obtain regulatory approval for our product candidates on a timely basis, or at all.

We, our collaborators and our products are subject to extensive and rigorous regulation by the federal government, principally the FDA, and by state and local government agencies. Both before and after regulatory approval, the development, testing, manufacture, quality control, labeling, storage, approval, advertising, promotion, sale, distribution and export of our potential products are subject to regulation. Pharmaceutical products that are marketed abroad are also subject to regulation by foreign governments. Our products cannot be marketed in the United States without FDA approval. The process for obtaining FDA approval for drug products is generally lengthy, expensive and uncertain. To date, we have not sought or received approval from the FDA or any corresponding foreign authority for any of our product candidates.

Even though we intend to apply for approval of most of our products in the United States under Section 505(b)(2) of the United States Food, Drug and Cosmetic Act, which applies to reformulations of approved drugs and which may require smaller and shorter safety and efficacy testing than that for entirely new drugs, the approval process will still

be costly, time-consuming and uncertain. We, or our collaborators, may not 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. Failure to comply with applicable regulatory requirements can, among other things, result in warning letters, imposition of civil penalties or other monetary payments, delay in approving or refusal to approve a product candidate, suspension

Table of Contents

or withdrawal of regulatory approval, product recall or seizure, operating restrictions, interruption of clinical trials or manufacturing, injunctions and criminal prosecution.

Regulatory authorities may not approve our product candidates even if the product candidates meet safety and efficacy endpoints in clinical trials or the approvals may be too limited for us to earn sufficient revenues.

The FDA and other foreign regulatory agencies can delay approval of, or refuse to approve, our product candidates for a variety of reasons, including failure to meet safety and efficacy endpoints in our clinical trials. Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Even if a product candidate is approved, it may be approved for fewer or more limited indications than requested or the approval may be subject to the performance of significant post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any limitation, condition or denial of approval would have an adverse affect on our business, reputation and results of operations.

Even if we are granted initial FDA approval for any of our product candidates, we may not be able to maintain such approval, which would reduce our revenues.

Even if we are granted initial regulatory approval for a product candidate, the FDA and similar foreign regulatory agencies can limit or withdraw product approvals for a variety of reasons, including failure to comply with regulatory requirements, changes in regulatory requirements, problems with manufacturing facilities or processes or the occurrence of unforeseen problems, such as the discovery of previously undiscovered side effects. If we are able to obtain any product approvals, they may be limited or withdrawn or we may be unable to remain in compliance with regulatory requirements. Both before and after approval we, our collaborators and our products are subject to a number of additional requirements. For example, certain changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims are subject to additional FDA review and approval. Advertising and other promotional material must comply with FDA requirements and established requirements applicable to drug samples. We, our collaborators and our manufacturers will be subject to continuing review and periodic inspections by the FDA and other authorities, where applicable, and must comply with ongoing requirements, including the FDA's Good Manufacturing Practices, or GMP, requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA and make certain other required reports. Product approvals may be withdrawn if regulatory requirements are not complied with or if problems concerning safety or efficacy of the product occur following approval. Any limitation or withdrawal of approval of any of our products could delay or prevent sales of our products, which would adversely affect our revenues. Further continuing regulatory requirements involve expensive ongoing monitoring and testing requirements.

Because our proprietary liposomal ciprofloxacin programs rely on the FDA's grant of orphan drug designation for potential market exclusivity, the product may not be able to obtain market exclusivity and could be barred from the market for up to seven years.

The FDA has granted orphan drug designation for our proprietary liposomal ciprofloxacin for the management of cystic fibrosis and bronchiectasis. Orphan drug designation is intended to encourage research and development of new therapies for diseases that affect fewer than 200,000 patients in the United States. The designation provides the opportunity to obtain market exclusivity for seven years from the date of the FDA's approval of a new drug application, or NDA. However, the market exclusivity is granted only to the first chemical entity to be approved by the FDA for a given indication. Therefore, if another inhaled ciprofloxacin product were to be approved by the FDA for a cystic fibrosis or bronchiectasis indication before our product, then we may be blocked from launching our

product in the United States for seven years, unless we are able to demonstrate to the FDA clinical superiority of our product on the basis of safety or efficacy. For example, Bayer HealthCare is developing an inhaled powder formulation of ciprofloxacin for the treatment of respiratory infections in cystic fibrosis. We may seek to develop additional products that incorporate drugs that have received orphan drug designations for specific indications. In

Table of Contents

each case, if our product is not the first to be approved by the FDA for a given indication, we may not be able to access the target market in the United States, which would adversely affect our ability to earn revenues.

We have limited manufacturing capacity and will have to depend on contract manufacturers and collaborators; if they do not perform as expected, our revenues and customer relations will suffer.

We have limited capacity to manufacture our requirements for the development and commercialization of our product candidates. We intend to use contract manufacturers to produce key components, assemblies and subassemblies in the clinical and commercial manufacturing of our products. We may not be able to enter into or maintain satisfactory contract manufacturing arrangements. For example, our agreement with Enzon Pharmaceuticals, Inc. to manufacture liposomal ciprofloxacin and AERx Strip® dosage forms may be terminated for unforeseen reasons, or we may not be able to reach mutually satisfactory agreements with Enzon to manufacture these at a commercial scale. There may be a significant delay before we find an alternative contract manufacturer or we may not find an alternative contract manufacturer at all.

We may decide to invest in additional clinical manufacturing facilities in order to internally produce critical components of our product candidates and to handle critical aspects of the production process, such as assembly of the disposable unit-dose packets and filling of the unit-dose packets. If we decide to produce components of any of our product candidates in-house, rather than use contract manufacturers, it will be costly and we may not be able to do so in a timely or cost-effective manner or in compliance with regulatory requirements.

With respect to some of our product development programs targeted at large markets, either our collaborators or we will have to invest significant amounts to attempt to provide for the high-volume manufacturing required to take advantage of these product markets, and much of this spending may occur before a product is approved by the FDA for commercialization. Any such effort will entail many significant risks. For example, the design requirements of our products may make it too costly or otherwise unfeasible for us to develop them at a commercial scale, or manufacturing and quality control problems may arise as we attempt to expand production. Failure to address these issues could delay or prevent late-stage clinical testing and commercialization of any products that may receive FDA approval.

Further, we, our contract manufacturers and our collaborators are required to comply with the FDA's GMP requirements that relate to product testing, quality assurance, manufacturing and maintaining records and documentation. We, our contract manufacturers or our collaborators may not be able to comply with the applicable GMP and other FDA regulatory requirements for manufacturing, which could result in an enforcement or other action, prevent commercialization of our product candidates and impair our reputation and results of operations.

We rely on a small number of vendors and contract manufacturers to supply us with specialized equipment, tools and components; if they do not perform as we need them to, we will not be able to develop or commercialize products.

We rely on a small number of vendors and contract manufacturers to supply us and our collaborators with specialized equipment, tools and components for use in development and manufacturing processes. These vendors may not continue to supply such specialized equipment, tools and components, and we may not be able to find alternative sources for such specialized equipment and tools. Any inability to acquire or any delay in our ability to acquire necessary equipment, tools and components would increase our expenses and could delay or prevent our development of products.

In order to market our proprietary products, we are likely to establish our own sales, marketing and distribution capabilities. We have no experience in these areas, and if we have problems establishing these capabilities, the

commercialization of our products would be impaired.

We intend to establish our own sales, marketing and distribution capabilities to market products to concentrated, easily addressable prescriber markets. We have no experience in these areas, and developing these capabilities will require significant expenditures on personnel and infrastructure. While we intend to market products that are aimed at a small patient population, we may not be able to create an effective sales force around even a niche market. In addition, some of our product development programs will require a large sales force to call

Table of Contents

on, educate and support physicians and patients. While we intend to enter into collaborations with one or more pharmaceutical companies to sell, market and distribute such products, we may not be able to enter into any such arrangement on acceptable terms, if at all. Any collaborations we do enter into may not be effective in generating meaningful product royalties or other revenues for us.

If any products that we or our collaborators may develop do not attain adequate market acceptance by healthcare professionals and patients, our business prospects and results of operations will suffer.

Even if we or our collaborators successfully develop one or more products, such products may not be commercially acceptable to healthcare professionals and patients, who will have to choose our products over alternative products for the same disease indications, and many of these alternative products will be more established than ours. For our products to be commercially-viable, we will need to demonstrate to healthcare professionals and patients that our products afford benefits to the patient that are cost-effective as compared to the benefits of alternative therapies. Our ability to demonstrate this depends on a variety of factors, including:

- the demonstration of efficacy and safety in clinical trials;
- the existence, prevalence and severity of any side effects;
- the potential or perceived advantages or disadvantages compared to alternative treatments;
- the timing of market entry relative to competitive treatments;
- the relative cost, convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of our product candidates by governmental and other third-party payors; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

Our product revenues will be adversely affected if, due to these or other factors, the products we or our collaborators are able to commercialize do not gain significant market acceptance.

We depend upon our proprietary technologies, and we may not be able to protect our potential competitive proprietary advantage.

Our business and competitive position is dependent upon our and our collaborators' ability to protect our proprietary technologies related to various aspects of pulmonary drug delivery and drug formulation. While our intellectual property rights may not provide a significant commercial advantage for us, our patents and know-how 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 non-patented trade secrets some of the key elements of our manufacturing technologies, for example, those associated with production of disposable unit-dose packets for our AERx delivery system.

Our ability to compete effectively will also depend to a significant extent on our and our collaborators' ability to obtain and enforce patents and maintain trade secret protection over our proprietary technologies. The coverage claimed in a

patent application typically is significantly reduced before a patent is issued, either in the United States or abroad. Consequently, any of our pending or future patent applications may not result in the issuance of patents and any patents issued may be subjected to further proceedings limiting their scope and may in any event not contain claims broad enough to provide meaningful protection. Any patents that are issued to us or our collaborators may not provide significant proprietary protection or competitive advantage, and may be circumvented or invalidated. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Further, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire and provide only a short period of protection, if any, following commercialization of products.

Table of Contents

In July 2006, we assigned 23 issued United States patents to Novo Nordisk along with corresponding non-United States counterparts and certain related pending applications. In August 2006, Novo Nordisk brought suit against Pfizer, Inc. claiming infringement of certain claims in one of the assigned United States patents. In December 2006, Novo Nordisk's motion for a preliminary injunction in this case was denied. Subsequently, Novo Nordisk and Pfizer settled this litigation out of court. In September 2008, Novo Nordisk informed us that they do not wish to maintain the assigned patents, and they assigned these patents back to us, at no charge to us. These patents may become the subject of future litigation. The patents encompass, in some instances, technology beyond inhaled insulin and, if all or any of these patents are invalidated, it could harm our ability to obtain market exclusivity with respect to other product candidates. We will no longer be able to rely upon Novo Nordisk to defend or enforce our rights related to the patents. If we are required to defend an action based on these patents or seek to enforce our rights under these patents, we could incur substantial costs and the action could divert management's attention, regardless of the lawsuit's merit or outcome.

We may infringe on the intellectual property rights of others, and any litigation could force us to stop developing or selling potential products and could be costly, divert management attention and harm our business.

We must be able to develop products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to compositions of matter, methods of use and methods of drug delivery, it could be difficult for us to use our technologies or develop products without infringing the proprietary rights of others. We may not be able to design around the patented technologies or inventions of others and we may not be able to obtain licenses to use patented technologies on acceptable terms, or at all. If we cannot operate without infringing on the proprietary rights of others, we will not earn product revenues.

If we are required to defend ourselves in a lawsuit, we could incur substantial costs and the lawsuit could divert management's attention, regardless of the lawsuit's merit or outcome. 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 any license required under any such patent may not be made available to us on acceptable terms, if at all. If any of our collaboration partners terminate an agreement with us, we may face increased risk and/or costs associated with defense of intellectual property that was associated with the collaboration.

Periodically, we review publicly available information regarding the development efforts of others in order to determine whether these efforts may violate our proprietary rights. We may determine that litigation is necessary to enforce our proprietary rights against others. Such litigation could result in substantial expense, regardless of its outcome, and may not be resolved in our favor.

Furthermore, patents already issued to us or our pending patent applications may become subject to dispute, and any disputes could be resolved against us. For example, Eli Lilly and Company 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 we may face other similar claims in the future and we may lose or settle cases at significant loss to us. In addition, because patent applications in the United States are currently maintained in secrecy for a period of time prior to issuance, patent applications in certain other countries generally are not published until more than 18 months after they are first filed, and 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 our pending patent applications or that we were the first to file patent applications on such inventions.

We are in a highly competitive market, and our competitors have developed or may develop alternative therapies for our target indications, which would limit the revenue potential of any product we may develop.

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of drugs and therapies

Table of Contents

for the disease indications we are targeting. Our competitors may succeed before we can, and many already have succeeded, in developing competing technologies for the same disease indications, obtaining FDA approval for products or gaining acceptance for the same markets that we are targeting. If we are not first to market, it may be more difficult for us and our collaborators to enter markets as second or subsequent competitors and become commercially successful. We are aware of a number of companies that are developing or have developed therapies to address indications we are targeting, including major pharmaceutical companies such as Bayer, Genentech, Gilead Sciences, GlaxoSmith Kline, Novartis and Pfizer. Certain of these companies are addressing these target markets with pulmonary products that are similar to ours. These companies and many other potential competitors have greater research and development, manufacturing, marketing, sales, distribution, financial and managerial resources and experience than we have and many of these companies may have products and product candidates that are on the market or in a more advanced stage of development than our product candidates. Our ability to earn product revenues and our market share would be substantially harmed if any existing or potential competitors brought a product to market before we or our collaborators were able to, or if a competitor introduced at any time a product superior to or more cost-effective than ours.

If we do not continue to attract and retain key employees, our product development efforts will be delayed and impaired.

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 management, manufacturing, engineering and development personnel. There is a shortage of skilled personnel in our industry, we face competition in our recruiting activities, and we may not be able to attract or retain qualified personnel. Losing any of our key employees, particularly our President and Chief Executive Officer, Dr. Igor Gonda, who plays a central role in our strategy shift to a specialty pharmaceutical company, could impair our product development efforts and otherwise harm our business. Any of our employees may terminate their employment with us at will.

Acquisition of complementary businesses or technologies could result in operating difficulties and harm our results of operations.

While we have not identified any definitive targets, we may acquire products, businesses or technologies that we believe are complementary to our business strategy. The process of investigating, acquiring and integrating any business or technology into our business and operations is risky and we may not be able to accurately predict or derive the benefits of any such acquisition. The process of acquiring and integrating any business or technology may create operating difficulties and unexpected expenditures, such as:

diversion of our management from the development and commercialization of our pipeline product candidates;

difficulty in assimilating and efficiently using the acquired assets or personnel; and

inability to retain key personnel.

