ARADIGM CORP
Form 10-Q
November 03, 2017
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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 September 30, 2017

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 October 26, 2017)
Common	**15,148,138**

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ARADIGM CORPORATION

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ARADIGM CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	September 30, 2017 (Unaudited)	December 31, 2016 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,594	$ 22,591
Restricted cash		1,006
Receivables	363	167
Prepaid and other current assets	630	1,037
Total current assets	13,587	24,801
Property and equipment, net	280	253
Other assets	92	
Total assets	$ 13,959	$ 25,054
LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 980	$ 711
Accrued clinical and cost of other studies	311	3,306
Accrued compensation	1,745	1,335
Deferred revenue related party, current	3,874	
Deferred revenue - other	155	
Other accrued liabilities	1,155	496
Total current liabilities	8,220	5,848
Deferred rent	21	
Deferred revenue related party, non-current	349	5,000
Convertible debt - non-current, net of discount	2,339	2,212
Convertible debt related party, non-current, net of discount	12,198	11,007
Total liabilities	23,127	24,067
Commitments and contingencies Shareholders equity (deficit):		

Preferred stock, 5,000,000 shares authorized, none outstanding		
Common stock, no par value; authorized shares: 35,045,765 at September 30, 2017 and December 31, 2016; issued and outstanding shares: 15,112,078 at September 30, 2017; 14,951,089 at December 31, 2016	441,826	439,406
Accumulated deficit	(450,994)	(438,419)
Total shareholders equity (deficit)	(9,168)	987
Total liabilities and shareholders equity (deficit)	$ 13,959	$ 25,054

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

As the Company elected to early adopt the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2017* using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 7.

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ARADIGM CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Contract revenue related party	$ 2,709	$ 40	$ 11,804	$ 40
Contract revenue	6		241	
Grant revenue	13	10	51	30
Total revenue	2,728	50	12,096	70
Operating expenses:				
Research and development	3,543	5,836	10,111	18,522
General and administrative	2,133	1,460	5,722	4,489
Restructuring and asset impairment				2
Total operating expenses	5,676	7,296	15,833	23,013
Loss from operations	(2,948)	(7,246)	(3,737)	(22,943)
Interest income	23	34	73	70
Interest expense	(970)	(898)	(2,882)	(1,475)
Other income (expense)	9	(76)	17	(653)
Net loss and comprehensive loss	$ (3,886)	$ (8,186)	$ (6,529)	$ (25,001)
Basic and diluted net loss per common share	$ (0.26)	$ (0.55)	$ (0.44)	$ (1.69)
Shares used in computing basic and diluted net loss per common share	14,860	14,782	14,836	14,774

See accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

As the Company elected to early adopt the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2017* using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 7.

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ARADIGM CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine months ended September 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (6,529)	$ (25,001)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	85	90
Stock-based compensation expense	1,899	1,185
Amortization of convertible debt discount	1,318	643
Financing costs, derivative liability and warrants		997
Change in value of derivative liability		(386)
Changes in operating assets and liabilities:		
Receivables	(196)	110
Prepaid and other current assets	407	2,196
Other assets	(92)	81
Accounts payable	269	(1,011)
Accrued compensation	854	184
Current deferred revenue related party	(6,647)	
Accrued liabilities	(2,336)	(693)
Deferred rent	21	(37)
Facility lease exit obligation		(104)
Net cash used in operating activities	(10,947)	(21,746)
Cash flows from investing activities:		
Transfer to/from restricted cash	1,006	(2,016)
Capital expenditures	(112)	(69)
Net cash provided by (used in) investing activities	894	(2,085)
Cash flows from financing activities:		
Proceeds from issuance of convertible debt		3,050
Proceeds from issuance of convertible debt related party		19,950
Proceeds from issuance of common stock	56	60
Payments for debt issuance costs		(2,192)
Net cash provided by financing activities	56	20,868

Net decrease in cash and cash equivalents	(9,997)	(2,963)
Cash and cash equivalents at beginning of period	22,591	31,462
Cash and cash equivalents at end of period	$ 12,594	$ 28,499
Supplemental disclosure of non-cash financing activities:		
Reclassification of derivative liability to equity		8,362
Reclassification of warrants to equity		11
Debt discount from warrants		662
Accrued financing costs		221
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

As the Company elected to early adopt the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606) as of January 1, 2017* using the modified retrospective method, there is a lack of comparability to the prior periods presented. See Note 7.

