ARADIGM CORP
Form 10-Q
May 15, 2018
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

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 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 No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth 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
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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

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 04, 2018)
Common	15,211,472

Table of Contents

ARADIGM CORPORATION

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ARADIGM CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	March 31, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,395	$ 7,095
Receivables	183	200
Prepaid and other current assets	709	389
Total current assets	2,287	7,684
Property and equipment, net	256	289
Other assets	92	92
Total assets	$ 2,635	$ 8,065
LIABILITIES AND SHAREHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 834	$ 903
Accrued clinical and cost of other studies	523	274
Accrued compensation	613	1,643
Deferred revenue related party, current	633	1,900
Deferred revenue other	154	183
Other accrued liabilities	1,015	563
Total current liabilities	3,772	5,466
Deferred rent	43	32
Deferred revenue related party, non-current	42	90
Convertible debt non-current, net of discount	2,427	2,382
Convertible debt related party, non-current, net of discount	13,064	12,626
Total liabilities	19,348	20,596
Commitments and contingencies Shareholders deficit:		
Preferred stock, 5,000,000 shares authorized, none outstanding		
	443,259	442,639

Common stock, no par value; authorized shares: 35,045,765 at March 31, 2018 and December 31, 2017; issued and outstanding shares: 15,211,472 at March 31, 2018; 15,170,200 at December 31, 2017		
Accumulated deficit	(459,972)	(455,170)
Total shareholders deficit	(16,713)	(12,531)
Total liabilities and shareholders deficit	$ 2,635	$ 8,065

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Table of Contents

ARADIGM CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

(Unaudited)

	Three months ended March 31,	
	2018	**2017**
Revenue:		
Contract revenue, related party	$ 1,315	$ 1,623
Contract revenue	29	39
Grant revenue	129	31
Total revenue	1,473	1,693
Operating expenses:		
Research and development	3,568	2,774
General and administrative	1,714	1,678
Total operating expenses	5,282	4,452
Loss from operations	(3,809)	(2,759)
Interest income	15	28
Interest expense	(1,004)	(953)
Other income (expense), net	(4)	6
Net loss and comprehensive loss	$ (4,802)	$ (3,678)
Basic and diluted net loss per common share	$ (0.32)	$ (0.25)
Shares used in computing basic and diluted net loss per common share	15,049	14,800

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Table of Contents

ARADIGM CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (4,802)	$ (3,678)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	34	28
Stock-based compensation expense	547	543
Amortization of convertible debt discount	483	424
Changes in operating assets and liabilities:		
Receivables	17	(152)
Prepaid and other current assets	(320)	(104)
Other assets		
Accounts payable	(69)	(179)
Accrued compensation	(1,030)	(79)
Current deferred revenue related party	(1,344)	
Other accrued liabilities	701	(656)
Deferred rent	11	
Deferred revenue related party		(1,524)
Net cash used in operating activities	(5,772)	(5,377)
Cash flows from investing activities:		
Capital expenditures	(1)	
Net cash used in investing activities	(1)	
Cash flows from financing activities:		
Proceeds from issuance of common stock	73	
Net cash provided by financing activities	73	
Net decrease in cash and cash equivalents	(5,700)	(5,377)
Cash and cash equivalents at beginning of period	7,095	22,591
Cash and cash equivalents at end of period	$ 1,395	$ 17,214
Supplemental disclosure of non-cash activities:		

Cumulative effect of adoption of new accounting standards	6,046
Stock issued in payment of officer bonus	444

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Table of Contents

ARADIGM CORPORATION

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2018

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 upcoming 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 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, 2017, as filed with the SEC on March 23, 2018 (the 2017 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, 2017 included above has been derived from the audited financial statements at that date, but does not include all 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 2017 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 and Financial Condition

As reflected in the accompanying condensed consolidated financial statements, the Company has incurred significant recurring operating losses and negative cash flows from operations and as of March 31, 2018, had an accumulated deficit of $460 million, a shareholder s deficit of $16.7 million and a working capital deficit of $1.5 million. These factors among others, raise substantial doubt about the Company s ability to continue as a going concern. Management expects operating losses to continue for the foreseeable future. Subsequent to the end of the fiscal quarter, on April 13, 2018, the Company entered into a note purchase agreement whereby entities affiliated with Grifols and First Eagle, the Company s two largest shareholders beneficially owning collectively approximately 67% of the Company s common stock as of March 12, 2018 and owning most of the Convertible Notes and Warrants described in Note 6 to

the consolidated financial statements included in this Quarterly Report on Form 10-Q, agreed to purchase up to approximately $7 million aggregate principal amount of bridge notes, or the Promissory Notes. The Company completed the first closing under the note purchase agreement on April 13, 2018, at which time the Company issued and sold approximately $2 million aggregate principal amount of Promissory Notes to the lenders thereunder. Subject to the satisfaction or waiver of the applicable closing conditions set forth in the note purchase agreement at each subsequent closing, the Company anticipates the sale of the remaining approximately $5 million principal amount of the Promissory Notes to occur in five subsequent monthly closings, the first of which is anticipated to occur on May 13, 2018. Management believes that this $7.0 million along with the cash balance of $1.4 million at March 31, 2018 will be sufficient to fund operations through the third quarter of 2018. However, because of the expected losses and negative cash flows from operations, the Company will continue to require additional capital through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund the Company s operations and continue the development of the Company s lead product candidate Linhaliq. No assurance can be given that the Company will be successful in raising such additional capital on favorable terms or at all. If the Company is unable to obtain additional funds when required, it will delay or reduce the scope of all or a portion of its development programs or dispose of assets or technology. Not achieving such funding on a timely basis would materially harm its business, financial condition and results of operations and could require the Company to dispose of its assets or technology or to cease operations. Accordingly, the Company may not be able to continue as a going concern. For more information, see Note 11: Going Concern.

Table of Contents

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

Net Loss Per Common Share

Basic net loss per common share is computed using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of restricted shares of common stock subject to repurchase. Potentially dilutive securities were not included in the net loss per common share calculation for the three months ended March 31, 2018 and 2017 because the inclusion of such shares would have had an anti-dilutive effect.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. This ASU requires most lessees to recognize right of use assets and lease liabilities, but recognize expenses in a manner similar to current accounting standards. The new standard is effective for fiscal years and interim periods beginning after December 15, 2018, and is effective for the Company s fiscal year beginning January 1, 2019. Entities are required to use a modified retrospective approach, with early adoption permitted. The Company is evaluating the impact of this new standard on the financial statements.

For additional information about our significant accounting policies, see Note 1 to the consolidated financial statements included in the 2017 Annual Report on Form 10-K and Part I, Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates below.

3. Cash and Cash Equivalents

At March 31, 2018, and December 31, 2017, 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 Measurement* 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 certain 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, 2018, and December 31, 2017, consist of cash and money market funds. Money market funds are valued using quoted market prices.

5. Other Accrued Liabilities

At March 31, 2018, other accrued liabilities consisted of accrued expenses for interest of $863,000, expenses for services of $146,000 and payroll withholding liabilities of $6,000. The liability for accrued interest of $863,000 is related to the Convertible Notes as outlined in Note 6 and represents the interest on the Convertible Notes that is accrued but unpaid as of March 31, 2018. At December 31, 2017, other accrued liabilities consisted of accrued expenses for interest of $345,000, expenses for services of $132,000 and payroll withholding liabilities of $86,000.

Table of Contents

6. Convertible Notes and Warrants

On April 21, 2016, the Company entered into a securities purchase agreement to conduct a private offering, or the Convertible Note Financing, consisting of $23 million in aggregate principal amount of 9% senior convertible notes due 2021 convertible into shares of common stock, or the Convertible Notes, and 263,436 warrants to purchase shares of the Company s common stock or the Warrants. The Convertible Notes bear interest at a rate of 9% per year, payable semiannually in arrears on November 1 and May 1 of each year commencing on November 1, 2016. The Convertible Notes mature on May 1, 2021, unless earlier redeemed or converted.

The Convertible Notes are senior unsecured and unsubordinated obligations; rank equal in right of payment to the Company s existing and future unsecured indebtedness that is not subordinated and are effectively subordinated in right of payment to the Company s existing and future secured indebtedness. On or after December 1, 2017, the Company may redeem for cash all or a portion of the Convertible Notes if the last reported sale price of the Company s common stock is at any time equal to or greater than 200% of the conversion price then in effect for at least twenty trading days immediately preceding the date on which the Company provides notice of redemption, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. The Indenture provides for customary events of default which may result in the acceleration of the maturity of the Notes, including, but not limited to, cross acceleration to certain other indebtedness of the Company and its subsidiaries. In the case of an event of default arising from specified events of bankruptcy or insolvency or reorganization, all outstanding Convertible Notes will become due and payable immediately without further action or notice. If any other event of default under the Indenture occurs or is continuing, the trustee or holders of at least 25% in the aggregate principal amount of the then outstanding Convertible Notes may declare all the Convertible Notes to be due and payable immediately.