In addition to the factors set forth above, we may encounter other unforeseen problems with acquisitions that we may not be able to overcome. Any future acquisitions may require us to issue shares of our stock or other securities that dilute the ownership interests of our other shareholders, expend cash, incur debt, assume liabilities, including contingent or unknown liabilities, or incur additional expenses related to write-offs or amortization of intangible assets, any of which could materially adversely affect our operating results.

If we market our products in other countries, we will be subject to different laws and we may not be able to adapt to those laws, which could increase our costs while reducing our revenues.

If we market any approved products in foreign countries, we will be subject to different laws, particularly with respect to intellectual property rights and regulatory approval. To maintain a proprietary market position in foreign countries, we may seek to protect some of our proprietary inventions through foreign counterpart patent applications. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. The diversity of patent laws may make our expenses associated with the

Table of Contents

development and maintenance of intellectual property in foreign jurisdictions more expensive than we anticipate. We probably will not obtain the same patent protection in every market in which we may otherwise be able to potentially generate revenues. In addition, in order to market our products in foreign jurisdictions, we and our collaborators must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety and quality. We may not be able to obtain regulatory approvals in such jurisdictions and we may have to 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 as we could not earn revenues from sales in those countries.

We may be exposed to product liability claims, which would hurt our reputation, market position and operating results.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates in humans and will face an even greater risk upon commercialization of any products. These claims may be made directly by consumers or by pharmaceutical companies or others selling such products. We may be held liable if any product we develop causes injury or is found otherwise unsuitable during product testing, manufacturing or sale. Regardless of merit or eventual outcome, liability claims would likely result in negative publicity, decreased demand for any products that we may develop, injury to our reputation and suspension or withdrawal of clinical trials. Any such claim will be very costly to defend and also may result in substantial monetary awards to clinical trial participants or customers, loss of revenues and the inability to commercialize products that we develop. Although we currently have product liability insurance, we may not be able to 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 results of operations.

If we cannot arrange for adequate third-party reimbursement for our products, our revenues will suffer.

In both domestic and foreign markets, sales of our potential products will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able to successfully develop may not be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not 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. If any products we develop do not receive adequate reimbursement, our revenues will be severely limited.

Our use of hazardous materials could subject us to liabilities, fines and sanctions.

Our laboratory and clinical testing sometimes involve use of hazardous and toxic materials. We are subject to federal, state and local laws and regulations governing how we use, manufacture, handle, store and dispose of these materials. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with all federal, state and local regulations and standards, there is always the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result and such liability could exceed our financial resources. Compliance with environmental and other laws may be expensive and current or future regulations may impair our development or commercialization efforts.

If we are unable to effectively implement or maintain a system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the

Table of Contents

effectiveness of our internal control over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also currently requires our independent registered public accounting firm, beginning with our fiscal year ending December 31, 2009, to attest to, and report on our internal control over financial reporting. Our ability to comply with the annual internal control report requirements will depend on the effectiveness of our financial reporting and data systems and controls across our company. We expect these systems and controls to involve significant expenditures and to become increasingly complex as our business grows and to the extent that we make and integrate acquisitions. To effectively manage this complexity, we will need to continue to improve our operational, financial and management controls and our reporting systems and procedures. Any failure to implement required new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Risks Related to Our Common Stock

Our stock price is likely to remain volatile.

The market prices for securities of many companies in the drug delivery and pharmaceutical industries, 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;

market conditions relating to our segment of the industry or the securities markets in general;

sales of our stock by certain large institutional shareholders to meet liquidity concerns during the current economic climate;

research analyst recommendations and our ability to meet or exceed quarterly performance expectations of analysts or investors;

failure to maintain existing or establish new collaborative relationships;

fluctuations in our operating results;

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;

developments or disputes concerning patents or proprietary rights;

delays in the development or approval of our product candidates;

regulatory developments in both the United States and foreign countries;

concern of the public or the medical community as to the safety or efficacy of our products, or products deemed to have similar safety risk factors or other similar characteristics to our products;

future sales or expected sales of substantial amounts of common stock by shareholders;

our ability to raise financing; and

economic and other external factors.

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

Table of Contents

Our common stock is quoted on the OTC Bulletin Board, which may provide less liquidity for our shareholders than the national exchanges.

On November 10, 2006, our common stock was delisted from the Nasdaq Capital Market due to non-compliance with Nasdaq's continued listing standards. Our common stock is currently quoted on the OTC Bulletin Board. As compared to being listed on a national exchange, being quoted on the OTC Bulletin Board may result in reduced liquidity for our shareholders, may cause investors not to trade in our stock and may result in a lower stock price. In addition, investors may find it more difficult to obtain accurate quotations of the share price of our common stock.

We have implemented certain anti-takeover provisions, which may make an acquisition less likely or might result in costly litigation or proxy battles.

Certain provisions of our articles of incorporation and the California Corporations Code could discourage a party from acquiring, or make it more difficult for a 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 our board of directors to authorize the issuance, without shareholder approval, 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 Corporations Code, which requires us to provide a fairness opinion 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 of our articles of incorporation, our poison pill, our severance plan and our change of control agreements, and provisions of the California Corporations Code may discourage, delay or prevent another party from acquiring us or reduce the price that a buyer is willing to pay for our common stock.

One of our shareholders may choose to pursue a lawsuit or engage in a proxy battle with management to limit our use of one or more of these anti-takeover protections. Any such lawsuit or proxy battle would, regardless of its merit or outcome, result in substantial costs and a diversion of management's attention and resources.

We have never paid dividends on our capital stock, and we do not anticipate paying cash dividends for at least the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying any cash dividends on our common stock for at least the foreseeable future. We currently intend to retain all available funds and future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for at least the foreseeable future.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

As of December 31, 2008, we leased one building with an aggregate of 72,000 square feet of office and laboratory facilities at 3929 Point Eden Way, Hayward, California. This building serves as our Corporate office and our research and development facility with a lease expiration of July 2016. In 2007, we entered into a long-term sublease with Mendel Biotechnology, Inc. (Mendel). The sublease with Mendel is for 48,000 square feet and expires concurrently

with our lease. Mendel may terminated the sublease early on September 1, 2012 for a termination fee of \$225,000. The sublease with Mendel substantially reduced our net outstanding lease commitment (see Note 6 to the financial statements included in this Form 10-K). Our current building is expected to meet our facility requirements for the foreseeable future.

Table of Contents**Item 3. *Legal Proceedings***

We are not currently a party to any material pending legal proceedings.

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

There were no submissions of matters to a vote of security holders in the quarter ended December 31, 2008.

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

Since December 21, 2006, our common stock has been quoted on the OTC Bulletin Board, an electronic quotation service for securities traded over-the-counter, under the symbol ARDM. Between June 20, 1996 and May 1, 2006 our common stock was listed on the Nasdaq Global Market (formerly the Nasdaq National Market). Between May 2, 2006 and November 9, 2006, our common stock was listed on the Nasdaq Capital Market (formerly the Nasdaq SmallCap Market). As of November 9, 2006, we were delisted from the Nasdaq Capital Market. Between November 10, 2006 and December 20, 2006, our common stock was quoted on the Pink Sheets.

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

	High	Low
2007		
First Quarter	\$ 1.46	\$ 0.90
Second Quarter	1.69	1.18
Third Quarter	1.40	1.12
Fourth Quarter	1.81	1.27
2008		
First Quarter	\$ 1.58	\$ 1.11
Second Quarter	1.09	0.62
Third Quarter	0.80	0.39
Fourth Quarter	0.40	0.20
2009		
First Quarter (through February 27, 2009)	\$ 0.29	\$ 0.11

On February 27, 2009, there were approximately 196 stockholders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our capital stock for at least the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends on our capital stock will be, subject to applicable law, at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions in loan agreements or other

agreements.

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.

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except share data)				
Statements of operations data:					
Contract and license revenues	\$ 251	\$ 961	\$ 4,814	\$ 10,507	\$ 28,045
Operating expenses:					
Research and development	16,499	16,770	22,198	30,174	46,477
General and administrative	6,679	8,401	10,717	10,895	11,934
Restructuring and asset impairment	79	2,182	6,003		
Total operating expenses	23,257	27,353	38,918	41,069	58,411
Loss from operations	(23,006)	(26,392)	(34,104)	(30,562)	(30,366)
Gain on sale of patent and royalty interest to related party			20,000		
Interest income	781	2,573	1,251	1,317	194
Interest expense	(408)	(393)	(197)	(6)	(16)
Other income (expense)		11	23	36	(1)
Income tax benefit	25				
Net loss	\$ (22,608)	\$ (24,201)	\$ (13,027)	\$ (29,215)	\$ (30,189)
Basic and diluted net loss per share	\$ (0.42)	\$ (0.48)	\$ (0.89)	\$ (2.01)	\$ (2.37)
Shares used in computing basic and diluted net loss per share	54,162	50,721	14,642	14,513	12,741

	As of December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents and short-term investments	\$ 19,140	\$ 40,510	\$ 27,514	\$ 27,694	\$ 16,763
Working capital	17,313	36,594	25,405	21,087	4,122
Total assets	25,519	45,813	32,226	39,497	79,741
	8,472	8,071	7,686		

Note payable and accrued interest to
former related party

Convertible preferred stock			23,669	23,669	23,669
Accumulated deficit	(334,674)	(312,066)	(287,865)	(274,838)	(245,623)
Total shareholders' equity (deficit)	8,756	30,299	(3,947)	7,171	35,754

Table of Contents

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 our filings with the Securities and Exchange Commission.

Our business is subject to significant risks including, but not limited to, our ability to obtain additional financing, our ability to implement our product development strategy, the success of product development efforts, our dependence on collaborators for certain programs, obtaining and enforcing patents important to our business, clearing the lengthy and expensive regulatory approval process and possible competition from other products. Even if product candidates appear promising at various stages of development, they may not reach the market or may not be commercially successful for a number of reasons. Such reasons include, but are not limited to, the possibilities that the potential products may be found to be ineffective during clinical trials, may fail to receive necessary regulatory approvals, may be difficult to manufacture on a large scale, are uneconomical to market, may be precluded from commercialization by proprietary rights of third parties or may not gain acceptance from health care professionals and patients. Further, even if our product candidates appear promising at various stages of development, our share price may decrease such that we are unable to raise additional capital without dilution that may be unacceptable to our shareholders.

Investors are cautioned not to place undue reliance on the forward-looking statements contained herein. We undertake no obligation to update these forward-looking statements in light of events or circumstances occurring after the date hereof or to reflect the occurrence of unanticipated events.

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. Over the last decade, we invested a large amount of capital to develop drug delivery technologies, particularly the development of a significant amount of expertise in pulmonary drug delivery. We also invested considerable effort into the generation of a large volume of laboratory and clinical data demonstrating the performance of our AERx pulmonary drug delivery platform. We have not been profitable since inception and expect to incur additional operating losses over at least the next several years as we expand product development efforts, preclinical testing and clinical trial activities, and possible sales and marketing efforts, and as we secure production capabilities from outside contract manufacturers. To date, we have not had any significant product sales and do not anticipate receiving any revenues from the sale of products in the near term. As of December 31, 2008, we had an accumulated deficit of \$334.7 million. Historically, we have funded our operations primarily through public offerings and private placements of our capital stock, proceeds from equipment lease financings, license fees and milestone payments from collaborators, proceeds from the January 2005 restructuring transaction with Novo Nordisk, borrowings from Novo Nordisk, sale of Intraject related assets and interest earned on investments. In February 2009, we closed the sale of 44,663,071 shares of common stock in a registered direct offering with net proceeds, after expenses, of \$4.1 million.

Historically, our development activities consisted primarily of collaborations and product development agreements with third parties. The most notable collaboration was with Novo Nordisk on the AERx iDMS for the treatment of Type I and Type II diabetes. This program began in 1998 and included nine Phase 3 clinical trials in Type I and Type II diabetes patients. On April 30, 2008, Novo Nordisk announced that following recent reports of lung cancer in Type II diabetes patients treated with Exubera*, an inhaled insulin product from Pfizer, the likelihood of achieving a positive benefit/risk ratio for future pulmonary diabetes projects had become more uncertain, and as a result, Novo Nordisk had decided to stop all research and development activities in the field. In May 2008, the July 3, 2006 License

Agreement between us and Novo Nordisk was terminated. Pursuant to the License Agreement, on September 25, 2008, Novo Nordisk assigned, at no charge to us, the inhaled insulin-related patents, which Novo purchased from us in July 2006, as well as certain related patents that originate from Novo Nordisk. The portfolio includes both U.S. and foreign patents. We assume the responsibility for the maintenance of this portfolio. Novo

Table of Contents

Nordisk is also providing us with the data from the preclinical and clinical research generated during the collaboration. We do not intend to complete the development of AERx iDMS on our own. We are attempting to out-license or sell the assets associated with inhaled insulin.

Over the last three years, our business has focused on opportunities for product development for treatment of severe respiratory disease that we could develop and commercialize in the United States without a partner. In selecting our proprietary development programs, we primarily seek drugs approved by the United States Food and Drug Administration (FDA) that can be reformulated for both existing and new indications in respiratory disease. Our intent is to use our pulmonary delivery methods and formulations to improve their safety, efficacy and convenience of administration to patients. We believe that this strategy will allow us to reduce cost, development time and risk of failure, when compared to the discovery and development of new chemical entities. It is our longer term strategy to commercialize our respiratory product candidates with our own focused sales and marketing force addressing pulmonary specialty doctors in the United States, where we believe that a proprietary sales force will enhance the return to our shareholders. Where our products can benefit a broader population of patients in the United States or in other countries, we may enter into co-development, co-promotion or other marketing arrangements with collaborators, thereby reducing costs and increasing revenues through license fees, milestone payments and royalties. Our lead development candidate is a proprietary liposomal formulation of the antibiotic ciprofloxacin that is delivered by inhalation for the treatment of infections associated with the severe respiratory diseases cystic fibrosis and non-cystic fibrosis bronchiectasis. We received orphan drug designations for both of these indications in the U.S.. We have recently reported the results of two successful Phase 2a trials with this product candidate in cystic fibrosis (CF) and non-cystic fibrosis bronchiectasis, respectively, as described below. In the near term given our financial resources, our focus will be on completing a Phase 2b clinical trial of liposomal ciprofloxacin in a single indication.

