ARADIGM CORP
Form 10-Q
August 09, 2013
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

or

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

For the transition period from _____ to _____.

Commission File Number: 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 x No ¨

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 x No ¨

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 ¨	Accelerated filer ¨
Non-accelerated filer ¨ (do not check if a smaller reporting company)	Smaller reporting company x

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

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 August 2, 2013)
Common	*252,407,221*

Table of Contents

ARADIGM CORPORATION

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ARADIGM CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	June 30, 2013 (Unaudited)	December 31, 2012 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,693	$ 7,414
Short-term investments	1,011	203
Receivables	59	41
Prepaid and other current assets	220	106
Total current assets	2,983	7,764
Property and equipment, net	549	727
Other assets	420	475
Total assets	$ 3,952	$ 8,966
LIABILITIES AND SHAREHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 798	$ 330
Accrued clinical and cost of other studies	234	500
Accrued compensation	297	184
Facility lease exit obligation	155	144
Other accrued liabilities	425	127
Total current liabilities	1,909	1,285
Deferred rent	144	144
Facility lease exit obligation, non-current	390	465
Note payable, net of discount and accrued interest	8,742	8,513
Total liabilities	11,185	10,407
Commitments and contingencies		
Shareholders deficit:		
Preferred stock, 5,000,000 shares authorized, none outstanding		
Common stock, no par value; authorized shares: 297,527,214 at June 30, 2013 and December 31, 2012; issued and outstanding shares: 252,407,221 at June 30, 2013; 251,346,385 at December 31, 2012	370,162	369,919
Accumulated deficit	(377,395)	(371,360)
Total shareholders deficit	(7,233)	(1,441)
Total liabilities and shareholders deficit	$ 3,952	$ 8,966

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Table of Contents

ARADIGM CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenue:				
Royalty revenue	$ 248	$ 240	$ 527	$ 522
Operating expenses:				
Research and development	1,423	700	3,407	1,486
General and administrative	1,118	913	2,338	1,996
Restructuring and asset impairment	7	9	14	18
Total operating expenses	2,548	1,622	5,759	3,500
Loss from operations	(2,300)	(1,382)	(5,232)	(2,978)
Interest income	1	3	3	7
Interest expense	(407)	(382)	(801)	(752)
Other income (expense), net	(4)		(5)	2
Net loss	$ (2,710)	$ (1,761)	$ (6,035)	$ (3,721)
Change in unrealized losses on available-for-sale securities				(1)
Comprehensive loss	$ (2,710)	$ (1,761)	$ (6,035)	$ (3,722)
Basic and diluted net loss per common share	$ (0.01)	$ (0.01)	$ (0.02)	$ (0.02)
Shares used in computing basic and diluted net loss per common share	250,417	198,406	250,180	198,166

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Table of Contents

ARADIGM CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six months ended June 30,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$ (6,035)	$ (3,721)
Adjustments to reconcile net loss to cash used in operating activities:		
Amortization and accretion of investments	28	16
Depreciation and amortization	185	200
Stock-based compensation expense	204	279
Amortization of note discount	42	26
Changes in operating assets and liabilities:		
Receivables	(18)	(17)
Prepaid and other current assets	(114)	(51)
Other assets	55	64
Accounts payable	468	(2)
Accrued compensation	113	97
Other liabilities	219	66
Deferred rent		12
Facility lease exit obligation	(64)	(52)
Net cash used in operating activities	(4,917)	(3,083)
Cash flows from investing activities:		
Capital expenditures	(7)	
Purchases of short-term investments	(2,622)	(1,800)
Proceeds from sales and maturities of short-term investments	1,786	6,505
Net cash provided by (used in) investing activities	(843)	4,705
Cash flows from financing activities:		
Proceeds from issuance of common stock	39	38
Net cash provided by financing activities	39	38
Net increase (decrease) in cash and cash equivalents	(5,721)	1,660
Cash and cash equivalents at beginning of period	7,414	2,148
Cash and cash equivalents at end of period	$ 1,693	$ 3,808

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Table of Contents

ARADIGM CORPORATION

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization, Basis of Presentation and Liquidity

Organization

Aradigm Corporation (the Company, we, our, or us) is a California corporation, incorporated in 1991, 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 consolidated 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 (GAAP) 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 consolidated 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, 2012, as filed with the SEC on March 27, 2013 (the 2012 Annual Report on Form 10-K). The results of the Company s consolidated operations for the interim periods presented are not necessarily indicative of operating results for the full fiscal year or any future interim period.

The consolidated balance sheet at December 31, 2012 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements. For further information, please refer to the consolidated financial statements and notes thereto included in the 2012 Annual Report on Form 10-K.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All inter-company accounts and transactions have been eliminated in consolidation.

Liquidity

The Company has incurred significant operating losses and negative cash flows from operations. At June 30, 2013, the Company had an accumulated deficit of $377.4 million, working capital of $1.1 million and shareholders deficit of $7.2 million. The Company had cash, cash equivalents and short-term investments of approximately $2.7 million as of June 30, 2013. Management believes that this amount will be sufficient to meet its obligations through the year ended December 31, 2013 because the Company may defer certain discretionary activities.

The Company will require additional capital to fund its drug development and operating activities and has arranged additional financing, subject to the closing of the collaboration transaction contemplated with Grifols, S.A. If the Company is unable to complete the transaction or is unable to obtain sufficient financing on acceptable terms or otherwise, the Company may be required to further reduce, defer or discontinue its activities or may not be able to continue as a going concern.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements, in conformity with GAAP, 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, assumptions for valuing options and warrants, and income taxes. Actual results could differ from these estimates.

6

Table of Contents

Cash and Cash Equivalents

All highly liquid investments with maturities of three months or less at the time of purchase are classified as cash equivalents.

Investments

Management determines the appropriate classification of the Company s marketable securities, 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. Fair values of investments are based on quoted market prices where available. Investment 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 were 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

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 consolidated statements of operations.

Accounting for Costs Associated with Exit or Disposal Activities

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. The Company accounted for the partial sublease of its headquarters building as an exit activity and recorded the sublease loss in its statement of operations (see Note 5).

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

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. The Company recognizes revenue under the provisions of the SEC issued Staff Accounting Bulletin 104, Topic 13, *Revenue Recognition Revised and Updated* and ASC 605-25, *Revenue Recognition-Multiple Elements* (ASC 605-25). Revenue for arrangements not having multiple deliverables, as outlined in ASC 605-25, is recognized once costs are incurred and collectability is reasonably assured.

In accordance with contract terms, milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements and, accordingly, are recognized as revenue either upon completion of the milestone effort, when payments are contingent upon completion of the effort, or are based on actual efforts expended over the remaining term of the agreement when payments precede the required efforts. Refundable development payments are deferred until specific performance criteria are achieved. Refundable development payments are generally not refundable once specific performance criteria are achieved and accepted.

7

Table of Contents

Collaborative license and development agreements that require the Company to provide multiple deliverables, such as a license, research and product steering committee services and other performance obligations, are accounted for in accordance with ASC 605-25. Under ASC 605-25, delivered items are evaluated to determine whether such items have value to the Company s collaborators on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate revenue recognition criteria are identified and applied to each separate unit of accounting.

Research and Development

Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and research-related overhead expenses. 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. These standards require companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. See Note 7 for further discussion of the Company s stock-based compensation plans.

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 June 30, 2013 and December 31, 2012, 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 and six months ended June 30, 2013 and 2012, because the inclusion of such shares would have had an anti-dilutive effect.

Table of Contents

Recently Issued Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the six months ended June 30, 2013, as compared to the recent accounting pronouncements described in the Company s recent 2012 Form 10-K that are of significance or potential significance to the Company.

3. Cash, Cash Equivalents and Short-Term Investments

At June 30, 2013 and December 31, 2012, the balance of the Company s cash, cash equivalents and short-term investments approximated their fair values. All short-term investments at June 30, 2013 mature in less than one year. The Company invests its cash and cash equivalents and short-term investments in money market funds, commercial paper, certificates of deposit 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 follows ASC 820, *Fair Value Measurements*, which clarifies the definition of fair value, prescribes methods for measuring fair value, establishes a fair value hierarchy based on the inputs used to measure fair value and expands disclosures about the use of fair value measurements. The fair value hierarchy has three levels based on the reliability of the inputs used to determine fair value. Level 1 values are based on quoted prices in active markets. Level 2 values are based on significant other observable inputs. Level 3 values are based on significant unobservable inputs. The following table presents the fair value level for 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 (In thousands)			
Description	**Balance June 30, 2013**	**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	$ 1,693	$ 1,365	$ 328	$
Short-term investments:				
Certificates of deposit	$ 245	$	$ 245	$
U.S. treasury and agencies	766		766	
Total	$ 1,011	$	$ 1,011	$

The Company s cash and cash equivalents at June 30, 2013 consist of cash, U.S. agency notes and money market funds. Money market funds are valued using quoted market prices. The Company s short-term investments at June 30, 2013 consist of certificates of deposit and U.S. agency notes. The Company uses an independent third party pricing service to value these securities. 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. The Company performs a review of prices reported by the pricing service to determine if they are reasonable estimates of fair value. In addition, the Company performs a review of its securities to determine the proper classification in accordance with the fair value hierarchy.

