ARADIGM CORP
Form 10-Q
May 14, 2010

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2010

or

o **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: 000-28402

Aradigm Corporation

(Exact name of registrant as specified in its charter)

California	**94-3133088**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

3929 Point Eden Way
Hayward, CA 94545

(Address of principal executive offices including zip code)

(510) 265-9000

(Registrant s telephone number, including area code)

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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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.

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

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

(Class)	*(Outstanding at April 30, 2010)*

Common	*102,726,452*

ARADIGM CORPORATION
TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION
Item 1. FINANCIAL STATEMENTS

ARADIGM CORPORATION
CONDENSED BALANCE SHEETS
(In thousands, except share data)

	March 31, 2010 (Unaudited)	December 31, 2009 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,861	$ 3,903
Short-term investments	3,006	5,228
Receivables	224	155
Prepaid and other current assets	374	328
Total current assets	9,465	9,614
Property and equipment, net	2,001	2,166
Notes receivable	52	52
Other assets	131	133
Total assets	$ 11,649	$ 11,965
LIABILITIES AND SHAREHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 766	$ 572
Accrued clinical and cost of other studies	160	670
Accrued compensation	282	341
Facility lease exit obligation	223	263
Other accrued liabilities	321	357
Total current liabilities	1,752	2,203
Deferred rent	130	136
Facility lease exit obligation, non-current	806	828
Other non-current liabilities	75	75
Note payable and accrued interest	9,004	8,896
Total liabilities	11,767	12,138
Commitments and contingencies		
Shareholders deficit:		
Preferred stock, 2,950,000 shares authorized, none outstanding		
	348,532	348,271

Common stock, no par value; authorized shares: 150,000,000 at March 31, 2010 and December 31, 2009; issued and outstanding shares: 102,369,616 at March 31, 2010; 102,381,116 at December 31, 2009		
Accumulated other comprehensive income		2
Accumulated deficit	(348,650)	(348,446)
Total shareholders deficit	(118)	(173)
Total liabilities and shareholders deficit	$ 11,649	$ 11,965

See accompanying Notes to the Unaudited Condensed Financial Statements

Table of Contents

ARADIGM CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except per share data)
(Unaudited)

	Three months ended March 31,	
	2010	**2009**
Revenue:		
Contract revenue	$	$
Royalty revenue	4,000	
Total revenue	4,000	
Operating expenses:		
Research and development	2,837	3,726
General and administrative	1,253	1,398
Restructuring and asset impairment	13	17
Total operating expenses	4,103	5,141
Loss from operations	(103)	(5,141)
Interest income	10	28
Interest expense	(109)	(104)
Other expense	(2)	(1)
Net loss	$ (204)	$ (5,218)
Basic and diluted net loss per common share	$ (0.00)	$ (0.07)
Shares used in computing basic and diluted net loss per common share	99,872	70,704

See accompanying Notes to the Unaudited Condensed Financial Statements

4

Table of Contents

ARADIGM CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three months ended March 31, 2010	Three months ended March 31, 2009
Cash flows from operating activities:		
Net loss	$ (204)	$ (5,218)
Adjustments to reconcile net loss to cash used in operating activities:		
Amortization and accretion of investments	15	(5)
Depreciation and amortization	165	303
Stock-based compensation expense	261	214
Changes in operating assets and liabilities:		
Receivables	(69)	350
Prepaid and other current assets	(46)	136
Restricted cash		
Other assets	2	6
Accounts payable	194	34
Accrued compensation	(59)	(129)
Other liabilities	(438)	835
Deferred rent	(6)	(24)
Deferred revenue		313
Facility lease exit obligation	(62)	(96)
Net cash used in operating activities	(247)	(3,281)
Cash flows from investing activities:		
Capital expenditures		(3)
Purchases of short-term investments		
Proceeds from sales and maturities of short-term investments	2,205	2,400
Net cash provided by investing activities	2,205	2,397
Cash flows from financing activities:		
Proceeds from public offering of common stock, net		3,927
Proceeds from issuance of common stock, net		
Net cash provided by financing activities		3,927
Net increase in cash and cash equivalents	1,958	3,043
Cash and cash equivalents at beginning of period	3,903	16,741
Cash and cash equivalents at end of period	$ 5,861	$ 19,784

See accompanying Notes to the Unaudited Condensed Financial Statements

Table of Contents

ARADIGM CORPORATION
NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS
March 31, 2010

1. Organization, Basis of Presentation and Liquidity

Organization

Aradigm Corporation (the Company, we, our, or us) 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, except for royalty revenue from Zogenix. The Company operates as a single operating segment.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with United States generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). In the opinion of management, the financial statements reflect all adjustments, which are of a normal recurring nature, necessary for fair presentation. The accompanying unaudited condensed financial statements should be read in conjunction with the financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2009, as filed with the SEC on March 24, 2010 (the 2009 Annual Report on Form 10-K). The results of the Company s operations for the interim periods presented are not necessarily indicative of operating results for the full fiscal year or any future interim period.

The balance sheet at December 31, 2009 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements. For further information, please refer to the financial statements and notes thereto included in the 2009 Annual Report on Form 10-K.