The Warrants have a five-year term and are exercisable at $5.21 per share of common stock. The exercise price is subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events or upon any distributions of assets, including cash, stock or other property to the Company s shareholders.

On April 25, 2016, the initial closing of the Convertible Notes took place under which the Company raised $20 million from a total of two investors and issued 4,319 Warrants to one investor. Of the $20 million, $19.9 million was financed by Grifols, a related party to the Company, as described in Note 8 below. The fair value of the warrants issued in the first closing was $11,000 and was recorded as a component of equity and discount to the debt host. There were 3,319,820 common shares underlying the conversion feature that was bifurcated as a derivative liability due to the Conversion Share Cap. The effective interest rate of the liability component was equal to 22.9% for the three months ended March 31, 2018.

On July 14, 2016, the second and final closing of the Convertible Notes took place under which the Company raised $3 million from a total of two investors and issued 259,117 Warrants. The fair value of the warrants issued in the second closing was $662,000 and was recorded as a component of equity and discount to the debt host. The effective interest rate of the liability component was equal to 16.24% for the three months ended March 31, 2018.

The financing costs of $2.4 million incurred in connection with the issuance of the Convertible Notes were allocated to the derivative liability, warrants and Convertible Note components based on their relative fair values. Financing costs of $1.4 million allocated to the Convertible Note host are being amortized using the effective interest rate method and recognized as non-cash interest expense over the expected term of the Convertible Notes.

As of March 31, 2018, the Convertible Notes consisted of the following:

		March 31, 2018 (in thousands, except conversion rate and conversion price)
Principal value	$	23,000
Unamortized debt discount		(6,529)
Unamortized debt issuance costs		(980)
Carrying value of the convertible notes	$	15,491
Conversion rate (shares of common stock per $1,000 principal amount of notes)		191.9386
Conversion price (per share of common stock)	$	5.21

Table of Contents

For the three months ended March 31, 2018 and 2017, the Company recognized interest expense associated with its Convertible Notes as follows:

	Three Months ended March 31, 2018 (in thousands)	Three Months ended March 31, 2017 (in thousands)
Cash Interest Expense		
Coupon interest expense	$ 518	$ 529
Other Interest expense	3	
Noncash Interest Expense		
Amortization of debt discount	420	368
Amortization of transaction costs	63	56
	$ 1,004	$ 953

As of March 31, 2018, the unamortized debt discount will be amortized over a remaining period of approximately 3.09 years. The if-converted value as of March 31, 2018 does not exceed the principal balance of the Convertible Notes. Accrued interest payable on March 31, 2018 is $863,000 and is included in other accrued liabilities. For more information on the Company s accounting for Convertible Notes and Warrants, see Note 7 to the consolidated financial statements included in the Company s 2017 Annual Report on Form 10-K. For the three months ended March 31, 2018 interest expense on the Company s Condensed Consolidated Statements of Operations and Comprehensive Loss is primarily composed of interest expense associated with the Convertible Notes but also includes $3,000 of other miscellaneous interest expense.

7. Revenue Recognition

For additional detail on the Company s accounting policy regarding revenue recognition, see Part I, Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates.

The following table presents changes in the Company s contract assets and liabilities for the three months ended March 31, 2018.

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
		(in thousands)		
Contract Assets	$ 67	$ 129	$ (76)	$ 120
Contract Liabilities: Deferred Revenue	$ 2,173	$	$ (1,344)	$ 829

During the three months ended March 31, 2018 and 2017, the Company recognized the following revenues (in thousands).

	Three Months ended March 31, 2018 (in thousands)	Three Months ended March 31, 2017 (in thousands)
Revenue recognized in the period from:		
Amounts included in contract liabilities at the beginning of the period:		
Performance obligations satisfied	$ 1,315	$ 1,662
New activities in the period:		
Changes in the estimated transaction price allocated to performance obligations satisfied in prior periods contract revenue	7	
Performance obligations satisfied from new activities in the current period contract revenue	22	
Performance obligations satisfied from new activities in the current period grant revenue	129	31
Total revenue	$ 1,473	$ 1,693

Table of Contents

8. Collaboration Agreement

Grifols License and Collaboration Agreement

See Note 9 to the audited consolidated financial statements included in Part II, Item 8 of the 2017 Annual Report on Form 10-K for information on the Grifols Collaboration Transaction (the Grifols Collaboration). Grifols is a 35% shareholder and, thus, a related party of the Company.

The Company s performance obligations under the Grifols Collaboration include those related to the worldwide license to commercialize products developed from the collaboration which was satisfied in 2013, development services for Phase 3 clinical trials that were completed as of December 31, 2016, regulatory submission services for the first indication that were complete as of September 30, 2017, regulatory approval services in the US for the first indication that were complete as of March 31, 2018, and regulatory approval services in the EU for the first indication which are in progress and forecast to be complete by Q1 2019. In addition, the Company identified that Grifols has an option that will create manufacturing obligations for the Company upon exercise by the customer. Further, these customer options for manufacturing services were evaluated and did not include a material right. The Company recognizes revenue from license rights when the customer can use and benefit from the license rights. The Company recognizes revenue from its services performance obligations over time using a cost-to-cost input method.

Under the License Agreement, the Company is eligible to receive up to $25.0 million in payments upon the achievement of regulatory filing and approval milestones. As of March 31, 2018, the Company has achieved two of the six milestones and has received $10.0 million in payments. Milestone payments related to regulatory submission and approval services are considered variable consideration and excluded from the transaction price for the period ended March 31, 2018 due to the constraint on variable consideration.

The Company has deferred $675 thousand of the transaction price in the Grifols arrangement that is allocated to the performance obligations that are unsatisfied (or partially unsatisfied) as of March 31, 2018. These amounts are expected to be recognized over time as services are performed through Q2 2019.

9. 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, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	**2017**
Costs and expenses:		
Research and development	$ 322	$ 306
General and administrative	225	237
Total stock-based compensation expense	$ 547	$ 543

There was no capitalized stock-based employee compensation cost for the three months ended March 31, 2018 and 2017. Since the Company did not record a tax provision during the quarters ended March 31, 2018 and 2017, there

was no recognized tax benefit associated with stock-based compensation expense.

During the three months ended March 31, 2018, the Company granted 730,000 performance-based options to the employees of the Company. These options were granted at-the-money, contingently vest upon the achievement of performance goals, and have contractual lives of ten years. The Company recognized approximately $120,000 in stock compensation expense as 162,500 of the performance-based options vested during the three months ended March 31, 2018.

In March 2016 and June and December of 2017, the Company granted to the Officers certain stock option bonus awards, that vested based upon meeting certain specified company-wide performance goals. These options and stock awards were granted at-the-money, contingently vest upon the achievement of performance goals, and have contractual lives of ten years. The Company recognized $53,000 in stock-based compensation expense as 20,000 of the performance-based awards vested during the three months ended March 31, 2018 due to the filing of the marketing authorization application, with the EMA. During the three months ended March 31, 2018, 1.4 million performance-based stock options were canceled due to the Company not meeting certain specified performance goals and the resignations of officers and a vice president. For the three months ended March 31, 2017, no stock-based compensation expense related to these performance-based stock options was recognized, as none of the performance-based goals were deemed probable of being achieved during the period.

Table of Contents

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 the Company s 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. In April 2017, the Company s Board of Directors amended, and in June 2017 the Company s shareholders approved, the amendment to the 2015 Plan increasing the shares of common stock authorized for issuance by 2,500,000 shares.

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, 2018:

	Shares Available for Future Grant
Balance at January 1, 2018	1,645,124
Increase in authorized shares	
Options granted	(980,500)
Options canceled	1,266,965
Restricted stock awards canceled	399,750
Balance at March 31, 2018	2,331,339

Stock Options	**Number of Shares**	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term**	**Aggregate Intrinsic Value**
Outstanding at January 1, 2018	3,727,581	$ 4.72		
Options granted	980,500	$ 1.12		
Options canceled	(1,266,965)	$ 4.99		
Outstanding at March 31, 2018	3,441,116	$ 3.60	7.82	$ 116,880
Exercisable at March 31, 2018	1,974,241	$ 4.32	6.44	$ 26,000

No stock options were exercised during the three months ended March 31, 2018. The total amount of unrecognized compensation cost related to non-vested stock options was $2,338,000 as of March 31, 2018. This amount will be recognized over a weighted average period of 1.83 years. There also was approximately $147,000 of unrecognized compensation expense related to the current ESPP offering period that is expected to be recognized through March 2019.