5. Sublease Agreement and Lease Exit Liability

On July 18, 2007, the Company entered into a sublease agreement with Mendel Biotechnology, Inc. (Mendel) to lease approximately 48,000 square feet of the Company s 72,000 square foot headquarters facility located in Hayward, CA. In April 2009, the Company entered into an amendment to its sublease agreement with Mendel to sublease an additional 1,550 square feet. In January 2012, the Company entered into a second amendment to the sublease with Mendel in which Mendel leased an additional 3,300 square feet and at this time Mendel waived their right to early termination. The sublease with Mendel now expires concurrently with the Company s master lease for the Hayward facility in July

of 2016.

During the year ended December 31, 2007, the Company recorded a $2.1 million lease exit liability and related expense for the expected loss on the sublease, 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 Company recorded an additional sublease loss on the subsequent amendment of the lease in April 2009. 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 consolidated statement of operations and comprehensive loss.

Table of Contents

The lease exit liability activity for the six months ended June 30, 2013 is as follows (in thousands):

	Six Months Ended June 30, 2013
Balance at January 1, 2013	$ 609
Accretion expense	14
Lease payments	(78)
Balance at June 30, 2013	$ 545

6. Royalty Agreement, Note Payable and Accrued Interest

Zogenix

In August 2006, the Company sold all assets related to its needle-free injector technology platform and products, including 12 U.S. patents along with foreign counterparts, to Zogenix, Inc. In July 2009, Zogenix was granted approval by the U.S. Food and Drug Administration (FDA) of the SUMAVEL* DosePro* (sumatriptan injection) needle-free delivery system for the treatment of acute migraine and cluster headache. The Company is entitled to quarterly royalty payments of 3% of net sales on all SUMAVEL DosePro sales. The Company recorded royalty revenue of $248,000 for the three months ended June 30, 2013.

Royalty Financing

On June 21, 2011, the Company entered into an $8.5 million royalty financing agreement with a syndicate of lenders. The agreement created a debt obligation (the Term Loan) that will be repaid through and secured by royalties from net sales of the SUMAVEL DosePro (sumatriptan injection) needle-free delivery system payable to the Company under its Asset Purchase Agreement (APA) with Zogenix.

Under the terms of the royalty financing agreement, the Company received a loan of $8.5 million, less fees and expenses (approximately $473,000) and an additional $250,000 set aside for an Interest Reserve Account. The lenders are entitled to receive 100% of all royalties payable to the Company under the APA until the principal and accrued interest of the Term Loan are fully repaid, after which time the benefit of any further royalties made under the APA will accrue to Aradigm. The Term Loan will accrue interest at the rate equal to the greater of a) LIBOR or b) 1.50%, plus a margin of 14.5%. To the extent royalty payments are insufficient to pay accrued and unpaid interest under the financing, the shortfall will be funded from the Interest Reserve Account or, if the account is insufficient to pay all of the interest due, the shortfall will be capitalized and added to the principal balance of the Term Loan. During the three months ended March 31, 2012, the Interest Reserve Account was fully utilized and future shortfalls have been and will continue to be capitalized and added to the principal balance of the Term Loan. The lenders were granted a security interest in the assets of an Aradigm subsidiary, Aradigm Royalty Financing LLC, which holds Aradigm s rights to receive royalty payments under the APA. The lenders have no recourse to other assets of Aradigm for repayment of the loan. Amortization of the Term Loan will occur to the extent that royalties payments received for any quarter exceed accrued interest due for that quarter.

While the term loan is non-recourse to the assets of Aradigm Corporation, the term loan agreement contains a minimum royalty covenant. If the minimum royalty covenant is breached and the subsidiary does not cure the breach through a cash contribution to pay down the accrued principal and interest, then the lenders have the right to declare the agreement in default and obtain the right to all future royalties and payments due to Aradigm under the Zogenix asset purchase agreement. In 2012, the minimum royalty covenant was breached and the Company made cash payments of approximately $167,000 to the lenders for accrued interest in order to cure the breach. In the six months ended June 30, 2013 the covenant was again breached. The Company is currently negotiating with the lenders to minimize or eliminate the amount of cash payments it will be required to make to prevent the agreement from going into default. If the amount of the cash payments required to be made by the Company are not reduced or eliminated the Company may elect to allow the agreement to go into default.

The Company has the right to prepay the Term Loan after June 21, 2012, subject to the payment of the principal balance plus a prepayment fee of 8% of the outstanding balance if prepaid in months 13-24 following the transaction closing date of June 21, 2011; 4% if prepaid in months 25-36; and 2% if prepaid in months 37-48. There will be no prepayment fee for prepaying the Term Loan

10

Table of Contents

after the 48 month anniversary of the closing date. In addition, the Company has the right to make partial prepayments in an amount no less than the greater of (i) 10% of the principal balance of the Term Loan outstanding as of the applicable prepayment date or (ii) $1,000,000. Under no circumstances will the receipt of royalty payments from Zogenix in excess of the accrued interest then due be considered prepayments under the Term Loan.

The Company capitalized the fees and expenses of approximately $473,000 and recorded this amount in other assets. The capitalized expenses will be amortized to interest expense using the effective interest method over a period of 48 months.

In connection with the transaction, the Company issued to the lenders warrants to purchase a total of 2,840,909 shares of the Company s common stock at a strike price of $0.22 per share, representing a 20% premium above the average closing price of the Company s common stock for the ten trading days immediately preceding the closing of the transaction. The warrants expire on December 31, 2016. In accordance with Accounting Standards Topic 815 *Derivatives and Hedging*, the warrants were accounted for as equity instruments and their fair value was determined to be approximately $390,000. The relative fair value of the warrants is considered a discount against the note and was recorded as a reduction of the note payable. The note discount is being amortized to interest expense using the effective interest method with an annual rate of 18.7% over a period of 48 months.

7. Stock-Based Compensation and Stock Options, Awards and Units

The following table shows the stock-based compensation expense included in the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2013 and 2012 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Costs and expenses:				
Research and development	$ 33	$ 32	$ 57	$ 77
General and administrative	76	116	147	202
Total stock-based compensation expense	$ 109	$ 148	$ 204	$ 279

There was no capitalized stock-based employee compensation cost for the three and six months ended June 30, 2013 and 2012. Since the Company did not record a tax provision during the quarters ended June 30, 2013 and 2012, 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 $0.3 million as of June 30, 2013. This amount will be recognized over a weighted average period of 0.88 years.

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 six months ended June 30, 2013 was $35,000. The Company retained purchase rights with respect to 1,908,083 shares of unvested restricted stock awards issued pursuant to stock purchase agreements at no cost per share as of June 30, 2013. As of June 30, 2013, there was $0.1 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 0.47 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.

11

Table of Contents

Stock Option Activity

The following is a summary of activity under the 1996 Plan, the 2005 Plan and the Directors Plan for the six months ended June 30, 2013:

	Shares Available for Future Grant
Balance at January 1, 2013	2,954,024
Options granted	(630,000)
Options cancelled	35,100
Restricted share awards granted	(713,333)
Balance at June 30, 2013	1,645,791

	Options Outstanding			
	Number of Shares	Exercise Price Range		Weighted Average Exercise Price
Balance at January 1, 2013	6,755,200	$ 0.12	$ 12.00	$ 0.83
Options granted	630,000	$ 0.12	$ 0.15	$ 0.15
Options cancelled	(35,100)	$ 4.75	$ 6.50	$ 5.35
Balance at June 30, 2013	7,350,100	$ 0.12	$ 12.00	$ 0.81

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 June 30, 2013 for those stock options for which the quoted market price was in excess of the exercise price (in-the-money options). As of June 30, 2013, options to purchase 6,743,975 shares of common stock were exercisable and had an aggregate intrinsic value of approximately $20,000. No stock options were exercised during the six months ended June 30, 2013.

A summary of the Company s unvested restricted stock and performance bonus stock awards as of June 30, 2013 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, 2012	1,453,084	$ 0.14
Restricted share awards issued	713,333	0.15
Restricted share awards vested	(258,334)	0.15
Balance at June 30, 2013	1,908,083	$ 0.15

In 2013, the non-employee members of the Board of Directors elected to forego all or a portion of their annual cash retainer in exchange for restricted stock awards.

8. 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 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 six month periods ended June 30, 2013 and 2012.