Liquidity

The Company had cash, cash equivalents and short-term investments of $8.9 million as of March 31, 2010. We believe that this amount, as well as anticipated recurring royalty payments from Zogenix, will be sufficient to enable us to fund our operations through the fourth quarter of 2010.

The Company is currently exploring means of raising additional capital to fund further development of the cystic fibrosis indication for ARD-3100, as well as the anticipated costs of our Phase 3 liposomal ciprofloxacin bronchiectasis trials, focusing primarily on establishing funded partnering agreements and through sale or out-licensing of non-strategic assets. If the Company is unsuccessful in raising sufficient funding at acceptable terms, it will be forced to suspend further development of our liposomal ciprofloxacin product candidate after our bronchiectasis Phase 2b trials are completed, or otherwise curtail operations.

2. Summary of Significant Accounting Policies

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 revenue recognition, assumptions for valuing options and warrants, and income taxes. Actual results could differ materially from these estimates.

Cash and Cash Equivalents

The Company considers all liquid investments purchased with an initial 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, commercial paper, corporate bonds and government notes in accordance with its investment policy.

Investments

Management determines the appropriate classification of the Company s investments, which consist solely of debt securities, at the time of purchase. All investments are classified as available-for-sale, carried at estimated fair value and reported in cash and cash equivalents or 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 accumulated other comprehensive income in shareholders equity until realized. Fair values of investments are based on quoted market prices where available. Interest income is recognized when earned and includes interest, dividends, amortization of purchase premiums and discounts, and realized gains and losses on sales of securities. The cost of securities sold is based on the specific identification method. The Company regularly 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 equal to the amount of any such decline. No such reductions have been required during any of the periods presented.

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.

Impairment of Long-Lived Assets

In accordance with Accounting Standards Codification (ASC) 360-10, *Property, Plant, and Equipment Overall*, 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.

Accounting for Costs Associated with Exit or Disposal Activities

In accordance with ASC 420, *Exit or Disposal Cost Obligations* (ASC 420), 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 ASC 420, 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.

Revenue Recognition

The Company recognizes revenue under the provisions of the SEC s Staff Accounting Bulletin 104, Topic 13, *Revenue Recognition Revised and Updated* (SAB 104) and ASC 605, *Revenue Recognition.* In addition, contract revenue from the Company s collaboration arrangements typically contain multiple elements and are accounted for under the guidance of ASC 605-25, *Revenue Recognition-Multiple Element Arrangements.*

Contract Revenue. Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. The Company records license fees, milestone fees and reimbursement of research and development expenses as contract revenue. The Company reviews all of these arrangements for the existence of multiple elements such as license fees, milestone fees, research and development reimbursements, product steering committee services and other performance obligations.

The Company reviews elements that have been delivered and determines 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 exists. Deliverables that meet these criteria are considered a separate unit of accounting and are recognized as revenue when delivered and collection is reasonably assured. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting.

Table of Contents

Revenue recognition criteria are identified and applied to each separate unit of accounting. The Company typically has not had reliable evidence of separate units and has treated the entire arrangement as a single unit of accounting.

Royalty Revenue. The Company earns royalty revenue under the terms of the asset sale agreement with Zogenix. Revenue is recognized when the amounts under this agreement can be determined and when collectability is probable. The Company has no performance obligations under this agreement. Revenue will be recognized from the quarterly royalty payments one quarter in arrears due to the contractual sixty day lag in royalty reporting under the asset sale agreement. In the first quarter of 2010, the Company received the $4.0 million milestone payment that was due upon the first commercial sale by Zogenix of a product using the DosePro* technology. This amount was recorded as royalty revenue for the three months ended March 31, 2010.

Research and Development

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

Stock-Based Compensation

The Company accounts for share-based payment arrangements in accordance with ASC 718, *Compensation-Stock Compensation* and ASC 505-50, *Equity-Equity Based Payments to Non-Employees* 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 Company s employee stock purchase plan. This guidance 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.

Income Taxes

The Company makes 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 the financial statements, the Company is required to estimate income taxes in each of the jurisdictions in which it operates. This process involves the Company estimating its 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 the balance sheets.

The Company assesses the likelihood that it will be able to recover its deferred tax assets. It considers all available evidence, both positive and negative, including the 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 the Company does not consider it more likely than not that it will recover its deferred tax assets, the Company records a valuation allowance against the deferred tax assets that it estimates will not ultimately be recoverable. At March 31, 2010 and December 31, 2009, the Company believed that the amount of its deferred income taxes would not be ultimately recovered. Accordingly, the Company recorded a full valuation allowance for deferred tax assets. However, should there be a change in the Company s ability to recover its deferred tax assets, the Company would recognize a benefit to its tax provision in the period in which it determines that it is more likely than not that it will recover its deferred tax assets.

Net Loss Per Common Share

Basic net loss per common share is computed using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of restricted shares of common stock subject to repurchase. Potentially dilutive securities were not included in the net loss per common share calculation for the three months ended March 31, 2010 and 2009, because the inclusion of such shares would have had an anti-dilutive effect.