A summary of the activity of the Company s unvested restricted stock and performance-based restricted stock award activities for the three months ended March 31, 2018 is presented below. The ending balance represents the maximum number of shares that could be earned or vested under the 2005 Plan and 2015 Plan:

Restricted Stock Awards	**Number of Shares**	**Weighted Average Grant Date Fair Value**
Outstanding at January 1, 2018	613,538	$ 1.95
Restricted stock awards canceled	(399,750)	$ 1.46
Restricted share awards vested	(115,213)	$ 3.32
Outstanding at March 31, 2018	98,575	$ 2.30

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. As of March 31, 2018, there was approximately $129,000 of total unrecognized compensation costs, net of forfeitures, related to non-vested stock award which are expected to be recognized over a weighted average period of 1.22 years.

Table of Contents

10. Net Loss Per Common Share

The Company computes basic net loss per common share using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of shares of common stock subject to repurchase. The effects of including the incremental shares associated with options, warrants and unvested restricted shares are anti-dilutive and are not included in the diluted weighted average number of shares of common stock outstanding for the three months ending March 31, 2018 and 2017.

The Company excluded the following securities from the calculation of diluted net loss per common share for the three months ended March 31 2018 and 2017, as their effect would be anti-dilutive (in thousands):

	Three months ended March 31,	
	2018	2017
Common shares underlying convertible notes	4,415	4,415
Outstanding stock options	3,441	2,536
Common shares underlying warrants	263	263
Unvested restricted stock	99	148
Unvested restricted stock units	10	10

11. Going Concern

As reflected in the accompanying condensed consolidated financial statements, the Company has incurred significant recurring operating losses and negative cash flows from its operations and, as of March 31, 2018, had an accumulated deficit of $460 million, a net shareholder s deficit of $16.7 million and a working capital deficit of $1.5 million. These factors among others, raise substantial doubt about the Company s ability to continue as a going concern. As of March 31, 2018, the Company s current assets of $2.3 million are less than current liabilities of $3.8 million by $1.5 million. In February 2018, the Board of Directors (the Board) implemented temporary measures intended to preserve the Company s cash resources until additional sources of capital can be secured, including the reduction of cash compensation and severance benefits for officers and the reduction of cash compensation for members of the Board. Subsequent to the end of the fiscal quarter, April 13, 2018, the Company entered into a note purchase agreement whereby entities affiliated with Grifols and First Eagle, the Company s two largest shareholders beneficially owning collectively approximately 67% of the Company s common stock as of March 12, 2018 and owning most of the Convertible Notes and Warrants described in Note 6 to the consolidated financial statements included in this Quarterly Report on Form 10-Q agreed to purchase up to approximately $7 million aggregate principal amount of Promissory Notes. The Company completed the first closing under the note purchase agreement on April 13, 2018, at which time the Company issued and sold approximately $2 million aggregate principal amount of Promissory Notes. Subject to the satisfaction or waiver of the applicable closing conditions set forth in the note purchase agreement at each subsequent closing, the Company anticipates the sale of the remaining approximately $5 million principal amount of the Promissory Notes to occur in five subsequent monthly closings, the first of which is anticipated to occur on May 13, 2018. Management believes that this $7.0 million along with the cash balance of $1.4 million at March 31, 2018 will be sufficient to fund operations through the third quarter of 2018. However, the Company will continue to require additional capital through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund the Company s operations and continue the development of the Company s lead product candidate Linhaliq.

Since cash and cash equivalents are insufficient to fund the Company s operations for the ensuing twelve months from the filing of this report, there is substantial doubt about the Company s ability to continue to operate as a going concern. While recoverability of the recorded asset amounts shown in the accompanying balance sheet is dependent upon continued operations of the Company, the condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

12. Commitments and Contingencies

Lease

On April 1, 2017, the Company entered into an amendment of the current lease for a building containing offices, laboratory, and manufacturing facilities, through March 31, 2023. The lease calls for annual minimum rental payments that increase at the rate of 3.5% per annum throughout the lease term. In accordance with GAAP, the Company recognizes rent expense on a straight-line basis.

Table of Contents

The Company recorded deferred rent for the difference between the amounts paid and recorded as an expense. At March 31, 2018 and December 31, 2017, the Company had $43,000 and $32,000 in deferred rent.

The landlord has a one-time termination right upon twelve months written notice to be delivered between January 1, 2018 and June 30, 2018. If the Company is unable to raise $20 million in new funding before the termination notice date, the Company has a one-time right to terminate the lease in its entirety effective September 30, 2018. Subsequent to December 31, 2018, if the lease is not terminated, the Company has the right to a one-time tenant improvement allowance of approximately $364,000.

If the lease is not terminated early in accordance with its terms the Company s future minimum rental payments required under the operating lease as of March 31, 2018, are as follows:

For the year ended	
March 31,	**(in thousands)**
2019	$ 499
2020	516
2021	535
2022	553
2023	140
Total	$ **2,243**

For the three months ended March 31, 2018, base rental expense was approximately $128,000.

Legal Matters

On May 1, 2017, the Company filed a post grant review, or a PGR, petition in the United States Patent and Trademark Office Patent Trial and Appeal Board, or PTAB, challenging the validity of all 26 claims of U.S. Patent No.9,402,845 or the 845 Patent, assigned to Insmed Incorporated, or Insmed. The 845 Patent issued on August 2, 2016, and is entitled Lipid-based compositions of antiinfectives for treating pulmonary infections and methods of use thereof.

PGR is a proceeding that became available in September 2012 in accordance with the America Invents Act. In a PGR, a petitioner may request that PTAB reconsider the validity of issued patent claims. Any patent claim PTAB determines to be unpatentable is stricken from the challenged patent.

In August 2017, Insmed filed a Preliminary Response. In November 2017, PTAB denied institution of our post-grant review of the 845 Patent. We are currently assessing the PTO s decision.

On January 11, 2018 a putative class action lawsuit, *Kevin Kheder v. Aradigm Corporation, et al.,* No. 3:18-cv-00261, was filed in the United States District Court for the Northern District of California against the Company and two of its former officers. The suit is purportedly brought on behalf of persons and entities who acquired or otherwise purchased Aradigm common stock between July 27, 2017 and January 8, 2018 (the Class Period). Plaintiff alleges that defendants made false and misleading statements during the Class Period that artificially inflated the price of Aradigm stock. Lead plaintiff did not file an amended complaint, and instead on May 9, 2018, the parties filed a stipulation asking the Court to dismiss the action with prejudice as to the lead plaintiff and without prejudice as to other putative class members. The Court entered the stipulated order of dismissal on May 11, 2018.

13

Table of Contents

13. Subsequent Events

On April 13, 2018, the Company entered into a note purchase agreement whereby entities affiliated with Grifols and First Eagle, the Company s two largest shareholders beneficially owning collectively approximately 67% of the Company s common stock as of March 12, 2018 and owning most of the Convertible Notes and Warrants described in Note 6 to the consolidated financial statements included in this Quarterly Report on Form 10-Q (see Note 8), agreed to purchase up to approximately $7 million aggregate principal amount of its senior unsecured promissory notes due 2021. The Company completed the first closing under the note purchase agreement on April 13, 2018, at which time the Company issued and sold approximately $2 million aggregate principal amount of Promissory Notes to the lenders thereunder. Subject to the satisfaction or waiver of the applicable closing conditions set forth in the note purchase agreement at each subsequent closing, the Company anticipates the sale of the remaining approximately $5 million principal amount of the Promissory Notes to occur in five subsequent monthly closings, the first of which is anticipated to occur on May 13, 2018. The Promissory Notes bear interest at a rate of 9% per annum payable semiannually in arrears on May 1 and November 1 of each year, beginning on May 1, 2018 in the case of Promissory Notes issued on April 13, 2018 and on November 1, 2018 and in the case of Promissory Notes issued thereafter, unless earlier redeemed or cancelled in accordance with the terms of the Promissory Notes. Unless the Company elects otherwise, interest will be capitalized on the applicable interest payment date by adding such accrued interest to the principal balance of such Promissory Notes, at which time such interest will be deemed to have been paid. The Promissory Notes are redeemable by the Company for cash at any time for a redemption price of 100% plus accrued and unpaid interest and are subject to acceleration upon certain events of default. Subject to the satisfaction or waiver of the applicable closing conditions set forth in the note purchase agreement at each subsequent closing, the Company anticipates the sale of the remaining approximately $5 million principal amount of the Promissory Notes to occur in five subsequent monthly closings, the first of which is anticipated to occur on May 13, 2018.

The Company intends to use the proceeds to, among other things, fund the European Medicines Agency regulatory application process for approval of Linhaliq, to determine a path forward for regulatory review of Linhaliq by the Food and Drug Administration and for general corporate purposes.

