ARADIGM CORP
Form 10-Q
May 10, 2016
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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 March 31, 2016

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: 001-36480

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 May 7, 2016)**

Common	*14,943,542*

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ARADIGM CORPORATION

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ARADIGM CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	March 31, 2016 (Unaudited)	December 31, 2015 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,421	$ 31,462
Receivables	367	150
Prepaid and other current assets	3,669	3,634
Total current assets	26,457	35,246
Property and equipment, net	310	299
Other assets	81	81
Total assets	$ 26,848	$ 35,626
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,533	$ 1,789
Accrued clinical and cost of other studies	2,954	4,315
Accrued compensation	690	1,159
Deferred rent	18	37
Facility lease exit obligation	55	104
Other accrued liabilities	307	112
Total current liabilities	6,557	7,516
Deferred revenue related party, non-current	5,000	5,000
Total liabilities	11,557	12,516
Commitments and contingencies		
Shareholders equity:		
Preferred stock, 5,000,000 shares authorized, none outstanding		
Common stock, no par value; authorized shares: 25,045,765 at March 31, 2016 and December 31, 2015; issued and outstanding shares: 14,927,351 at March 31, 2016; 14,761,351 at December 31, 2015	428,858	428,591
Accumulated deficit	(413,567)	(405,481)

Total shareholders equity	15,291	23,110
Total liabilities and shareholders equity	$ 26,848	$ 35,626

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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ARADIGM CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

(Unaudited)

	Three months ended March 31,	
	2016	**2015**
Revenue:		
Contract revenue related party	$	$ 8,739
Grant revenue	6	29
Total revenue	6	8,768
Operating expenses:		
Research and development	6,451	8,361
General and administrative	1,644	1,542
Restructuring and asset impairment	1	4
Total operating expenses	8,096	9,907
Loss from operations	(8,090)	(1,139)
Interest income	10	8
Other expense	(6)	(32)
Net loss and comprehensive loss	$ (8,086)	$ (1,163)
Basic and diluted net loss per common share	$ (0.55)	$ (0.08)
Shares used in computing basic and diluted net loss per common share	14,761	14,727

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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ARADIGM CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (8,086)	$ (1,163)
Adjustments to reconcile net loss to cash provided by (used in) operating activities:		
Depreciation and amortization	29	77
Stock-based compensation expense	400	185
Changes in operating assets and liabilities:		
Receivables	(217)	547
Prepaid and other current assets	(35)	(235)
Other assets		15
Accounts payable	744	(660)
Accrued compensation	(469)	(269)
Current deferred revenue		47
Deferred rent	(19)	(12)
Accrued liabilities	(1,249)	2,039
Accrued clinical and cost of other studies, non-current		49
Facility lease exit obligation	(49)	(43)
Net cash provided by (used in) operating activities	(8,951)	577
Cash flows from investing activities:		
Capital expenditures	(40)	9
Net cash provided by (used in) investing activities	(40)	9
Cash flows from financing activities:		
Payments of convertible notes and warrants issuance costs	(50)	
Net cash used in financing activities	(50)	
Net increase (decrease) in cash and cash equivalents	(9,041)	586
Cash and cash equivalents at beginning of period	31,462	47,990
Cash and cash equivalents at end of period	$ 22,421	$ 48,576

Supplemental disclosure of cash flow information:	
Deferred issuance costs for planned convertible notes and warrants in accrued expenses	(83)

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

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ARADIGM CORPORATION

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2016

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 th development and commercialization of drugs delivered by inhalation for the treatment and prevention 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 revenues from the sale of any of its products during the 2016 fiscal year. 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 (GAAP) 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 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, 2015, as filed with the SEC on March 30, 2016 (the 2015 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, 2015 has been derived from the audited 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 2015 Annual Report on Form 10-K.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. 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 March 31, 2016, the Company had an accumulated deficit of $413.6 million, working capital of $19.9 million and shareholders equity of $15.3 million. The Company had cash and cash equivalents of approximately $22.4 million as of March 31, 2016. Management believes that this amount, together with the proceeds from the convertible debt transaction described in Subsequent Events below, will be sufficient to meet its obligations through at least December 31, 2016. However, the Company s business strategy will require it to raise additional capital through equity or debt financing(s), strategic transactions or otherwise, to develop and seek licensure of the Company s investigational product candidate. In addition, the Company may decide to raise capital opportunistically.

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, accruals for clinical trial expenses, assumptions for valuing options and warrants, and income taxes. Actual results could differ from these estimates.

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.

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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 no internally-developed computer software. Leasehold improvements are amortized 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 Condensed Consolidated Statement of Operations and Comprehensive Loss (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. License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreement typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of milestones and royalties on net product sales. The Company recognizes revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin 104, Topic 13, Revenue Recognition Revised and Updated (SAB Topic 13) and ASC 605-25, Revenue Recognition-Multiple Elements. Revenue for arrangements not having multiple deliverables, as outlined in ASC 605-25, is recognized once costs are incurred and collectability is reasonably assured.

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collection is reasonably assured. Multiple-deliverable arrangements, such as license and development agreements, are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price method and the appropriate revenue recognition principles are applied to each unit. When the Company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized.

The Company estimates its performance period used for revenue recognition based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Significant management judgment may be required to determine the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

The Company adopted the provisions of Accounting Standards Update No. 2009-13, Revenue Recognition (Topic 605); Multiple-Deliverable Revenue Arrangements (ASU 2009-13) for new and materially modified arrangements originating on or after January 1, 2010. ASU 2009-13 provides updated guidance on how the deliverables in an arrangement should be separated, and how consideration should be allocated, and it changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available.