In June 2008, we completed a multi-center 14-day treatment Phase 2a trial in Australia and New Zealand in 21 CF patients to investigate safety, efficacy and pharmacokinetics of once daily inhaled liposomal ciprofloxacin. The primary efficacy endpoint in this Phase 2a study was the change from baseline in the sputum *Pseudomonas aeruginosa* colony forming units (CFU), an objective measure of the reduction in pulmonary bacterial load. Data analysis in 21 patients who completed the study demonstrated that the CFUs decreased by a mean 1.43 log over the 14-day treatment period ($p < 0.0001$). Evaluation one week after study treatment was discontinued showed that the *Pseudomonas* bacterial density in the lung was still reduced from the baseline without additional antibiotic use. Pulmonary function testing as measured by the forced expiratory volume in one second (FEV1) showed a significant mean increase of 6.86% from baseline after 14 days of treatment ($p = 0.04$). The study drug was well tolerated, and there were no serious adverse events reported during the trial.

In December 2008, we completed an open-label, four week treatment study of efficacy, safety and tolerability of once daily inhaled liposomal ciprofloxacin in patients with non-CF bronchiectasis. The study was conducted at eight leading centers in the United Kingdom and enrolled a total of 36 patients. The patients were randomized into two equal size groups, one receiving 3 mL of inhaled liposomal ciprofloxacin and the other receiving 6 mL of inhaled liposomal ciprofloxacin , once-a-day for the four-week treatment period. The primary efficacy endpoint was the change from baseline in the sputum *Pseudomonas aeruginosa* CFU, the standard objective measure of the reduction in pulmonary bacterial load. The 3 mL and 6 mL doses of inhaled liposomal ciprofloxacin in the evaluable patient population demonstrated significant mean decreases against baseline in the CFUs over the 28-day treatment period of 3.5 log ($p < 0.001$) and 4.0 log ($p < 0.001$) units, respectively.

In 2004, we executed a development agreement with Defence Research and Development Canada (DRDC), a division of the Canadian Department of National Defence, for the development of liposomal ciprofloxacin for the treatment of biological terrorism-related inhalation anthrax, using the same formulation that we are exploring for the studies of the treatment of respiratory infections associated with cystic fibrosis and with non-cystic fibrosis bronchiectasis. If we apply in the future for approval of this product candidate for the prevention and treatment of inhalation anthrax and

possibly other inhaled life-threatening bioterrorism infections, we anticipate using safety data from these studies to support our application.

Our current programs include a collaboration with Lung Rx, a wholly owned subsidiary of United Therapeutics, for the development of inhalation treatments for pulmonary arterial hypertension. We conducted two

Table of Contents

collaborative research projects on inhaled treprostinil using our AERx delivery system with United Therapeutics. The first project was with an aqueous formulation of treprostinil. The second project involved development of a slow-acting liposomal formulation of treprostinil, with the view to achieve once-a-day dosing. On August 30, 2007, we signed an Exclusive License, Development and Commercialization Agreement with Lung Rx pursuant to which we granted Lung Rx a license, which becomes exclusive upon the payment of specified sums, to develop and commercialize inhaled treprostinil using our AERx Essence technology for the treatment of PAH and other potential therapeutic indications. Under the terms of the Lung Rx Agreement, we received an upfront fee of \$440,000 and an additional fee of \$440,000 four months after the signing date. These fees are nonrefundable and were included in deferred revenue in the balance sheet at December 31, 2007. Under the terms of the agreement with Lung Rx, we were responsible for conducting and funding the feasibility study that included a clinical trial to compare AERx Essence to a nebulizer used in a completed Phase 3 registration trial conducted by United Therapeutics. We began this study in April 2008 and announced results in November 2008. At the same time, we announced receipt of \$2.75 million from Lung Rx which included the first milestone of \$2 million and development costs. We are now in discussions with Lung Rx regarding the next steps required on the clinical, manufacturing and regulatory paths toward the approval and launch of this product. Lung Rx will be responsible for funding the remainder of the development of treprostinil in the AERx delivery system through registration and commercial launch. We could receive additional milestone payments of up to \$7 million. Following commercialization of the product, we would receive royalties from Lung Rx on a tiered basis of up to 10% of net sales for any licensed products.

Lung Rx was to pay a \$650,000 license fee for an exclusive license and had the right under the Lung Rx Agreement to purchase \$3.47 million of our common stock at an average closing price over a certain trailing period within 15 days of Lung Rx's determination that the feasibility study was successful. Lung Rx determined that, while the results of the clinical trial warranted continuation of the development of AERx Essence technology with treprostinil, the performance of the AERx Essence inhaler in the clinical study was different from the nebulizer. As such, they did not pay the license fee or purchase our stock.

We have conducted in vitro and market research in a collaboration with CyDex for inhalation treatments for asthma and chronic obstructive pulmonary disease in which we have shared the cost of this work.

We have a proprietary program for smoking cessation treatment for which we are currently seeking a partner. We have encouraging data from our first human clinical trial delivering aqueous solutions of nicotine using the palm-sized AERx Essence system. Our randomized, open-label, single-site Phase 1 trial evaluated arterial plasma pharmacokinetics and subjective acute cigarette craving when one of three nicotine doses was administered to 18 adult male smokers. Blood levels of nicotine rose much more rapidly following a single-breath inhalation compared to published data on other approved nicotine delivery systems. Cravings for cigarettes were measured on a scale from 0-10 before and after dosing for up to four hours. Prior to dosing, mean craving scores were 5.5, 5.5 and 5.0, respectively, for the three doses. At five minutes following inhalation of the nicotine solution through the AERx Essence device, craving scores were reduced to 1.3, 1.7 and 1.3, respectively, and did not return to pre-dose baseline during the four hours of monitoring. Nearly all subjects reported an acute reduction in craving or an absence of craving immediately following dosing. No serious adverse reactions were reported in the study.

We believe these results provide the foundation for further research with the AERx Essence device as a means toward smoking cessation. We are seeking collaborations with government, non-government and commercial organizations to further develop this product.

In August 2006, we sold all of our assets related to the Intraject needle-free injector technology platform and products, including 12 United States patents along with foreign counterparts, to Zogenix, Inc., a private company. Zogenix is responsible for further development and commercialization efforts of Intraject (now rebranded under the name DosePro™). We received a \$4 million initial payment from Zogenix, and we will be entitled to a milestone payment

upon initial commercialization, and royalty payments upon any commercialization of products in the U.S. and other countries, including the European Union, that may be developed and sold using the DosePro technology. In December 2007, Zogenix submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the migraine drug sumatriptan using the needle-free injector DosePro (Sumavert[®] DosePro). The NDA was accepted for filing by the FDA in March 2008.. The same month, Zogenix entered into a

Table of Contents

license agreement to grant exclusive rights in the European Union to Desitin Pharmaceuticals, GmbH to develop and commercialize Sumavel DosePro in the European Union. On October 31, 2008 Zogenix received a Complete Response Letter from the FDA on its NDA. On February 18, 2009, Zogenix disclosed that the Complete Response letter from the FDA cited the need for a single additional in vitro test to be conducted and that Zogenix recently submitted this information to the FDA. The FDA accepted this resubmission as a complete response, providing the new Prescription Drug User Fee Act (PDUFA) review date of July 15, 2009. Zogenix stated that it is their intention to launch Sumavel DosePro following FDA approval in the second half of 2009.

Critical Accounting Policies and Estimates

We consider certain accounting policies related to revenue recognition, impairment of long-lived assets, exit/disposal activities, research and development, income taxes and stock-based compensation 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 United States 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 periods for payments received from product development and license agreements as they relate to the revenue recognition, and assumptions for valuing options, warrants and other stock-based compensation. Our actual results could differ from these estimates.

Revenue Recognition

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. We recognize revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin Topic 13, *Revenue Recognition* (SAB Topic 13) and Emerging Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Revenue for arrangements not having multiple deliverables, as outlined in EITF 00-21, is recognized once costs are incurred and collectability is reasonably assured. Under some agreements our collaborators have the right to withhold reimbursement of costs incurred until the work performed under the agreement is mutually agreed upon. For these agreements, we recognize revenue upon acceptance of the work and confirmation of the amount to be paid by the collaborator.

Deferred revenue includes the portion of all refundable and nonrefundable research billings and payments that have been received, but 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 recognized as revenue either upon 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 agreement when payments precede the required efforts. Costs of contract revenues are approximate to or are greater than such revenues, and are included in research and development expenses. We defer refundable development and license fee payments until specific performance criteria are achieved. Refundable development and license fee payments are generally not refundable once specific performance criteria are achieved and accepted.

Collaborative license and development agreements often require us to provide multiple deliverables, such as a license, research and development, product steering committee services and other performance obligations. These agreements are accounted for in accordance with EITF 00-21. Under EITF 00-21, delivered items are evaluated to determine whether such items have value to our collaborators on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exist. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate revenue recognition criteria are identified and applied to each separate unit of accounting. For

example, at December 31, 2008, we have \$4.1 million in deferred revenue on our balance sheet, representing up-front fees for the feasibility study, milestone payments and development payments received from Lung Rx. We are obligated to provide multiple deliverables under the Lung Rx Agreement, including transfer of the AERx technology and any future improvements thereto during the term of the Lung Rx Agreement and participation on a product steering committee during the term of the Lung Rx Agreement. All of the deliverables under the Lung Rx Agreement are treated as a single unit of accounting under EITF 00-21 as the fair value of the undelivered

Table of Contents

performance obligations associated with these activities could not be objectively determined and the activities are not economically independent of each other. Since the deliverables are treated as a single unit of accounting, the upfront fees for the feasibility study and the milestone and development payments, together with any and future license fee and milestone and royalty payments will be recognized as revenue ratably over the estimated term of the Lung Rx Agreement, using a time-based model. Revenue recognition will commence with the delivery of the last deliverable, which is the license to the AERx technology and improvements thereto.

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*, we review 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, we write down the assets to their estimated fair values and recognize the loss in the statements of operations.

Accounting for Costs Associated with Exit or Disposal Activities

In accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146), we recognize a liability for the cost associated with an exit or disposal activity that is measured initially at its fair value in the period in which the liability is incurred, except for a liability for one-time termination benefits that is incurred over time. According to SFAS 146, costs to terminate an operating lease or other contracts are (a) costs to terminate the contract before the end of its term or (b) costs that will continue to be incurred under the contract for its remaining term without economic benefit to the entity. In periods subsequent to initial measurement, changes to the liability are measured using the credit-adjusted risk-free rate that was used to measure the liability initially. We recorded a non-cash charge of \$2.1 million for exit activities related to the subleasing of a portion of our facility in July 2007.

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. We expense research and development costs as such costs are incurred.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes. As part of the process of preparing our financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in our balance sheets.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including our historical levels of income and losses, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If we do not consider it more likely than not that we will recover our deferred tax assets, we will record a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. At

December 31, 2008 and 2007, we believed that the amount of our deferred income taxes would not be ultimately recovered. Accordingly, we recorded a full valuation allowance for deferred tax assets. However, should there be a change in our ability to recover our deferred tax assets, we would recognize a

Table of Contents

benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

In June 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FAS 109, Accounting for Income Taxes* (FIN 48), to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes, by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on de-recognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition.. We adopted FIN 48 as of January 1, 2007. See Note 13 of the notes to our financial statements included in this Form 10-K for further analysis on the impact of the adoption of FIN 48 on our financial statements.

Stock Based Compensation

We follow the fair value method of accounting for stock-based compensation arrangements in accordance with Financial Accounting Standards Board Statement of Financial Accounting Standards, or SFAS 123(R), *Share-Based Payment* (SFAS 123(R)). We adopted SFAS 123(R) effective January 1, 2006 using the modified prospective method of transition. Under SFAS 123(R), the estimated fair value of share-based compensation, including stock options and restricted stock awards and purchases of common stock by our employees under the Employee Stock Purchase Plan is recognized as compensation expense.

We recorded \$811,000 and \$1,382,000 of employee stock-based compensation expense for the years ended December 31, 2008 and 2007, respectively. Stock-based compensation expense is allocated to research and development and general and administrative expenses based on the function of the related employee. This charge had no impact on our cash flows for the periods presented.

We used the Black-Scholes option-pricing model to estimate the fair value of share-based awards as of the grant date. The Black-Sholes model, by its design, is highly complex, and dependent upon key data inputs estimated by management. The primary data inputs with the greatest degree of judgments are the estimated lives of the stock based awards and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two inputs. The expected term of the options represents the period of time that options granted are expected to be outstanding. We use a lattice model to estimate the expected term as an input into the Black-Scholes option pricing model. We determine expected volatility using the historical method, which is based on the daily historical daily trading data of our common stock over the expected term of the option. For more information about SFAS 123(R), see Note 7 to the financial statements included in this Form 10-K.

Recent Accounting Pronouncements

See Note 1 to the financial statements included in this Form 10-K for information on recent accounting pronouncements.

Results of Operations

Years Ended December 31, 2008 and 2007

Revenue

**Years Ended
December 31,**

	2008	2007	Decrease	
	(In thousands)			
Revenue:				
Related parties	\$	\$ 23	\$ (23)	
Unrelated parties	251	938	(687)	(73)%
Total revenue	\$ 251	\$ 961	\$ (710)	(74)%

Table of Contents

We recorded no related party revenue in 2008, and recorded related party revenue from Novo Nordisk of \$23,000 for 2007. The reason for the decrease in 2008 was the conclusion of the restructuring agreement with Novo Nordisk. We recorded revenues from unrelated parties of \$251,000 in 2008 primarily related to a feasibility study evaluating the delivery of certain compounds using the AERx system. For the year ended 2007, we recorded revenue of \$566,000 related to ARD-1100, \$192,000 for our final payment from APT related to ARD-1300, \$161,000 from our transition agreement with Zogenix and \$19,000 from Respiroics. The reason for the decrease in revenue in 2008 compared to 2007 was primarily due to the fact that revenue from milestone and development payments received from the Lung Rx collaboration cannot be recognized under the current revenue recognition rules. These rules require us to record amounts received as deferred revenue and to recognize the deferred revenue over the term of the Lung Rx Agreement, using a time-based model. The revenue recognition will commence with the delivery of the last deliverable in the Agreement, which is the delivery of the AERx technology license and future improvements thereto.

Research and Development Expenses

	Years Ended December 31, 2008 2007 (In thousands)		Increase / (Decrease)	
Research and development expenses:				
Collaborative	\$ 2,111	\$ 862	\$ 1,249	145%
Self-initiated	14,388	15,908	(1,520)	(10)%
Total research and development expenses	\$ 16,499	\$ 16,770	\$ (271)	(2)%

Research and development expenses represent proprietary research expenses and costs related to contract research revenue, including salaries, payments to contract manufacturers and contract research organizations, contractor and consultant fees, stock-based compensation expense and other support costs including facilities, depreciation and travel. The \$1.2 million increase in collaborative program expenses in 2008 as compared with 2007, was primarily due to activities related to the ARD-1550 bridging study and development of the ARD-1550 manufacturing process. In addition, we conducted a small AERx technology feasibility study with a third party. The \$1.5 million decrease in research and development expense for self-initiated program expenses was primarily due to lower spending on the AERx nicotine program and lower ARD-3100 manufacturing activities. Overall, research and development costs decreased slightly in 2008 as compared with the prior year. We expect research and development expenses to increase slightly over the next few quarters as we continue the development of ARD-3100 and manufacture supplies for the next ARD-1550 clinical trial. Expenses related to ARD-1550 activities will be reimbursed by Lung Rx.