On April 18, 2018, following receipt of the requisite consent of holders of the Company s Convertible Notes, the Company entered into a Supplemental Indenture (the Supplemental Indenture), dated as of April 18, 2018, between the Company and U.S. Bank National Association, as trustee, amending the terms of the Indenture, dated as of April 25, 2016 (the Original Indenture) governing the Convertible Notes to give effect to specified amendments. Such amendments include (i) the addition of provisions permitting the Company to make future payments of interest, including the interest payment due on May 1, 2018, on the Convertible Notes by increasing the outstanding principal amount of the Notes in the amount of the accrued interest being so paid and (ii) the removal of the Convertible Note holders option to require the Company to repurchase the Convertible Notes upon the occurrence of certain events, any of which constituted a Fundamental Change as defined in the Original Indenture.

Table of Contents

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

Cautionary Note Regarding Forward-Looking Statements

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 are based on the current beliefs of management, as well as current assumptions made by, and information currently available to, management. All statements contained in this Quarterly Report on Form 10-Q, other than statements that are purely historical, are forward-looking statements. Words such as anticipate, expect, intend, plan, believe, may, will, could, continue, seek, estimate, or the negative thereof and similar expressions also identify 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, those risks and uncertainties discussed in this section, as well as Part II, Item 1A Risk Factors, in this Quarterly Report on Form 10-Q and in our other filings with the United States Securities and Exchange Commission, or the SEC. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements regarding: (i) our belief that our cash and cash equivalents as of March 31, 2018, together with additional funding pursuant to the Note Purchase Agreement, will be sufficient to fund our operations through the third quarter of 2018, (ii) our business strategies, including our intent to pursue selected opportunities for prevention and treatment of severe respiratory diseases by seeking collaborations, government grants and other non-dilutive types of financing that will fund development and commercialization; (iii) our ability to obtain any further regulatory authority clearances (EMA) or approvals for our lead development product candidate, Linhaliq , and other product development candidates; (iv) our reliance on our collaboration partners such as Grifols and third-party contract manufacturers and our ability to maintain partnerships; (v) our strategy to commercialize certain of our unlicensed respiratory product candidates (vi) our plans to work with the US and other allied governments to supply them with our inhaled antibiotic for biodefense supplies; (vii) our intent to use our pulmonary delivery methods and formulations of drugs and biologics to improve their safety, efficacy and convenience of administration to patients; (viii) our expectations regarding future clinical trials; and (ix) our expectation that we will incur additional operating losses.

These forward-looking statements and our business are subject to significant risks such as the risks and uncertainties discussed in the section entitled Part II, Item 1A. Risk Factors, including, but not limited to, our ability to maintain and/or enter into partnering agreements. 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 unsafe in animal or human trials, 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, may not be purchased by government organizations for biodefense, or may not gain acceptance from healthcare professionals, health insurance companies, third party payors 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, 2017, as filed with the SEC on March 23, 2018 and other disclosures (including the disclosures under Part II, Item 1A. Risk Factors) included in this Quarterly Report on Form 10-Q.

You are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date of the filing of this Quarterly Report on Form 10-Q. We undertake no obligation to update these

forward-looking statements in light of events or circumstances occurring after the date of the filing of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of products for the treatment and prevention of severe respiratory diseases. 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 Linhaliq, inhaled ciprofloxacin, formerly known as Pulmaquin® that completed two Phase 3 clinical trials. We also invested considerable effort into the development of a large volume of laboratory and clinical data demonstrating the performance of our AERx® pulmonary drug delivery platform and other proprietary technologies. The key asset we have focused our efforts on in recent years is our inhaled ciprofloxacin product candidates.

Table of Contents

We have not been profitable since inception and expect to incur additional operating losses over at least the foreseeable future as we continue with our efforts towards approval of Linhaliq for non-cystic fibrosis bronchiectasis, or NCFBE, patients who have chronic lung infections with *Pseudomonas aeruginosa.*

Our business has focused on opportunities in the development of drugs for the treatment of severe respiratory disease. We believe that there are significant unmet medical needs in severe respiratory diseases, as well as opportunities to replace some of the existing therapies with products that are more efficacious, safer and more convenient to use by patients. In selecting our proprietary development programs, we primarily seek drugs approved by the Food and Drug Administration, or the FDA, that can be reformulated for both existing and new indications in respiratory disease or drugs that have been discovered by others. 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 of new drugs.

Inhaled Ciprofloxacin Program

Our lead development candidates are proprietary formulations of the potent antibiotic ciprofloxacin (Linhaliq (ARD-3150) and Lipoquin® (ARD-3100)) that are delivered by inhalation for the management of infections associated with the severe respiratory diseases of cystic fibrosis, or CF, and NCFBE.

In January 2018, we announced that the FDA provided a Complete Response Letter (CRL) regarding the NDA stating that it cannot approve the NDA in its present form and providing specific reasons for this action along with requisite recommendations resubmission; the areas of concern include clinical data, human factors validation study and product quality. The recommendations in the CRL include an independent third party verification of the Phase 3 results via analyses of source data as per the statistical analysis plan (SAP) and an additional Phase 3 clinical trial or trials that demonstrates a significant treatment effect on clinically meaningful endpoints which could evaluate the co-primary endpoints of frequency and severity of exacerbations to assess for durable evidence of efficacy over a period of two years (or more, if scientifically justified). The CRL also included a request to conduct another Human Factors Study to demonstrate that the product packaging and instructions for use are effective, and the CRL requested, among other things, additional product quality information with respect to microbiology and an in vitro drug release method development report. We remain confident in the efficacy, safety and quality of Linhaliq and plan to request meetings with the FDA to discuss the topics covered in the CRL with the view to developing plans to move towards resubmission of the Linhaliq NDA as soon as possible. We are committed to continue working on the approval of Linhaliq in the US for NCFBE patients who have very severe disease with high morbidity and mortality and no available treatment options.

As planned in March 2018 we submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking approval for Linhaliq for the treatment of NCFBE patients suffering chronic lung infection with *P. aeruginosa.* Our submission is based on the positive Phase 3 clinical trials ARD-3150-1202 or Orbit 4 with a primary endpoint of time to first exacerbations and the secondary endpoints of frequency of all and severe exacerbations including supporting evidence from proprietary preclinical and other clinical studies, as well as referencing additional information about ciprofloxacin from publicly available sources. Two previous Scientific Advice procedures indicated that the EMA is focused primarily on the frequency of exacerbations and totality of evidence in their decision-making. The EMA completed its validation of the MAA and the formal start date of the MAA review procedure is March 29, 2018. The EMA review of the MAA for Linhaliq will be according to standard timelines, with an opinion of the Committee for Medicinal Products for Human Use (CHMP) expected within 210 days (less any clock-stops for the applicant to provide answers to question(s) from the CHMP). After the adoption of a CHMP opinion, a final decision regarding the MAA assessment is carried out by the European Commission on Day 277 of the procedure. The Company expects to receive initial comments and/or questions 120 days after validation.

In August 2013, we entered into a partnership with Grifols whereby we licensed to Grifols, on an exclusive, worldwide basis, our inhaled liposomal ciprofloxacin product candidates for the indication of NCFBE and other indications pursuant to the Grifols License Agreement. The Company is responsible for developing its lead product candidate Linhaliq for the treatment of NCFBE, with Grifols funding $65 million for the development of this product. The Grifols-funded budget was fully utilized by the year ended December 31, 2015. We also received milestone payments of $5 million upon initiation of the Phase 3 program and $5 million upon the filing of the U.S. NDA. Additionally, Grifols will pay additional development milestone payments to us for up to a total of $15 million, including a $5 million milestone payment payable upon U.S. approval of Linhaliq and the remainder contingent upon achieving first regulatory approvals of Linhaliq in the EU, Japan and China, along with royalty payments on net sales of the Aradigm products.

Table of Contents

Liposomal Ciprofloxacin for Non-Tuberculous Mycobacteria

In August 2013, the National Institutes of Health, or the NIH, awarded us a Small Business Initiative Research, or SBIR, grant in the amount of approximately $278,000 to investigate the treatment of PNTM infections with our inhaled liposomal ciprofloxacin product candidates, Linhaliq and Lipoquin. The research program was conducted in collaboration with Oregon State University, Corvallis (OSU).

According to a 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. A recent study from NIH reported that in 2010 they estimated 86,244 national cases, totaling to $815 million burden, of which 87% were inpatient-related ($709 million), and 13% were outpatient-related ($106 million) costs. Of all costs incurred, medications comprised 76% of nontuberculous mycobacterial disease expenditures. 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.

The Phase II SBIR grant builds upon the encouraging results demonstrated in the Phase I SBIR grant that found both Linhaliq and Lipoquin to have significant efficacy against *M. avium* complex and *M. abscessus* infection. The current standard of treatment of mycobacterial infections is the simultaneous use of multiple antibiotics, and the Phase II grant will focus on combination therapies using a variety of techniques that were used and developed in the Phase 1 stage of this research.