Recently Issued Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-17, *Milestone Method of Revenue Recognition a consensus of the FASB Emerging Issues Task Force.* This standard provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method for revenue recognition for research

Table of Contents

and development arrangements. This standard provides guidance on the criteria that should be met to recognize revenue upon achievement of the related milestone event. This guidance will be effective for us for the three months ending September 30, 2010. We will evaluate the impact of this guidance upon entering into any future collaboration arrangements.

In February 2010, the FASB issued ASU 2010-09, *Subsequent Events* (ASU 2010-09). ASU 2010-09 updates ASC 855, *Subsequent Events*, and removes the requirement to disclose the date through which an entity has evaluated subsequent events. ASU 2010-09 became effective immediately. The adoption this guidance did not have an impact on the Company s financial position or results of operations.

On January 21, 2010, the FASB issued ASU 2010-06, which amends ASC 820 to add new requirements for disclosures about transfers into and out of Levels 1 and 2 and separate disclosures about purchases, sales, issuances, and settlements relating to Level 3 measurements. The ASU also clarifies existing fair value disclosures about the level of disaggregation and about inputs and valuation techniques used to measure fair value. We adopted this guidance for the quarter ended March 31, 2010. Adoption did not have an impact on the Company s financial position or results of operations.

In September 2009, the FASB issued ASU 2009-13 *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements* (formerly EITF Issue No. 08-1 Revenue Arrangements with Multiple Deliverables). This standard modifies the revenue recognition guidance for arrangements that involve the delivery of multiple elements, such as product, license fees and research and development reimbursements, to a customer at different times as part of a single revenue generating transaction. This standard provides principles and application guidance to determine whether multiple deliverables exist, how the individual deliverables should be separated and how to allocate the revenue in the arrangement among those separate deliverables. The standard also significantly expands the disclosure requirements for multiple deliverable revenue arrangements. We will evaluate the impact of this standard for any multiple-deliverable arrangements that are entered into in the future.

In August 2009, the FASB issued ASU 2009-05 to provide guidance on measuring the fair value of liabilities under ASC 820, *Fair Value Measurements and Disclosures*. ASU 2009-05 became effective for us during the quarter ended December 31, 2009. ASU 2009-05 provides guidance regarding valuation for liabilities which trade as an asset in an active market. The adoption of ASU 2009-05 did not have an impact on the Company s financial position or results of operations.

In June 2009, the FASB issued SFAS 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No 162* (now referred to as ASC 105). This guidance states that the codification will become the source of authoritative United States generally accepted accounting principles (GAAP). Once the codification is in effect, all of its content will carry the same level of authority. Thus, the GAAP hierarchy was modified to include only two levels of GAAP, authoritative and nonauthoritative. ASC 105 was effective for the Company in the quarter ended September 30, 2009. Beginning with this period, all references to authoritative accounting guidance refers to the topics contained in the Accounting Standards Codification. The adoption of ASC 105 did not have an impact on the Company s financial position or results of operations.

3. Cash, 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
March 31, 2010				
Cash and cash equivalents	$ 5,861	$	$	$ 5,861

Short-term investments:								
Commercial paper	$	500	$		$		$	500
Certificates of deposit		980						980
U.S. treasury and agencies		1,526						1,526
Total	$	3,006	$		$		$	3,006
December 31, 2009								
Cash and cash equivalents	$	3,903	$		$		$	3,903
Short-term investments:								
Commercial paper	$	500	$		$		$	500
Certificates of deposit		3,183		2				3,185
U.S. treasury and agencies		1,543						1,543
Total	$	5,226	$	2	$		$	5,228

Table of Contents

The Company considers all liquid investments purchased with a maturity of three months or less to be cash equivalents. All short-term investments at March 31, 2010 mature in less than one year.

The Company invests its cash and cash equivalents and short-term investments in money market funds, commercial paper and corporate and government notes. All of these securities are classified as available for sale with the unrealized gain and loss being recorded in accumulated other comprehensive income.

4. Fair Value Measurements

The Company records its cash and cash equivalents and its short term investments at fair value. The Company classifies these assets by using the fair value hierarchy which is based on the inputs used to measure fair value. 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 the assets that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy. The Company does not have any liabilities that are measured at fair value.

		Fair Value Measurements at Reporting Date Using		
Description	Balance March 31, 2010	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	$ 5,861	$ 5,861	$	$
Short-term investments:				
Commercial paper	$ 500	$	$ 500	$
Certificates of deposit	980		980	
U.S. treasury and agencies	1,526		1,526	
Total	$ 3,006	$	$ 3,006	$

The Company s cash and cash equivalents at March 31, 2010 consist of cash and money market funds. Money market funds are valued using quoted market prices. The Company s short-term investments at March 31, 2010 consisted of commercial paper, certificates of deposits and U.S. agency notes. The Company uses an independent third party pricing service to value its commercial paper, and other Level 2 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.

5. Sublease Agreement and Lease Exit Liability

On July 18, 2007, the Company entered into a sublease agreement with Mendel Biotechnology, Inc. (Mendel), under which the Company subleases to Mendel approximately 48,000 square feet of the 72,000 square foot facility located at 3929 Point Eden Way, Hayward, CA. The Company recorded a $2.1 million impairment expense related to the sublease for the year ended December, 31, 2007.