The Company excluded the following securities from the calculation of diluted net loss per common share for the six months ended June 30, 2013 and 2012, as their effect would be anti-dilutive (in thousands):

	Six months ended June 30,	
	2013	**2012**
Outstanding stock options	7,350	6,755
Unvested restricted stock	1,908	1,291
Unvested restricted stock units	412	412

Table of Contents

9. Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive loss, 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 consolidated statements of operations in computing net loss and reported separately in shareholders equity (deficit). Comprehensive loss and its components are as follows (in thousands):

	Six months ended June 30,	
	2013	2012
Net loss	$ (6,035)	$ (3,721)
Other comprehensive loss:		
Change in unrealized loss on available-for-sale securities		(1)
Comprehensive loss	$ (6,035)	$ (3,722)

10. Subsequent Event

Grifols Collaboration Transaction

On May 20, 2013, the Company and Grifols, S.A., (Grifols) and certain other investors (the Investors) entered into a Stock Purchase Agreement (the Stock Purchase Agreement), pursuant to which the Company agreed, subject to the terms and conditions set forth in the Stock Purchase Agreement, to issue and sell a total of 209,774,558 shares of the Company s common stock (Common Stock), to Grifols and an additional 124,193,546 shares of Common Stock to the Investors, for a total sale of 333,968,104 shares of Common Stock (the Company Stock Sale), for a purchase price of $0.124 per share. The aggregate gross consideration payable to the Company in the Company Stock Sale is approximately $41.4 million.

In conjunction with signing the Stock Purchase Agreement, the Company and Grifols agreed to enter into a License and Collaboration Agreement (the License Agreement) at the closing of the Company Stock Sale. The License Agreement would exclusively license the Company s inhaled liposomal ciprofloxacin compound for the indication of non-cystic fibrosis bronchiectasis and other indications (the Program) to Grifols on a worldwide basis. Grifols would fund development expenses and commercialize products from the Program (Products), and pay development milestones and royalties on future commercial sales of Products. The License Agreement is described further below.

The Company held a special meeting of its shareholders on July 15, 2013 to (i) approve certain amendments to the Company s charter, including amendments necessary to increase the total number of shares of Common Stock authorized to be issued by the Company to at least 706,830,627 shares, including the 333,968,104 shares to be sold in the Company Stock Sale (the Charter Amendment) and (ii) to approve the Company s closing of the Company Stock Sale and entering into the License Agreement, Governance Agreement and other agreements described below and in the Stock Purchase Agreement (the Transactions). Shareholders of the Company holding more than 50% of the outstanding shares of the Company s Common Stock voted in favor of these proposals at the special meeting.

The closing of the Transactions is subject to certain closing conditions, including, among others the Company s entering into binding terms with a third party to commercially manufacture Products to permit the Company to satisfy its obligation to commercially supply Grifols with Products.

The Stock Purchase Agreement contains certain termination rights for both the Company and Grifols, including if the Transactions are not concluded on or before November 20, 2013

Table of Contents

License Agreement

The License Agreement will be signed simultaneously with the closing of the Company Stock Sale. Under the License Agreement, the Company will grant to Grifols an exclusive license to the Program, the lead product candidate under which is named *Pulmaquin*®. The license permits Grifols to commercialize Products throughout the world and grants Grifols a back-up manufacturing right to produce Products.

The Company will develop the Product for non-cystic fibrosis bronchiectasis or pulmonary infections associated with non-cystic fibrosis bronchiectasis, in accordance with an agreed upon development plan and pursuant to a Grifols-funded budget of $65 million (which includes allocations for the Company s internal, fully-burdened expenses). Any excess expenses will be borne by the Company. The Company will develop the Product for additional indications at Grifols sole expense if Grifols elects to pursue such development.

The Company will be responsible for obtaining regulatory approval of the first indication for the Product in the United States and the European Union. Additional regulatory expenses will be borne by Grifols, including the cost of obtaining approval outside the United States and European Union, and the cost of maintaining approvals globally. Grifols will use diligent efforts to commercialize the Product in countries where regulatory approval has been obtained.

The Company will be responsible for supplying Grifols requirements of the Product, and must establish primary and back-up suppliers acceptable to Grifols. Grifols will purchase Products from the Company on a cost pass-through basis plus a margin.

The collaboration between Grifols and the Company will be governed by a joint committee comprised of equal representation by the Company and Grifols and operated on a consensus basis. In the event that the parties do not agree, Grifols shall have deciding authority, except with respect to specific matters specified in the License Agreement.

Grifols will make development milestone payments of up to $25 million (with an initial payment of $5 million for initiation of the first Phase III clinical trial). On a country-by-country basis, Grifols will make royalty payments on net sales at a rate of either 12.5% or 20% (depending on the amount of net sales) for so long as there is patent coverage or orphan drug designation (or, if longer, 10 years), except that payments will be reduced by half in the event that a competitive product is being sold.

The License Agreement includes representations and warranties on behalf of Aradigm as are customarily found in transactions of this nature, including representations and operative provisions as to the licensed intellectual property, regulatory matters and compliance with applicable laws. The License Agreement also provides for certain mutual indemnities for breaches of representations, warranties and covenants.

Option Agreement

Simultaneously with execution of the License Agreement, Aradigm will enter into an Option Agreement (the Option Agreement) with Grifols granting Grifols a limited term option to license Aradigm s *AERx*® pulmonary drug delivery platform for use with another molecule. The Option Agreement affords Grifols a limited period of time to conduct a diligence assessment. If Grifols elects to proceed with a license, Grifols will pay Aradigm a low single digit royalty on net sales but bear all costs associated with development and commercialization.

Governance Agreement

In connection with and simultaneously with the closing of the Company Stock Sale, the Company and Grifols will enter into a Governance Agreement (the Governance Agreement), which sets forth certain rights and obligations of the Company and Grifols concerning, among other things, certain corporate governance matters, certain limitations on future acquisitions of shares of Common Stock by Grifols, and certain rights by Grifols to maintain a target level of ownership in the Company.

On the date the Governance Agreement is executed, the Company s board of directors will be reconstituted to consist of its chief executive officer, three independent directors under the NASDAQ Marketplace Rules and two persons designated by Grifols. The number of persons Grifols is entitled to designate for consideration for election to the Company s board of directors by the Company s nominating committee will thereafter depend on the percentage of beneficial ownership of the Company held by Grifols.

The Governance Agreement also provides that during the period beginning on the date of Closing and ending 12 months after the first commercial sale of a Product (the Restricted Period), Grifols will not directly or indirectly acquire or offer to acquire any shares of Common Stock except (i) with the approval of the Company s board of directors and a majority of its independent directors,

14

Table of Contents

(ii) effected solely to the extent necessary to maintain the beneficial ownership of Grifols and its affiliates at an amount equal to 35% (the Target Percentage) of the shares of Common Stock on a Fully Diluted Basis (as defined in the Governance Agreement), or (iii) in order to maintain its ownership percentage in the event that the Company issues new securities, in accordance with the provisions of the Governance Agreement. The Restricted Period terminates upon the occurrence of certain events, including a change in control of the Company and a third party publicly proposing to acquire the Company. The Governance Agreement further imposes certain standstill obligations on Grifols during the Restricted Period, pursuant to which Grifols and certain related persons are prohibited from soliciting proxies from the Company s shareholders, granting proxies or entering into voting agreements and seeking additional representation on the Company s board of directors.

The Governance Agreement provides Grifols with certain preemptive rights to participate in future issuances of Common Stock or equivalents of Common Stock by the Company, or the right to acquire shares of Common Stock from third parties or on the open market to maintain its Fully Diluted Ownership at the Target Percentage.

The Governance Agreement requires the approval of Grifols for certain actions by the Company which would adversely affect Grifols rights under the Governance Agreement, and for the Company to terminate the employment of its Chief Executive Officer or to appoint any successor Chief Executive Officer.

Registration Rights Agreements

In connection with and concurrently with the closing of the Company Stock Sale, the Company will enter into a Registration Rights Agreement with Grifols (the Grifols Registration Rights Agreement), pursuant to which the Company agreed to provide registration rights to Grifols with respect to the shares of Common Stock to be acquired in the Company Stock Sale. Under such agreement, Grifols will be entitled to require the Company to file with the SEC certain registration statements under the Securities Act of 1933, as amended (the Securities Act), with respect to the resale of the shares of Common Stock acquired by Grifols in the Company Stock Sale up to three times on Form S-1 and up to six times on Form S-3, and to include its shares of Common Stock in any registration the Company proposes for its own account or for the account of one or more of its shareholders.