General and Administrative Expenses

	Years Ended December 31, 2008 2007 (In thousands)		Decrease	
General and administrative expenses	\$ 6,679	\$ 8,401	\$ (1,722)	(20)%

General and administrative expenses are comprised of salaries, legal fees including patent related costs, insurance, marketing research, contractor and consultant fees, stock-based compensation expense and other support costs including facilities, depreciation and travel. General and administrative expenses decreased from 2007 primarily due to a reduction in headcount, as well as a reduction in building rent stemming from the subleasing of a portion of our office space to Mendel Biotechnology, Inc. (Mendel) in July 2007. In addition, employee stock-based compensation expense included in general and administrative expenses was lower in 2008 as compared with 2007. We expect that our general and administrative expenses will remain relatively constant over the next few quarters.

Table of Contents*Restructuring and Asset Impairment*

	Years Ended December 31,		Decrease	
	2008	2007		
	(In thousands)			
Restructuring and impairment expenses	\$ 79	\$ 2,182	\$ (2,103)	(96)%

Restructuring and impairment expenses in 2008 represent the accretion expense associated with the 2007 facility lease exit obligation. In 2007, restructuring and impairment expenses represents lease exit activities expense which consisted of the \$2.1 million loss recorded concurrent with the Mendel sublease loss and related expense accretion, as well as \$98,000 of severance-related costs relating to our 2006 restructuring efforts.

Interest Income, Interest Expense and Other Income (Expense)

	Years Ended December 31,		Increase (Decrease)	
	2008	2007		
	(In thousands)			
Interest income, interest expense and other income (expense):				
Interest income	\$ 781	\$ 2,573	\$ (1,792)	(70)%
Interest expense	(408)	(393)	(15)	(4)%
Other income (expense)		11	(11)	
Total interest income, interest expense and other income (expense)	\$ 373	\$ 2,191	\$ (1,818)	(83)%

Interest income in 2008 decreased from 2007 due to lower average invested balances and lower effective interest rates earned. Substantially all of the interest expense for 2008 and 2007 relates to the Promissory Note from Novo Nordisk. See Note 12 to the financial statements included in this Form 10-K.

Liquidity and Capital Resources

As of December 31, 2008, we had cash, cash equivalents and short-term investments of \$19.1 million and total working capital of \$17.3 million. Our principal requirements for cash are to fund operations, research activities and capital expenditures. We assess our liquidity primarily by the amount of our cash and cash equivalents and short term investments less our liabilities. In this assessment, we exclude deferred revenue from our liabilities as we do not believe this item will require the future use of cash.

Net cash used in operating activities in 2008 was \$19.0 million reflecting our net loss of \$22.6 million. Net cash used in operating activities was less than our net loss due to the recurring non cash expenses for depreciation and stock based compensation and a significant increase in deferred revenue. In 2008, the change in deferred revenue provided \$3.2 million in cash. The increase in deferred revenue was from milestone and expense reimbursement payments

received from a partner under a collaboration agreement, but not recognized as revenue due to our revenue recognition policy. In 2007, net cash used in operating activities was \$19.2 million reflecting our net loss of \$24.2 million offset by non-cash charges including leased facility exit cost, stock-based compensation expense, and depreciation and amortization expense.

Net cash provided by investing activities was \$5.6. million during 2008. Cash was provided by the maturity of short-term investments net of purchases, partially offset by capital expenditures of \$2.5 million. Net cash used in investing activities was \$11.1 million during 2007. We used \$1.1 million for purchases of equipment and \$10.0 million for the net purchase of short-term investments.

Cash provided by financing activities was \$0.2 million in 2008 as compared with \$33.3 million in 2007. In 2008, we did not generate cash from any equity financing offerings while in 2007, we had net proceeds of \$33.2 million from a public equity financing completed on January 30, 2007.

Our research and development efforts have required a commitment of substantial funds to conduct the costly and time-consuming research and preclinical and clinical testing activities necessary to develop and refine our

Table of Contents

technology and proposed products and to bring any such products to market. Our long term capital requirements will depend on many factors, including continued progress and the results of the research and development of our technology and drug delivery systems, our ability to establish and maintain favorable collaborative arrangements with others, progress with preclinical studies and clinical trials and the results thereof, the time and costs involved in obtaining regulatory approvals, the cost of development and the rate of scale-up of our production technologies, the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, and the need to acquire licenses or other rights to new technology. In the near term given our financial resources, our focus will be on completing a Phase 2b clinical trial of liposomal ciprofloxacin in a single indication.

Since inception, we have financed our operations primarily through public offerings and private placements of our capital stock, proceeds from equipment lease financings, contract research funding, proceeds from the sale of assets to Novo Nordisk in connection with restructuring transactions including sale of patents and royalty interest, borrowings from Novo Nordisk and interest earned on investments.

We continue to review our planned operations through the end of 2009, and beyond. We focus on capital spending requirements to ensure that capital outlays are not expended sooner than necessary. We currently expect our total capital expenditures for 2009 to be approximately \$0.3 million. We anticipate the majority of our total 2009 outlays to be associated with our lead product candidate, inhaled liposomal ciprofloxacin.

We have incurred significant losses and negative cash flows from operations since our inception. At December 31, 2008, we had an accumulated deficit of \$334.7 million, working capital of \$17.3 million, and shareholders' equity of \$8.8 million. We believe that cash, cash equivalents and short term investments at December 31, 2008, together with the proceeds from our common stock offering in February 2009, will be sufficient to enable us to meet our obligations at least through the end of the first quarter of 2010.

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 have one inactive, wholly-owned subsidiary domiciled in the United Kingdom.

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

The disclosures in this section are not required since the Company qualifies as a smaller reporting company.

Table of Contents

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, 2008 and 2007, and the related statements of operations, convertible preferred stock and shareholders' equity (deficit), and cash flows for the years then ended. 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 audits 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 audited by us present fairly, in all material respects, the financial position of Aradigm Corporation at December 31, 2008 and 2007, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, on January 1, 2008 the Company adopted Statement of Financial Accounting Standard No. 157, *Fair Value Measurement*. Also as discussed in Note 1 to the financial statements, on January 1, 2007 the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FAS 109*.

/s/ Odenberg Ullakko Muranishi & Co LLP

San Francisco, California
March 25, 2009

Table of Contents**ARADIGM CORPORATION****BALANCE SHEETS**

December 31,
2008 2007
(In thousands, except
share data)

ASSETS

Current assets:		
Cash and cash equivalents	\$ 16,741	\$ 29,964
Short-term investments	2,399	10,546
Receivables	393	500
Restricted cash	225	152
Prepaid and other current assets	387	971
 Total current assets	 20,145	 42,133
Property and equipment, net	5,093	3,223
Notes receivable	34	33
Restricted cash		153
Other assets	247	271
 Total assets	 \$ 25,519	 \$ 45,813

LIABILITIES AND SHAREHOLDERS EQUITY

Current liabilities:		
Accounts payable	\$ 739	\$ 1,658
Accrued clinical and cost of other studies	94	789
Accrued compensation	1,051	1,252
Deferred revenue		880
Facility lease exit obligation	318	376
Other accrued liabilities	630	584
 Total current liabilities	 2,832	 5,539
Deferred rent, non-current	199	283
Facility lease exit obligation, non-current	1,056	1,373
Deferred revenue, non-current	4,122	
Other non-current liabilities	82	248
Note payable and accrued interest	8,472	8,071
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, 2,950,000 shares authorized, none outstanding		
Common stock, no par value; authorized shares: 150,000,000 at December 31, 2008 and 100,000,000 at December 31, 2007; issued and outstanding shares: 55,029,384 at December 31, 2008; 54,772,705 at December 31, 2007	343,426	342,355
Accumulated other comprehensive income	4	10

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Accumulated deficit	(334,674)	(312,066)
Total shareholders' equity	8,756	30,299
Total liabilities and shareholders' equity	\$ 25,519	\$ 45,813

See accompanying Notes to Financial Statements.

Table of Contents

ARADIGM CORPORATION
STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2008	2007
	(In thousands, except share data)	
Contract and license revenues:		
Related parties	\$	\$ 23
Unrelated parties	251	938
Total revenues	251	961
Operating expenses:		
Research and development	16,499	16,770
General and administrative	6,679	8,401
Restructuring and asset impairment	79	2,182
Total expenses	23,257	27,353
Loss from operations	(23,006)	(26,392)
Interest income	781	2,573
Interest expense	(408)	(393)
Other income, net		11
Loss before income taxes	(22,633)	(24,201)
Income tax benefit	25	
Net loss	\$ (22,608)	\$ (24,201)
Basic and diluted net loss per common share	\$ (0.42)	\$ (0.48)
Shares used in computing basic and diluted net loss per common share	54,162	50,721

See accompanying Notes to Financial Statements.

Table of Contents**ARADIGM CORPORATION****STATEMENT OF CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY (DEFICIT)**

	Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders Equity (Deficit)
	Shares	Amount	Shares	Amount			
	(In thousands, except share data)						
Balances at December 31, 2006	1,544,626	\$ 23,669	14,765,474	\$ 283,914	\$ 4	\$ (287,865)	\$ (3,947)
Issuance of common stock in a public offering, net of issuance costs			37,950,000	33,178			33,178
Issuance of common stock for conversion of preferred stock related to public offering	(1,544,626)	(23,669)	1,235,699	23,669			23,669
Issuance of common stock under the employee stock purchase plan			100,407	103			103
Issuance of common stock under the restricted stock award plan			726,000				
Stock-based compensation				1,491			1,491
Reversal of restricted stock award due to forfeiture			(4,875)				
Comprehensive loss:							
Net loss						(24,201)	(24,201)
Unrealized gain on available-for-sale investments					6		6
Total comprehensive loss							(24,195)
Balances at December 31, 2007			54,772,705	342,355	10	(312,066)	30,299
Issuance of common stock under the employee stock purchase plan			300,524	190			190
Issuance of common stock upon exercise of common stock options			3,750	4			4
Stock-based compensation				877			877
Reversal of restricted stock award due to forfeiture			(47,595)				

Comprehensive loss:							
Net loss						(22,608)	(22,608)
Unrealized (loss) on available-for-sale investments					(6)		(6)
Total comprehensive loss							(22,614)
Balances at December 31, 2008	\$	55,029,384	\$	343,426	\$	4	\$ (334,674) \$ 8,756

See accompanying Notes to Financial Statements.

Table of Contents**ARADIGM CORPORATION****STATEMENTS OF CASH FLOWS**

	Years Ended December 31,	
	2008	2007
	(In thousands)	
Cash flows from operating activities:		
Net loss	\$ (22,608)	\$ (24,201)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash asset impairment on property and equipment		182
Facility lease exit costs		1,443
Amortization and accretion of investments	26	(26)
Depreciation and amortization	871	730
Stock-based compensation expense	877	1,491
Loss on disposition of property and equipment	1	33
Changes in operating assets and liabilities:		
Receivables	106	141
Prepaid and other current assets	584	31
Restricted cash	80	(305)
Other assets	24	173
Accounts payable	(1,113)	36
Accrued compensation	(201)	(562)
Accrued liabilities	(414)	1,188
Deferred rent	(84)	(132)
Deferred revenue	3,242	880
Facility lease exit obligation	(375)	(314)
Net cash used in operating activities	(18,984)	(19,212)
Cash flows from investing activities:		
Capital expenditures	(2,548)	(1,115)
Disposition of property and equipment		10
Purchases of available-for-sale investments	(3,629)	(17,013)
Proceeds from maturities of available-for-sale investments	11,744	7,000
Net cash provided (used) by investing activities	5,567	(11,118)
Cash flows from financing activities:		
Proceeds from public offering of common stock, net		33,178
Proceeds from issuance of common stock to Employee Stock Purchase Plan	190	103
Proceeds from exercise of common stock options	4	
Net cash provided by financing activities	194	33,281
Net increase (decrease) in cash and cash equivalents	(13,223)	2,951

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Cash and cash equivalents at beginning of year	29,964	27,013
Cash and cash equivalents at end of year	\$ 16,741	\$ 29,964
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 7	\$ 9
Supplemental disclosure of non-cash financing activities:		
Conversion of convertible preferred stock to common stock	\$	\$ 23,669
Supplemental disclosure of non-cash investing activities:		
Purchase of property and equipment in trade accounts payable	\$ 194	\$ 471

See accompanying Notes to Financial Statements.

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization

Aradigm Corporation (the Company) is a California corporation focused on the development and commercialization of drugs delivered by inhalation for the treatment of severe respiratory diseases. The Company's principal activities to date have included conducting research and development and developing collaborations. Management does not anticipate receiving any revenues from the sale of products in the upcoming year. The Company operates as a single operating segment.

Liquidity and Financial Condition

The Company has incurred significant losses and negative cash flows from operations since its inception. At December 31, 2008, the Company had an accumulated deficit of \$334.7 million, working capital of \$17.3 million and shareholders' equity of \$8.8 million. Management believes that cash, cash equivalents and short-term investments at December 31, 2008, along with its subsequent equity financing (see Note 20) will be sufficient to enable the Company to meet its obligations at least through the first quarter of 2010. Management plans to continue to fund the Company's operations with cash obtained through collaborative arrangements, equity issuances and/or debt arrangements.

Use of Estimates

The preparation of financial statements, in conformity with United States 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, assumptions for valuing options and warrants, and income taxes. 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 to be cash equivalents. The Company invests cash and cash equivalents not needed for operations in money market funds and commercial paper in accordance with its investment policy.

Investments

Management determines the appropriate classification of the Company's marketable securities, which consist solely of debt securities, at the time of purchase. All marketable securities are classified as available-for-sale, carried at estimated fair value and reported in short-term investments. Unrealized gains and losses on available-for-sale securities are excluded from earnings and losses and are reported as a separate component in the statement of convertible preferred stock and shareholders' equity (deficit) 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 reviews all of its investments for other-than-temporary declines in fair value. When the Company determines that the decline in fair value of an

investment below the Company's 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.

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)*****Notes Receivable***

Notes receivable are related to advances granted to employees for relocation or continuing education and are classified as current if due within 12 months, or non-current if due beyond one year in the accompanying balance sheets. One note in the amount of \$34,000 remains outstanding as of December 31, 2008.

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:

Computer equipment and software	3 to 5 years
Furniture and fixtures	5 to 7 years
Lab equipment	5 to 7 years
Machinery and equipment	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 (see Notes 14 and 16).