The Company recorded this expense and the related lease exit liability 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 for the three months ended March 31, 2010 is as follows (in thousands):

10

Table of Contents

		Three Months Ended March 31, 2010
Balance at January 1, 2010	$	1,091
Accretion expense		13
Lease payments		(75)
Balance at March 31, 2010	$	1,029

As of March 31, 2010, $223,000 of the $1,029,000 balance was recorded as a current liability and $806,000 was recorded as a non-current liability.

6. Collaborations and Royalty Agreements

Zogenix

In August 2006, the Company sold all of its 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 privately-held pharmaceutical company. Zogenix is responsible for further development and commercialization efforts of Intraject (now rebranded under the name DosePro*). Under the terms of the asset sale agreement, the Company received a $4.0 million initial payment from Zogenix and it will be entitled to a $4.0 million milestone payment upon initial U.S. commercialization as well as quarterly royalty payments upon the sale of DosePro products. 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). The NDA was accepted for filing by the FDA in March 2008. The same month, Zogenix entered into a 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 July 16, 2009, Zogenix announced that it had received approval from the FDA for its NDA for SUMAVEL DosePro needle-free delivery system. On August 3, 2009, Zogenix and Astellas Pharma US, Inc. announced that they had entered into an exclusive co-promotion agreement in the U.S. for the SUMAVEL DosePro needle-free delivery system. Under the announced terms of the agreement, the companies will collaborate on the promotion and marketing of SUMAVEL DosePro with Zogenix focusing their sales activities primarily on the neurology market while Astellas will focus mostly on primary care physicians. Zogenix will have responsibility for manufacturing and distribution of the product.

On January 13, 2010, Zogenix announced the U.S. commercial launch of its SUMAVEL DosePro product. The U.S. launch entitled the Company to the $4.0 million milestone payment which it received and recorded as royalty revenue during the three months ended March 31, 2010. The Company did not record any recurring royalty revenue for the three months ended March 31, 2010. Revenue will be recognized from the quarterly royalty payments one quarter in arrears due to the contractual sixty day lag in royalty reporting under the asset sale agreement.

7. Stock-Based Compensation and Stock Options and Awards

The following table shows the stock-based compensation expense included in the accompanying condensed statements of operations for the three months ended March 31, 2010 and 2009 (in thousands):

		March 31, 2010		March 31, 2009
Costs and expenses:				
Research and development	$	51	$	116
General and administrative		210		98
Total stock-based compensation expense	$	261	$	214

There was no capitalized stock-based employee compensation cost for the quarters ended March 31, 2010 and 2009. Since the Company incurred net losses during the quarters ended March 31, 2010 and 2009, there was no recognized tax benefit associated with stock-based compensation expense.

The total amount of unrecognized compensation cost related to non-vested stock options and stock purchases, net of forfeitures, was $0.5 million as of March 31, 2010. This amount will be recognized over a weighted average period of 1.93 years.

Table of Contents

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 total fair value of restricted stock awards that vested during the three months ended March 31, 2010 was $29,000. The Company retained purchase rights with respect to 2,450,689 shares of unvested restricted stock awards issued pursuant to stock purchase agreements at no cost per share as of March 31, 2010. As of March 31, 2010, there was $0.3 million of total unrecognized compensation costs, net of forfeitures, related to non-vested stock awards which are expected to be recognized over a weighted average period of 1.51 years.

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 selected officers, 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 employees, directors, officers, scientific advisory board members and consultants of the Company are eligible to participate in the 2005 Plan. During 2000, the board of directors approved the termination of the 1996 Non-Employee Directors Stock Option Plan (the Directors Plan). This termination had no effect on options already outstanding under the Directors Plan.

Stock Option Activity

The following is a summary of activity under the 1996 Plan, the 2005 Plan and the Directors Plan for the three months ended March 31, 2010:

		Options Outstanding			
	Shares Available for Grant of Option or Award	Number of Shares	Exercise Price Range		Weighted Average Exercise Price
Balance at January 1, 2010	763,185	5,088,443	$ 0.15	$ 120.63	$ 2.49
Options authorized					
Options granted					
Options exercised					
Options cancelled	120,043	(120,043)	$ 0.25	$ 120.63	$ 20.16
Restricted share awards granted					
Restricted share awards cancelled	11,500				
Plan shares cancelled and not reauthorized	(4,136)		$ 120.63	$ 120.63	$ 120.63
Balance at March 31, 2010	890,592	4,968,400	$ 0.15	$ 115.00	$ 2.07

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 March 31, 2010 for those stock options for which the quoted market price was in excess of the exercise price (in-the-money options). As of March 31, 2010, options to purchase 3,279,951 shares of common stock were exercisable and had an aggregate intrinsic value of zero. In addition, options that were not yet exercisable also had an intrinsic value of zero. Thus, all of the Company s options were under water since all the exercise prices of the Company s outstanding options exceeded the market value of the Company s common stock as of March 31, 2010.

No options were exercised during the three months ended March 31, 2010.