In connection with and concurrently with the closing of the Company Stock Sale, the Company and the Investors also entered into a Registration Rights Agreement (the Investors Registration Rights Agreement). Pursuant to the Investors Registration Rights Agreement, the Company is required to file a registration statement to cover the resale of the shares of the Common Stock acquired by the investors in the Company Stock Sale. The failure on the part of the Company to satisfy the deadlines set forth in the Investors Registration Rights Agreement may subject the Company to payment of certain monetary penalties. In addition, pursuant to the terms of the Stock Purchase Agreement, the Company has agreed, among other things, not to file any other registration statement (other than any registration statement on Form S-4 or Form S-8, and subject to certain other limitations and exclusions) until the Common Stock subject thereto is covered by an effective registration statement or freely salable under Rule 144 under the Securities Act.

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, continue, seek, estimate, probably, potentially, 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 June 30, 2013 will be sufficient to enable us to fund our operations through at least the year ended December 31, 2013, our expectation that we will advance Pulmaquin into Phase 3 clinical trials, our expectation that we will incur operating losses for the foreseeable future, our anticipation regarding revenue, collaboration agreements (including the collaboration transaction contemplated with Grifols, S.A.) and our longer-term strategy and our expectations regarding clinical trials and orphan drug designations.

Table of Contents

These forward-looking statements and our business are subject to significant risks including, but not limited to, our ability to obtain additional financing, 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.

Investors 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

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 (respiratory) drug delivery as incorporated in our lead product candidate entering Phase 3 clinical trials, Pulmaquin. 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 technologies, including our inhaled ciprofloxacin formulations. We have not been profitable since inception and expect to incur additional operating losses over at least the foreseeable future as we continue product development efforts, clinical trial activities, animal toxicology and safety testing 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 June 30, 2013, we had an accumulated deficit of $377.4 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 our 2005 restructuring transaction with Novo Nordisk, borrowings from Novo Nordisk, the milestone and royalty payments associated with the sale of assets to Zogenix, proceeds from our June 2011 royalty financing transaction and interest earned on cash equivalents and short-term investments.

Over the last seven years, our business has focused on opportunities in the development of drugs for the treatment of severe respiratory disease that could be developed by us and commercialized in the United States, or another significant territory such as the European Union (EU). With the exception of our Pulmaquin program which will be partnered with Grifols upon the closing of that transaction, our longer term strategy is to commercialize our respiratory product candidates with our own focused marketing and sales 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.

More recently, we have restarted work on development of our inhaled nicotine program for smoking cessation. Changes in the regulatory environment in the U.S. and other countries brought about by the introduction of electronic cigarettes have created the opportunity to develop our AERx nicotine product for direct to consumer markets outside of the traditional pharmaceutical markets, thus potentially significantly decreasing the time-to-market for this product. We are also exploring the traditional regulatory path of approval of our nicotine inhaler as an approval under the FDA drug regulations may enable us to make health benefits claims and such approval would also mitigate the risk the FDA in the future would prevent the marketing of unregulated nicotine-containing products.

Inhaled Ciprofloxacin Program

See Note 10 to the accompanying unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for information on the Grifols Collaboration Transaction.

Table of Contents

Our lead development candidates are proprietary formulations of the potent antibiotic ciprofloxacin (Pulmaquin (ARD-3150) and Lipoquin® (ARD-3100)) that are delivered by inhalation for the management of infections associated with the severe respiratory diseases cystic fibrosis (CF) and non-cystic fibrosis bronchiectasis (BE). The formulations differ in the proportion of rapidly available and slow release ciprofloxacin. Pulmaquin uses the slow release liposomal formulation (Lipoquin) mixed with a small amount of ciprofloxacin dissolved in an aqueous medium. We received orphan drug designations for Lipoquin for both of these indications in the United States and for CF in the EU. We requested orphan drug designation from the FDA for Pulmaquin for the management of BE and we were granted orphan drug designation for ciprofloxacin for inhalation for this indication. In June 2012, we received orphan drug designation in the U.S. for liposomal ciprofloxacin plus ciprofloxacin for cystic fibrosis. We may seek orphan drug designation for other eligible product candidates we develop. We have been issued three U.S. patents covering composition of matter and method of treatment for our inhaled ciprofloxacin formulations with the longest patent protection until 2031. We have reported the results of one successful Phase 2b trial with Lipoquin and one successful Phase 2b trial with Pulmaquin in BE. We have also conducted one successful Phase 2a trial with Lipoquin in CF and one successful Phase 2a trial with Lipoquin in BE.

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 (Lipoquin, 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 against baseline 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 (Lipoquin, ARD-3100) in patients with BE. 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* CFUs, 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 August 2009, the European Medicines Agency granted Orphan Drug Designation to our inhaled liposomal ciprofloxacin drug product candidate Lipoquin (ARD-3100) for the treatment of lung infections associated with CF. 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 EU. Orphan drug designation also allows the candidate s sponsor to seek assistance from the European Medicines Agency in optimizing the candidate s clinical development through participation in designing the clinical protocol and preparing the marketing application. Additionally, a drug candidate designated by the Commission as an Orphan Medicinal Product may qualify for a reduction in regulatory fees as well as a EU-funded research grant. We had previously been granted orphan drug designations by the FDA for inhaled liposomal ciprofloxacin Lipoquin (ARD-3100) for the management of CF and for BE.

In November 2009, the first patient was dosed in the ORBIT-2 (Once-daily Respiratory Bronchiectasis Inhalation Treatment) trial, a 168 day, multicenter, international Phase 2b clinical trial of inhaled ciprofloxacin with the Pulmaquin (ARD-3150) formulation in 42 adult patients with BE. ORBIT-2 explored whether the novel formulation Pulmaquin, which has a different drug release profile than Lipoquin, may have additional therapeutic benefits. The randomized, double-blind, placebo-controlled trial was conducted in Australia and New Zealand. Following a 14 day screening period, the patients were 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 was repeated three times. The primary endpoint was defined as the mean change in *Pseudomonas aeruginosa* density in sputum (CFUs - per gram) from baseline to day 28 of the active treatment group versus placebo. Safety and tolerability assessments of the treatment versus placebo group were performed and secondary efficacy endpoints being assessed included 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.

In October 2010, we announced positive top line data from the ORBIT-2 study. Statistical significance was achieved in the primary endpoint the mean change in *Pseudomonas aeruginosa* density in sputum from baseline to day 28. In the full analysis population (full analysis set includes all patients who were randomized, received at least one dose and provided samples for at least

Table of Contents

two time points), there was a significant mean reduction of 4.2 log10 units in the Pulmaquin group, reflecting an almost sixteen-thousand fold decrease in bacterial load, versus a very small mean decrease of 0.1 log10 units in the placebo group (p=0.004). Secondary endpoint analysis showed that 17 subjects in the placebo group required supplemental antibiotics for respiratory-related infections versus 8 subjects in the Pulmaquin group (p=0.05). As announced in January 2011, the Kaplan-Meier analysis showed that the median time to first pulmonary exacerbation in the per protocol evaluation increased from 58 days in the placebo group to 134 days in the active treatment group and was statistically significant (p<0.05, log rank test). Pulmaquin was well tolerated and there were no significant decreases in lung function, as measured by FEV1 (forced expiratory volume in one second), at 28 days in either group. Overall, the incidence and severity of adverse events were similar in both the placebo and treatment groups; however, Pulmaquin had a superior pulmonary safety profile reflected in the number and severity of pulmonary adverse events. As announced in May 2011, further statistical analysis concluded that the reduction from baseline in *Pseudomonas aeruginosa* CFUs with Pulmaquin was rapid and persistent throughout the treatment cycles as exemplified by the statistically significant reductions of the mean log CFU values in the Pulmaquin group versus the placebo at day 14 and day 28 during the first treatment cycle, as well as at the end of the second and third cycles of treatment (days 84 and 140, respectively).

In February 2010, the first patient was dosed in the U.S. as part of the ORBIT-1 trial. This Phase 2b trial, an international, double-blind, placebo-controlled study being conducted under a U.S. FDA IND, randomized 95 patients and completed enrollment in March 2011. The ORBIT-1 study design called for four weeks of once-daily inhaled doses of the active drug (Lipoquin) or once-daily inhaled placebo. Two doses of the active drug were included in the study 100 or 150 mg ciprofloxacin delivered by inhalation as 2 or 3 mL of liposomal dispersion, respectively. The primary efficacy endpoint was a standard measure of antibacterial activity the change from baseline in sputum *Pseudomonas aeruginosa* CFUs. Secondary endpoints included quality of life measurements and improvement of outcomes with respect to exacerbations. Lung function changes were monitored for safety.

In June 2011, we announced positive top line data from the ORBIT-1 study. The primary endpoint - the mean change in *Pseudomonas aeruginosa* CFUs per gram of sputum from baseline to day 28 was met in the full analysis population: The full analysis set included all patients who were randomized, received at least one dose and provided samples for at least two time points. There was a significant mean reduction (p<0.001) of 2.942 log10 CFUs in the 3mL Lipoquin group and a significant mean reduction (p< 0.001) of 3.842 log10 CFUs in the 2mL Lipoquin group compared to placebos. Pooled placebo groups had a mean reduction of log10 CFUs of 0.437. There was no statistically significant difference between the 2 mL and 3 mL Lipoquin doses. Lipoquin was well-tolerated and no bronchodilator treatment was mandated before inhaled study treatments. There were no statistically significant differences between the active and placebo groups in the number of patients experiencing at least one respiratory treatment-emergent adverse event. The incidence of serious adverse events (SAEs) was low; there were a total of 6 SAEs and none of them were treatment related.