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ARADIGM CORPORATION

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2017

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 2017 fiscal year. The Company operates as a single operating segment.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with 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, 2016, as filed with the SEC on March 30, 2017 (the 2016 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, 2016 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 2016 Annual Report on Form 10-K.

Effective January 1, 2017, the Company elected to early adopt the requirements of Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)* using the modified retrospective method as discussed below in Note 2: Summary of Significant Accounting Policies. All amounts and disclosures set forth in this Form 10-Q reflect these changes.

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 Going Concern

The Company has incurred significant operating losses and negative cash flows from operations. At September 30, 2017, the Company had an accumulated deficit of $451.0 million that includes a net loss of $6.5 million, working capital of $5.4 million and shareholders deficit of $9.2 million. The Company s current assets of $13.6 million exceed

current liabilities of $8.2 million by $5.4 million. The Company believes that its cash and cash equivalents of approximately $12.6 million as of September 30, 2017 will be sufficient to fund its operations at least through 2017. The Company will need to raise additional capital in 2017 or early in 2018 to maintain the Company s operations for the ensuing twelve months, including efforts to obtain approval to market its leading product candidate Linhaliq in the US and EU. Accordingly, the Company anticipates raising additional capital in 2017 or early in 2018, through issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise. 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 may delay or reduce the scope of all or a portion of its development programs or dispose of assets or technology.

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The factors discussed above raise doubt about the Company s ability to continue as a going concern. As stated above, the Company believes that its cash and cash equivalents of approximately $12.6 million as of September 30, 2017 are sufficient to fund its operations at least through 2017. However, 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 condensed consolidated 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.

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.

Cash and Cash Equivalents

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

Restricted Cash

The Company classifies transfers to or from the restricted cash balance in the statement of cash flows based on the nature of the restriction. At September 30, 2017, the Company had no restricted cash.

Property and Equipment

The Company records property and equipment at cost and calculates depreciation using the straight-line method over the estimated useful lives of the respective assets. Machinery and equipment includes external costs incurred for validation of the equipment. The Company does not capitalize internal validation expense. Computer equipment and software includes capitalized computer software. All the Company s capitalized software is purchased; the Company has no internally-developed computer software. Leasehold improvements are amortized over the shorter of the term of the lease or useful life of the improvement.

Convertible Instruments

The Company accounts for hybrid contracts that feature conversion options in accordance with generally accepted accounting principles in the United States. ASC 815, Derivatives and Hedging Activities, or ASC 815, requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate

instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Company accounts for convertible instruments (when it has determined that the embedded conversion options should be bifurcated from their host instruments) in accordance with ASC 815. Under ASC 815, a portion of the proceeds received from the issuance of the hybrid contract is allocated to the fair value of the derivative. The derivative is subsequently marked to market at each reporting date based on current fair value, with the changes in fair value reported in results of operations.

Warrants Issued in Connection with Financings

The Company generally accounts for warrants issued in connection with financings as a component of equity, unless there is a possibility that the Company may have to settle the warrants in cash. For warrants issued with the deemed possibility of a cash settlement, the Company records the fair value of the issued warrants as a liability at each reporting date and records changes in the estimated fair value as a non-cash gain or loss in the condensed consolidated statements of operations. The fair values of warrants

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have been determined using the Black Scholes Merton Option Pricing valuation model, or the Black-Scholes Model. The Black-Scholes Model provides for assumptions regarding volatility, call and put features and risk-free interest rates within the total period to maturity. These values are subject to a significant degree of judgment on the part of the Company.

Accounting for Costs Associated with Exit or Disposal Activities

The Company recognizes a liability for the cost associated with an exit or disposal activity that is measured initially at its fair value in the period in which the liability is incurred.

Costs to terminate an operating lease or other contracts are (a) costs to terminate the contract before the end of its term or (b) costs that will continue to be incurred under the contract for its remaining term without economic benefit to the entity. In periods subsequent to initial measurement, changes to the liability are measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

Revenue Recognition

Beginning January 1, 2017, the Company has followed the provisions of ASC Topic 606, *Revenue from Contracts with Customers*. The guidance provides a unified model to determine how revenue is recognized.