A summary of the Company s unvested restricted stock and performance bonus stock award activities as of March 31, 2010 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, 2009	2,668,006	$ 0.41
Restricted share awards issued		
Restricted share awards vested	(205,817)	0.26
Restricted share awards cancelled	(11,500)	0.25
Balance at March 31, 2010	2,450,689	$ 0.43

10. Net Loss Per Common Share

The Company computes basic net loss per common share using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of shares of common stock subject to repurchase. The effects of

Table of Contents

including the incremental shares associated with options, warrants and unvested restricted stock are anti-dilutive, and are not included in the diluted weighted average number of shares of common stock outstanding for the three months ended March 31, 2010 and 2009.

The Company excluded the following securities from the calculation of diluted net loss per common share for the three months ended March 31, 2010 and 2009, as their effect would be anti-dilutive (in thousands):

	Three months ended March 31,	
	2010	**2009**
Outstanding stock options	4,968	5,184
Unvested restricted stock	2,450	907

11. Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive income, which for the Company is primarily comprised of unrealized holding gains and losses on the Company s available-for-sale securities that are excluded from the accompanying condensed statements of operations in computing net loss and reported separately in shareholders equity. Comprehensive loss and its components are as follows (in thousands):

	Three months ended March 31,	
	2010	**2009**
Net loss	$ (204)	$ (5,218)
Other comprehensive income:		
Change in unrealized gain (loss) on available-for-sale securities	(2)	(4)
Comprehensive loss	$ (206)	$ (5,222)

Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on the current beliefs of management, as well as current assumptions made by, and information currently available to, management. All statements contained in this Quarterly Report on Form 10-Q, other than statements that are purely historical, are forward-looking statements. Words such as anticipate, expect, intend, plan, believe, may, will, could, estimate, or the negative thereof and similar expressions also identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause our future actual results, performance or achievements to 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 risks and uncertainties discussed in this section, as well as in the section entitled Risk Factors in this Quarterly Report on Form 10-Q and other reports filed with the United States Securities and Exchange Commission (the SEC). Forward looking statements include our belief that our cash, cash equivalents and short-term investments as of March 31, 2010 and the Zogenix quarterly royalty payments will be sufficient to enable us to fund our operations through the fourth quarter of 2010.

These forward-looking statements and 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, 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.*

You are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date of the filing of this Quarterly Report on Form 10-Q. We undertake no obligation to update these forward-looking statements in light of events or circumstances occurring after the date of the filing of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

Overview

Table of Contents

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 and other proprietary technology, including our liposomal ciprofloxacin formulation for inhalation. We have not been profitable since inception and expect to incur additional operating losses over at least the next several years as we continue product development efforts, clinical trial activities, and possible sales, marketing and contract manufacturing efforts. To date, we have not had any significant product sales and do not anticipate receiving revenues from the sale of any of our products in the near term. As of March 31, 2010, we had an accumulated deficit of $348.7 million. Historically, we have funded our operations primarily through public offerings and private placements of our capital stock, license fees and milestone payments from collaborators, proceeds from the January 2005 restructuring transaction with Novo Nordisk, borrowings from Novo Nordisk, the sale of Intraject-related assets to Zogenix, the milestone payment received from Zogenix during the three months ended March 31, 2010 and interest earned on cash equivalents and short-term investments.

Over the last four years, our business has focused on opportunities in the development of drugs for the treatment of severe respiratory disease that could be developed by the Company and commercialized in the United States, or another significant territory such as the European Union (EU). 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 or in the EU, 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. 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. 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. and for cystic fibrosis in the European Union. We have reported the results of two successful Phase 2a trials with this product candidate in cystic fibrosis (CF) and non-cystic fibrosis bronchiectasis (BE), respectively, as described below.

In June 2008, we completed a multi-center 14-day treatment Phase 2a trial in Australia and New Zealand in 21 CF patients with once daily dosing of 6 mL of inhaled liposomal ciprofloxacin (ARD-3100). 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 with once daily inhaled liposomal ciprofloxacin (ARD-3100) 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 July 2009, we announced that clearance was received from the U.S. Food and Drug Administration for the inhaled liposomal ciprofloxacin (ARD-3100) Investigational New Drug (IND) application for the management of non-cystic fibrosis bronchiectasis.

In November 2009, the first patient was dosed in the ORBIT-2 (Once-daily Respiratory Bronchiectasis Inhalation Treatment) trial, a 6-month, multicenter, international Phase 2b clinical trial of inhaled ciprofloxacin with the ARD-3150 formulation in 40 adult patients with non-cystic fibrosis bronchiectasis. The randomized, double-blind, placebo-controlled trial is being conducted in Australia and New Zealand. Following a 14 day screening period, the patients are treated once-a-day for 28 days with either the active drug, or placebo, followed by a 28 day off-treatment period. This on-off sequence will be repeated three times. The primary endpoint is

Table of Contents

defined as the mean change in *Pseudomonas aeruginosa* density in sputum (colony forming units CFU per gram) from baseline to day 28 of the active treatment group versus placebo. Safety and tolerability assessments of the treatment versus placebo group will be performed and secondary efficacy endpoints will include long term microbiological responses, time to an exacerbation, severity of exacerbations, length of time to resolve exacerbations and changes in lung function and in quality of life measurements.