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 infective colonies at ciprofloxacin concentrations of 200 mcg/ml, which is an order-of-magnitude below the peak sputum levels observed in humans in the ORBIT-3 and ORBIT-4 Phase 3 clinical trials. At a lower concentration of 20 mcg/ml, the liposomal concentrations still showed statistically significant decreases in colony forming units (CFUs) 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 Linhaliq significantly reduced the growth of PNTM after 3 weeks of once-daily respiratory tract dosing in mice. The number of CFUs of *Mycobacterium avium subsp hominissuis* was reduced by 79% and 77% by Lipoquin and Linhaliq, 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 Linhaliq 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 Linhaliq, respectively; after 6 weeks of treatment, the CFUs were further reduced ($p<0.05$) by 99.7% and 99.4% for Lipoquin and Linhaliq, respectively. In contrast, unencapsulated ciprofloxacin had no effect.

This collaboration between OSU and Aradigm resulted in inventions leading to several patent applications. In January 2017, Patent no. 9,532,986 titled Liposomal Ciprofloxacin Formulations with Activity Against Non-Tuberculous Mycobacteria was issued by the US Patent Office, with OSU and Aradigm being the assignees.

In August 2017, the National Institute of Allergy and Infectious Diseases (NIAID) and National Institutes of Health (NIH) awarded us a Small Business Initiative Research (SBIR) grant to investigate the treatment of two pulmonary non-tuberculous

Table of Contents

mycobacteria (PNTM) infections, *Mycobacterium avium (M. avium)* and *Mycobacterium abscessus (M. abscessus)*, with Linhaliq and Lipoquin and a novel liposomal formulation containing nanocrystalline ciprofloxacin. This novel formulation is described in Patent nos. 9,844,548 titled Liposomal Ciprofloxacin Formulations with encapsulated ciprofloxacin nanocrystals that was issued in May 2018 and 9,968,555 titled Novel Liposomal Formulations that Form Drug Nanocrystals after Freeze-Thaw that was issued in May 2018 by the US Patent Office, with Aradigm being the assignee. Aradigm will work together with Oregon State University, Corvallis (OSU), who will lead the laboratory research as a part of the consortium funded by this two year grant of approximately $972,000.

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

In addition to our programs addressing BE, CF, and PTNM, our inhaled ciprofloxacin has also been tested for the prevention and treatment of inhaled bioterrorism infections, such as *Coxiella burnetii*, or Q fever, inhalation anthrax, tularemia, melioidosis and pneumonic plague. We have obtained a royalty-bearing license for the biodefense applications from Grifols.

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

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

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

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

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

In the study, exposure to aerosolized *Y. pestis* was lethal. Animals were followed for up to 28 days post-exposure. All untreated mice succumbing to a systemic infection by day 3 post-exposure. A single dose of oral ciprofloxacin administered at 24 hours post-exposure did not prevent mortality and only increased the mean time to death to 5 days compared to 3 days for untreated mice. In comparison, a single dose of Lipoquin delivered via the nose into the lungs

of the animals provided 100% protection and significantly improved survival compared to a single dose of oral ciprofloxacin (P<0.0001); a single dose of aerosolized Lipoquin administered at 24 hours post-exposure provided approximately 70% protection and significantly improved survival when compared to a single dose of oral ciprofloxacin (P<0.001).

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

Table of Contents

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

In October 2016, we announced that Dstl received funding of up to $6.9 million from the U.S. Defense Threat Reduction Agency, or DTRA, for a program entitled Inhalational ciprofloxacin for improved protection against biowarfare agents . The inhalational ciprofloxacin formulations used in this program are our proprietary investigational drugs Linhaliq and Lipoquin. The total potential funding provided to Dstl is $3.2 million for the base period and $3.7 million for the option period. The initial funding released is $1.7 million. Dstl, in conjunction with its key sub-contractors, including Aradigm, will conduct research relating to the efficacy of Linhaliq and Lipoquin in animal models of *Francisella tularensis* (tularemia), *Burkholderia pseudomallei* (melioidosis), *Burkholderia mallei* (glanders) and Q fever. The most likely method for infection with biowarfare agents is via the pulmonary route. The main advantage of the inhaled liposomal ciprofloxacin approach is that it delivers the antibiotic rapidly and directly in high concentrations to the respiratory tract - the area of primary infection - and the liposomal formulation retains antibiotic there over a prolonged period of time. The liposomal formulation also facilitates intracellular uptake, essential to treat these life-threatening intracellular infections. The funding from DTRA will enable us to validate and expand this approach with the goal of providing broad-spectrum prophylaxis and treatment against multiple bioterrorism threats.

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, termed the *Animal Rule*. 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. We plan to meet with the FDA later this year to discuss approval of Linhaliq under the *Animal Rule* initially for tularemia.

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 condensed 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. For additional information about our significant accounting policies, see Note 2 to the condensed consolidated financial statements presented in this report and Note 1 to the consolidated financial statements included in the 2017 Annual Report on Form 10-K.

Table of Contents

Revenue Recognition

Beginning January 1, 2017, we have followed the provisions of ASC Topic 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized. See Note 7 to the condensed consolidated financial statements presented in this report.

Our 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.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. Our performance obligations include license rights, development services, and services associated with regulatory submission and approval processes.

We have optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for the future supply of drug substance or drug product for either clinical development or commercial supply at the customer s or our discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, such material rights are accounted for as separate performance obligations. Payments associated with optional items are allocated to the performance obligations in the separate contract.

Transaction Price

We have both fixed and variable consideration. Non-refundable upfront fees are considered fixed, while milestone payments are identified as variable consideration. Funding of research and development activities is considered variable until such costs are reimbursed at which point they are considered fixed. We allocate the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price, such as a regulatory submission by us. Milestone payments that are not within our control, such as approvals from regulators, are not considered probable of being achieved until those approvals are received. When our assessment of probability of achievement changes and variable consideration becomes probable, any additional estimated consideration is allocated to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation

and recorded in license, collaboration, and other revenues based upon when the customer obtains control of each element.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

We allocate the total transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. Estimated selling prices for license rights are calculated using an income approach model and include the following key assumptions: the development timeline, revenue forecast, commercialization expenses, discount rate and probabilities of technical and regulatory success. To estimate selling prices for development services, regulatory submission services, and product supply, we use a cost-plus margin approach.

Table of Contents

Timing of Recognition

Significant management judgment may be required to determine the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under the arrangement. We estimate the performance period or measure of progress at the inception of the contract and reevaluate it each reporting period. This re-evaluation may shorten or lengthen the period over which revenue is recognized. 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. For performance obligations that are services, revenue is recognized over time proportionate to the costs that we incur to perform the services using the input method. Revenues are recognized for licenses of functional intellectual property at the point in time the customer can use and benefit from the license.

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 condensed consolidated statements of operations and comprehensive loss.

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. We expense research and development costs as incurred.

We are eligible under the AusIndustry research and development tax incentive program to obtain a cash amount from the Australian Taxation Office. The tax incentive is available to us on the basis of specific criteria with which we must comply. Specifically, we must have revenue of less than AUD $20.0 million and cannot be controlled by income tax exempt entities. These research and development tax incentives are recognized as contra research and development expense when the right to receive has been attained, and funds are considered to be collectible. The tax incentive is denominated in Australian dollars and, therefore, the related receivable is remeasured into U.S. dollars as of each reporting date.

We recognize the funds related to our Australian research and development tax incentives that are not subject to refund provisions as an offset to research and development expense. The amounts are determined on a cost reimbursement basis, and the incentive is related to our research and development expenditures and is refundable regardless of whether any Australian tax is owed. These Australian research and development tax incentives are recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred, and the amount of the consideration can be reliably measured.

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, or 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 condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Table of Contents

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 condensed 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 condensed consolidated financial statements. The aforementioned differences result in deferred tax assets and liabilities, which are included in our condensed 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 December 31, 2017 and December 31, 2016, 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.

Recent Accounting Pronouncements

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

Results of Operations

Three months ended March 31, 2018 and 2017

Our net loss increased by $1.1 million for the three months ended March 31, 2018 as compared with the three months ended March 31, 2017. The increase in net loss resulted primarily from an increase in operating expenses of $800 thousand related to the FDA advisory committee meeting held in January, a decrease in revenue of $200 thousand and an increase in interest expense of $100 thousand related to the Note Financing (as described below) that was completed in 2016.

Total revenue was $1.5 million for the three months ended March 31, 2018 as compared with $1.7 million in the comparable period in 2017. We recognized $1.3 million in contract revenue-related party, $29,000 in government contract revenue and $129,000 in government grant revenue for the quarter ended March 31, 2018, as compared to $1.6 million in contract revenue-related party, $39,000 in government contract revenue and $31,000 in government grant revenue for the quarter ended March 31, 2017. The decrease in contract revenue-related party of $300 thousand related to the completion of regulatory submission services for which a higher percentage of the transaction price had been allocated at contract inception, as compared to regulatory approval services.