The Company s contract revenues consist of revenues from grants, collaboration agreements, and feasibility studies. License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreement typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of milestones and royalties on net product sales. The Company has both fixed and variable consideration. Non-refundable upfront fees and funding of research and development activities are considered fixed, while milestone payments are identified as variable consideration.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs 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) the Company satisfies each performance obligation.

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. The Company s performance obligations include license rights, development services, and services associated with regulatory submission and approval processes. Significant management judgment is required to determine the level of effort required under an arrangement and the period over which the Company expects to complete its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory

success.

The Company allocates 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. 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, the Company uses a cost plus margin approach.

Licenses of intellectual property: If the license to the Company s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

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Milestone payments: At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates 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 value of the associated milestone (such as a regulatory submission by the Company) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are received.

Royalties: 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, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

The Company has 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 future supply of drug substance or drug product for either clinical development or commercial supply at the customer s discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded in license, collaboration, and other revenues when the customer obtains control of the goods, which is upon delivery.

Research and Development

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

The Company is 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 the Company on the basis of specific criteria with which the Company must comply. Specifically, the Company 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 re-measured into U.S. dollars as of each reporting date.

The Company recognizes the funds related to its Australian research and development tax incentives that are not subject to refund provisions as a reduction of research and development expense. The amounts are determined on a cost reimbursement basis, and the incentive is related to the Company s 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. During the nine months ended September 30, 2017, the Company offset its research and development costs by $0.9 million through the recognition of tax incentive credits.

Stock-Based Compensation

The Company accounts for share-based payment arrangements in accordance with ASC 718, *Compensation-Stock Compensation* and ASC 505-50, *Equity-Equity Based Payments to Non-Employees* which requires the recognition of compensation expense, using a fair-value-based method, for all costs related to share-based payments including stock options and restricted stock awards and stock issued under the employee stock purchase plan. These standards require companies to estimate the fair value of share-based payment awards on the date of the grant using an option-pricing model. See Note 9 for further discussion of the Company s stock-based compensation plans.

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Income Taxes

The Company makes certain estimates and judgments in determining income tax expense for consolidated financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes. As part of the process of preparing the financial statements, the Company is required to estimate income taxes in each of the jurisdictions in which it operates. This process involves the Company estimating its current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities which are included in the Company s condensed consolidated balance sheets.

The Company assesses the likelihood that it will be able to recover its deferred tax assets. The Company considers all available evidence, both positive and negative, including the historical levels of income and losses, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If the Company does not consider it more likely than not that it will recover its deferred tax assets, the Company records a valuation allowance against the deferred tax assets that it estimates will not ultimately be recoverable. At September 30, 2017, and December 31, 2016, the Company believed that the amount of its deferred income taxes would not be ultimately recovered. Accordingly, the Company recorded a full valuation allowance for deferred tax assets. However, should there be a change in the Company s ability to recover its deferred tax assets the Company would recognize a benefit to its tax provision in the period in which it determines that it is more likely than not that it will recover its deferred tax assets.

Net Income/(Loss) Per Common Share

Basic net income/(loss) per common share is computed using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of restricted shares of common stock subject to repurchase. Potentially dilutive securities were not included in the net loss per common share calculation for the three and nine months ended September 30, 2017 and 2016 because the inclusion of such shares would have had an anti-dilutive effect.

Accounting Changes

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606). In August 2015 and March, April, May and December 2016, the FASB issued additional amendments to the new revenue guidance relating to reporting revenue on a gross versus net basis, identifying performance obligations, licensing arrangements, collectability, noncash consideration, presentation of sales tax, transition, and clarifying examples. This new standard replaces all current GAAP guidance on this topic and eliminates all industry-specific guidance. The new revenue recognition guidance provides a unified model to determine how revenue is recognized. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In doing so, companies need to use more judgment and make more estimates than under prior guidance. Judgments may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each performance obligation. Topic 606, as amended, is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted one year earlier.