ORBIT-2 is exploring whether the novel formulation ARD-3150, which has a different drug release profile than ARD-3100, may have additional therapeutic benefits. We expect that the 6-month study will also generate valuable data on the long term impact of once daily inhaled ciprofloxacin in patients with severe bronchiectasis. In March 2010, we announced that we had completed enrollment and administered the first dose to the last patient enrolled in this trial.

In February 2010, the first patient was dosed in the U.S. as part of the ORBIT-1 trial, an international, randomized, double-blind, placebo-controlled Phase 2b study designed to evaluate inhaled liposomal ciprofloxacin with the ARD-3100 formulation in patients with BE under the aforementioned U.S. IND. The ORBIT-1 trial will randomize 96 patients, who will receive for four weeks, either one of two different once-daily inhaled doses (100 or 150 mg ciprofloxacin delivered by inhalation as 2 or 3 mL of liposomal dispersion, respectively) or once-daily inhaled placebo. The primary efficacy endpoint will be the change from baseline in sputum *Pseudomonas aeruginosa* colony forming units (CFUs). Secondary endpoints will include quality of life measurements and improvement of outcomes with respect to exacerbations. Lung function changes will be monitored for safety.

The results from each of these trials, expected in the second half of 2010, will produce an extensive data base of information from which we hope to select the optimum product and the most appropriate endpoints to test in Phase 3. In order to expedite anticipated time to market and increase market acceptance, we have elected to deliver our formulations via an approved, widely-accepted nebulizer system for each of these Phase 2b trials.

In May 2010, we announced that clearance was received from the U.S. Food and Drug Administration for the inhaled liposomal ciprofloxacin (ARD-3100) Investigational New Drug (IND) application for the management of cystic fibrosis (CF). The first trial planned under this IND is a Phase 1/2a study in pediatric CF patients.

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

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. We are currently seeking U.S. government funding to complete the development of this product.

In August 2006, we sold all of the 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 privately-held pharmaceutical company. Zogenix is responsible for further development and commercialization efforts of Intraject (now rebranded under the name DosePro). Under the terms of the asset sale agreement, we received a $4.0 million initial payment from Zogenix and would be entitled to a $4.0 million milestone payment upon initial U.S. commercialization, as well as quarterly royalty payments upon commercialization of DosePro products. 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). The NDA was accepted for filing by the FDA in March 2008. The same month, Zogenix entered into a 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 July 16, 2009, Zogenix announced that it had received approval from the FDA for its NDA for SUMAVEL DosePro needle-free delivery system. On August 3, 2009, Zogenix and Astellas Pharma US, Inc. announced that they had entered into an exclusive co-promotion agreement in the U.S. for the SUMAVEL DosePro needle-free delivery system. Under the announced terms of the agreement, the companies will collaborate on the promotion and marketing of SUMAVEL DosePro with Zogenix focusing their sales activities primarily on the neurology market while Astellas will focus mostly on primary care physicians. Zogenix will have responsibility for manufacturing and distribution of the product.

On January 13, 2010, Zogenix announced the U.S. commercial launch of its SUMAVEL DosePro product. The U.S. launch entitled the Company to the $4.0 million milestone payment which we received and recorded as royalty revenue during the three months ended March 31, 2010.

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 revenue recognition, and assumptions for valuing options, warrants and other stock-based compensation. Our actual results could differ from these estimates.

Revenue Recognition

The Company recognizes revenue under the provisions of the SEC s Staff Accounting Bulletin (SAB) 104, Topic 13, *Revenue Recognition Revised and Updated* and ASC 605, *Revenue Recognition.* In addition, contract revenue from our collaboration arrangements typically contain multiple elements and are accounted for under the guidance of *ASC* 605-25, *Revenue Recognition-Multiple Element Arrangements.*

Contract Revenue. Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. We record license fees, milestone fees, reimbursement of research and development expenses as contract revenue. We review all of these arrangements for the existence of multiple elements. The Company reviews elements that have been delivered and determines 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 exists. Deliverables that meet these criteria are considered a separate unit of accounting and are recognized as revenue when delivered and collection is reasonably assured. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. Revenue recognition criteria are identified and applied to each separate unit of accounting. The Company typically has not had reliable evidence of separate units and has treated the entire arrangement as a single unit of accounting.

Royalty Revenue. We earn royalty revenue under the terms of the asset sale agreement with Zogenix. We recognize revenue when the amounts under this agreement can be determined and when collectability is probable. We have no performance obligations under this agreement. We recognize revenue from our quarterly royalty payments one quarter in arrears due to the lag in royalty reporting from Zogenix. In the first quarter of 2010, we received the $4 million milestone payment that was due upon the first commercial sale by Zogenix of a product using the DosePro technology. This amount was recorded as royalty revenue for the three months ended March 31, 2010.

Impairment of Long-Lived Assets

In accordance with ASC 360-10, *Property Plant and Equipment Overall*, 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 ASC 420, *Exit or Disposal Cost Obligations* (ASC 420), 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 this guidance, 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.

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 March 31, 2010 and December 31, 2009, 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.