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The Company allocates non-contingent consideration to each stand-alone deliverable based upon the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, the Company uses best estimated selling price, or BESP, for that deliverable.

Assuming the elements meet the revenue recognition guidelines, the revenue recognition methodology prescribed for each unit of accounting is summarized below:

Upfront Fees The Company defers recognition of non-refundable upfront fees if there are continuing performance obligations without which the technology licensed has no utility to the licensee. If the Company has continuing performance obligations through research and development services that are required because know-how and expertise related to the technology is proprietary to the Company, or can only be performed by the Company, then such up-front fees are deferred and recognized over the estimated period of the performance obligation. The Company bases the estimate of the period of performance on factors in the contract. Actual time frames could vary and could result in material changes to the results of operations. When the collaboration partners request the Company to continue performing the research and development services in collaboration beyond the initial period of performance the remaining unamortized deferred revenue and any new continuation or license fees are recognized over the extended period of performance.

Funded Research and Development and Grant Revenue Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. The full-time equivalent amount can vary each year if the contracts allow for a percentage increase determined by relevant salary surveys, if applicable. Reimbursements from collaborative partners and grants for agreed upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical and clinical studies and contract manufacturing are classified as revenue and recognized in the period the reimbursable expenses are incurred. Payments received in advance are recorded as deferred revenue until the research and development services are performed or costs are incurred.

Milestones Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement; substantive effort is involved in achieving the milestone; the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment. If any of these conditions are not met, the milestone payments are deferred and recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Royalties The Company recognizes royalty revenues from licensed products upon the sale of the related products.

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 employee stock purchase plan. These standards require companies to estimate the fair value of share-based payment awards on the date of the 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

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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 Company s consolidated balance sheets. The Company estimated its current tax exposure to be zero as it expects to be able to utilize its net operating loss carryovers (NOLs) to offset the income recognized in the quarter and year to date. The Company has updated its Section 382 analysis through December 31, 2015 and noted no additional changes since the last change in 2010.

The Company assesses the likelihood that it will be able to recover its deferred tax assets. The Company considers all available evidence, both positive and negative, including the historical levels of income and losses, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If the Company does not consider it more likely than not that it will recover its deferred tax assets, the Company records a valuation allowance against the deferred tax assets that it estimates will not ultimately be recoverable. At March 31, 2016, and December 31, 2015 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 Income/(Loss) Per Common Share

Basic net income/(loss) per common share is computed using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of restricted shares of common stock subject to repurchase. Potentially dilutive securities were not included in the net loss per common share calculation for the three months ended March 31, 2016, and 2015 because the inclusion of such shares would have had an anti-dilutive effect.

Recently Issued Accounting Pronouncements

There have been no recent accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 2016, as compared to the recent accounting pronouncements described in the Company s 2015 Annual Report on Form 10-K that are of significance or potential significance to the Company.

3. Cash and Cash Equivalents

At March 31, 2016 and December 31, 2015, the amortized cost of the Company s cash and cash equivalents approximated their fair values. The Company currently invests its cash and cash equivalents in money market funds.

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 requires 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 Company s cash and cash equivalents at March 31, 2016 consist of cash and money market funds. Money market funds are valued using quoted market prices.

5. Sublease Agreement and Lease Exit Liability

See Note 5 to the audited consolidated financial statements included in Part II, Item 8 of the 2015 Annual Report on Form 10-K for information on the sublease agreement.

The lease exit liability activity for the three months ended March 31, 2016 is as follows (in thousands):

	Three Months Ended March 31, 2016
Balance at January 1, 2016	$ 104
Accretion expense	1
Lease payments	(50)
Balance at March 31, 2016	$ 55

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As of March 31, 2016, all of the balance was recorded as a current liability.

6. Collaboration Agreement

Grifols License and Collaboration Agreement

See Note 6 to the audited consolidated financial statements included in Part II, Item 8 of the 2015 Annual Report on Form 10-K for information on the Grifols Collaboration Transaction. Grifols is a 35% shareholder and, thus, a related party of the Company.

Pursuant to the License Agreement, the Company recognized reimbursements for services performed and costs incurred related to the development of the Pulmaquin® product candidate for non-cystic fibrosis bronchiectasis from Grifols as Contract revenue related party totaling zero and $8.7 million for the quarters ended March 31, 2016 and 2015, respectively. As of September 30, 2015, the Company has fully utilized the Grifols-funded budget of $65 million provided under the License Agreement and will not be recognizing any future revenue related to this budget. In addition, the Company has a long-term deferred revenue related party balance of $5 million. The long term deferred revenue related party balance consists of a $5 million milestone received upon the dosing of the first patient in a Phase III clinical trial and will be recognized as revenue upon receiving the first regulatory approval. Under the License Agreement, the Company is eligible to receive up to an additional $20 million in payments upon the achievement of regulatory filing and approval milestones.

Reimbursable costs incurred under the Grifols License Agreement in the quarters ended March 31, 2016 and 2015 are zero and $8.7 million, respectively. Research and development expenses incurred under the Grifols License Agreement for the quarters ended March 31, 2016 and 2015 are zero and $8.1 million, respectively. General and administrative expenses incurred under the Grifols License Agreement for the quarters ended March 31, 2016 and 2015 are zero and $0.6 million, respectively. Development expenses are fully burdened and include direct costs reported as research and development expenses and collaboration-related general and administrative expenses.