Accounting for Costs Associated with Exit or Disposal Activities

In accordance with Statement of SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146), the Company recognizes a liability for the cost associated with an exit or disposal activity that is measured initially at its fair value in the period in which the liability is incurred. According to SFAS 146, costs to terminate an operating lease or other contracts are (a) costs to terminate the contract before the end of its term or (b) costs that will continue to be incurred under the contract for its remaining term without economic benefit to the entity. In periods subsequent to initial measurement, changes to the liability are measured using the credit-adjusted risk-free rate that was used to measure the liability initially (see Notes 14 and 16).

Revenue Recognition

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. The Company recognizes revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin Topic 13, *Revenue Recognition* (SAB Topic 13) and Emerging Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Revenue for arrangements not having multiple deliverables, as outlined in EITF 00-21, is recognized once costs are incurred and collectability is reasonably assured. Under some agreements the Company's collaborators have the right to withhold reimbursement of costs incurred until the work performed under the agreement is mutually agreed upon. For these agreements,

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

revenue is recognized upon acceptance of the work and confirmation of the amount to be paid by the collaborator. Deferred revenue includes 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 recognized as revenue either upon 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 agreement when payments precede the required efforts. Costs of contract revenues are approximate to or are greater than such revenues, and are included in research and development expenses. Refundable development and license fee payments are deferred until specific performance criteria are achieved. Refundable development and license fee payments are generally not refundable once specific performance criteria are achieved and accepted.

Collaborative license and development agreements that require the Company to provide multiple deliverables, such as a license, research and product steering committee services and other performance obligations, are accounted for in accordance with EITF 00-21. Under EITF 00-21, delivered items are evaluated to determine whether such items have value to the Company's collaborators on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exist. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate revenue recognition criteria are identified and applied to each separate unit of accounting.

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, 2008 and 2007 were \$7,000 and zero.

Stock-Based Compensation

The Company accounts for share-based payment arrangements in accordance with Statement of Financial Accounting Standards 123(R), *Share-Based Payment*, or SFAS 123(R), which requires the recognition of compensation expense, using a fair-value based method, for all costs related to share-based payments including stock options and restricted stock awards and stock issued under the employee stock purchase plan. SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of the grant using an option-pricing model. The Company has adopted the simplified method to calculate the beginning balance of the additional paid-in capital, or APIC, pool of excess tax benefits, and to determine the subsequent effect on the APIC pool and statement of cash flows of the tax effects of stock-based compensation awards. See Note 7 for further discussion of the Company's stock-based compensation plan.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes. As part of the process of preparing our financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

accounting purposes. These differences result in deferred tax assets and liabilities, which are included in our balance sheets.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including our historical levels of income and losses, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If we do not consider it more likely than not that we will recover our deferred tax assets, we will record a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. At December 31, 2008 and 2007, we believed that the amount of our deferred income taxes would not be ultimately recovered. Accordingly, we recorded a full valuation allowance for deferred tax assets. However, should there be a change in our ability to recover our deferred tax assets, we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

In July 2006, the FASB issued FASB Interpretation No. 48 *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109 (FIN 48), to clarify certain aspects of accounting for uncertain tax positions, including issues related to the recognition and measurement of those tax positions. FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognizing, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. This interpretation is effective for fiscal years beginning after December 15, 2006. The Company adopted FIN 48 on January 1, 2007 (see Note 13).

Net Loss Per Common Share

Basic net loss per common share is computed using the weighted-average number of shares of common stock outstanding less the weighted-average number of shares subject to repurchase. Unvested restricted stock awards subject to repurchase totaled 704,000 shares and 771,000 shares for the years ended December 31, 2008 and 2007, respectively. Potentially dilutive securities were not included in the net loss per share calculation for the years ended December 31, 2008 and 2007 because the inclusion of such shares would have had an anti-dilutive effect.

Potentially dilutive securities include the following (in thousands):

	Years Ended December 31,	
	2008	2007
Outstanding stock options	4,185	3,493
Unvested restricted stock	704	771
Performance bonus stock award		100
Warrants to purchase common stock		427

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 and corporate notes 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 accompanying balance sheets.

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

Comprehensive Income (Loss)

SFAS No. 130, *Reporting Comprehensive Income* requires unrealized gains or losses on the Company's available-for-sale securities to be recorded in other comprehensive income (loss). Total comprehensive loss has been disclosed on the statement of convertible preferred stock and shareholders' equity (deficit).

Recently Issued Accounting Pronouncements

In February 2008, the FASB issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), which defers the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), for fiscal years beginning after November 15, 2008 and interim periods within those fiscal years for items within the scope of FSP FAS 157-2. We do not expect that the adoption of FSP FAS 157-2 will have a material impact on the Company's financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)), which replaces FAS No. 141. SFAS 141(R) establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. FAS 141(R) is to be applied prospectively to business combinations for which the acquisition date is on or after an entity's fiscal year that begins after December 15, 2008. We will assess the impact of SFAS 141(R) if and when a future acquisition occurs.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1). Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute, and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a virtual joint venture). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. The consensus requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. EITF 07-1 is effective for collaborative arrangements in place at the beginning of the annual period beginning after December 15, 2008. We do not expect that the adoption of EITF 07-1 will have a material impact on the Company's financial position and results of operations.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 provides guidance on whether non-refundable advance payments for goods that will be used or services that will be performed in future research and development activities should be accounted for as research and development costs or deferred and capitalized until the goods have been delivered or the related services have been rendered. EITF 07-3 is effective for

fiscal years beginning after December 15, 2007. Adoption of EITF 07-3 did not have a material impact on the Company's financial position and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company has not elected to measure any

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

eligible financial instruments of other items at fair value, except for its short-term investments which had been previously measured at fair value.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). Among other requirements, SFAS 157 defines fair value and establishes a framework for measuring fair value and also expands disclosure about the use of fair value to measure assets and liabilities. SFAS 157 is effective beginning the first fiscal year that begins after November 15, 2007. We adopted this standard on January 1, 2008 and adoption has not had a material impact on the Company's financial position and results of operations.

2. Cash and Cash Equivalents and Short-term Investments

A summary of cash and cash equivalents and short-term investments, classified as available-for-sale and carried at fair value is as follows (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Estimated Fair Value
December 31, 2008				
Cash and cash equivalents	\$ 16,741	\$	\$	\$ 16,741
Short-term investments:				
Commercial paper	\$ 2,395	\$ 4	\$	\$ 2,399
U.S. Treasury and agencies				
Total	\$ 2,395	\$ 4	\$	\$ 2,399
December 31, 2007				
Cash and cash equivalents	\$ 29,960	\$ 4	\$	\$ 29,964
Short-term investments:				
Commercial paper	\$ 1,496	\$	\$	\$ 1,496
Corporate bonds	8,213	4	(1)	8,216
U.S. Treasury and agencies	831	3		834
Total	\$ 10,540	\$ 7	\$ (1)	\$ 10,546

All short-term investments at December 31, 2008 and 2007 mature in less than one year. Unrealized holding gains and losses on securities classified as available-for-sale are recorded in accumulated other comprehensive income. As of December 31, 2008 and 2007 the difference between the fair value and amortized cost of available-for-sale securities were gains of \$4,000 and \$10,000, respectively.

3. Fair Value Measurements

Effective January 1, 2008, we adopted SFAS 157, *Fair Value Measurements*. SFAS 157 clarifies the definition of fair value, prescribes methods for measuring fair value, establishes a fair value hierarchy based on the inputs used to measure fair value and expands disclosures about the use of fair value measurements. The fair value hierarchy has three levels based on the reliability of the inputs used to determine fair value. Level 1 values are based on quoted prices in active markets. Level 2 values are based on significant other observable inputs. Level 3 values are based on significant unobservable inputs. The following table presents the fair value level for our cash and cash equivalents

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

and short-term investments which represents our assets that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy. We do not have any liabilities that are measured at fair value.

Description	Balance			
	December 31, 2008	Level 1	Level 2	Level 3
		(In thousands)		
Cash and cash equivalents	\$ 16,741	\$ 13,542	\$ 3,199	\$
Short-term investments	2,399		2,399	
Total	\$ 19,140	\$ 13,542	\$ 5,598	\$

The Company's cash and cash equivalents at December 31, 2008 consist of cash, money market funds and commercial paper. Money market funds are valued using quoted market prices. The Company's short-term investments at December 31, 2008 consists of commercial paper. The Company uses an independent third party pricing service to value our commercial paper investments. The pricing service uses observable inputs such as new issue money market rates, adjustment spreads, corporate actions and other factors and applies a series of matrices pricing model.

4. Property and Equipment

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

	December 31,	
	2008	2007
Machinery and equipment	\$ 5,282	\$ 4,049
Furniture and fixtures	1,142	993
Lab equipment	2,488	2,472
Computer equipment and software	2,636	3,876
Leasehold improvements	1,901	577
Property and equipment at cost	13,449	11,967
Less accumulated depreciation and amortization	(9,512)	(10,033)
Net depreciable assets	3,937	1,934
Construction in progress	1,156	1,289
Property and equipment, net	\$ 5,093	\$ 3,223

Depreciation expense was \$871,000 and \$730,000 for the years ended December 31, 2008 and, 2007 respectively.

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****5. Other Liabilities**

Other liabilities consist of the following (in thousands):

	December 31,	
	2008	2007
Other accrued liabilities:		
Accrued expense for services	\$ 389	\$ 308
Payroll withholding liabilities	76	120
Deposits	153	147
Other short term obligations	12	9
Total other accrued liabilities	\$ 630	\$ 584
Other non-current liabilities:		
Deposits	\$ 75	\$ 228
Other long term obligations	7	20
Total other non-current liabilities	\$ 82	\$ 248

6. Leases, Commitments and Contingencies

The Company has a lease for a building containing office and laboratory and manufacturing facilities, which expires in 2016. A portion of this lease obligation was offset by a sublease to Mendel Biotechnology, Inc. (Mendel). Future minimum non-cancelable lease payments at December 31, 2008 are as follows (in thousands):

	Operating Leases	Mendel Sub-Lease	Net Operating Lease Payments
Year ending December 31:			
2009	\$ 2,312	\$ (900)	\$ 1,412
2010	2,220	(928)	1,292
2011	1,992	(955)	1,037
2012	2,068	(875)	1,193
2013	2,148		2,148
2014 and thereafter	5,724		5,724
Total minimum lease payments	\$ 16,464	\$ (3,658)	\$ 12,806

On July 18, 2007, the Company entered into a sublease agreement with Mendel to lease approximately 48,000 square feet of the 72,000 square foot facility located at 3929 Point Eden Way, Hayward, CA. The Company leases the space pursuant to a lease agreement dated January 28, 1998, as amended with Hayward Point Eden I Limited Partnership.

The sublease commenced on July 18, 2007 and expires on July 8, 2016. Under the sublease, Mendel will make monthly base rent payments totaling \$3.4 million through August 2012 that will offset a portion of the Company's existing building lease obligation. Mendel has the option to terminate the sublease early on September 1, 2012 for a termination fee of \$225,000. If the option to terminate the sublease is not exercised by Mendel, the Company will receive an additional \$4.0 million through the expiration of the sublease in 2016. Mendel will also pay the Company for its share of all pass through costs such as taxes, operating expenses, and utilities based on the percentage of the facility space occupied by them. On July 18, 2007, Mendel paid \$75,000 in cash and provided a letter of credit in the amount of \$150,000 as collateral for a security deposit. The letter of credit expires on July 3, 2012.

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

The Company's building lease has a rent escalation clause and, accordingly, the Company recognizes rent expense on a straight-line basis. At December 31, 2008 and 2007, the Company had \$0.2 million and \$0.3 million of deferred rent, respectively. During 2007, a portion of the deferred rent liability associated with the subleased space to Mendel was reversed in the amount of \$0.6 million (see Note 14).

For the years ended December 31, 2008 and 2007, building rent expense under operating leases totaled \$0.7 million and \$1.6 million, respectively.

Property Tax Assessment

In March 2008, the Company received assessments of \$508,000 from the Alameda County Tax Collector for personal property taxes for the period July 2004 through June 2007, for which the Company recorded an expense of \$194,000 in the second quarter of 2008. Of the \$508,000 total assessment, \$194,000 relates to property owned and used by the Company during the assessment periods, and \$314,000 relates to property the Company sold to Novo Nordisk as part of a January 26, 2005 restructuring agreement (the "January 26, 2005 Agreement") and owned by Novo Nordisk during the tax assessment period. Under the terms of the January 26, 2005 Agreement, Novo Nordisk is responsible for tax assessments on property it owned during the assessment period, and therefore the Company believes the likelihood that the Company will ultimately bear the cost of the related \$314,000 assessment is remote. Accordingly, no accrual was recorded for this portion of the assessment. Management has filed an appeal with the Alameda County Tax Collector to dispute portions of the total assessment, and believes there is at least a reasonable possibility that the Company's \$194,000 liability ultimately will be reduced upon resolution of the appeal. However, at this time management cannot estimate the ultimate outcome of the appeal. Accordingly, management's current best estimate of the Company's ultimate liability for the property tax assessment is \$194,000.

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 at December 31, 2008 or 2007.

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.

7. Shareholders' Equity

On January 30, 2007, the Company received \$33.9 million from the closing of its public offering of 37,950,000 shares of common stock in an underwritten public offering with net proceeds, after underwriting discount and expenses, of approximately \$33.2 million. This public offering triggered the automatic conversion of all outstanding shares of Series A convertible preferred stock to common stock and eliminated the Series A liquidation preference of \$41.9 million, 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). Following the offering, the 1,544,626 shares of Series A convertible preferred stock were converted to 1,235,699 shares of common stock, and no liquidation preference or other preferential rights remain.

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

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. As of December 31, 2008, all of these warrants had expired and none of these warrants were exercised.

Reserved Shares

At December 31, 2008, the Company had 4,185,061 shares reserved for issuance upon exercise of options under all stock option plans. In addition, the Company had 3,987,599 shares of our common stock reserved for issuance of new option grants and 939,916 shares available for future issuances under the Employee Stock Purchase Plan.

Shareholder Rights Plan

In September 2008, the Company adopted an amended and restated shareholder rights plan, which replaced the rights plan originally adopted in August 1998. Pursuant to the rights plan, as amended and restated, the Company distributes rights to purchase shares of Series A Junior Participating Preferred Stock as a dividend at the rate of one right for each share of common stock outstanding. Until the rights are distributed, the rights trade with, and are not separable from, the Company's common stock and are not exercisable. The rights are designed to guard against partial tender offers and other abusive and coercive tactics that might be used in an attempt to gain control of the Company or to deprive the Company's shareholders of their interest in the Company's long-term value. The shareholder rights plan seeks to achieve these goals by encouraging a potential acquirer to negotiate with the Company's board of directors. The rights will expire at the close of business on September 8, 2018.