Employee Stock-Based Compensation

We follow the fair value method of accounting for employee stock-based compensation arrangements in accordance with ASC 718, *Compensation Stock Compensation*. We record expense for stock-based compensation, which includes stock options, restricted stock awards and purchases of common stock under the Employee Stock Purchase Plan. The expense amount that is recorded is based on the fair value of the award and is recognized as compensation expense. Expense is recognized over the vesting period of the award.

We used the Black-Scholes option-pricing model to estimate the fair value of stock-based awards as of the grant date. The Black-Scholes model, by its design, is complex, and dependent upon key data inputs estimated by management. 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. Effective during the three months ended March 31, 2010, we began using the safe harbor method to calculate the expected term, as allowed by SAB 110. We believe that use of this method is most appropriate for us considering the very limited, relevant historical experience of stock option exercises.

Recent Accounting Pronouncements

See Note 2 to the accompanying unaudited condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for information on recent accounting pronouncements.

Results of Operations

Three months ended March 31, 2010 and 2009

We significantly reduced our net loss for the three months ending March 31, 2010 as compared with the three months ended March 31, 2009. These favorable results benefited from higher revenue and lower operating expenses as compared with the prior year period. Operating expenses were lower despite our continued investment in our liposomal ciprofloxacin clinical programs.

Total revenue was $4.0 million for the three months ended March 31, 2010 as compared with zero in the comparable period in 2009. For the three months ended March 31, 2010, we recorded $4.0 million in royalty revenue related to our Zogenix royalty rights. The amount that was recorded as royalty revenue was the milestone payment that was due upon the initial commercialization of Zogenix s DosePro product. We are also entitled to quarterly royalty payments based on sales of the DosePro product. We anticipate recording this recurring royalty revenue beginning with the three months ending September 30, 2010 since the terms of the asset sale agreement provides for royalty payments to be based on cash received by Zogenix on their product sales and there is a sixty day lag following the end of the quarter in royalty reporting. We have been informed by Zogenix that wholesalers distributing the SUMAVEL DosePro product were given net 90 day payments terms for the first quarter sales, resulting in the effective delay of first quarter 2010 royalties until the second quarter 2010 royalty payment due in late August 2010. After first quarter

2010, the payment terms for wholesalers reverted to net 30 days.

For the three months ended March 31, 2009, the Company s revenue was zero since all amounts invoiced under the Lung Rx collaboration agreement were deferred and not recognized as revenue until a subsequent period.

Operating expenses were $4.1 million for the three months ended March 31, 2010, which represented a $1.0 million decrease from the prior year. Research and development expenses decreased $0.9 million and general and administrative expenses decreased $0.1 million.

The decrease in research and development expenses was due to lower AERx-related expenses for headcount, contract manufacturing and depreciation expenses. AERx-related expenses decreased due to the termination of the Lung Rx collaboration in June 2009 and the subsequent suspension of AERx-related development activity. These decreases were partially offset by higher direct clinical expenses related to our liposomal ciprofloxacin Phase 2b trials.

Liquidity and Capital Resources

As of March 31, 2010, we had cash, cash equivalents and short-term investments of $8.9 million and total working capital of $7.7 million. We believe that cash and cash equivalents on hand at March 31, 2010, as well as anticipated recurring royalty payments from Zogenix, will be sufficient to enable us to fund our operations through the fourth quarter of 2010.

We are currently exploring means of raising additional capital to fund further development of the cystic fibrosis indication for ARD-3100, as well as the anticipated costs of our Phase 3 liposomal ciprofloxacin bronchiectasis trials, focusing primarily on establishing funded partnering agreements and through sale or out-licensing of non-strategic assets. If we are unsuccessful in raising sufficient funding at acceptable terms, we will be forced to suspend further development of our liposomal ciprofloxacin product candidate after our Phase 2b trials in bronchiectasis are completed or otherwise curtail operations.

Three months ended March 31, 2010

Total cash and cash equivalents increased by $2.0 million for the three months ended March 31, 2010. The increase in cash was primarily due to the net proceeds of short-term investments of $2.2 million. This increase was partially offset by cash used in operations of $0.2 million. Cash used for operations was favorably impacted by the receipt of the $4.0 million milestone payment from Zogenix.

Three months ended March 31, 2009

Total cash increased by $3.0 million for the three months ended March 31, 2009. The increase was due to net proceeds of $3.9 million from the sale of common stock in our registered direct offering and proceeds of $2.4 million from the maturity of short-term investments. These increases were partially offset by cash used by operations of $3.3 million. Cash was used by operations by our net loss of $5.2 million. Cash used by operations was less than our net loss due to non-cash expenses for depreciation and stock-based compensation and for Lung Rx payments that were received but deferred.

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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of the end of the period covered by this report, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended) were effective as of the end of the period covered by this report to ensure that information that we are 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.

Table of Contents

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our Chief Executive Officer and Chief Financial Officer have concluded that these controls and procedures are effective at the reasonable assurance level. We believe 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.

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, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

There have been no reportable developments in the Lung Rx, Inc. arbitration proceedings previously disclosed in Part I, Item 3, Legal Proceedings of the 2009 Annual Report on Form 10-K.