In October 2012, scientists from the Virginia Commonwealth University (Richmond, VA) reported findings about the anti-inflammatory effects of our inhaled ciprofloxacin in human bronchial lung cells stimulated by the lipopolysaccharide (LPS) produced by *Pseudomonas aeruginosa. Pseudomonas aeruginosa* is one of the most significant bacterial pathogens in patients with cystic fibrosis, bronchiectasis and severe COPD. LPS produced by this organism is a key virulence-causing factor associated with the respiratory infections due to this microorganism.

In the experiments reported by the School of Pharmacy, Virginia Commonwealth University, liposomal ciprofloxacin and free ciprofloxacin were applied onto the monolayer of human bronchial lung cells for 24 hours. LPS from *Pseudomonas aeruginosa* was then added to stimulate the inflammatory response. At 24 and 48 hours of this stimulation, samples were taken for determination of cellular release of an important pro-inflammatory cytokine, interleukin-8 (IL-8). IL-8 release was negligible from the unstimulated negative control cells. In contrast, 10 µg/ml LPS stimulation for 24 and 48 hours caused significant 24.1 ± 9.2 and 39.5 ± 11.6 ng of IL-8 release, respectively (positive control). Despite its application 24 hours prior to the LPS stimulation, liposomal ciprofloxacin at 0.1 mg/ml still inhibited this LPS-induced IL-8 release (60.1 ± 9.8% and 45.6 ± 4.8% inhibition, respectively). Free ciprofloxacin alone also showed comparable inhibition, but was eliminated much faster from the surface of the cells.

Chronic respiratory infections with *Pseudomonas aeruginosa* with the associated airway inflammation are the key cause of the deterioration in the quality of life and premature death of patients with cystic fibrosis and bronchiectasis. These findings suggest that liposomal ciprofloxacin could exert both anti-pseudomonal and anti-inflammatory effects in the lungs.

In April 2013, we were issued another patent covering our inhaled sustained release ciprofloxacin formulations (Lipoquin and Pulmaquin) in the U.S. and also received a notice of allowance in Japan. U.S. patent 8,414,915 entitled Dual Action, Inhaled Formulations Providing Both an Immediate and Sustained Release Profile issued on April 9, 2013. It provides additional protection for our Lipoquin and Pulmaquin product candidates. It is anticipated that US patent 8,414,915 will remain in force until at least October 22, 2027. This is the fourth issued US patent from this patent family. We are also pursuing additional coverage worldwide; a patent from this family issued in Australia on August 17, 2012.

18

Table of Contents

We have completed the analysis of all preclinical and clinical data from the two different formulations of inhaled ciprofloxacin (Pulmaquin and Lipoquin) and determined that Pulmaquin showed superior performance. We plan, therefore, to take Pulmaquin forward into Phase 3 clinical trials. In order to expedite anticipated time to market and increase market acceptance, we have elected to deliver our formulations via an FDA-approved, widely-accepted nebulizer system for each of our clinical trials and we intend to continue using this approach and obtain initial marketing approval also with a currently FDA-approved nebulizer system. In March 2012, we announced the FDA clearance of the Phase 3 IND for Pulmaquin in BE patients; the first human study under this IND is the first of the two identical Phase 3 studies in BE patients with Pulmaquin. Because we have chosen Pulmaquin as our lead formulation and in order to reduce the administrative burden of maintaining open regulatory filings, the existing IND filings for Lipoquin for BE and CF have been inactivated.

Liposomal Ciprofloxacin for Biodefense Purposes: Treatment of Q Fever, Tularemia, Pneumonic Plague, Inhalation Anthrax and other biodefense purposes

In addition to our programs addressing bronchiectasis and cystic fibrosis, our inhaled ciprofloxacin has also been tested for the prevention and treatment of inhaled bioterrorism infections, such as Q fever, inhalation anthrax, tularemia and pneumonic plague.

In September 2012, UK scientists from the Health Protection Agency (HPA) and Defence Science and Technology Laboratory (Dstl) reported the successful testing of our inhaled liposomal ciprofloxacin against *Coxiella burnetii* (Q fever) in a mouse model of this virulent infection. This work was conducted as part of the collaborative consortium that we formed with HPA and Dstl to evaluate the efficacy of our inhaled liposomal ciprofloxacin against high threat microbial agents.

Coxiella burnetii is a Gram-negative intracellular bacterium and the causative agent of the disease Q fever. *C. burnetii* is endemic worldwide, infects a wide variety of animals and humans and has a low infectious dose by the inhalational route. Clinical presentation in humans may lead to an acute infection with flu-like symptoms, or a chronic life-threatening disease. A recent epidemic of Q fever in humans took place in the Netherlands in 2009, with 2,357 reported cases and 6 deaths. Current oral antibiotic treatment of Q fever can be lengthy and complex.

In the experiments reported by the UK scientists, mice that were infected with *C. burnetii* via inhalation and treated 24 hours later with twice-daily oral ciprofloxacin continuing for 6 additional days, or infected drug-free control-treated animals that had the same treatment schedule, lost almost 20% of body weight by day 7 and exhibited clinical signs of the disease. In contrast, infected mice treated 24 hours later with once-daily lung-delivered liposomal ciprofloxacin continuing for 6 additional days, were significantly protected against weight loss and showed no clinical signs of disease throughout the 14-day duration of the study.

In November 2012, scientists from the UK Defence Science and Technology Laboratory (Dstl) reported in a preliminary study that they demonstrated that a single dose of Aradigm s liposomal ciprofloxacin formulation Lipoquin administered 24 hours after exposure to a lethal dose of the bacterium *Yersinia pestis* provided full protection in a murine model of pneumonic plague. In comparison, a single dose of oral ciprofloxacin administered 24 hours post-exposure provided no protection.

The Gram-negative bacterium *Yersinia pestis* is the causative agent of plague, a disease thought to be responsible for the death of 200 million people through devastating pandemics such as the Black Death. Inhalation of *Y. pestis* can result in the most severe form of the disease, pneumonic plague, which if untreated may have a mortality rate of 100%. Currently, there is no licensed vaccine for use in humans.

In the study, exposure to aerosolized *Y. pestis* was lethal. Animals were followed for up to 28 days post-exposure. All untreated mice succumbing to a systemic infection by day 3 post-exposure. A single dose of oral ciprofloxacin administered at 24 hours post-exposure did not prevent mortality and only increased the mean time to death to 5 days compared to 3 days for untreated mice. In comparison, a single dose of Lipoquin delivered via the nose into the lungs of the animals provided 100% protection and significantly improved survival compared to a single dose of oral ciprofloxacin ($P<0.0001$); a single dose of aerosolized Lipoquin administered at 24 hours post-exposure provided approximately 70% protection and significantly improved survival when compared to a single dose of oral ciprofloxacin ($P<0.001$).

In their report, the scientists state that the study demonstrated the superior efficacy of Lipoquin compared to oral ciprofloxacin as post-exposure prophylaxis against *Y. pestis*.

Table of Contents

The Dstl team also demonstrated in another series of experiments that a single dose of our inhaled liposomal ciprofloxacin protects animals against lethal doses of inhaled *Francisella tularensis* (tularemia) infection another microbial threat. These results confirmed and extended the research that we began originally under a technology demonstration program funded by the Defence Research and Development Canada (DRDC) as part of their interest in developing products to counter bioterrorism, such as inhaled anthrax and tularemia infections. DRDC had already demonstrated the feasibility of inhaled liposomal ciprofloxacin for post-exposure prophylaxis of *Francisella tularensis.* Mice were exposed to a lethal dose of *Francisella tularensis* and then 24 hours later were exposed via inhalation to a single dose of free ciprofloxacin, liposomal ciprofloxacin or saline. All the mice in the control group and the free ciprofloxacin group were dead within 11 days post-infection; in contrast, all the mice in the liposomal ciprofloxacin group were alive 14 days post-infection. The same results were obtained when the mice received the single inhaled treatment as late as 48 or 72 hours post-infection.

With inhalation anthrax, once symptoms appear, fatality rates are high even with the initiation of antibiotic and supportive therapy. Further, a portion of the anthrax spores, once inhaled, may remain dormant in the lung for several months and then germinate. Anthrax has been identified by the Centers for Disease Control as a likely potential agent of bioterrorism.