Effective January 1, 2017, the Company elected to early adopt the requirements of Topic 606 using the modified retrospective method, applying the new guidance to the most current period presented with the cumulative effect of

changes reflected in the opening balance of accumulated deficit. See Note 7 for further details.

In March 2016, the FASB issued Accounting Standards Update, or ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which simplifies the accounting for income taxes, among other changes, related to stock-based compensation. The Company adopted this ASU as of the beginning of fiscal 2017. The treatment of forfeitures has changed as the Company has elected to discontinue its past process of estimating the number of forfeitures and now account for forfeitures as they occur. As such, this had a cumulative effect on retained earnings of $22,000, net of tax.

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.

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3. Cash and Cash Equivalents

At September 30, 2017, and December 31, 2016, the Company s cash and cash equivalents approximated their fair values. The Company currently invests its cash and cash equivalents in money market funds.

4. Fair Value Measurements

The Company follows ASC 820, *Fair Value Measurements*, which clarifies the definition of fair value, prescribes methods for measuring fair value, establishes a fair value hierarchy based on the inputs used to measure fair value and requires disclosures about the use of fair value measurements. The fair value hierarchy has three levels based on the reliability of the inputs used to determine fair value. Level 1 values are based on quoted prices in active markets. Level 2 values are based on significant other observable inputs. Level 3 values are based on significant unobservable inputs.

The Company s cash and cash equivalents at September 30, 2017, consist of cash and money market funds. Money market funds are valued using quoted market prices.

5. Other Accrued Liabilities

At September 30, 2017, other accrued liabilities consisted of accrued expenses for interest of $863,000, expenses for services of $178,000 and payroll withholding liabilities of $114,000. 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 September 30, 2017. At December 31, 2016, other accrued liabilities consisted of accrued expenses for interest of $340,000, expenses for services of $105,000 and payroll withholding liabilities of $51,000.

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 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 and nine months ended September 30, 2017.

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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 and nine months ended September 30, 2017.

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. For the three and nine months ended September 30, 2016, financing costs of $61,000 and $997,000 respectively, allocated to the derivative liability and Warrant components were expensed and are included in other expense in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

As of September 30, 2017, the Convertible Notes consisted of the following:

	September 30, 2017 (in thousands, except conversion rate and conversion price)
Principal value	$ 23,000
Unamortized debt discount	(7,357)
Unamortized debt issuance costs	(1,106)
Carrying value of the convertible notes	$ 14,537
Conversion rate (shares of common stock per $1,000 principal amount of notes)	191.9386
Conversion price (per share of common stock)	$ 5.21

For the three and nine months ended September 30, 2017, the Company recognized interest expense associated with its Convertible Notes as follows:

	Three Months ended September 30, 2017 (in thousands)	Nine Months ended September 30, 2017 (in thousands)
Cash Interest Expense		
Coupon interest expense	$ 517	$ 1,557
Noncash Interest Expense		
Amortization of debt discount	393	1,143
Amortization of transaction costs	60	174
	$ 970	$ 2,874

As of September 30, 2017, the unamortized debt discount will be amortized over a remaining period of approximately 3.59 years. The if-converted value as of September 30, 2017 does not exceed the principal balance of the Convertible Notes. Accrued interest payable on September 30, 2017 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 2016 Annual Report on Form 10-K. For the nine months ended September 30, 2017, interest expense on the Company s Consolidated Statement of Operations and Comprehensive Loss is primary composed of interest expense associated with the Convertible Notes but also includes $8,000 of other miscellaneous interest expense.

7. Revenue Recognition

Adoption of ASC Topic 606, Revenue from Contracts with Customers

On January 1, 2017, the Company adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of January 1, 2017. Results for reporting periods beginning after January 1, 2017 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company s historical accounting under Topic 605.

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The adoption of the new revenue recognition guidance resulted in increases of $6.0 million in deferred revenue and the accumulated deficit as of January 1, 2017. For the three and nine months ended September 30, 2017, revenue increased by $2.6 million and $11.7 million, respectively, for services performed in the period which under the prior milestone recognition methodology would not be recognized until the milestone was achieved. For the three and nine months ended September 30, 2017, net loss decreased by $2.6 million and $11.7 million, and basic and diluted net loss per share decreased by $0.18 and $0.79 per share, respectively.