Operating expenses were $5.3 million for the three months ended March 31, 2018, which represented a $800 thousand increase from the comparable period ended March 31, 2017. General and administrative costs were unchanged compared to the prior quarter. Research and development expenses increased $800 thousand. In the first quarter of

2018, our research and development costs were higher due to higher consulting costs related to the FDA meeting and the submission fees for our MAA application as well as severance expenses, offset by lower costs for clinical expense and lower employee related expenses due to a reduction in headcount. The receipt of a tax incentive in Australia offset a portion of the research and development expenses in the first quarter of 2017.

Table of Contents

Liquidity and Capital Resources

As reflected in the accompanying condensed consolidated financial statements, the Company has incurred significant recurring operating losses and negative cash flows from operations and as of March 31, 2018, had an accumulated deficit of $460 million, a shareholder s deficit of $16.7 million and a working capital deficit of $1.5 million. These factors, among others, raise substantial doubt about the Company s ability to continue as a going concern. We believe that our cash and cash equivalents as of March 31, 2018 of approximately $1.4 million were only sufficient to fund our operations through April of 2018. Subsequent to the end of the fiscal quarter, on April 13, 2018, we entered into a note purchase agreement whereby entities affiliated with Grifols and Frist Eagle, our two largest shareholders beneficially owning collectively approximately 67% of our common stock as of March 12, 2018 and owning most of our Convertible Notes and Warrants described in Note 6 to the consolidated financial statements included in this Quarterly Report on Form 10-Q agreed to purchase up to approximately $7 million aggregate principal amount of bridge notes (the 9% senior promissory notes due 2021, or the Promissory Notes). We completed the first closing under the note purchase agreement on April 13, 2018, at which time we issued and sold approximately $2 million aggregate principal amount of Promissory Notes to the lenders thereunder. Subject to the satisfaction or waiver of the applicable closing conditions set forth in the note purchase agreement at each subsequent closing, we anticipate the sale of the remaining approximately $5 million principal amount of the Promissory Notes to occur in five subsequent monthly closings, the first of which is expected to occur on May 13, 2018. We believe that this $7.0 million along with our cash and cash equivalents of $1.4 million as of March 31, 2018, will be sufficient to fund operations through the third quarter of 2018. However, because of the expected losses and negative cash flows from operations we will continue to require additional capital through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund our operations and to continue the development of our lead product candidate Linhaliq. No assurance can be given that we will be successful in raising such additional capital on favorable terms or at all. If we are unable to obtain additional funds when required, it will delay or reduce the scope of all or a portion of our development programs or require us to dispose of our assets or technology or to cease operations. See also Item 1A. Risk Factors Although our financial statements have been prepared on a going concern basis, we will require additional monies to finance our operating expenses. Additional funding may not be available on terms that are acceptable to us or at all. Changing circumstances may cause us to expend cash significantly faster that we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

We have funded our operations with a variety of financing arrangements including bridge notes, convertible debt such as the Note Financing, development contract expense reimbursements, license fees, milestone payments from collaborators, government contracts, public offerings and private placements of our capital stock, the milestone and royalty payments associated with the sale of assets to third parties, proceeds from a royalty financing transaction and interest earned on cash equivalents and short-term investments. We have incurred significant losses and negative cash flows from operations since our inception. Management expects operating losses to continue for the foreseeable future including the year ended December 31, 2018.

Three months ended March 31, 2018

Total cash and cash equivalents decreased by $5.7 million for the three months ended March 31, 2018. The decrease primarily resulted from the use of cash to fund our ongoing operations in support of our Linhaliq program.

Three months ended March 31, 2017

Total cash and cash equivalents decreased by $5.4 million for the three months ended March 31, 2017. The decrease primarily resulted from the use of cash to fund our ongoing operations in support of our Linhaliq program, partially

offset by the receipt of $670,000 from the Australian Taxation Office related to the Australian research and development program.

Off-Balance Sheet Financings and Liabilities

We do not have any off-balance sheet financing arrangements, as defined in Item 303 of the SEC s Regulation S-K (which includes, but is not limited to, any transaction, agreement or other contractual arrangement to which an entity unconsolidated with the registrant is a party, under which the registrant has any obligation under guarantee contract, retained or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity that is held by, and material to, the Company, where such entity provides financing, liquidity, market risk or credit risk support to, or engages in leasing, hedging or research and development services with, the Company). We have one inactive, wholly-owned subsidiary incorporated in Delaware, Aradigm Royalty Financing LLC, one active wholly-owned subsidiary domiciled in Australia and one active, wholly-owned subsidiary domiciled in the UK.

Table of Contents

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 his evaluation as of the end of the period covered by this report, our Executive Chairman, Interim Principal Executive Officer and Acting Principal Financial Officer has 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 Executive Chairman, Interim Principal Executive Officer and Acting Principal Financial Officer has concluded that these controls and procedures are effective at the reasonable assurance level. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

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

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

On May 1, 2017, the Company filed a post grant review, or a PGR, petition in the United States Patent and Trademark Office Patent Trial and Appeal Board, or PTAB, challenging the validity of all 26 claims of U.S. Patent No.9,402,845 or the 845 Patent, assigned to Insmed Incorporated, or Insmed. The 845 Patent issued on August 2, 2016, and is entitled Lipid-based compositions of antiinfectives for treating pulmonary infections and methods of use thereof.

PGR is a proceeding that became available in September 2012 in accordance with the America Invents Act. In a PGR, a petitioner may request that PTAB reconsider the validity of issued patent claims. Any patent claim PTAB determines to be unpatentable is stricken from the challenged patent.

In August 2017, Insmed filed a Preliminary Response. In November 2017, PTAB denied institution of our post-grant review of the 845 Patent. We are currently assessing the PTO s decision.

On January 11, 2018 a putative class action lawsuit, *Kevin Kheder v. Aradigm Corporation, et al.,* No. 3:18-cv-00261, was filed in the United States District Court for the Northern District of California against the Company and two of its former officers. The suit is purportedly brought on behalf of persons and entities who acquired or otherwise purchased

Aradigm common stock between July 27, 2017 and January 8, 2018 (the Class Period). Plaintiff alleges that defendants made false and misleading statements during the Class Period that artificially inflated the price of Aradigm stock. Lead plaintiff did not file an amended complaint, and instead on May 9, 2018, the parties filed a stipulation asking the Court to dismiss the action with prejudice as to the lead plaintiff and without prejudice as to other putative class members. The Court entered the stipulated order of dismissal on May 11, 2018.

Table of Contents

Item 1A. ***Risk Factors***

Except for historical information contained herein, the discussion of this Quarterly Report on Form 10-Q contains forward-looking statements, including, without limitation, statements regarding preparation and filing for regulatory approvals, 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. The risks described below are not the only risks we face. Additional risks not presently known to us or other factors that we do not presently perceive to present significant risks to us at this time may also impair our business, financial condition, results of operations or cash flows, or the value of our common stock.

The risk factors included herein include any material changes to and supersede the risk factors associated with our business previously disclosed in Part 1, Item 1A, Risk Factors of the 2017 Annual Report on Form 10-K. We have marked with a double asterisk (**) those risk factors that reflect substantive changes from the risk factors included in the 2017 Annual Report on Form 10-K.

Risks Related to Our Business

Our cash resources will only be sufficient to fund our operations through the third quarter of 2018. Additional funds may not be available on terms that are acceptable to us or at all.

Our independent registered public accounting firm for the fiscal year ended December 31, 2017 has indicated in its audit opinion, contained in our consolidated financial statements included in our Annual Report on Form 10-K, that our current liquidity position raises substantial doubt about our ability to continue as a going concern.

We believe that our cash and cash equivalents of approximately $1.4 million as of March 31, 2018, were only sufficient to fund our operations through April of 2018. On April 13, 2018, we entered into a note purchase agreement whereby entities affiliated with Grifols and First Eagle, our two largest shareholders beneficially owning collectively approximately 67% of our common stock as of March 12, 2108 and owning most of the Convertible Notes and Warrants described in Note 6 to the consolidated financial statements included in this Quarterly Report on Form 10-Q agreed to purchase up to approximately $7 million aggregate principal amount of bridge notes, and issued and sold approximately $2 million aggregate principal amount of bridge notes to the lenders. Subject to the satisfaction or waiver of the applicable closing conditions set forth in the note purchase agreement at each subsequent closing we anticipate the sale of the remaining approximately $5 million principal amount of the Promissory Notes to occur in five subsequent monthly closings, the first of which is anticipated to occur on May 13, 2018. We believe that this $7.0 million along with the cash balance of $1.4 million at March 31, 2018 will be sufficient to fund operations through the third quarter of 2018. However, we will not be able to maintain our current level of regulatory and product development activity and there is substantial doubt about our company s ability to continue as a going concern unless we raise additional capital in 2018. We cannot assure you that the closing conditions to the subsequent monthly closings will be satisfied. For example, if the EMA issues an Adverse Decision, the additional monthly notes will not be issued. Accordingly, we intend to raise additional capital through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund our operations and to continue the development of our lead product candidate Linhaliq. We cannot assure you that we will be successful in raising additional capital on favorable terms or at all. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. If we are unable to obtain additional funds when required, it may delay or reduce the scope of all or a portion of our development programs, or require us to dispose of our assets or technology or to cease operations, and we may not be able to continue as a going concern.

Changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. For these reasons, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities.

Table of Contents

We have received a CRL from the FDA which states that it cannot approve the NDA for Linhaliq in its present form. Even if we resubmit the NDA for Linhaliq, the FDA may not approve Linhaliq for marketing.

We have focused primarily on the development of our lead product candidate Linhaliq for the treatment of NCFBE. In July 2017, we submitted the NDA for Linhaliq to the FDA based on the positive results from the ORBIT-4 study in the Phase 3 clinical program for Linhaliq and confirmatory evidence from the ORBIT-2 and ORBIT-3 studies. In January 2018, we received a CRL from the FDA regarding the NDA for Linhaliq which states that the FDA determined it cannot approve the NDA in its present form and provides specific reasons for this action along with recommendations needed for resubmission; the areas of concern include clinical data, human factors validation study and product quality. The recommendations in the CRL include an independent third party verification of the Phase 3 results via analyses of source data as per the statistical analysis plan and an additional Phase 3 clinical trial that demonstrates a significant treatment effect on clinically meaningful endpoints which could evaluate the co-primary endpoints of frequency and severity of exacerbations to assess for durable evidence of efficacy over a period of two years (or more, if scientifically justified). The CRL also included a request to conduct another Human Factors Study to demonstrate that the product packaging and instructions for use are effective, and the CRL requested, among other things, additional product quality information with respect to microbiology and a new in vitro drug release method development report. The Company plans to request a Type B post-action meeting with the FDA to discuss the topics covered in the CRL with the view to developing plans to move towards resubmission of the Linhaliq NDA. While we currently plan to resubmit the NDA for Linhaliq, we cannot assure you that we will be able to resubmit the NDA, that the information previously provided, or to be provided, to the FDA will be adequate to address the recommendations made in the Linhaliq CRL or that we will be successful in obtaining FDA approval of Linhaliq. Even if we resubmit an NDA for Linhaliq, the FDA could require us to complete further clinical, Human Factors or other studies, which could further delay or preclude any approval of the NDA and require us to obtain significant additional funding. In addition, the FDA may choose not to approve our NDA for any of a variety of reasons, including a decision related to the safety or efficacy data for Linhaliq, or for any other issues that it may identify related to our development of Linhaliq for the treatment of NCFBE.

Changes to our management and board of directors may cause uncertainty regarding the future of our business, and may adversely impact employee hiring and retention, our stock price, and our revenue, operating results, and financial condition.

Since February 2018, there have been significant changes in our management and board of directors. For example, several members of management have departed the Company. Effective February 11, 2018, each of Igor Gonda, President and Chief Executive Officer; Juergen Froehlich, Chief Medical Officer; and Nancy Pecota, Vice President, Finance, Chief Financial Officer and Corporate Secretary resigned all offices and positions held by him or her with Aradigm. In addition, in February, 2018, Dr. Gonda and David Bell resigned from the Board of Directors. In addition, in February 2018, our board of directors approved temporary measures intended to preserve our cash resources until additional sources of capital can be secured, and we reduced our headcount. These changes, and the potential for additional changes to our management, organizational structure and strategic business plan, may cause speculation and uncertainty regarding our future business strategy and direction. These changes may cause or result in:

- disruption of our business or distraction of our employees and management;
- difficulty in recruiting, hiring, motivating and retaining talented and skilled personnel;

stock price volatility; and

difficulty in negotiating, maintaining or consummating business or strategic relationships or transactions.

If we are unable to mitigate these or other potential risks, our revenue, operating results and financial condition may be adversely impacted.

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

We have never been profitable and have incurred significant net losses in each year since our inception. As of March 31, 2018, we have an accumulated deficit of approximately $460 million. We have not had any direct product sales and do not anticipate receiving revenues from the sale of any of our products in 2018, if ever. We expect to incur net losses over the next several years and may never become profitable. While our agreement with our partner Grifols has resulted in reduced net operating losses and capital expenditures as a portion of our research and development expenses for the Linhaliq program was reimbursed by Grifols through 2015, 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.

The amount of future losses is uncertain and will depend, in part, on the rate of growth of our expenses.

Table of Contents

To achieve and sustain profitability, we must, alone or with others such as 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. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the processes described above, we anticipate incurring significant costs associated with seeking regulatory approval for our product candidates.

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.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. We and our products are subject to extensive and rigorous regulation in the United States by the federal government, principally the FDA, by state and local government agencies, and also by governmental and regulatory agencies outside the United States, such as the EMA. 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. Despite the time and expense expended, regulatory approval is never guaranteed. The FDA and 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.

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.

Our pharmaceutical product candidates may not be approved even if they achieve their safety and efficacy endpoints in 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 or label changes would have an adverse effect on our business, reputation, and results of operations.

Even if we are granted initial FDA or EMA 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, the EMA 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. 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. 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 or EMA review and approval. Advertising and other promotional material must comply with FDA or EMA requirements. We, our collaborators and our manufacturers will be subject to continuing review and periodic inspections by the FDA, the EMA and other authorities, where applicable, and must comply with ongoing requirements, including the FDA s GMP requirements. Once the FDA or the EMA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA or the EMA 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.

Table of Contents

We are a development-stage company and will require substantial capital to complete the development of our product candidates and commercialize them. Any such future financing could result in dilution to shareholders or increased fixed payment obligations and could also result in restrictive covenants or other operating restrictions that could adversely impact our ability to conduct our business.

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 lead product candidate, Linhaliq. 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 or the EMA, 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, royalty or 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 shareholders or impose restrictive covenants that may adversely impact our business. The incurrence of indebtedness would result in increased fixed payment obligations and could also 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 or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves, or cease operations and liquidate.

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 or EMA 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. For example, Bayer has developed an inhaled dry powder formulation of ciprofloxacin for the treatment of respiratory infections in CF and NCFBE. Bayer filed an

NDA for U.S. approval and was accepted for Priority Review. In November 2017, the FDA s Advisory Committee voted not to recommend Bayer s dry powder ciprofloxacin to be approved for the treatment of bronchiectasis. Bayer in its 2017 Annual Report have announced that they have decided to discontinue development of Cipro DPI in NCFBE for the time being and will evaluate possible further options for this asset.

There are a number of other inhaled products under development to treat respiratory infections, including a nebulized levofloxacin by Raptor (acquired by Horizon) for CF, inhaled colistin for bronchiectasis, and a nebulized liposomal amikacin by Insmed for the treatment of *Mycobacterium avium* (a pulmonary non-tuberculous mycobacteria infection). These and many other potential competitors have greater research and development, manufacturing, marketing, sales, distribution, financial and managerial resources and experience than we have and 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.

In addition, we believe there are a number of additional drug candidates and pulmonary delivery technologies in various stages of development that, if approved, could compete with any future products we may develop.

Table of Contents

Because our inhaled ciprofloxacin programs may rely on the FDA s and EMA 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 drug product 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 NCFBE 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 the NCFBE indication, Bayer has obtained orphan drug status for their inhaled powder formulation of ciprofloxacin in the United States for the treatment of bronchiectasis and in the United States and European Union for the treatment of CF. Bayer filed an NDA for U.S. approval, however in November 2017 the FDA s Advisory Committee voted not to recommend Bayer s dry powder ciprofloxacin to be approved for the treatment of bronchiectasis.

In August 2009, the EMA 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.

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.

We used contract research organizations (CROs) to conduct our global Phase 3 clinical trials and are using contract research organizations for other analysis and testing activities. We may not be able to maintain satisfactory contract research arrangements, or we may have contractual disputes with such CROs that could adversely impact the timelines for the delivery of data or other materials from the CRO. If our CROs are delayed in their activities or issues are uncovered regarding the quality of the data provided by the CROs it could result in significant delays in our Linhaliq program and adversely impact our ability to obtain regulatory approval for our product candidate.

Our commercialization strategy for certain of our product candidates depends on our ability to enter into or maintain agreements with collaborators, such as our collaboration with Grifols, 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 NCFBE, 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.