7. Stock-Based Compensation and Stock Options and Awards

The following table shows the stock-based compensation expense included in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2016 and 2015 (in thousands):

	March 31, 2016	March 31, 2015
Costs and expenses:		
Research and development	$ 167	$ 78
General and administrative	233	107
Total stock-based compensation expense	$ 400	$ 185

There was no capitalized stock-based employee compensation cost for the three months ended March 31, 2016 and 2015. Since the Company did not record a tax provision during the quarters ended March 31, 2016 and 2015, there was no recognized tax benefit associated with stock-based compensation expense.

For restricted stock awards, the Company recognizes compensation expense over the vesting period for the fair value of the stock award on the measurement date. The Company retained purchase rights with respect to 166,300 shares of unvested restricted stock awards issued pursuant to stock purchase agreements at no cost per share as of March 31, 2016. As of March 31, 2016, there was approximately $574,000 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 2.79 years.

Stock Option Plans: 2005 Equity Incentive Plan (the 2005 Plan) and 2015 Equity Incentive Plan (the 2015 Plan)

On March 13, 2015 the Board adopted and, on May 14, 2015 the Company s shareholders approved the 2015 Plan. The 2015 Plan replaces the Company s 2005 Plan which expired in March 2015. The 2015 Plan is intended to promote our long-term success and increase shareholder value by attracting, motivating, and retaining non-employee directors, officers, employees, advisors, consultants and independent contractors, and allows the flexibility to grant a variety of awards to eligible individuals, thereby strengthening their commitment to the Company s success and aligning their interests with those of the Company s shareholders. The Company did not request that shareholders authorize any new shares of Common Stock in connection with the approval of the 2015 Plan, rather, the remaining shares authorized under the 2005 Plan are available for issuance under the 2015 Plan.

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Stock Option Activity

The following is a summary of activity under the 2005 Plan and the 2015 Plan for the three months ended March 31, 2016:

	Shares Available for Future Grant
Balance at January 1, 2016	252,725
Options granted	(216,000)
Options cancelled	2,670
Balance at March 31, 2016	39,395

	Options Outstanding			
	Number of Shares	**Weighted Average Exercise Price**	**Weighted Remaining Contractual Term**	**Aggregate Intrinsic Value**
Outstanding at January 1, 2016	947,142	$ 11.40		
Options granted	50,000	$ 4.01		
Options cancelled	(2,670)	$ 88.64		
Outstanding at March 31, 2016	994,472	$ 10.82	7.77	$ 21,720
Exercisable at March 31, 2016	406,004	$ 15.13	6.53	$ 830

No stock options were exercised during the three months ended March 31, 2016. The total amount of unrecognized compensation cost related to non-vested stock options and stock purchases, net of forfeitures, was $2,065,000 as of March 31, 2016. This amount will be recognized over a weighted average period of 2.02 years.

8. Net Loss and Comprehensive 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 three months ended March 31, 2016 and 2015.

The Company excluded the following securities from the calculation of diluted net loss per common share for the three months ended March 31, 2016 and 2015, as their effect would be anti-dilutive (in thousands):

	Three months ended March 31,	
	2016	2015
Outstanding stock options	995	738
Restricted stock	166	
Unvested restricted stock units	10	10

9. Subsequent Events

On April 21, 2016, the Company entered into a securities purchase agreement in connection with the private placement of $23 million aggregate principal amount of its senior convertible notes due 2021 and related warrants to purchase 263,436 shares of the Company s common stock and completed its first closing whereby the Company issued $20 million of the notes and warrants. The notes bear interest at a rate of 9% per annum, payable semi-annually in arrears, and mature on May 1, 2021. The initial conversion price of the notes is $5.21 per share of common stock, equivalent to an initial conversion rate of 191.9386 shares of common stock per $1,000 aggregate principal amount of notes. The warrants are exercisable at an exercise price of $5.21 per share beginning on the later of 180 days after the date of issuance or the date the Company issues a press release announcing data related to the ORBIT-3 and ORBIT-4 Phase 3 pivotal clinical trials for the Company s investigational product Pulmaquin inhaled ciprofloxacin. The second closing is expected to occur after the Company s resale registration statement on Form S-1 relating to the notes and warrants issued in connection with the private placement has been declared effective by the Securities and Exchange Commission, subject to customary closing conditions.

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The net proceeds from the sale of the $23 million aggregate principal amount of the notes and the warrants, after deducting fees and expenses, are expected to be approximately $20.7 million. The Company deposited $1.8 million of the net proceeds into an escrow account at the first closing and intends to deposit $270,000 at the second closing to fund, when due, the first two scheduled semi-annual interest payments on the notes. The Company intends to use the remaining net proceeds to fund the current clinical development and regulatory submission for licensure of Pulmaquin and for general corporate purposes.

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations and other parts of this Quarterly Report on Form 10-Q contain forward looking statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as may, believe, expect, forecast, intend, anticipate, predict, should, planned, likely, opportunity, estimated, and potential, these words or other similar words. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements, including, but not limited to, our ability to maintain our collaboration agreement with Grifols, our ability to implement our product development strategy, the success of product development efforts, obtaining and enforcing patents important to our business, clearing the lengthy and expensive regulatory approval process and possible competition from other products. Even if product candidates appear promising at various stages of development, they may not reach the market or may not be commercially successful for a number of reasons. Such reasons include, but are not limited to, the possibilities that the potential products may be found to be ineffective during clinical trials, may fail to receive necessary regulatory approvals, may be difficult to manufacture on a large scale, are uneconomical to market, may be precluded from commercialization by proprietary rights of third parties or may not gain acceptance from health care professionals and patients.