Other Common Stock 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, the Company 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. As of December 31, 2008, all of these warrants had expired and none of these warrants were exercised.

Stock Option Plans: 1996 Equity Incentive Plan, 2005 Equity Incentive Plan and 1996 Non-Employee Directors Plan

The 1996 Equity Incentive Plan (the "1996 Plan") and the 2005 Equity Incentive Plan (the "2005 Plan"), which amended, restated and retitled the 1996 Plan, were adopted to provide a means by which officers, non-employee directors, scientific advisory board members and employees of and consultants to the Company and its affiliates could be given an opportunity to acquire an equity interest in the Company. All officers, non-employee directors, scientific advisory board members and employees of and consultants to the Company are eligible to participate in the 2005 Plan.

In April 1996, the Company's Board of Directors adopted and the Company's shareholders approved the 1996 Plan, which amended and restated an earlier stock option plan. The 1996 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 2,000,000 shares. 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 shares of common stock of the Company or such lesser number of shares as determined

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

by the board of directors on the date of the annual meeting of shareholders of each fiscal year beginning 2001 and ending 2005.

Options granted under the 1996 Plan may be immediately exercisable if permitted in the specific grant approved by the Company's board of directors and, if exercised early, the issued shares may be subject to repurchase provisions. The shares acquired generally vested over a period of four years from the date of grant. The 1996 Plan also provided for a transition from employee to consultant status without termination of the vesting period as a result of such transition. Any unvested stock issued was subject to repurchase agreements whereby the Company had the option to repurchase unvested shares upon termination of employment at the original issue price. The common stock subject to repurchase has voting rights but does not have resale rights prior to vesting. The Company had repurchased a total of 7,658 shares in accordance with these agreements through December 31, 1998. Subsequently, no grants with early exercise provisions have been made under the 1996 Plan and no shares have been repurchased. As of December 31, 2008, the Company had 519,021 options outstanding and 39,888 shares were available for future grants 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 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. Pursuant to the 2005 Plan, the Company had 2,918,638 shares of common stock authorized for issuance. 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 919,386 shares became available for future grant under the 2005 Plan. In March 2006, the Company's board of directors amended, and in May 2006 the Company's shareholders approved, the amendment to the 2005 Plan, increasing the shares of common stock authorized for issuance by 2,000,000. In April 2007, the Company's board of directors amended, and in June 2007, the Company's shareholders approved the amendment to the 2005 Plan, increasing the shares of common stock authorized for issuance by 1,600,000 shares. In March 2008, the Company's board of directors amended, and in May 2008 the Company shareholder's approved, the amendment to the 2005 Plan, increasing the shares of common stock authorized by 2,700,000. As of December 31, 2008, 3,947,711 shares were available for future grants.

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 Company's 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.

Options granted under the 2005 Plan may be immediately exercisable 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, 2008 and 2007, 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 subject to repurchase 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. The Company granted options to purchase 898,000 shares and 1,414,750 shares during the years ended December 31, 2008 and 2007, respectively, under the 2005 Plan, which included option grants to the Company's non-employee directors in the

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

amount of 125,000 shares and 95,000 shares during 2008 and 2007, respectively. The 2005 Plan had 3,652,897 option shares outstanding as of December 31, 2008.

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 had no effect on the options already outstanding. There were 1,500 and 6,543 share cancellations due to option expirations for the years ended December 31, 2008 and 2007, respectively. As of December 31, 2008, 13,143 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 as of December 31, 2008:

	Shares Available for Grant of Option or Award	Number of Shares	Options Outstanding			Weighted
			Price per Share			Average Exercise Price
Balance at December 31, 2006	1,394,002	3,063,981	\$ 1.02	-	\$ 120.63	\$ 8.90
Options authorized	1,600,000			-		
Options granted	(1,414,750)	1,414,750	\$ 1.23	-	\$ 1.60	\$ 1.44
Restricted stock awards granted	(726,000)			-		
Options cancelled	985,577	(985,577)	\$ 1.15	-	\$ 120.63	\$ 10.71
Restricted share awards cancelled	4,875			-		
Plan shares cancelled and not reauthorized	(6,543)		\$ 41.25	-	\$ 120.63	\$ 93.63
Balance at December 31, 2007	1,837,161	3,493,154	\$ 1.02	-	\$ 120.63	\$ 5.37
Options authorized	2,700,000			-		
Options granted	(898,000)	898,000	\$.39	-	\$ 1.57	\$.80
Options exercised		(3,750)	\$ 1.15		\$ 1.15	\$ 1.15
Options cancelled	202,343	(202,343)	\$ 1.23	-	\$ 71.25	\$ 10.65
Restricted share awards cancelled	147,595			-		
Plan shares cancelled and not reauthorized	(1,500)		\$ 71.25	-	\$ 71.25	\$ 71.25
Balance at December 31, 2008	3,987,599	4,185,061	\$.39	-	\$ 120.63	\$ 6.45

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

The following table summarizes information about stock options outstanding and exercisable as of December 31, 2008:

Exercise Price Range	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$.39 - \$1.02	747,500	9.54	\$.63	101,967	\$.87
\$1.03 - \$1.52	669,510	7.85	1.32	400,604	1.31
\$1.53 - \$1.70	1,150,500	8.38	1.62	428,937	1.65
\$1.71 - \$4.20	1,067,760	6.94	1.97	837,810	1.95
\$4.21 - \$5.95	231,302	4.87	5.48	226,712	5.47
\$5.96 - \$10.80	41,500	4.68	8.18	41,500	8.18
\$10.81 - \$20.05	110,994	3.66	15.33	110,994	15.33
\$20.06 - \$98.13	138,260	2.10	40.32	138,260	40.32
\$98.14 - \$120.63	27,735	1.30	112.48	27,735	112.48
	4,185,061	7.52	\$ 4.14	2,314,519	\$ 6.45

Aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's stock exceeded the exercise price of the stock options at December 31, 2008 and 2007 for those stock options for which the quoted market price was in excess of the exercise price (in-the-money options). As of December 31, 2008 and 2007, the aggregate intrinsic value of options outstanding was zero and \$167,000, respectively. As of December 31, 2008, options to purchase 2,314,519 shares of common stock were exercisable and had an aggregate intrinsic value of zero. The total intrinsic value of stock options exercised was \$200 for the year ended December 31, 2008. No stock options were exercised in 2007.

A summary of the Company's unvested restricted stock and performance bonus stock award activities as of December 31, 2008 is presented below representing the maximum number of shares that could be earned or vested under the 2005 Plan:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance at December 31, 2006	169,849	\$ 2.40
Restricted stock awards granted	726,000	1.54

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Restricted share awards vested	(20,250)	3.60
Restricted share awards cancelled	(4,875)	1.80
Balance at December 31, 2007	870,724	1.66
Restricted share awards vested	(19,594)	3.63
Restricted share awards cancelled	(47,595)	1.70
Performance bonus award cancelled	(100,000)	1.64
Balance at December 31, 2008	703,535	1.60

For restricted stock awards, the Company recognizes compensation expense over the vesting period for the fair value of the stock award on the measurement date. The Company's 2007 restricted stock awards granted included 450,000 shares with vesting provisions based solely on the achievement of performance-based milestones. None of the restricted performance-based milestone awards have yet been achieved. In addition, the performance stock bonus award for up to 100,000 shares award did not vest prior by its expiration date and was subsequently cancelled

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

in 2008. The total fair value of restricted stock awards that did vest during the years ended December 31, 2008 and 2007 was \$16,000 and \$28,000, respectively. The Company retained purchase rights to 704,000 and 771,000 shares of unvested restricted stock awards issued pursuant to stock purchase agreements at no cost per share as of December 31, 2008 and 2007, respectively. Total employee-stock based compensation expense for restricted stock awards was \$206,000 and \$107,000 for the years ended December 31, 2008 and 2007, respectively.

Performance Bonus Stock Award

In October 2006, as provided in his employment offer letter, the Company agreed to pay to Dr. Gonda, its President and Chief Executive Officer, a stock bonus of up to 100,000 shares of its common stock to be earned based on the common stock price reaching certain price targets after each of the first two years of his employment. The Company valued Dr. Gonda's stock bonus on a Monte-Carlo simulation due to the path-dependency of the award. The Company believes that the Monte-Carlo simulation provides a more precise estimate for the grant date fair value of a market-based equity award as the simulation allows for vesting throughout the vesting period. The fair value of the performance bonus stock award was \$94,000. The performance targets were not met by the expiration date and the award was cancelled in 2008.

Employee Stock Purchase Plan

Employees generally are eligible to participate in the Employee Stock Purchase Plan (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 shareholder. 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 15% of earnings or \$25,000.

As of December 31, 2008, a total of 1,110,084 shares had been issued under the Purchase Plan. In April 2008, the Company's board of directors amended, and in May 2008 the Company shareholder's approved, the amendment to the 2005 Plan, increasing the shares of common stock authorized by 1,000,000. As of December 31, 2008, there was a balance of 939,916 available authorized shares. Compensation expense was \$42,000 and \$112,000 for the years ended December 31, 2008 and 2007, respectively. The fair value of employee stock purchase rights under the Purchase Plan is determined using the Black-Scholes option pricing model and the following weighted average assumptions:

	Years Ended December 31,	
	2008	2007
Employee Stock Purchase Plan		
Dividend yield	0.0%	0.0%
Volatility factor	64.8%	78.1%
Risk-free interest rate	1.7%	4.6%
Expected life (years)	0.52	1.18
Weighted-average fair value of purchase rights granted during the period	\$ 0.15	\$ 0.59

Share-Based Compensation Expense

The Company adopted the fair value recognition provisions of SFAS No. 123(R) (revised 2004), *Share-based Payment*, (SFAS 123(R)) effective January 1, 2006. Stock-based compensation expense is based on the fair value of that portion of employee stock options that are ultimately expected to vest during the period. Stock-based compensation expense recognized in our statement of operations during 2008 and 2007 included compensation expense for stock-based awards granted prior to, but not yet vested, as of December 31, 2005, based on the grant

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

date fair value estimated in accordance with the pro forma provisions of SFAS 123, and share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with SFAS 123(R). For stock options granted after January 1, 2006, the fair value of each award is amortized using the straight-line single-option method. For share awards granted prior to 2006, the fair value of each award is amortized using the accelerated multiple-option valuation method prescribed by SFAS 123. Stock-based compensation expense is based on awards ultimately expected to vest, therefore, it has been reduced for estimated forfeitures. The Company estimated forfeitures based on historical experience.

The following table shows share-based employee compensation expense included in the statement of operations for the years ended December 31, 2008 and 2007, respectively (in thousands, except per share amounts):

	2008	2007
Costs and expenses:		
Research and development	\$ 530	\$ 664
General and administrative	281	718
Total stock-based employee compensation expense	\$ 811	\$ 1,382
Impact on basic and diluted net loss per common share	\$ (0.01)	\$ (0.03)

There was no capitalized stock-based employee compensation cost as of December 31, 2008. Since the Company has cumulative net losses through December 31, 2008, there was no tax benefit associated with stock-based compensation expense. As of December 31, 2008, \$843,000 of total unrecognized compensation costs, net of forfeitures, related to non-vested awards is expected to be recognized over a weighted average period of 2.56 years.

Valuation Assumptions

The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model. Expected volatility is based on the historical volatility of the Company's common stock. The expected life was estimated using a lattice model to estimate the expected term as an input into the Black-Scholes option pricing model. The expected term represents the estimated period of time that stock options are expected to be outstanding. The risk-free interest rate is based on the U.S. Treasury yield. The expected dividend yield is zero, as the Company does not anticipate paying dividends in the near future. The weighted average assumptions are as follows:

	Years Ended December 31 2008	2007
Employee Stock Options		
Dividend yield	0.0%	0.0%

Volatility factor	67.7%	76.7%
Risk-free interest rate	2.8%	4.0%
Expected life (years)	3.8	4.0
Weighted-average fair value of options granted during the periods	\$ 0.33	\$ 0.86

Stock-Based Compensation for Non-Employees

The Company accounts for options and warrants issued to non-employees under SFAS 123 and 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. Share-based compensation expense related to options and warrants issued to non-employees was \$66,000 and \$109,000 during the years ended December 31, 2008 and 2007, respectively.

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

8. Convertible Preferred Stock

Pursuant to the completion of the Company's public offering on January 30, 2007, the outstanding shares of the convertible preferred stock were automatically converted to shares of common stock at a conversion ratio of 0.8 shares of common stock for each share of preferred stock. Prior to the public offering, 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 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, was convertible at the option of the holder into 0.8 shares of common stock. An automatic conversion feature was triggered under the preferred stock financing upon either a public offering with gross proceeds to the Company exceeding \$25 million (before underwriting discounts, commissions and fees), which occurred in January 2007, or the date on which the common stock closing bid price was above \$52.9375 per share for at least 20 consecutive trading days. There were no dividends declared on the convertible preferred stock.

9. Employee Benefit Plans

The Company has a 401(k) Plan which provides 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 \$15,500 annually on a pretax basis in 2008. Subject to a maximum dollar match contribution of \$7,750 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 \$108,000 and \$120,000 in 2008 and 2007, respectively.

10. Related Parties

CyDex

On August 31, 2007, the Company and CyDex entered into a Collaboration Agreement (the "CyDex Agreement"), which contemplates that the parties will collaborate on the development and commercialization of products that utilize the Company's AERx pulmonary delivery technology and CyDex's solubilization and stabilization technologies to deliver combinations of inhaled corticosteroids, anticholinergics and beta-2 agonists for the treatment of asthma and chronic obstructive pulmonary diseases (COPD). John Siebert, a member of our Board of Directors, was the Chief Executive Officer and a member of the Board of CyDex until October 2008. The Company and CyDex may develop combination inhalation products for certain respiratory diseases. Single agent steroid products and combination products containing steroids for asthma are part of the license CyDex granted to AstraZeneca. The agreement CyDex has with AstraZeneca entitles the latter with the right of first negotiation for combination products for the treatment of asthma containing corticosteroids.

Under the terms of the CyDex Agreement, the parties will share in the revenue from sales and licensing of such products to a third party for further development and commercialization. Details of each collaboration project will be determined by a joint steering committee consisting of members appointed by each of the parties. Costs of each collaboration project will be borne 60% by the Company and 40% by CyDex. Revenues from each collaboration project will be shared in the same ratio. The CyDex Agreement commenced on August 31, 2007, and unless terminated earlier, will extend for a minimum period of two years. Either party may terminate the Agreement upon advance notice to the other party, and the non-terminating party will retain an option to continue the development and

commercialization of any terminated product, subject to payment of a royalty to the terminating party. The Company did not recognize any revenue and incurred expenses of \$131,000 and \$8,000 relating to the CyDex Agreement during the years ended December 31, 2008 and 2007, respectively.