Table of Contents

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

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and commercial operations. Rather, we rely on various third-party contract manufacturers to produce our products. There may be long lead times to obtain materials. There can be no assurance that we will be able to identify, contract with, qualify and obtain prior regulatory approval for additional sources of materials. We may also not be able to maintain satisfactory contract manufacturing arrangements with our current contract manufacturers. 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. If there are any interruptions in this supply for any reason, including a decision by the third parties to discontinue manufacturing, technical difficulties, labor disputes, natural or other disasters, or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our investigational drug candidates and may not be able to successfully commercialize these investigational drug candidates.

Our third-party contract manufacturers and collaborative partners may encounter delays and problems in manufacturing our investigational drug candidates and future commercial products for a variety of reasons, including accidents during operation, failure of equipment, delays in receiving materials, natural or other disasters, political or governmental changes, or other factors inherent in operating complex manufacturing facilities. Supply-chain management is difficult. Commercially available starting materials, reagents, excipients, and other materials may become scarce, more expensive to procure, or not meet quality standards, and we may not be able to obtain favorable terms in agreements with subcontractors. Our third-party contract manufacturers may not be able to operate manufacturing facilities in a cost-effective manner or in a time frame that is consistent with our expected future manufacturing needs. If our third-party manufacturers cease or interrupt production or if our third-party manufacturers and other service providers fail to supply materials, products or services to us for any reason, such interruption could delay progress on our programs, or interrupt the commercial supply, with the potential for additional costs and lost revenues. If this were to occur, we might also need to seek alternative means to fulfill our manufacturing needs.

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.

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. Many of these alternative products may be more established and acceptable 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;

Table of Contents

the sufficiency of coverage and reimbursement of our product candidates by governmental and other third-party payors; and

the product labeling or product insert required by the FDA or regulatory authorities in other countries.

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

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

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.

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 or our collaborator Grifols 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. For example, we are aware of patents recently issued in the U.S. and assigned to Insmed with claims covering methods of treatment with quinolone antibiotics, which includes ciprofloxacin, against pulmonary infections. We filed a PGR petition in the PTAB challenging the validity of the claims of Insmed s U.S. Patent No. 9,402,845 or the 845 Patent. In a PGR, a petitioner may request that the PTAB reconsider the validity of issued patent claims and any patent claim PTAB determines to be unpatentable is stricken from the challenged patent. In August 2017, Insmed filed a Preliminary Response to our petition. In November 2017, PTAB denied institution of our post-grant review of the 845 Patent. We are currently assessing the PTO s decision.

If we or our collaborator Grifols are required to defend an infringement 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 issued patents or pending patent applications or that we were the first to file patent applications on such inventions. For example, we are aware of patents recently issued in the U.S. and assigned to Insmed with claims covering methods of treatment with quinolone antibiotics, which includes ciprofloxacin, against pulmonary infections.

Table of Contents

If our 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 and EMA 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 any future clinical trials may result in increased costs, program delays, or both, and the loss of potential revenues.

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. Our former President and Chief Executive Officer, Dr. Igor Gonda, our former Chief Medical Officer, Dr. Juergen Froehlich, and our former Chief Financial Officer, Nancy Pecota resigned on February 11, 2018. These resignations and losing any of our remaining key employees could impair our product development efforts and otherwise harm our business. Any of our employees may terminate their employment with us at will.

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

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

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 reimbursement status of newly approved pharmaceutical products. Any products we are able to develop successfully may be deemed not reimbursable by third-party payors. In addition, our products may not be considered cost-effective, and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. If any products we develop do not receive adequate reimbursement, our revenues will be severely limited.

Table of Contents

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

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

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal year. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or 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 2017 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.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

We store sensitive data, including intellectual property, our proprietary business information and personally identifiable information of our employees, on our network servers, located in our data centers. The secure maintenance of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, damage our reputation and adversely impact our operating results. Numerous United States federal and state laws and regulations and foreign laws and regulations, including data breach notification laws, health information privacy laws, and federal and consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and

telecommunication and electrical failures. Such an event could cause interruption of our operations. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

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 shareholders;

Table of Contents

announcements of clinical trial results, technological innovations or new commercial products by our competitors or us;

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;

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 our competitors or us;

investor perception of us;

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

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

our ability to raise capital; and

economic and other external factors.

In the past, class action securities litigation has often been instituted against companies promptly following volatility in the market price of their securities, and a class action securities suit was instituted against us in the first quarter of 2018 as a result of the decline in the market price of our common stock Any such litigation against us may, regardless of its merit, result in substantial costs and a diversion of management s attention and resources.

Nasdaq has notified us that we are no longer in compliance with Nasdaq s continued listing requirements. If we fail to regain compliance, we will be subject to delisting by Nasdaq. If we are delisted, our stock price may decline and the liquidity of our securities and our ability to raise capital could be significantly impaired.

Our common stock is listed on the Nasdaq Capital Market, or Nasdaq. In order to maintain that listing, we must sustain a minimum market value of listed securities of $35 million or shareholder s equity of at least $2.5 million, among other requirements for continued listing. On March 7, 2018 we received a notice from Nasdaq that we are not in compliance with Nasdaq s Listing Rule 5550(b)(1), as we have not maintained a minimum of $2,500,000 in our shareholder s equity. The notification of noncompliance has no immediate effect on the listing or trading of the Company s common stock on Nasdaq under the symbol ARDM. Pursuant to the Nasdaq Listing Rules, we have 180 days, or until September 4, 2018, to regain compliance with the minimum shareholder s equity requirement. The notification of noncompliance has no immediate effect on the listing or trading of our common stock on Nasdaq.

However, if we are unable to meet these requirements, we will be subject to delisting by Nasdaq. Even if we regain compliance with Nasdaq s listing requirements, we cannot assure you that we will be able to main compliance in future periods.

If our stock is delisted from Nasdaq, this would likely impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which might be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor may find it significantly more difficult to dispose of our common stock, and our ability to raise future capital through the sale of the shares of our common stock or other securities convertible into or exercisable for our common stock could be materially limited. If we are delisted from Nasdaq, trading in our shares of common stock may be conducted, if available, on the OTC Bulletin Board Service or, if available, via another market.

On February 28, 2018, we received a notice from Nasdaq that, effective as of the appointment of John Siebert as our Executive Chairman and Interim Principal Executive Officer on February 11, 2018, we are no longer in compliance with Nasdaq s independent director and audit committee requirements as set forth in Nasdaq Listing Rule 5605. On March 9, 2018, we received a notice from Nasdaq, stating that based on information regarding the appointment of an independent director to the Board and the Audit Committee, the staff of Nasdaq has determined that we now comply with Nasdaq Listing Rule 5605 and that the matter is now closed.

Table of Contents

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 the 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 (which was temporarily suspended in the first quarter of 2018) 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 and, capital appreciation, if any, of our common stock will be our shareholders sole source of gain for the foreseeable future. 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 our other shareholders and us.

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 Grifols ownership of approximately 35% of our outstanding common stock, or 47.4% of our common stock if Grifols converts all of its Convertible Notes, conflicts of interest may arise between Grifols and us 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 our other shareholders and us. 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 significant control over matters submitted to our shareholders for approval, including delaying or preventing a change in control of our company.

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, beneficially own approximately 67% of the class of our common stock as of March 12, 2018. These two shareholders purchased most of the Convertible Notes and related Warrants described in Note 6 to the consolidated financial statements included in this Quarterly Report on Form 10-Q, 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 as 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.

Table of Contents

Item 1B. ***Unresolved Staff Comments***
None.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS
Not applicable.

Item 3. DEFAULTS UPON SENIOR SECURITIES
Not applicable.

Item 4. MINE SAFETY DISCLOSURES
Not applicable.

Item 5. OTHER INFORMATION
Not applicable.

Table of Contents

Item 6. EXHIBITS

Exhibit Number	Description
10.1+	Employment Agreement between Aradigm Corporation and John Siebert, March 22, 2018.(1)
31.1*	Certification of the Executive Chairman, Interim Principal Executive Officer and Acting 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 Executive Chairman, Interim Principal Executive Officer and Acting 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, 2018 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.

* Filed with this Quarterly Report on Form 10-Q.
** Furnished with this Quarterly Report on Form 10-Q.
\+ Represents a management contract or compensatory plan or arrangement.
(1) Incorporated by reference to the Company s Amendment No. 1 to Current Report on Form 8-K/A (No. 001-36480) filed on March 28, 2018.

Aradigm, Pulmaquin, Lipoquin, AERx and AERx Essence are registered trademarks of Aradigm Corporation.
Linhaliq is a registered trademark of Grifols, S.A.

Table of Contents

SIGNATURES

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

ARADIGM CORPORATION

/s/ John Siebert
Executive Chairman, Interim Principal Executive Officer, and Acting Principal Financial Officer

Dated: May 14, 2018