You should read the following management s discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 30, 2016 and other disclosures (including the disclosures under Part II. Item 1A. Risk Factors) included in this Quarterly Report on Form 10-Q.

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of products 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 respiratory (pulmonary) drug delivery as incorporated in our lead product candidate in 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 incurred significant losses and negative cash flow from our operations since our 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 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.

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, and/or another significant territory such as the European Union (EU), Japan and China. 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.

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Inhaled Ciprofloxacin Program

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 have been granted orphan drug designation from the FDA for ciprofloxacin for inhalation for the management of BE. We may seek orphan drug designation for other eligible product candidates we develop. In May 2014, the FDA designated Pulmaquin as a Qualified Infectious Disease Product (QIDP). The QIDP designation, granted for the treatment of non-cystic fibrosis bronchiectasis patients with chronic lung infections with *Pseudomonas aeruginosa*, makes Pulmaquin eligible to benefit from certain incentives for the development of new antibiotics provided under the Generating Antibiotic Incentives Now Act (GAIN Act). These incentives include priority review and eligibility for fast-track status. In September 2014, we announced that the FDA granted Fast Track Designation to Pulmaquin for non-CF BE patients with chronic lung infections with *Pseudomonas aeruginosa*. In March 2016, we announced that the European Medicines Agency (EMA) had approved our request to review Pulmaquin under the Centralised Authorisation Procedure drug review process; this procedure results in a single marketing authorization that is valid in all 28 European Union countries, as well as three European Economic Area countries. We requested, and were granted, the centralized pathway on the basis that Pulmaquin represents a significant technical innovation for the potential treatment of non-cystic fibrosis bronchiectasis associated with chronic *Pseudomonas aeruginosa* infection.

We have been issued seven 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 also been granted key composition of matter patents for our inhaled ciprofloxacin formulations in Europe, Canada, Japan and Australia/New Zealand. We are currently fully enrolled and dosing patients in two Phase 3 clinical trials with Pulmaquin in BE.

In order to expedite anticipated time to market and increase our market acceptance, we have elected to deliver our formulations via an FDA-approved, widely-accepted nebulizer system for our clinical trials and we intend to continue using this approach and obtain initial marketing approval also with a currently FDA-approved nebulizer system.

The ongoing Phase 3 clinical program for Pulmaquin in BE consists of two worldwide, double-blind, placebo-controlled pivotal trials (ORBIT-3 and ORBIT-4) that are identical in design except for a pharmacokinetics sub-study to be conducted in one of the trials. Each trial has enrolled patients (278 in ORBIT-3 and 304 in ORBIT-4) into a 48 week double blind period consisting of 6 cycles of 28 days on treatment with Pulmaquin or placebo plus 28 days off treatment, followed by a 28 day open label extension in which all participants will receive Pulmaquin (total treatment duration approximately one year). The superiority of Pulmaquin versus placebo during the double blind period is being evaluated in terms of the time to first pulmonary exacerbation (primary endpoint), while key secondary endpoints include the reduction in the number of pulmonary exacerbations and improvements in quality of life measures. Lung function is being monitored as a safety indicator.

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 licensed to Grifols, our inhaled ciprofloxacin has also been tested for the prevention and treatment of inhaled bioterrorism infections, such as Q fever, inhalation anthrax, tularemia, melioidosis and pneumonic plague. We have obtained a royalty-bearing license for the biodefense applications from Grifols.

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, melioidosis and pneumonic plague.

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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 was conducted in collaboration with Oregon State University, Corvalis (OSU).

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 also common in patients with other chronic lung conditions, such as cystic fibrosis and emphysema. In patients with AIDS, the infection is disseminated. These infections are particularly difficult to treat as the mycobacteria can form biofilms in the airways and they are able to cause intracellular infections, e.g. by invasion of pulmonary macrophages. 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, and may have significant side effects.

On April 15, 2015, we announced the first results from the collaboration between scientists from OSU and Aradigm funded by NIH. The research demonstrated that after 4 days of in vitro treatment of human macrophages infected with *Mycobacterium avium* and *Mycobacterium abscessus*, Aradigm s liposomal ciprofloxacin was associated with a decrease of greater than 99% of these infections at ciprofloxacin concentrations of 200 mcg/ml, which approximate the peak sputum levels observed in humans in prior Aradigm clinical studies. At a lower concentration of 20 mcg/ml, the liposomal concentrations still showed statistically significant decreases greater than 70% for *M. avium* and greater than 90% for *M. abscessus*. Unencapsulated ciprofloxacin showed smaller decreases which were only statistically significant at 200 mcg/ml. Liposomal ciprofloxacin at a concentration of 100 mcg/ml significantly reduced the population of these mycobacteria in a biofilm assay by more than 50% whereas unencapsulated ciprofloxacin did not show statistically significant decreases.

In May 2015, we announced that scientists from OSU and Aradigm demonstrated that Aradigm s investigational drugs Lipoquin and Pulmaquin significantly reduced the growth of PNTM after 3 weeks of once daily respiratory tract dosing in mice. The number of colony forming units (CFUs) of *Mycobacterium avium subsp hominissuis* was reduced by 79% and 77% by Lipoquin and Pulmaquin, respectively ($p<0.05$) compared to saline controls. In contrast, unencapsulated ciprofloxacin had no effect.