Item 1A. RISK FACTORS

In addition to the other information contained in this Quarterly Report on Form 10-Q, and risk factors set forth in the 2009 Annual Report on Form 10-K and our other filings with the SEC, the following risk factors should be considered carefully before you decide whether to buy, hold or sell our common stock. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also impair our business, financial conditions, results of operations and stock price.

The risk factors included herein include any material changes to and supersede the risk factors associated with our business previously disclosed in Part I, Item 1A, Risk Factors of the 2009 Annual Report on Form 10-K. We have marked with a double asterisk (**) those risk factors that reflect substantive changes from the risk factors included in the 2009 Annual Report on Form 10-K.

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 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.

We will need additional capital, and we may not be able to obtain it on a timely basis, or at all.

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, especially in light of the current difficult financing environment. Our operations to date have consumed substantial amounts of cash and have generated no significant direct 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 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, contract research funding and interest earned on investments. We believe that our cash and cash equivalents at March 31, 2010 and anticipated future recurring royalty payments will be sufficient to fund operations at least through the fourth 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 March 31, 2010, we have an accumulated deficit of $348.7 million. We have not had any significant direct product sales and do not anticipate receiving revenues from the sale of any of our products for at least the next few years, if ever. While our shift in development strategy has resulted in reduced operating and capital expenditures, we expect to continue to incur substantial losses over at least the next several years as we:

- continue 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.

We are dependent upon Zogenix and its partners to successfully market and sell the SUMAVEL DosePro needle-free delivery system in order to realize value from this asset.

We have no control over decisions made by Zogenix and/or its partners and collaborators on the marketing, sale or continued development of the SUMAVEL DosePro product and any subsequent products utilizing the DosePro technology. Any delay in, or failure to receive royalties could adversely affect our financial position and we may not be able to find another source of cash to continue our operations.

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 and/or collaborative partnerships. 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 delay the potential receipt of revenues.

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

Regulatory authorities may delay or 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 future 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

Table of Contents

approval. Advertising and other promotional material must comply with FDA requirements and established requirements applicable to drug samples. We, our future 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 and European Medicines Agency 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 in the US for up to seven years or European Union for up to ten years.

The FDA has granted orphan drug designation for our proprietary liposomal ciprofloxacin drug product candidate 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 and bronchiectasis. Bayer has obtained orphan drug status for their inhaled powder formulation of ciprofloxacin in the United States and European Union for the treatment of cystic fibrosis.

In August 2009, the European Medicines Agency (EMEA) granted orphan drug designation to our inhaled liposomal ciprofloxacin drug product candidate for the treatment of lung infections associated with cystic fibrosis. Under European guidelines, Orphan Medicinal Product Designation provides 10 years of potential market exclusivity if the product candidate is the first product candidate for the indication approved for marketing in the European Union. We may seek to develop additional products that incorporate drugs that have received orphan drug designations for specific indications. In each case, if our product is not the first to be approved by the FDA or EMEA for a given indication, we may not be able to access the target market in the United States and/or the European Union, 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 our products. We may not be able to enter into or maintain satisfactory contract manufacturing arrangements. For example, our agreement with sigma-tau Group to manufacture liposomal ciprofloxacin may be terminated for unforeseen reasons, or we may not be able to reach mutually satisfactory agreements with sigma-tau Group 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.

Further, we, our contract manufacturers and our future 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 future 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.

Our dependence on future 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 collaborators could delay or terminate their agreements, and our products subject to collaborative arrangements may never be successfully commercialized.

Further, our 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, or they may be terminated altogether. 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 future collaborators, such as the interpretation of terms in our agreements. For example, we currently have a disagreement with United Therapeutics concerning its right to terminate the Lung Rx Agreement, and we are currently in arbitration with Lung Rx regarding this disagreement. 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.

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 future collaborative arrangements may not be successful.

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 candidates will require a large sales force to call 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 collaboration 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 future 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 future 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 future 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 future 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 liposomal ciprofloxacin.

Our ability to compete effectively will also depend to a significant extent on our and our future 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 future 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.

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.

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 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 future 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 (now a part of

Roche), 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 future 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 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.

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 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 future 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.

Table of Contents

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

Our laboratory and clinical testing sometimes involves the 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 effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal year. The rules adopted by the SEC pursuant to Section 404 also currently requires our independent registered public accounting firm, beginning with our Annual Report on Form 10-K for the fiscal year ending December 31, 2010, 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;
- investor perception of the value of the royalty stream from Zogenix;
- 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 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;

Table of Contents

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.

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. Therefore, our shareholders will not receive any funds absent a sale of their shares. We cannot assure shareholders of a positive return on their investment if they sell their shares, nor can we assure that shareholders will not lose the entire amount of their investment.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Table of Contents

Item 4. (REMOVED AND RESERVED)

Item 5. OTHER INFORMATION

Not applicable.

Table of Contents

Item 6. EXHIBITS

Exhibit Number	Description
31.1	Certification of the Principal Executive Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Principal Financial Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Aradigm and AERx 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 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.

ARADIGM CORPORATION

/s/ Igor Gonda
Igor Gonda
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Nancy E. Pecota
Nancy E. Pecota
Vice President, Finance and Chief
Financial Officer (Principal Financial and
Accounting Officer)

Dated: May 13, 2010

Table of Contents

INDEX TO EXHIBITS

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