Novo Nordisk

In May 2008, the Second Amended and Restated License Agreement between Novo Nordisk and the Company (the July 3, 2006 License Agreement) was terminated, ending a business collaboration between the two

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

companies to develop a pulmonary delivery system for administering insulin by inhalation using the AERx iDMS. There are various consequences for the Company as a result of the termination by Novo Nordisk of the July 3, 2006 License Agreement, including the following:

All rights to the inhaled insulin program. Novo Nordisk must enable the Company to continue to pursue commercialization of inhaled insulin. In order to do this, Novo Nordisk is required to:

Supply the Company with insulin for use in continuing development of inhaled insulin.

Identify in writing the patent claims that describe the insulin formulation used by Novo Nordisk in its development of inhaled insulin so that the Company can make such formulation (and permitted alternatives).

Provide the Company full access to the data generated in the development of inhaled insulin, including data from all the clinical trials, as well as relevant sections of applicable regulating filings.

Transfer of technology. Novo Nordisk transferred the AERx iDMS technology documentation to the Company. The technology transfer also included certain AERx iDMS-related development and production equipment at its fair market value.

Intellectual Property transfer. In September 2008, Novo Nordisk transferred to the Company, at no charge, a portfolio of U.S. and foreign patents related to inhaled insulin. The Company assumes responsibility for the maintenance of this portfolio.

Prior to the Company's public offering completed on January 30, 2007 (see Note 7), Novo Nordisk and its affiliate, Novo Nordisk Pharmaceuticals, Inc. were considered related parties. At December 31, 2006, Novo Nordisk effectively owned 1,573,674 shares of the Company's common stock, representing 10.6% of the Company's total outstanding common stock (9.8% on an as-converted basis). As a result of the Company's public offering on January 30, 2007, Novo Nordisk's ownership was reduced to approximately 3.0% of the Company's stock on an as-converted basis, and as of December 31, 2008, Novo Nordisk owned less than 1% of the Company's common stock.

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 was granted exclusive rights to worldwide sales and marketing rights for any products developed under the terms of the agreement. On July 3, 2006, the Company and Novo Nordisk entered into the Second Amended and Restated License Agreement (the "July 3, 2006 License Agreement"). On January 14, 2008, the Company received a 120-day notice from Novo Nordisk terminating the July 3, 2006 License Agreement. Additionally, on January 14, 2008, Novo Nordisk issued a press release announcing the termination of its phase 3 clinical trials for fast-acting inhaled insulin delivered via the AERx iDMS. The press release stated that Novo Nordisk was not terminating the trials because of any safety concerns.

The July 3, 2006 License Agreement reflected: (i) the transfer by the Company of certain intellectual property, including all rights, title and interest to the patents that contain claims that pertain generally to breath control or specifically to the pulmonary delivery of monomeric insulin and monomeric insulin analogs, together with interrelated patents, which are linked via terminal disclaimers, as well as certain pending patent applications and continuations

thereof by the Company for a cash payment of \$12.0 million, with the Company retaining exclusive, royalty-free control of these patents outside the field of glucose control; (ii) the receipt of a royalty prepayment of \$8.0 million in exchange for a one percent reduction on the average royalty rate for the commercialized AERx iDMS product and; (iii) a loan to the Company in the principal amount of \$7.5 million (see Note 12).

From 1998 through December 31, 2007, the Company received approximately \$150 million in product development and milestone payments from Novo Nordisk, and the Company has recognized all of these funds as contract revenues. For the years ended December 31, 2008 and 2007, the Company recognized revenue in the amount of zero and \$23,000, respectively, related to product development and milestone payments.

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****11. Revenue and Deferred Revenue:**

Payments from and amounts billed to collaborators, revenue recognized and deferred revenue for the years ended December 31, 2008 and 2007 are as follows (thousands):

	2008	2007
Deferred revenue at beginning of the year	\$ 880	\$
Amounts billed or received from collaborator funded programs:		
Lung Rx	3,242	880
Other collaborator-funded programs	251	961
Total	3,493	1,841
Contract revenues recognized:		
Lung Rx		
Other collaborator-funded programs	251	961
Total	251	961
Deferred revenue at end of the year	4,122	880
Less: non-current portion of deferred revenue	4,122	
Current portion of deferred revenue	\$	\$ 880

The Company receives revenues from other collaborator-funded programs. These programs include early-stage feasibility programs which may not necessarily develop into long-term development agreements with the collaborators.

12. Promissory Note

On July 3, 2006, Novo Nordisk, pursuant to the July 3, 2006 License Agreement (see Note 10), loaned the Company a principal amount of \$7.5 million under a Promissory Note and Security Agreement (Promissory Note). The Promissory Note bears interest accruing at 5% per annum and the principal, along with the accrued interest, is payable in three equal payments of \$3.5 million at July 2, 2012, July 1, 2013 and June 30, 2014. The amount outstanding under the Promissory Note, including accrued interest, was \$8.5 million and \$8.1 million as of December 31, 2008 and 2007, respectively. The Promissory Note does contain a number of covenants that include restrictions in the event of changes to corporate structure, change in control and certain asset transactions. The Promissory Note was also secured by a pledge of the net royalty stream payable to the Company by Novo Nordisk pursuant to the July 3, 2006 License Agreement.

The Company subsequently received a notice of termination of the July 3, 2006 License Agreement by Novo Nordisk in January 2008. The termination of the July 3, 2006 License Agreement does not accelerate any of the payment provisions under the Promissory Note. As of March 25, 2009, there were no covenant violations or any event of default.

13. Income Taxes

In 2008 the Company recorded a \$25,000 income tax benefit resulting from a refundable research and development credit. In 2007, the Company had no income tax provision. 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 as well as net operating loss and tax credit carryforwards.

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

Significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2008	2007
Net operating loss carryforwards	\$ 2,600	\$ 102,700
Research and development credits	6,300	20,300
Capitalized research and development		3,100
Other	3,000	1,400
Total deferred tax assets	11,900	127,500
Valuation allowance	(11,900)	(127,500)
Net deferred tax assets	\$	\$

The Company considers all available evidence, both positive and negative, including historical levels of taxable income, expectations and risks associated with estimates of future taxable income, and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. At December 31, 2008 and 2007, based on the Company's analysis of all available evidence, both positive and negative, it was considered more likely than not that the Company's deferred tax assets would not be realized, and as a result, the Company recorded a valuation allowance for its deferred tax assets. The valuation allowance decreased by \$115.6 million during the year ended 2008 and increased by \$8.6 million during the year ended December 31, 2007. The reduction in the valuation allowance for the year ended December 31, 2008 includes the reversal of fully reserved deferred tax assets related to net operating loss and credit carryforwards that may not be available prior to their expiration as a result of federal and state ownership change limitations. In accordance with SFAS 123R, the Company has excluded from deferred tax assets tax benefits attributable to employee stock option exercises.

The difference between the income tax benefit and the amount computed by applying the federal statutory income tax rate to loss before income taxes is as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Income tax benefit at federal statutory rate	\$ (7,921)	\$ (8,471)
Expired net operating losses	554	1,407
State taxes (net of federal)	(1,461)	(1,339)
Credits	(289)	(951)
Other		748
Reduction in deferred tax assets due to Section 382 limitations	124,743	
Change in valuation allowance	(115,651)	8,606

Total	\$	(25)	\$
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As of December 31, 2008, the Company had federal net operating loss carryforwards of approximately \$6.7 million and federal research and development tax credit carryforwards of approximately \$.1 million, which expire in the years 2009 through 2028. The Company also had California net operating loss carryforwards of approximately \$4.5 million, which expire in the years 2010 through 2028, and California research and development tax credit carryforwards of approximately \$9.5 million, which do not expire. None of the federal and state net operating loss carryforwards represent stock option deductions arising from activity under the Company's stock option plan.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is subject to U.S. federal and state income tax examinations by tax authorities for tax years 1994 through 2008 due to net operating losses that are being carried forward for tax purposes.

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

The Company adopted the provisions of FIN 48 on January 1, 2007. The Company did not have any unrecognized tax benefits at January 1, 2007, and does not have any unrecognized tax benefits at December 31, 2008 and, as a result, there was no effect on the Company's financial condition or results of operations as a result of implementing FIN 48.

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of the date of adoption of FIN 48, the Company did not have any accrued interest or penalties associated with any unrecognized tax benefits, nor was any interest expense recognized for the years ended December 31, 2008 and 2007.

Federal and state laws limit the use of net operating loss and credit carryforwards in certain situations where changes occur in the stock ownership of a company. The Company conducted a preliminary analysis of its stock ownership changes under Internal Revenue Code Section 382 as of December 31, 2008 and has reported its deferred tax assets related to net operating loss and credit carryforwards after recognizing change of control limitations that may have occurred in 2008. The reduction in deferred tax assets was offset by a reduction in the valuation allowance. Utilization of the Company's net operating loss and credit carryforwards may still be subject to additional substantial annual limitations for ownership changes after December 31, 2008. Such additional annual limitations could result in the expiration of the net operating loss and credit carryforwards available as of December 31, 2008 before their utilization.

14. Sublease Agreement and Lease Exit Liability:

On July 18, 2007, the Company entered into a sublease agreement with Mendel to lease approximately 48,000 square feet of the 72,000 square foot facility located at 3929 Point Eden Way, Hayward, CA (see Note 6).

During the year ended December 31, 2007, the Company recorded a \$2.1 million lease exit liability and related expense for the expected loss on the sublease, in accordance with SFAS 146, because the monthly payments the Company expects to receive under the sublease are less than the amounts that the Company will owe the lessor for the sublease space. The fair value of the lease exit liability was determined using a credit-adjusted risk-free rate to discount the estimated future net cash flows, consisting of the minimum lease payments to the lessor for the sublease space and payments the Company will receive under the sublease. The sublease loss and ongoing accretion expense required to record the lease exit liability at its fair value using the interest method have been recorded as part of restructuring and asset impairment expense in the statement of operations. The lease exit liability activity from inception in July 2007 through December 31, 2008 is as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Balance at beginning of year	\$ 1,749	\$
Loss on sublease upon subleasing to Mendel in July 2007		2,063
Accretion expense	79	39
Lease payments	(454)	(353)

Balance at end of the year	\$ 1,374	\$ 1,749
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The Company recorded \$318,000 of the \$1,374,000 lease exit liability in current liabilities and the remaining \$1,056,000 in non-current liabilities in the accompanying balance sheet at December 31, 2008. In addition to recording the lease exit liability and related loss, the Company reversed the deferred rent liability, and wrote off

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)**

leasehold improvements, related to the sublease space. These amounts have been recorded in restructuring and asset impairment expense in the statement of operations and are summarized as follows (in thousands):

	Year Ended December 31,	
	2008	2007
Loss on sublease upon subleasing to Mendel in July 2007	\$	\$ 2,063
Lease commission		420
Accretion expense	79	39
Reversal of deferred rent liability related to sublease space		(620)
Write-off of leasehold improvements and equipment related to sublease space, net		182
Total expense	\$ 79	\$ 2,084

15. Restricted Cash

In accordance with the terms of the Company's sublease agreement with Mendel dated July 18, 2007 (see Note 14), the Company is maintaining a certificate of deposit as collateral against a letter of credit to secure the refund to Mendel of any unapplied portion of the prepaid rent paid by Mendel. The restriction on the Company's cash will be lifted as rent is paid by Mendel on the 12th, 18th, 24th and 27th month of the sublease. The letter of credit expires on November 18, 2009.

16. 2006 Restructuring and Asset Impairment

The following table summarizes the Company's restructuring and asset impairment expenses related to the 2006 Restructuring for the year ended December 31, 2007 (in thousands). The \$98,000 additional restructuring charge was recorded to restructuring and asset impairment expense in 2007.

Type of Liability	Balance at December 31, 2006	Restructuring Charges	Payments	Balance at December 31, 2007
Severance and related benefits	\$ 716	\$ 98	\$ (814)	\$
Out-placement services	36		(36)	
	\$ 752	\$ 98	\$ (850)	\$

17. Collaborations and Licensing Agreements

Lung Rx

On August 30, 2007, the Company signed an Exclusive License, Development and Commercialization Agreement (the Lung Rx Agreement) with Lung Rx, Inc., (Lung Rx), a wholly-owned subsidiary of United Therapeutics, pursuant to which the Company granted Lung Rx, upon the payment of certain fees, an exclusive license to develop and commercialize inhaled treprostinil using the Company's AERx Essence technology for the treatment of pulmonary arterial hypertension (PAH) and other potential therapeutic indications.

Under the terms of the Lung Rx Agreement, the Company received an upfront fee of \$440,000 and an additional fee of \$440,000 four months after the signing date. These fees are nonrefundable and were included in deferred revenue in the accompanying balance sheet at December 31, 2007. Under the terms of the Lung Rx Agreement, the Company was responsible for conducting and funding a feasibility bridging study that included a clinical trial to compare the AERx Essence inhaler to a nebulizer used in a completed Phase 3 registration trial conducted by United Therapeutics. We began the clinical portion of the study in April 2008 and announced results in November 2008. At the same time, we announced receipt of \$2.75 million from Lung Rx, which included the first

Table of Contents

ARADIGM CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

milestone of \$2 million and development costs. Lung Rx will be responsible for funding the remainder of the development of treprostinil in the AERx delivery system through registration and commercial launch. We could receive additional milestone payments of up to \$7 million. These payments are generally dependent upon Lung Rx's development of the product, and are expected to be paid within three years of signing the Lung Rx Agreement. Following commercialization of the product, we will receive royalties from Lung Rx on a tiered basis of up to 10% of net sales for any licensed products. The Lung Rx Agreement remains effective until the expiration of the underlying patents and approval of a generic product, on a country-by-country basis, unless terminated earlier by Lung Rx in accordance with its terms.

Lung Rx was to pay a \$650,000 license fee for an exclusive license and had the right under the Lung Rx Agreement to purchase \$3.47 million of the Company's common stock at an average closing price over a certain trailing period within 15 days of Lung Rx's determination that the feasibility study was successful. Lung Rx determined that, while the results of the clinical trial warranted continuation of the development of AERx Essence technology with treprostinil, the performance of the AERx Essence inhaler in the clinical study was different from the nebulizer. As such, they did not pay the license fee or purchase the Company's common stock.