In September 2015, we announced that scientists from OSU and Aradigm demonstrated that Aradigm s investigational drugs Lipoquin and Pulmaquin significantly reduced PNTM with *Mycobacterium abscessus* using once daily respiratory tract dosing in mice that had established colonization with this microorganism. After 3 weeks of treatment, the number of CFUs in the lungs was significantly reduced ($p<0.05$) by 95.2% and 96.1% by Lipoquin and Pulmaquin, respectively; after 6 weeks of treatment, the CFUs were further reduced ($p<0.05$) by 99.7% and 99.4% for Lipoquin and Pulmaquin, respectively. In contrast, unencapsulated ciprofloxacin had no effect.

ARD-1600 Inhaled Nicotine

According to the National Center for Health Statistics (NCHS), 21% of the U.S. population age 18 and above currently smoke cigarettes. The World Health Organization s (WHO) recent report states that tobacco smoking is the single most preventable cause of death in the world today. Already tobacco kills more than five million people per year more than tuberculosis, HIV/AIDS and malaria combined. WHO warns that by 2030, the death toll could exceed

eight million a year. Unless urgent action is taken, tobacco could kill one billion people during this century. According to the National Institute on Drug Abuse, more than $75 billion of total U.S. healthcare costs each year is attributable directly to smoking. However, this cost is well below the total cost to society because it does not include burn care from smoking-related fires, perinatal care for low birth-weight infants of mothers who smoke, and medical care costs associated with disease caused by secondhand smoke. In addition to healthcare costs, the costs of 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.

An inhaled nicotine product utilizing our AERx delivery system that would effectively address the acute craving for cigarettes and, through gradual reduction of the peak nicotine levels, could wean-off patients from cigarette smoking and from the nicotine addiction. 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 effecting 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.

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We are seeking collaborations to further develop and commercialize this product.

Other Programs

In August 2013, the NIH awarded us an SBIR grant in the amount of approximately $340,000 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 being conducted at UCSF.

Grifols Collaboration Transaction

See Note 6 to the audited consolidated financial statements included in Item 8 of our 2015 Annual Report on Form 10-K for information on the Grifols Collaboration Transaction.

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 consolidated financial statements. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization periods for payments received from product development and license agreements as they relate to the revenue recognition, and assumptions for valuing options, warrants and other stock-based compensation. Our actual results could differ from these estimates.

Revenue Recognition

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. We recognize revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin 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.

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 1) have value to our collaborators on a stand-alone basis and 2) if the item includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the vendor.

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. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price method and the appropriate revenue recognition principles are applied to each unit. We allocate non-contingent consideration to each stand-alone

deliverable based upon the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, we use best estimated selling price, or BESP, for that deliverable. Significant management judgment may be required to determine the relative selling price of each element.

When we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which the performance obligations will be performed and revenue will be recognized. We estimate our performance period used for revenue recognition based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Significant management judgment may be required to determine the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under the arrangement. If we cannot reasonably estimate when our performance obligations either are completed or become inconsequential, then revenue recognition is deferred until we can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

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Royalty revenue may be earned in the future under the Grifols License Agreement. We recognize royalty revenue when the amounts can be determined and when collectability is probable. 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 from collaboration partners.

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.

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 consolidated 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 consolidated financial statements. The aforementioned differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including our historical levels of income and losses, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If we do not consider it more likely than not that we will recover our deferred tax assets, we will record a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. At March 31, 2016 and December 31, 2015, 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.

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 (ESPP). 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 expected terms 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 9 to the consolidated financial statements included in our 2015 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.

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Results of Operations

Three months ended March 31, 2016 and 2015

Our net loss increased by $6.9 million for the three months ended March 31, 2016 as compared with the three months ended March 31, 2015. The increase in net loss resulted primarily from a decrease in the reimbursement of Pulmaquin non-cystic fibrosis bronchiectasis project-related expenses as we have utilized the full amount of the $65 million of the Grifols-funded budget provided under the License Agreement for the non-cystic fibrosis bronchiectasis program, offset by a decrease in our operating expenses related to the Pulmaquin bronchiectasis program.

Total revenue was $6,000 for the three months ended March 31, 2016 as compared with $8.8 million in the comparable period in 2015. For the three months ended March 31, 2016 and 2015, we recorded zero and $8.7 million, respectively, under the Grifols agreement for the reimbursement of fully burdened development expenses for collaboration services performed. Contract revenue-related party was zero for the quarter ended March 31, 2016 as we have fully utilized the $65 million of the Grifols-funded budget provided under the License Agreement for the Pulmaquin non-cystic fibrosis bronchiectasis program.

Operating expenses were $8.1 million for the three months ended March 31, 2016, which represented a $1.8 million decrease from the prior period ended March 31, 2015. Research and development expenses decreased $1.9 million and general and administrative costs increased by $0.1 million. The decrease in research and development expenses was due to lower contract manufacturing and clinical trial costs because the manufacturing, labeling and packaging expenses for clinical supplies and the enrollment activities of the Pulmaquin Phase 3 clinical trials are complete, offset by higher employee-related expenses due to the higher number of employees and higher consulting expenses in support of the Pulmaquin bronchiectasis regulatory process towards US and EU approvals for market authorization. General and administrative costs were higher primarily due to increased non-cash stock compensation expense and slightly higher legal expense.