Ciprofloxacin has been approved by the FDA for use orally and via injection for the treatment of inhalation anthrax (post-exposure) since 2000. We believe that our product candidate may be able to deliver a long-acting formulation of ciprofloxacin directly into the lungs and be more effective and could potentially have fewer side effects, which is important for patient compliance, to prevent and treat inhalation tularemia and anthrax, Q fever, pneumonic plague and other inhaled bacterial bioterrorism agents than currently available therapies.

If we can obtain sufficient additional funding, including government grants or collaborative funding from organizations such as the Canadian DRDC and the UK Dstl, we may be able to complete the development of our liposomal ciprofloxacin for approval under FDA regulations relating to new drugs or biologics for potentially fatal diseases where human studies cannot be conducted ethically or practically. Unlike most drugs, which require large, well-controlled Phase 3 clinical trials in patients with the disease or condition being targeted, these regulations allow a drug to be evaluated and approved by the FDA on the basis of demonstrated safety in humans combined with studies in animal models to show effectiveness. We plan to use our preclinical and clinical safety data from our BE and CF programs to supplement the data needed to have this product candidate considered for approval for use in prevention and treatment of a number of potential bioterrorism infections including anthrax, tularemia, Q fever and pneumonic plague.

Liposomal Ciprofloxacin for Non-Tuberculous Mycobacteria

In August 2013, the National Institutes of Health (NIH) awarded us a Small Business Initiative Research (SBIR) grant in the amount of approximately $278,000 to investigate the treatment of pulmonary non-tuberculous mycobacteria (PNTM) infections with our inhaled liposomal ciprofloxacin products Pulmaquin and Lipoquin. The research program will be conducted in collaboration with Oregon State University, Corvalis.

According to a recent report from the National Institutes of Health based on an epidemiological study in U.S. adults aged 65 years or older, PNTM infections are an important cause of morbidity among older adults in the United States. From 1997 to 2007, the annual prevalence significantly increased from 20 to 47 cases/100,000 persons, or 8.2% per year. Forty-four percent of PNTM-affected people in the study had bronchiectasis compared to 1% in the non-PNTM cases pointing to an important co-morbidity. PNTM infections are common also in patients with other chronic lung conditions, such as cystic fibrosis and emphysema. In patients with AIDS, the infection is disseminated. The current clinical paradigm is to treat patients with lung or disseminated disease with combination therapy given orally or by IV. Unfortunately, these therapies often fail.

Inhaled Nicotine Program

According to the National Center for Health Statistics (NCHS), 19% of the U.S. population age 18 and above currently smoke cigarettes. Statistics from the National Cancer Institute indicate that cigarette smoking in the U.S. causes an estimated 443,000 deaths each year, including approximately 49,400 deaths due to exposure of secondhand smoke. According to the American Cancer Society, almost a third of all cancer deaths in the U.S. are caused by smoking. The World Health Organization s (WHO) recent report states that tobacco smoking is the single most preventable cause of death in the world today. Already tobacco kills more than five million people per year more than tuberculosis, HIV/AIDS and malaria combined. WHO warns that by 2030, the death toll could exceed eight million a year. Unless urgent action is taken, tobacco could kill one billion people during this century. According to the National Institute on Drug Abuse, more than $75 billion of total U.S. healthcare costs each year is attributable directly to smoking. However, this cost is well below the total cost to society because it does not include burn care from smoking-related fires, perinatal care for low birth-weight infants of mothers who smoke, and medical care costs associated with disease caused by secondhand smoke. In addition to healthcare costs, the costs of lost productivity due to smoking effects are estimated at $82 billion per year, bringing a conservative estimate of the economic burden of smoking to more than $150 billion per year.

NCHS indicates that nicotine dependence is the most common form of chemical dependence in this country. Quitting tobacco use is difficult and often requires multiple attempts, as users often relapse because of withdrawal symptoms and the acute craving for cigarettes. Smokers attempting to quit often turn to nicotine replacement products (gums, lozenges, patches) in order to reduce these cravings. However, recent research indicates that, while these products help in the short term, they are ineffective in preventing long term relapse in many smokers trying to quit. Many smokers will not even try to use the existing nicotine replacement products because they believe that these products will not satisfy their craving for cigarettes.

Our goal is to develop an inhaled nicotine product that would address the acute craving for cigarettes and, therefore, could provide a significantly more effective tool to quit tobacco smoking than the currently available products.

Table of Contents

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

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

We believe these results provide the foundation to complete the development of our inhaled nicotine product candidate as a means toward smoking cessation as it demonstrates in smokers cigarette-like nicotine concentrations with nearly instantaneous high plasma levels of nicotine, and a rapid and lasting reduction in the craving for cigarettes. To achieve the best safety profile our inhaled nicotine formulation is pure nicotine salt dissolved in a very small amount of water. No heating is used to generate the fine nicotine mist and there is no secondhand smoke as the user takes a single deep inhalation from the inhaler, instead of puffing on it.

In September 2012, we were issued a new U.S. patent for our inhaled nicotine technology from a second patent family that provides protection until at least 2024. Previously, we had two issued U.S. patents covering systems for effective smoking cessation, which provided exclusivity until 2019. The first two patents are method of treatment patents, covering systems, devices and containers for delivering aerosolized nicotine formulations in specific ways which we believe to be important for cigarette smokers who want to quit smoking. This new patent extends the coverage to containers with novel features anticipated to provide additional smoking cessation benefits.

Presently, the FDA has no mandate to regulate nicotine products derived from tobacco that do not make healthcare claims and are not already a part of the current FDA mandate. This is a reflection of the recent Sottera, Inc. v. FDA, No. 10-5032 D.C. Circuit court decision that has allowed electronic cigarettes to stay on the market in the U.S. after the FDA attempted to remove them from the market because they were deemed to be drug / device products. As a result, we believe that the AERx nicotine inhaler may be introduced to the U.S. market today as a non-regulated product; however, no health claims can be made. A similar opportunity to enter the market may exist in other countries where electronic cigarettes are not regulated as drugs (e.g., UK, most of Europe, New Zealand and China). We are also exploring the traditional regulatory path of approval of our nicotine inhaler as an approval under the FDA drug regulations may enable us to make health benefits claims and such approval would also mitigate the risk that the FDA in the future would prevent the marketing of unregulated nicotine-containing products.

We are seeking collaborations and non-dilutive financing to further develop this product for either the pharmaceutical market or the direct-to-consumer market or both.

Other Programs

In August 2013, the NIH awarded us an SBIR grant in the amount of approximately $260,000 to investigate the development and validation of tests for gastro-esophageal reflux with aspirations into the respiratory tract. The Principal Investigators and co-inventors of the new diagnostic tests are Professor Homer Boushey, University of California, San Francisco (UCSF) and Dr. Igor Gonda, Aradigm Corporation. The grant is funding laboratory work and a human clinical trial to be conducted at UCSF.

Aspiration of gastric contents into the respiratory tract causes significant morbidity and mortality and is accepted as the key initiating event for aspiration pneumonitis - a form of acute lung injury caused by the acidity of the gastric contents, and aspiration pneumonia - the consequence of the growth of pathogenic bacteria contained in the oropharynx aspirated into the tracheobronchial tree. When subclinical events of gastric aspiration occur, it is described as silent aspiration or microaspiration. Chronic, recurrent microaspirations have been implicated in the pathogenesis and worsening of many severe chronic pulmonary diseases of unknown origin, such idiopathic pulmonary fibrosis, bronchiolitis obliterans after lung transplantation, pulmonary disease in conditions associated with esophageal dysfunction and delayed gastric emptying such as cystic fibrosis and scleroderma, and the very common conditions of community acquired pneumonia in the elderly, asthma and COPD.

Research into the role of microaspirations has been severely hampered by the insensitivity, expense, inconvenience, invasiveness, and discomfort of current diagnostic methods for this condition. Development of a simple, patient-convenient, diagnostic test that is safe and can be used repeatedly over time could significantly impact the diagnosis and management of several pulmonary diseases that may be affected by recurrent microaspirations of gastro-intestinal contents into the respiratory tract.

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

Revenue Recognition

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. We recognize revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin 104, Topic 13, *Revenue Recognition Revised and Updated* (SAB 104) and Accounting Standards Codification (ASC) 605-25, *Revenue Arrangements-Multiple Element Arrangements* (ASC 605-25). Revenue for arrangements not having multiple deliverables, as outlined in ASC 605-25, is recognized once costs are incurred and collectability is reasonably assured.

Table of Contents

Collaborative license and development agreements often require us to provide multiple deliverables, such as a license, research and development, product steering committee services and other performance obligations. These agreements are accounted for in accordance with ASC 605-25. Under this standard, delivered items are evaluated to determine whether such items have value to our collaborators on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exist.

Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate revenue recognition criteria are identified and applied to each separate unit of accounting.