The Company is obligated to provide multiple deliverables under the Lung Rx Agreement, including transfer of the AERx technology and any future improvements thereto during the term of the Lung Rx Agreement and participation on a product steering committee during the term of the Lung Rx Agreement. All of the deliverables under the Lung Rx Agreement are treated as a single unit of accounting under EITF 00-21 as the fair value of the undelivered performance obligations associated with these activities could not be objectively determined and the activities are not economically independent of each other. Since the deliverables are treated as a single unit of accounting, the upfront fees for the feasibility study, and the milestone and development payments, together with any future license fee and milestone and royalty payments, will be recognized as revenue ratably over the term of the Lung Rx Agreement, using a time-based model. The revenue recognition will commence with the delivery of the last deliverable, which is the license to the AERx technology and any future improvements thereto.

Zogenix

In August 2006, we sold all of our assets related to the Intraject needle-free injector technology platform and products, including 12 United States patents along with foreign counterparts, to Zogenix, Inc., a private company. Zogenix is responsible for further development and commercialization efforts of Intraject (now rebranded under the name DosePro™). We received a \$4 million initial payment from Zogenix, and we will be entitled to a milestone payment upon initial commercialization, and royalty payments upon any commercialization of products.

18. Manufacturing and Supply Agreement

On August 8, 2007, the Company entered into a Manufacturing and Supply Agreement (the "Enzon Agreement") with Enzon Pharmaceuticals, Inc. ("Enzon") related to its ARD-3100 program, an inhaled formulation of liposomal ciprofloxacin. Under the Enzon Agreement, Enzon will manufacture and supply the Company with ciprofloxacin, liposomal ciprofloxacin, and other products that may be identified by management. For manufacturing the initial two products, the Company will pay Enzon costs and fees totaling \$3.3 million in addition to costs and fees for stability studies or other services that may be agreed by both parties. Thereafter, the agreement specifies that purchases are made on a purchase order basis without any committed order level. The agreement commenced on August 8, 2007,

and will extend for a period of five years, unless terminated earlier by either party. During the year ended December 31, 2008, and 2007, respectively, the Company paid \$2.9 million and \$2.8 million, respectively, under the Enzon Agreement.

Table of Contents**ARADIGM CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****19. Quarterly Results of Operations (unaudited)**

Following is a summary of the quarterly results of operations for the years ended December 31, 2008 and 2007 (amounts in thousands, except per share amounts):

	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008
Contract and license revenues	\$	\$ 54	\$ 197	\$
Operating expenses:				
Research and development	4,329	5,364	3,199	3,607
General and administrative	1,549	1,825	1,615	1,690
Restructuring and asset impairment	22	20	19	18
Total expenses	5,900	7,209	4,833	5,315
Loss from operations	(5,900)	(7,155)	(4,636)	(5,315)
Interest income	361	202	146	72
Interest expense	(98)	(100)	(105)	(105)
Other income (expense)	(1)	1	(1)	1
Loss before income taxes	(5,638)	(7,052)	(4,596)	(5,347)
Income tax benefit				25
Net loss	\$ (5,638)	\$ (7,052)	\$ (4,596)	\$ (5,322)
Basic and diluted net loss per common share	\$ (0.10)	\$ (0.13)	\$ (0.08)	\$ (0.10)
Shares used in computing basic and diluted net loss per common share	54,007	54,159	54,165	54,317
	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007
Contract and license revenues	\$ 416	\$ 297	\$ 230	\$ 18
Operating expenses:				
Research and development	3,407	3,841	3,899	5,623
General and administrative	1,987	2,628	1,757	2,029
Restructuring and asset impairment	98		2,059	25

Total expenses	5,492	6,469	7,715	7,677
Loss from operations	(5,076)	(6,172)	(7,485)	(7,659)
Interest income	637	699	684	553
Interest expense	(96)	(96)	(101)	(100)
Other income (expense)	(31)	46		(4)
Net loss	\$ (4,566)	\$ (5,523)	\$ (6,902)	\$ (7,210)
Basic and diluted net loss per common share	\$ (0.11)	\$ (0.10)	\$ (0.13)	\$ (0.13)
Shares used in computing basic and diluted net loss per common share	40,820	53,942	53,948	53,997

20. Subsequent Events

On February 23 and February 25, 2009, we entered into definitive agreements with investors to sell up to approximately 44.7 million shares of our common stock for gross proceeds of approximately \$4.5 million (\$4.1 million net of expenses) in a registered direct offering. The investors agreed to purchase the shares of common stock at a negotiated purchase price of \$0.10 per share. The transaction closed on February 26, 2009.

Table of Contents

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 as of the end of the period covered by this report, the Company's chief executive officer and chief financial officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of the end of the period covered by this report to ensure that information that the Company is required to disclose in reports that management files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

The Company's disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and the Company's chief executive officer and chief financial officer have concluded that these controls and procedures are effective at the reasonable assurance level. The Company believes that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control 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.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

There are inherent limitations in the effectiveness of any system of internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurances with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal control may vary over time.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission in *Internal Control - Integrated Framework*. Based on its assessment using the COSO criteria, management concluded that, as of December 31, 2008, the Company's internal control over financial reporting is effective.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. The Company's internal control over financial reporting was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over

financial reporting.

Item 9B. *Other Information*

None.

Table of Contents

PART III

Item 10. *Directors, Executive Officers and Corporate Governance*

The information required by this Item concerning (i) identification and business experience of the Company's directors, as well as legal proceedings involving such directors and any family relationships between directors and executive officers of the Company, (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 15, 2009, to be filed by the Company with the SEC (the "Proxy Statement").

Identification of Executive Officers

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

Section 16(a) Compliance

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

Item 11. *Executive Compensation*

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

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

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

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

The information required by this Item is incorporated by reference from the section captioned "Certain Transactions" 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.

Table of Contents**PART IV****Item 15. Exhibits and Financial Statement Schedules****(a)(1) Financial Statements.**

Included in Part II of this Report:

	Page in Form 10-K
<u>Report of Independent Registered Public Accounting Firm</u>	44
<u>Balance Sheets December 31, 2008 and 2007</u>	45
<u>Statements of Operations Years ended December 31, 2008 and 2007</u>	46
<u>Statements of Convertible Preferred Stock and Shareholders Equity (Deficit) Years ended December 31, 2008 and 2007</u>	47
<u>Statements of Cash Flows Years ended December 31, 2008 and 2007</u>	48
<u>Notes to Financial Statements</u>	49

(2) Financial Statement Schedules.

All financial statement schedules are omitted because they are not applicable or not required or because the required information is included in the financial statements or notes thereto.

(3) Exhibits.

Exhibit No.	Description
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3.1(1)	Amended and Restated Articles of Incorporation of the Company.
3.2(2)	Bylaws of the Company, as amended.
3.3(3)	Certificate of Determination of Series A Junior Participating Preferred Stock.
3.4(4)	Amended and Restated Certificate of Determination of Preferences of Series A Convertible Preferred Stock.
3.5(3)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.6(3)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.7(5)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.8(5)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.9(6)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.10(17)	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, 3.8, 3.9 and 3.10.
4.2(1)	Specimen common stock certificate.
10.1(1)+	Form of Indemnity Agreement between the Registrant and each of its directors and officers.

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10.2(1)+	Form of the Company's Incentive Stock Option Agreement under the 2005 Equity Incentive Plan.
10.3(1)+	Form of the Company's Non-statutory Stock Option Agreement under the 2005 Equity Incentive Plan.
10.4(1)+	1996 Non-Employee Directors' Stock Option Plan.
10.5(1)+	Form of the Company's Non-statutory Stock Option Agreement under the 1996 Non-Employee Directors' Stock Option Plan.
10.6(1)+	Form of the Company's Employee Stock Purchase Plan Offering Document.
10.7(6)+	Form of the Company's Restricted Stock Bonus Agreement under the 2005 Equity Incentive Plan.
10.8(7)	Promissory Note and Security Agreement, dated July 3, 2006, by and between the Company and Novo Nordisk A/S.

Table of Contents

Exhibit No.	Description
10.9(7)	Amended and Restated Stock Purchase Agreement, dated as of January 26, 2005, by and among the Company, Novo Nordisk A/S and Novo Nordisk Pharmaceuticals, Inc.
10.10(7)#	Asset Purchase Agreement, dated as of August 25, 2006, by and between the Company and Zogenix, Inc.
10.11(7)+	Employment Agreement, dated as of August 10, 2006, with Dr. Igor Gonda.
10.12(8)	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(9)#	Restructuring Agreement, dated as of September 28, 2004, by and among the Company, Novo Nordisk A/S and Novo Nordisk Delivery Technologies, Inc.
10.14(10)	Securities Purchase Agreement, dated as of December 17, 2004, by and among the Company and the purchasers named therein.
10.15(11)#	Second Amended and Restated License Agreement, dated as of July 3, 2006, by and between the Company and Novo Nordisk A/S.
10.16(12)	Consulting Agreement effective as of July 2, 2007 by and between the Company and Norman Halleen.
10.17(13)	Sublease between the Company and Mendel Biotechnology, Inc., dated July 11, 2007, under the Lease Agreement by and between the Company and Hayward Point Eden I Limited Partnership, a Delaware limited partnership, as successor-in-interest to Britannia Point Eden, LLC, as amended, for 3929 Point Eden Way, Hayward, California.
10.18(14)	Manufacturing Agreement between the Company and Enzon Pharmaceuticals, Inc. dated August 8, 2007.
10.19(15)#	Exclusive License, Development and Commercialization Agreement, dated as of August 30, 2007, by and between the Company and Lung Rx, Inc.
10.20(15)#	Collaboration Agreement, dated as of August 31, 2007, by and between the Company and CyDex, Inc.
10.21(16)+	2005 Equity Incentive Plan, as amended
10.22(17)+	Employee Stock Purchase Plan, as amended.
10.23(18)	Amended and Restated Rights Agreement, dated as of September 5, 2008 by and between the Company and ComputerShare Trust Company, N.A.
10.24(19)	Separation Agreement between the Company and Dr. Babatunde Otulana, dated as of December 12, 2008.
10.25(19)	Consulting Agreement for Independent Contractors between the Company and Dr. Babatunde Otulana, effective as of January 1, 2009.
10.26(19)	International Scientific Advisory Agreement between the Company and Dr. Babatunde Otulana, effective as of January 1, 2009.
10.27(20)+	Amended and Restated form of Change of Control Agreement entered into between the Company and certain of the Company's senior officers.
10.28(20)+	Amended and Restated Executive Officer Severance Benefit Plan.
23.1	Consent of Odenberg Ullakko Muranishi & Co LLP, 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.

+ 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) filed on April 30, 1996, as amended.

75

Table of Contents

- (2) Incorporated by reference to the Company's Form 10-Q filed on August 14, 1998.
- (3) Incorporated by reference to the Company's Form 10-K filed on March 29, 2002.
- (4) Incorporated by reference to the Company's Form S-3 (No. 333-76584) filed on January 11, 2002, as amended.
- (5) Incorporated by reference to the Company's Form 10-Q filed on August 13, 2004.
- (6) Incorporated by reference to the Company's Form 10-K filed on March 31, 2006.
- (7) Incorporated by reference to the Company's Form S-1 (No. 333-138169) filed on October 24, 2006, as amended.
- (8) Incorporated by reference to the Company's Form 10-K filed on March 24, 1998, as amended.
- (9) Incorporated by reference to the Company's Form 8-K filed on December 23, 2004.
- (10) Incorporated by reference to the Company's Form 10-Q filed on August 14, 2006.
- (11) Incorporated by reference to the Company's Form 8-K filed on October 13, 2005.
- (12) Incorporated by reference to the Company's Form 8-K filed on July 11, 2007.
- (13) Incorporated by reference to the Company's Form 8-K filed on July 24, 2007.
- (14) Incorporated by reference to the Company's Form 8-K filed on August 14, 2007.
- (15) Incorporated by reference to the Company's Form 10-Q filed on November 14, 2007.
- (16) Incorporated by reference to the Company's definitive proxy statement filed on April 7, 2008.
- (17) Incorporated by reference to the Company's Form 10-Q filed on August 8, 2008.
- (18) Incorporated by reference to the Company's Form 10-Q filed on November 12, 2008.
- (19) Incorporated by reference to the Company's Form 8-K filed on December 19, 2008.
- (20) Incorporated by reference to the Company's Form 8-K filed on January 8, 2009.

(b) Index to Exhibits.

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

(c) Financial Statement Schedules.

All financial statement schedules are omitted because they are not applicable or not required or because the required information is included in the financial statements or notes thereto.

Aradigm, AERx, AERx Essence and AERx Strip are registered trademarks of Aradigm Corporation.

* Other names and brands may be claimed as the property of others.

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 26th day of March 2009.

ARADIGM CORPORATION

By: /s/ Igor Gonda

Igor Gonda

President and Chief Executive Officer

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

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

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

Signature	Title	Date
/s/ Igor Gonda Igor Gonda	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2009
/s/ Nancy E. Pecota Nancy E. Pecota	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2009
/s/ Virgil D. Thompson Virgil D. Thompson	Chairman of the Board and Director	March 26, 2009
/s/ Frank H. Barker Frank H. Barker	Director	March 26, 2009
/s/ John M. Siebert	Director	March 26, 2009

John M. Siebert

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10.17(13)	

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Sublease between the Company and Mendel Biotechnology, Inc., dated July 11, 2007, under the Lease Agreement by and between the Company and Hayward Point Eden I Limited Partnership, a Delaware limited partnership, as successor-in-interest to Britannia Point Eden, LLC, as amended, for 3929 Point Eden Way, Hayward, California.

- 10.18(14) Manufacturing Agreement between the Company and Enzon Pharmaceuticals, Inc. dated August 8, 2007.
- 10.19(15)# Exclusive License, Development and Commercialization Agreement, dated as of August 30, 2007, by and between the Company and Lung Rx, Inc.
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- 10.21 (16)+ 2005 Equity Incentive Plan, as amended

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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.

+ Represents a management contract or compensatory plan or arrangement.

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- (9) Incorporated by reference to the Company's Form 8-K filed on December 23, 2004.
- (10) Incorporated by reference to the Company's Form 10-Q filed on August 14, 2006.

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- (11) Incorporated by reference to the Company's Form 8-K filed on October 13, 2005.
- (12) Incorporated by reference to the Company's Form 8-K filed on July 11, 2007.
- (13) Incorporated by reference to the Company's Form 8-K filed on July 24, 2007.
- (14) Incorporated by reference to the Company's Form 8-K filed on August 14, 2007.
- (15) Incorporated by reference to the Company's Form 10-Q filed on November 14, 2007.
- (16) Incorporated by reference to the Company's definitive proxy statement filed on April 7, 2008.
- (17) Incorporated by reference to the Company's Form 10-Q filed on August 8, 2008.
- (18) Incorporated by reference to the Company's Form 10-Q filed on November 12, 2008.
- (19) Incorporated by reference to the Company's Form 8-K filed on December 19, 2008.
- (20) Incorporated by reference to the Company's Form 8-K filed on January 8, 2009.