Liquidity and Capital Resources

As of March 31, 2016, we had cash and cash equivalents of $22.4 million and total working capital of $19.9 million. We assess our liquidity primarily by the amount of our cash and cash equivalents less our current liabilities. We believe that this amount, together with the proceeds from the convertible debt transaction described in Note 9 to the accompanying unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, will be sufficient to meet our obligations through at least December 31, 2016. However, our business strategy will require us to raise additional capital through equity or debt financing(s), strategic transactions or otherwise, to further develop and seek licensure of our Pulmaquin investigational product candidate for non-cystic fibrosis bronchiectasis or other potential product candidates. In addition, we may decide to raise capital opportunistically.

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, borrowings and convertible debt, and interest earned on investments. We have incurred significant losses and negative cash flows from operations since our inception. In 2015, we utilized the full $65 million of the Grifols-funded budget provided under the License Agreement for the non-cystic fibrosis bronchiectasis program. At March 31, 2016, we had an accumulated deficit of $413.6 million and shareholders equity of $15.3 million.

Three months ended March 31, 2016

Total cash and cash equivalents decreased by $9.0 million for the three months ended March 31, 2016, as compared to December 31, 2015. The decrease primarily resulted from the use of cash to fund our ongoing operations in support of our Pulmaquin program. The cash and cash equivalents balance at March 31, 2016 does not include any proceeds from the convertible debt transaction described in Note 10 to the accompanying unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Three months ended March 31, 2015

Total cash and cash equivalents increased by $0.6 million for the three months ended March 31, 2015, as compared to December 31, 2014. The increase reflects the payment from Grifols for reimbursable Pulmaquin program expenses.

Off-Balance Sheet Financings and Liabilities

Other than contractual obligations incurred in the normal course of business, we do not have any off-balance sheet financing arrangements or liabilities, guarantee contracts, retained or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity. We have one inactive, wholly-owned subsidiary incorporated in Delaware, Aradigm Royalty Financing LLC, one active wholly-owned subsidiary domiciled in Australia and one inactive, wholly-owned subsidiary domiciled in the UK.

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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.

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PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

None

Item 1A. Risk Factors

Except for historical information contained herein, the discussion of this Annual Report on form 10-K contains forward-looking statements, including, without limitation, statements regarding timing and results of clinical trials, the maintenance and establishment of corporate partnering arrangements, the anticipated commercial introduction of our products and the timing of our cash requirements. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those expressed in, or implied by, any such forward-looking statements. Potential risks and uncertainties include, without limitation, those mentioned in this report and in particular the factors described below.

Risks Related to Our Business

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 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 non-cystic fibrosis bronchiectasis (BE) and our Phase 2a clinical trials showed promising results in patients with cystic fibrosis (CF) and BE, there is no guarantee that longer term studies, such as our Phase 3 studies (ORBIT-3 and ORBIT-4), 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 are a development-stage company and will require substantial capital to complete the development of our product candidates and commercialize them.

We are a development-stage company and our ability to generate revenue and become profitable depends on our ability to successfully complete the development of our product candidates. All of our potential products are in research or development, and we will need to raise additional capital prior to approval and commercialization of our leading product candidate Pulmaquin. Our potential drug products require extensive research and development, including 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 with quality systems acceptable to the regulatory authorities 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. Running clinical trials and developing an investigational drug for commercialization involve significant expense, and any unexpected delays or other issues in the development process can result in significant additional expense.

Until we can generate a sufficient amount of revenue, we expect to finance future cash needs through public or private equity financings, debt financings, corporate alliances, joint ventures or licensing agreements. We may sell additional equity or debt securities to fund our operations, which would result in dilution to all of our stockholders or impose restrictive covenants that adversely impact our business. The incurrence of indebtedness would result in increased fixed payment obligations and could also

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result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our dependence on collaborators and other third parties 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 or maintain agreements with collaborators (such as the Grifols collaboration transaction) and 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. Collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we would over a proprietary development and commercialization program. We may determine that continuing a collaboration under the terms provided is not in our best interest and, if we are able to under the terms of the agreement, we may terminate the collaboration. Our collaborators could delay or terminate their agreements with us, and our products subject to collaborative arrangements may never be successfully commercialized. Under our existing collaboration agreement with Grifols, we have granted Grifols exclusive rights with respect to inhaled ciprofloxacin compounds for other indications besides the treatment of non-CF BE, and we have limited ability to terminate that agreement.

Further, our present or future collaborators may pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, 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 present or 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, or programs that Grifols has declined its exclusive right to fund and commercialize, 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 using contract research organizations in order to conduct our global Phase 3 clinical trials and for other testing activities. We may not be able to maintain satisfactory contract research arrangements. If we are not, there may be significant delays before we find an alternative contract research organization or we may not find an alternative contract research organization at all. If our contract research organizations are delayed in their activities or issues are uncovered regarding the quality of the data provided by the contract research organization it could result in significant delays in our Pulmaquin clinical program and adversely impact our ability to file for regulatory approval of our product candidate.

Because our 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 liposomal ciprofloxacin drug product candidate for the management of CF and BE and to our ciprofloxacin for inhalation for the management of bronchiectasis. FDA also 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 our product on the basis of safety or efficacy. For example, Bayer HealthCare is developing an inhaled dry 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 for the treatment of BE and in the United States and European Union for the treatment of CF.

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

We have never been profitable and have incurred significant losses in each year since our inception. As of March 31, 2016, we have an accumulated deficit of approximately $413.6 million. We have not had any 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 agreement with Grifols, which includes reimbursement of the majority of development expenses associated with our Pulmaquin program, 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; and

outsource the commercial-scale production of our products.

To achieve and sustain profitability, we must, alone or with others such as our partner Grifols, 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.