Royalty revenue will be earned under the terms of the asset sale agreement with Zogenix. We will 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 anticipate recognizing revenue from quarterly royalty payments one quarter in arrears since we believe that we will not be able to determine quarterly royalty earnings until we receive our royalty statements and payments from Zogenix.

Impairment of Long-Lived Assets

We review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. 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 consolidated statements of operations.

Accounting for Costs Associated with Exit or Disposal Activities

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 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 risk-free interest rate that was used to measure the liability initially. We recorded losses under this standard for the Mendel sublease in 2007 and for the sublease of additional space in 2009 since the sublease rate was less than the rental rate that we are paying.

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 that are reimbursed under collaborative and government grants approximate the revenue recognized under such agreements. We expense research and development costs as 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. In addition, we evaluate our tax positions to ensure that a minimum recognition threshold is met before we recognize the tax position in the financial statements. The aforementioned 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 June 30, 2013 and December 31, 2012, 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.

22

Table of Contents

Stock-Based Compensation

We recognize compensation expense, using a fair-value based method, for all costs related to stock-based payments including stock options, restricted stock awards and stock issued under the employee stock purchase plan. ASC topics require companies to estimate the fair value of stock-based payment awards on the date of the grant using an option pricing model.

We use the Black-Scholes option pricing model to estimate the fair value of stock-based awards as of the grant date. The Black-Scholes model is complex and dependent upon key data input estimates. The primary data inputs with the greatest degree of judgment are the estimated lives of the stock options and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two inputs. The expected term of the options represents the period of time that options granted are expected to be outstanding. We use the simplified method to estimate the expected term as an input into the Black-Scholes option pricing model. We determine expected volatility using the historical method, which is based on the historical daily trading data of our common stock over the expected term of the option. For more information about our accounting for stock-based compensation, see Note 7 to the audited financial statements included in our Annual Report on Form 10-K.

Recent Accounting Pronouncements

See Note 2 to the accompanying unaudited condensed consolidated 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 and six months ended June 30, 2013 and 2012

Our net loss was approximately $2.7 million for the three months ended June 30, 2013 as compared with a net loss of approximately $1.8 million for the three months ended June 30, 2012. Operating expenses were higher due to the expenses associated with the 9 month inhalation dog study which started in October 2012 and to higher legal expenses related to the pending Grifols collaboration. Our net loss increased by approximately $2.3 million for the six months ended June 30, 2013 as compared to the six months ended June 30, 2012 due to higher operating expenses as discussed above.

We recorded approximately $248,000 in revenue, all of which represented royalty revenue from Zogenix, for the three months ended June 30, 2013 as compared to approximately $240,000 in revenue for the three months ended June 30, 2012. Total revenue was approximately $0.5 million for the six months ended both June 30, 2013 and June 30, 2012.

Operating expenses were approximately $2.5 million for the three months ended June 30, 2013, which represented an approximately $0.9 million increase from the three months ended June 30, 2012. Research and development expenses increased approximately $0.7 million and general and administrative expenses increased by approximately $0.2 million as compared with the three months ended June 30, 2012. Operating expenses were approximately $5.8 million for the six months ended June 30, 2013, which represented an approximately $2.3 million increase as compared with the six months ended June 30, 2012. Research and development expenses increased approximately $2.0 million and general and administrative expenses increased approximately $0.3 million. The increase in research and development expenses was due to higher contract manufacturing and contract testing costs related to the 9 month inhalation dog study which is underway. General and administrative costs were higher because of higher legal expenses in the three and six months ended June 30, 2013 associated with the pending Grifols transaction.

Liquidity and Capital Resources

As of June 30, 2013, we had cash, cash equivalents and short-term investments of approximately $2.7 million and total working capital of approximately $1.1 million. We assess our liquidity primarily by the amount of our cash and cash equivalents and short investments less our current liabilities. We believe that this amount will be sufficient to enable us to fund our operations through December 31, 2013 because we may defer certain discretionary activities.

Since inception, 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 milestone and royalty payments associated with the sale of Intraject-related assets to Zogenix,

23

Table of Contents

proceeds from the June 2011 royalty financing transaction and interest earned on investments. We have incurred significant losses and negative cash flows from operations since our inception. At June 30, 2013, we had an accumulated deficit of approximately $377.4 million and shareholders deficit of approximately $7.2 million.

We are currently focusing primarily on establishing funded partnering agreements (such as the pending Grifols collaboration transaction) and sale or out-licensing of non-strategic assets as the means to generate the capital resources needed to fund the further development and commercialization of inhaled ciprofloxacin for the bronchiectasis indication. If we are unable to find financing on acceptable terms, we may be required to defer our product development activities or discontinue operations.

Six months ended June 30, 2013

Total cash and cash equivalents decreased by approximately $5.7 million for the six months ended June 30, 2013, compared to December 31, 2012. The overall decrease primarily resulted from the use of cash to fund operations of $4.9 million, as well as the purchase of short-term investments of $2.6 million offset by the proceeds from the maturity of short-investments of $1.8 million.

Six months ended June 30, 2012

Total cash and cash equivalents increased by approximately $1.7 million for the six months ended June 30, 2012, compared to December 31, 2011. The increase in cash and cash equivalents was primarily due to maturity of short-term investments of $6.5 million offset by the purchase of short-term investments of $1.8 million, as well as cash used in operations of approximately $3.1 million.

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 active, wholly-owned subsidiary incorporated in Delaware, Aradigm Royalty Financing LLC, and 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 Exchange Act of 1934, as amended (the, Exchange Act)) 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.

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.

24

Table of Contents

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

None

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 2012 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 2012 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 2012 Annual Report on Form 10-K.

Risks Related to Our Business

***** We are not in control of certain conditions to closing the Grifols collaboration transaction and we may not be able to close the transaction on a timely basis or at all.***

The closing of the transaction is subject to certain closing conditions, including, among others our entering into binding terms with a third party to commercially manufacture Products to permit us to satisfy our obligation to commercially supply Grifols with Products. We cannot guarantee that we will be able to enter into such an agreement on reasonable terms or at all.

The Stock Purchase Agreement associated with the collaboration transaction contains certain termination rights for both us and Grifols, including if the transaction is not concluded on or before November 20, 2013. If we are not able to close the Griols collaboration transaction we will face an urgent need to raise capital and it may be difficult or impossible for us to do so on favorable terms, or at all.

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

We believe our cash, cash equivalents and short-term investments as of June 30, 2013 will be sufficient to enable us to fund our operations through December 31, 2013 because we may defer certain discretionary activities. However, our current financial resources are inadequate to advance our product candidates development activities. Although we are making efforts to form collaborative partnerships with other companies that would fully or partly fund the development of our product candidates (such as the pending Grifols collaboration transaction), we cannot guarantee that we will be able to complete such transactions on time or at all, or that such transactions alone will be adequate to complete the development of any of our product candidates.

We will need access to additional funds to continue our operations at their current levels in 2014 and will need to commit substantial additional funds in order to develop our product candidates, particularly to commence and complete Phase 3 clinical trials for our inhaled ciprofloxacin program. We may not be able to obtain funds to support our operations or development activities on acceptable terms or at all. If we are unable to obtain capital on acceptable terms, we may be required to defer our product development activities and curtail or discontinue our operations. 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:

- the scope, rate of progress, results and costs of clinical trials of our product candidates and preclinical testing of those candidates and other potential candidates;

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

the time and costs associated with seeking and maintaining regulatory approvals;

Table of Contents

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;

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;

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, license fees and milestone payments from collaborators, proceeds from our January 2005 restructuring transaction with Novo Nordisk, borrowings from Novo Nordisk, the milestone and royalty payments associated with the sale of Intraject-related assets to Zogenix, proceeds from our June 2011 royalty financing transaction and interest earned on cash equivalents and short-term investments. 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 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 equity securities, our shareholders may suffer significant dilution and our stock price may drop.

We are a development-stage company.

You must evaluate us in light of the uncertainties and complexities present in a development-stage company. All of our potential products are in research or development. Our potential drug 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 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 June 30, 2013, we have an accumulated deficit of approximately $377.4 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 expenses and capital expenditures, we expect to continue to incur losses for the foreseeable future 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.

Table of Contents

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

Our dependence on future collaborators may delay or require that we 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 (such as the pending Grifols collaboration transaction) to obtain assistance and funding for the development and potential commercialization of our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, 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. 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.

We are in the early stages of development and commercialization for our inhaled nicotine product and commercialization of this product cannot be assured.

While the preliminary development work and early testing of the commercial potential of this direct-to-consumer product have been favorable, there are many significant issues that are unresolved and could severely limit the commercial potential of this product. The changes to the regulatory environment discussed in Management s Discussion and Analysis of Financial Condition and Results of Operations-Overview are evolving and the resolution of any necessary regulatory approvals is uncertain at this time. Smokers acceptance of this product for use in smoking cessation or as a cigarette replacement is unknown. Competition for our product exists from currently marketed smoking cessation products, such as nicotine replacement products, as well as from electronic cigarettes. In order to commercialize this product, substantial amounts of capital will be required to establish and operate a high volume manufacturing facility. We have no experience with developing, manufacturing or selling commercial products.