The following table shows the reconciliation of contract liabilities from what was disclosed in the Form 10-K for the year ended December 31, 2016 and gives effect to the modified retrospective adoption of the revenue guidance on January 1, 2017 (in thousands):

Deferred Revenue, balance at December 31, 2016	$ 5,000
Changes in estimated consideration	
Unsatisfied performance obligations	6,026
Deferred Revenue, balance at January 1, 2017	$ 11,026

Revenue Recognition

Revenues are recognized for services as they are satisfied over time, and the Company recognizes revenue for licenses of functional intellectual property at the point in time the customer can use and benefit from the license.

For additional detail on the Company s accounting policy regarding revenue recognition, refer to Note 2 above.

The following table presents changes in the Company s contract assets and liabilities for the nine months ended September 30, 2017.

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
		(in thousands)		
Contract Assets	$	$ 13	$	$ 13
Contract Liabilities: Deferred Revenue	$ 11,026	$ 5,356	$ (12,004)	$ 4,378

During the nine months ended September 30, 2017, the Company recognized the following revenues (in thousands).

Revenue recognized in the period from:	
Amounts included in contract liabilities at the beginning of the period:	
Performance obligations satisfied	$ 7,083
Changes in the period:	
Changes in the estimated transaction price allocated to performance obligations satisfied in prior periods	4,521

Performance obligations satisfied from new activities in the period - contract revenue	441
Performance obligations satisfied from new activities in the period - grant revenue	51
Total revenue	$ 12,096

8. Collaboration Agreement

Grifols License and Collaboration Agreement

See Note 8 to the audited consolidated financial statements included in Part II, Item 8 of the 2016 Annual Report on Form 10-K for information on the Grifols Collaboration Transaction. Grifols is a 35% shareholder and, thus, a related party of the Company.

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Upon adoption of ASU No. 2014-09, the Company deferred $6.0 million for the portion of the transaction price allocated to development phase services delivered prior to January 1, 2017, which under the new guidance is allocated to unsatisfied (or partially satisfied) performance obligations as of January 1, 2017. As a result of adoption, an additional $2.7 million and $11.8 million of contract revenue was recognized for performance obligations satisfied during the three and nine months ended September 30, 2017, respectively. 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 September 30, 2017, the Company has achieved two of the six milestones and has received $10.0 million in payments.

The Company s performance obligations include those related to the worldwide license to commercialize products developed from the collaboration 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, and regulatory approval services in the US and EU for the first indication. 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 do not include a material right.

Milestone payments related to regulatory approval services are considered variable consideration and excluded from the transaction price as of the date of adoption. In the second quarter of 2017, the Company determined that the $5.0 million milestone payment associated with NDA submission (the first regulatory filing) is probable and updated the estimated transaction price accordingly. The milestone payment was allocated to the performance obligations based upon relative estimated selling prices resulting in recognition of $4.5 million for performance obligations that had been satisfied in prior periods. Milestone payments related to regulatory approval services have been excluded from the transaction price for the quarter ended September 30, 2017.

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.

The Company has deferred $4.2 million of the transaction price in the Grifols arrangement that is allocated to the performance obligations that are unsatisfied (or partially unsatisfied) as of September 30, 2017.

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 Income/(Loss) for the three and nine months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Costs and expenses:				
Research and development	$ 368	$ 190	$ 1,001	$ 564
General and administrative	368	196	898	621
Total stock-based compensation expense	$ 736	$ 386	$ 1,899	$ 1,185

There was no capitalized stock-based employee compensation cost for the three and nine months ended September 30, 2017, and 2016. Since the Company did not record a tax provision during the quarters ended September 30, 2017, and 2016, there was no recognized tax benefit associated with stock-based compensation expense.

In March 2016, the Company granted to the Officers certain stock option bonus awards, (contingent upon shareholder approval that was received in June 2016) that vested based upon meeting certain specified company-wide performance goals. In June 2017, the Company granted to the Officers additional stock awards whose vesting was also dependent upon meeting 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. In June 2017, the Company also canceled certain officer stock option awards made in March 2016 as the specified company-wide performance goal was not achieved.