Regulatory authorities have requested toxicology studies in our lead program with Pulmaquin for non-cystic fibrosis 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 or marketing 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 and approval, regulatory authorities have requested that we conduct a 2 year carcinogenicity study in rats with inhaled Pulmaquin. This study is currently underway. 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. We have taken the initiative to conduct this study. Although this study has been completed and the final audited study report has been submitted to the FDA, we do not know if the FDA or EU regulatory authorities will require further toxicology studies. 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. Toxicology findings from animal studies may also be the reason for more extensive safety monitoring in humans.

If our present or future clinical trials are delayed for any reason, we would incur additional costs and delay the potential receipt of revenues.

Before we or any current or 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 many factors. Delays in completing our present or future clinical trials may result in increased costs, program delays, or both, and the loss of potential revenues.

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

We and our products are subject to extensive and rigorous regulation by the federal government, principally the FDA, and by state and local government agencies. Both before and after regulatory approval, the development, testing, manufacture, quality control, labeling, storage, approval, advertising, promotion, sale, distribution and export of our potential products are subject to regulation. Pharmaceutical products that are marketed abroad are also subject to regulation by foreign governments. Our products cannot be marketed in the United States without FDA approval. The process for obtaining FDA approval for drug products is generally lengthy, expensive and uncertain. In September 2014, we were granted Fast Track Designation for Pulmaquin for non-CF BE patients with chronic lung infections with *Pseudomonas aeruginosa*, The FDA gives Fast Track status to facilitate the development of new drugs intended to treat serious or life-threatening conditions and which demonstrate the potential to address unmet medical needs, with the goal of getting important new drugs to patients earlier. However, having Fast Track Designation is no guarantee that the approval process will actually result in a faster or more streamlined process and to date, we have not sought or received approval from the FDA or any corresponding foreign authority for any of our drug product candidates.

The approval process is 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 effect 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 present and 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. We, our collaborators and our manufacturers will be subject to continuing review and periodic inspections by the FDA and other authorities, where applicable, and must comply with ongoing requirements, including the FDA s 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.

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 maintain satisfactory contract manufacturing arrangements. If we are not, 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 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 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.

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

Even if we or our collaborators successfully develop one or more products, such products may not be commercially acceptable to healthcare professionals and patients, who will have to choose our products over alternative products for the same disease indications, and many of these alternative products will be more established than ours. For our products to be commercially viable we will need to demonstrate to healthcare professionals and patients that our products afford benefits to the 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;
- the pricing relative to competitive products;
- the relative cost, convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of our product candidates by governmental and other third-party payors; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

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

We are in the early stages of development for our inhaled nicotine product for smoking cessation 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 regulatory environment for inhaled nicotine products is evolving and the resolution of any necessary regulatory approvals is uncertain at this time. Smokers acceptance of this product for use

in smoking cessation 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 commercial product-manufacturing or selling. There is no guarantee that we will be able to find an entity interested in manufacturing and commercializing our inhaled nicotine product.

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

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 present and 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.

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

We must be able to commercialize 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 commercialize 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, or we could incur significant expenses in royalty payments to a licensor.

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, patent applications in the United States are currently maintained in secrecy for a period of time prior to issuance and patent applications in certain other countries generally are not published until more than 18 months after they are first filed. Publication of discoveries in scientific or patent literature often lags behind actual discoveries, therefore, we cannot be certain that we were the first creator of inventions covered by our pending patent applications or that we were the first to file patent applications on such inventions.

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

We 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 present and 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 HealthCare. While the FDA has granted orphan drug designation for our liposomal ciprofloxacin product candidate and the designation provides the opportunity to obtain market exclusivity for seven years from the date of the FDA s approval, our ability to launch our product in the United States could be blocked if another similar product developed by our competitors is approved by the FDA for the same indication before our product, unless we are able to demonstrate to the FDA clinical superiority of our product on the basis of safety or efficacy. For example, Bayer HealthCare is developing an inhaled dry 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 for the treatment of BE and in the United States and European Union for the treatment of CF. We are aware that Bayer has completed one Phase 3 clinical trial and is currently conducting one Phase 3 clinical trial of their inhaled ciprofloxacin dry powder formulation in non-cystic fibrosis bronchiectasis patients in several countries. Bayer 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 present and 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, and Dr. Juergen Froehlich, our Chief Medical Officer, could impair our product development efforts and otherwise harm our business. Any of our employees may terminate their employment with us at will.

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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 present and 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 clinical trials and 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.

Our current facility lease is scheduled to expire and we may not be able to secure a new facility lease on terms commercially favorable for us.

We lease office and laboratory space in an office building at 3929 Point Eden Way, California, which is scheduled to expire in March of 2017. Due to the competitive commercial real estate market in Silicon Valley, we may not be able to secure a new facility lease on terms commercially favorable for us. In addition, the relocation of our current corporate headquarters could be disruptive to our business operations, result in increased expenses, hinder our ability to attract and retain qualified personnel, and may also cause employee turnover if the commute time for our headquartered employees is significantly increased.

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.

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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. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Reform Act) became law. The Reform Act includes a provision that indefinitely exempts companies that qualify as either a non-accelerated filer or smaller reporting company from the auditor attestation requirement of Section 404(b) of the Sarbanes-Oxley Act of 2002. For our fiscal 2016 and subsequent foreseeable fiscal years, we expect to be exempt from such requirement. However, 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. These broad market fluctuations may adversely affect the trading price of our common stock. The market prices for our common stock may also be influenced by many factors, including:

- the limited trading volume for shares of our common stock and the fact that a large percentage of our outstanding shares are held by a small number of shareholder;
- announcements of clinical trial results, technological innovations or new commercial products by us or our competitors;
- investor perception of us;
- sales of our stock by certain large institutional shareholders;
- research analyst recommendations and our ability to meet or exceed quarterly performance expectations of analysts or investors;

fluctuations in our operating results;

failure to maintain or establish collaborative relationships;

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.