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 safety testing and clinical trials do not necessarily predict the results that we will get from subsequent or more extensive preclinical safety testing and clinical trials. Pre-clinical safety testing and clinical trials of our product candidates may not demonstrate that they are safe and effective to the extent necessary to obtain collaborative partnerships and/or regulatory approvals. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after receiving promising results in earlier trials. If we cannot adequately demonstrate through pre-clinical studies and the clinical trial process that a

Table of Contents

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 both of our Phase 2b clinical trials (ORBIT-1 and ORBIT-2) with inhaled ciprofloxacin showed promising initial efficacy and safety results in patients with BE and our Phase 2a clinical trials showed promising results in both patients with CF and BE, there is no guarantee that longer term studies in larger patient populations will confirm these results or that we will be able to conduct studies that will provide satisfactory evidence of all efficacy and safety endpoints required by the regulatory authorities.

We intend to use Pulmaquin in our future clinical trials in cystic fibrosis. We have not yet tested Pulmaquin in CF patients; all previous clinical trial work in CF patients was conducted using our Lipoquin formulation. Although Pulmaquin performed well in BE patients in the Phase 2b study ORBIT-2 and the liposomal component of Pulmaquin (Lipoquin) performed well in a Phase 2a study in CF patients, there is no guarantee that Pulmaquin will prove safe and effective in CF patients.

For our lead product candidate, Pulmaquin, regulatory authorities have requested additional animal toxicology and safety studies prior to product approval for bronchiectasis (BE). Our Phase 3 clinical trials in BE may be successful but the results of these animal toxicology studies may be unacceptable to the regulatory authorities and may delay or prevent the approval of Pulmaquin for BE.

Although we have already submitted a substantial amount of safety data to the regulatory authorities on Pulmaquin and we also have conducted a variety of preclinical studies to support our product development, regulatory authorities have requested that we conduct a 2 year carcinogenicity study in rats with inhaled Pulmaquin prior to product approval for BE. A 9 month inhalation safety study in dogs may also be needed to support approval for marketing this product for BE in the U.S. and the EU and this study is underway. Longer term animal safety studies may produce toxicity findings that were not found in shorter, earlier studies, which could prevent commercialization of Pulmaquin or could necessitate the conduct of further animal safety studies, leading to delays and additional costs.

The results of animal toxicology (preclinical safety) studies of our product candidates required for clinical development and product approval may not be as favorable as the results from earlier experiments. Adverse toxicology findings may necessitate additional animal safety studies, or lead to more extensive requirements for safety information from human studies. These factors could result in additional costs and delays or prevent commercialization of our products.

Although we typically select drugs for development that already have a substantial amount of safety data associated with them, and we also conduct a variety of preclinical studies, including animal inhalation toxicology studies, to support our product development, longer term safety studies in animals may be required by regulatory authorities before clinical trials and product approval. Longer term animal safety studies, such as the 9 month dog study we are currently conducting, may produce toxicity findings that were not found in shorter, earlier studies, which could prevent commercialization of our products or could necessitate the conduct of further animal safety studies, leading to delays and additional costs. Toxicology findings from animal studies may also be the reason for more extensive safety monitoring and longer and larger human clinical trials than we originally anticipated, further adding to the cost and time prior to product commercialization.

If our future clinical trials are delayed because of delays in obtaining 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, obtaining 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. We are aware that Bayer is currently preparing to begin a Phase 3 clinical trial of their inhaled ciprofloxacin dry powder formulation in non-cystic fibrosis bronchiectasis patients in several countries where we would conduct our Pulmaquin Phase 3 trials which could make recruiting individuals for clinical trials more difficult. Delays in our future clinical trials because of delays in planned patient enrollment or other problems 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

28

Table of Contents

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 FDCA, 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/or efficacy endpoints in our clinical trials. Our pharmaceutical 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 that can be long and costly. 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 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 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 may involve expensive ongoing monitoring and testing requirements.

Because our proprietary inhaled ciprofloxacin programs may 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 CF and BE and to our ciprofloxacin for inhalation for the management of bronchiectasis. In June 2012, the FDA granted orphan drug designation to our proprietary drug product of liposomal ciprofloxacin for the management of CF. 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, even in the absence of a granted patent or other intellectual property protection, for seven years from the date of the FDA s approval of an 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 similar inhaled ciprofloxacin product were to be approved by the FDA for a CF or BE 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

29

Table of Contents

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 CF and BE. Bayer has obtained orphan drug status for their inhaled powder formulation of ciprofloxacin in the United States and European Union for the treatment of CF.

In August 2009, the European Medicines Agency granted orphan drug designation to our inhaled liposomal ciprofloxacin drug product candidate Lipoquin (ARD-3100) for the treatment of lung infections associated with CF. 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 EU. 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 European Medicines Agency for a given orphan indication, we may not be able to access the target market in the United States and/or the EU, which would adversely affect our ability to earn revenues.

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

We intend to use contract manufacturers to produce our products. We may not be able to enter into or maintain satisfactory contract manufacturing arrangements. We may not be able to reach mutually satisfactory agreements to manufacture 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 and 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.

In order to market certain of our proprietary products, we may 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 may establish our own sales, marketing and distribution capabilities to market certain 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 may 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 patients 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;

30

Table of Contents

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 the production of inhaled 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. 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.

Table of Contents

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 compete 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, 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, Johnson & Johnson, Novartis and Pfizer. For example, we are aware that Bayer is currently preparing to begin a Phase 3 clinical trial of their inhaled ciprofloxacin dry powder formulation in non-cystic fibrosis bronchiectasis patients in several countries. 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, clinical, regulatory 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, 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 regulations and we may not be able to adapt to those laws and regulations, 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 and regulations, 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.

32

Table of Contents

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

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

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

Our laboratory and clinical testing sometimes 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. 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. 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. The market prices for our common stock may continue to be highly volatile in the future. The market prices for our common stock may be influenced by many factors, including:

- investor perception of us;
- our available cash;
- failure to establish or delays in establishing new collaborative relationships;
- market conditions relating to our segment of the industry or the securities markets in general;

investor perception of the future royalty stream from Zogenix;

sales of our stock by certain large institutional shareholders;

Table of Contents

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

fluctuations in our operating results;

announcements of technological innovations or new commercial products by us or our competitors;

publicity regarding actual or potential developments relating to products under development by us or our competitors;

developments or disputes concerning patents or proprietary rights;

delays in the development or approval of our product candidates;

regulatory developments in both the United States and foreign countries;

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

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

our ability to raise capital; 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.

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. Trading of our common stock through the OTC Bulletin Board is frequently thin and highly volatile, and there is no assurance that a sufficient market will develop in our common stock, in which case it could be difficult for our shareholders to sell their stock.

Our common stock may be considered penny stock and may be difficult to sell.

The SEC has adopted regulations which generally define penny stock to include an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The market price of our common stock is currently less than $5.00 per share and therefore may be designated as a penny stock according to SEC rules. This designation requires any broker or dealer selling these securities to disclose some information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell the common stock and may affect the ability of investors to sell their shares. These regulations may likely have the effect of limiting the trading activity of our common stock and reducing the liquidity of an investment in 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

Table of Contents

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 entered into change of control agreements with our executive officers, both of which may provide for the payment of benefits to our officers and other key employees 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.

A small number of shareholders own a large percentage of our common stock and can influence the outcome of matters submitted to our shareholders for approval.

A small number of our shareholders own a large percentage of our common stock and can, therefore, influence the outcome of matters submitted to our shareholders for approval. Based on information known to us as of February 16, 2013, our two largest investors, collectively, control in excess of a majority of our outstanding common stock. As a result, these shareholders have the ability to influence the outcome of matters submitted to our shareholders for approval, including certain proposed amendments to our amended and restated articles of incorporation (for example, amendments to increase the number of our authorized shares and transactions such as the Grifols collaboration transaction) and any proposed merger, consolidation or sale of all or substantially all of our assets. These shareholders may support proposals and actions with which you may disagree. The concentration of ownership could delay or prevent a change in control of our company or otherwise discourage a potential acquirer from attempting to obtain control of our company, which in turn could reduce the price of our common stock.

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

Not applicable.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

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
101.1(1)	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 are formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.
(1)	Rule 406T of Regulation S-T, the XBRL files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

Aradigm, Pulmaquin, Lipoquin 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, Chief Financial Officer and Corporate Secretary

(Principal Financial and Accounting Officer)

Dated: August 9, 2013

Table of Contents

INDEX TO 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
101.1(1)	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 are formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.
(1)	Pursuant to Rule 406T of Regulation S-T, the XBRL files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.