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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.

In addition, although our shares are currently listed by NASDAQ, we cannot assure you that we will be successful in maintaining a NASDAQ listing continuously or that we will be able to meet NASDAQ listing standards going forward. The failure to maintain the NASDAQ listing for our common stock could adversely affect the price for , and liquidity of, our common stock.

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

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

We have adopted a shareholder rights plan, commonly known as a poison pill. We have also adopted an executive officer severance plan and 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 or more 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.

We have never declared or paid cash dividends on our capital stock. 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 may 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.

Disputes may arise between Grifols and us that may be resolved in a manner unfavorable to us and our other shareholders.

In August 2013, we entered into several agreements with Grifols as part of the completion of a private sale of shares of common stock to Grifols, including in particular the License Agreement, the Governance Agreement, and a registration rights agreement with respect to shares of common stock owned by Grifols. As a result of the various obligations under these agreements, in addition to Grifol s ownership of a significant amount of our outstanding common stock, conflicts of interest may arise between us and Grifols from time to time. Disagreements regarding the rights and obligation of Grifols under these agreements could create conflicts of interest for one of our directors, who has been designated by Grifols and subsequently nominated by us for election to our board of directors. Any such

disagreements could also lead to actual disputes or legal proceedings that may be resolved in a manner unfavorable to us and our other shareholders. In addition, Grifols has a number of consent rights under the Governance Agreement, including the right to consent to any termination of our Chief Executive Officer or our appointment of a successor Chief Executive Officer and certain preemptive rights to participate in any future issuances of common stock (or common stock equivalents) by us or to acquire shares in the open market to maintain ownership thresholds specified in the Governance Agreement. Grifols may exercise any of these rights, or any of its other rights contained in its agreements with us, in a manner which is not necessarily in the best interest of us or our other shareholders. The result of any of these conflicts could adversely affect our business, financial condition, results of operations or the price of our common stock.

Our principal shareholders own a large percentage of our common stock and will be able to exert a significant control over 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, our two largest shareholders, collectively, control in excess of a majority of our outstanding common stock. These two shareholders purchased most of the notes and related

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warrants described in Note 9 to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this report, leading to a corresponding increase in their respective ownership on a fully-diluted basis. 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 any other material transactions we may undertake in the future, such a financing transaction or a 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 1B. ***Unresolved Staff Comments***

None.

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

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. **MINE SAFETY DISCLOSURES**

Not applicable.

Item 5. OTHER INFORMATION

None.

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Item 6. EXHIBITS

Exhibit Number	Description
3.1(1)	Amended and Restated Articles of Incorporation of the Company.
3.2(2)	Certificate of Determination of Series A Junior Participating Preferred Stock.
3.3(3)	Amended and Restated Certificate of Determination of Preferences of Series A Convertible Preferred Stock.
3.4(2)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.5(2)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.6(4)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.7(4)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.8(5)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.9(6)	Certificate of Correction to Certificate of Amendment of Articles of Incorporation of the Company.
3.10(7)	Certificate of Amendment of Articles of Incorporation of the Company.
3.11(8)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.12(2)	Amended and Restated Bylaws of the Company, as amended.
3.13(9)	Certificate of Amendment to the Amended and Restated Bylaws of the Company.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10, 3.11, 3.12 and 3.13.
4.2(1)	Specimen common stock certificate.
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	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 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) Incorporated by reference to the Company s Form S-1 (No. 333-4236) filed on April 30, 1996, as amended.
(2) Incorporated by reference to the Company s Form 10-Q filed on August 14, 1998.
(3) Incorporated by reference to the Company s Form S-3 (No. 333-76584) filed on January 11, 2002, as amended.

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(4) Incorporated by reference to the Company s Form 10-Q filed on August 13, 2004.
(5) Incorporated by reference to the Company s Form 10-K filed on March 31, 2006.
(6) Incorporated by reference to the Company s Form 8-K filed on September 20, 2010.
(7) Incorporated by reference to the Company s Form 8-K filed on February 4, 2015.
(8) Incorporated by reference to the Company s Form 10-Q filed on May 14, 2015.
(9) Incorporated by reference to the Company s Form 8-K filed on September 4, 2015.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ARADIGM CORPORATION

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

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

Dated: May 10, 2016

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4.2(1)	Specimen common stock certificate.
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	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 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) Incorporated by reference to the Company s Form S-1 (No. 333-4236) filed on April 30, 1996, as amended.
(2) Incorporated by reference to the Company s Form 10-Q filed on August 14, 1998.
(3) Incorporated by reference to the Company s Form S-3 (No. 333-76584) filed on January 11, 2002, as amended.

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(4) Incorporated by reference to the Company s Form 10-Q filed on August 13, 2004.
(5) Incorporated by reference to the Company s Form 10-K filed on March 31, 2006.
(6) Incorporated by reference to the Company s Form 8-K filed on September 20, 2010.
(7) Incorporated by reference to the Company s Form 8-K filed on February 4, 2015.
(8) Incorporated by reference to the Company s Form 10-Q filed on May 14, 2015.
(9) Incorporated by reference to the Company s Form 8-K filed on September 4, 2015.