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-

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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 nine months ended September 30, 2017:

	Shares Available for Future Grant
Balance at January 1, 2017	1,510,272
Increase in authorized shares	2,500,000
Options granted	(1,046,401)
Options canceled	179,963
Awards granted	(539,100)
Balance at September 30, 2017	2,604,734

	Options Outstanding			
	Number of Shares	**Weighted Average Exercise Price**	***Weighted Remaining Contractual Term***	**Aggregate Intrinsic Value**
Outstanding at January 1, 2017	1,923,595	$ 6.86		
Options granted	1,046,401	$ 1.73		
Options canceled	(179,963)	$ 6.82		
Outstanding at September 30, 2017	2,790,033	$ 4.94	7.97	$ 2,652,746
Exercisable at September 30, 2017	1,945,931	$ 5.57	7.67	$ 1,408,304

No stock options were exercised during the nine months ended September 30, 2017. The total amount of unrecognized compensation cost related to non-vested stock options and stock purchases was $1.4 million as of September 30, 2017. This amount will be recognized over a weighted average period of 1.11 years. There also was $221,000 of unrecognized compensation expense related to the current ESPP offering period that is expected to be recognized through March 2019. During the quarter ended March 31, 2017 the Board approved the issuance of approximately 360,000 stock options in aggregate, which vested immediately, to the Company s Officers in lieu of a cash bonus for their performance in 2016. The Company charged approximately $444,000 to accrued bonuses which were outstanding at December 31, 2016 related to these shares.

A summary of the activity of the Company s unvested restricted stock and performance bonus stock award activities for the nine months ending September 30, 2017 is presented below representing the maximum number of shares that could be earned or vested under the 2005 Plan and the 2015 Plan:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance at December 31, 2016	152,238	$ 3.96
Restricted shares granted	539,100	$ 1.39
Restricted share awards vested	(43,588)	$ 2.24
Balance at September 30, 2017	647,750	$ 1.94

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 September 30, 2017, there was approximately $352,000 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 0.59 years.

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10. Net Loss and Comprehensive Loss Per Common Share

The Company computes basic net loss per common share using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of shares of common stock subject to repurchase. The effects of including the incremental shares associated with options, warrants and unvested restricted stock are anti-dilutive, and are not included in the diluted weighted average number of shares of common stock outstanding for the nine months ending September 30, 2017 and 2016.

The Company excluded the following securities from the calculation of diluted net loss per common share for the nine months ended September 30, 2017 and 2016, as their effect would be anti-dilutive (in thousands):

	Nine months ended September 30,	
	2017	2016
Common shares underlying convertible notes	4,415	4,263
Outstanding stock options	2,790	1,686
Common shares underlying warrants	263	334
Unvested restricted stock	227	157
Unvested restricted stock units	10	10

11. Lease Commitment

The Company has 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 U.S. generally accepted accounting principles, the Company recognizes rent expense on a straight-line basis. The Company recorded deferred rent for the difference between the amounts paid and recorded as an expense. At September 30, 2017, the Company had $21,000 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 September 30, 2017, are as follows:

For the year ended September 30,	(in thousands)
2018	$ 478
2019	495
2020	512
2021	530
2022	548

Thereafter	279
Total	$ **2,842**

For the three and nine months ended September 30, 2017, base rental expense was approximately $152,000 and $363,000, respectively.

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

You should read the following management s discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the SEC on March 30, 2017 and other disclosures (including the disclosures under Part II. Item 1A. Risk Factors) included in this Quarterly Report on Form 10-Q.

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of products for the treatment 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 that completed two Phase 3 clinical trials, Linhaliq inhaled ciprofloxacin, formerly known as Pulmaquin®. 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 candidate products.

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. Pulmonary delivery by inhalation is an effective, widely used and well-accepted method of administration of a variety

of drugs for the treatment of respiratory and other diseases. Compared to other routes of administration, inhalation provides local delivery of the drug to the respiratory tract which offers a number of potential advantages, including rapid onset of action, less drug required to achieve the desired therapeutic effect, and reduced side effects because the rest of the body has lower exposure to the drug. We believe that there 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 the patients.

In selecting our proprietary development programs, we primarily seek drugs approved by 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. The formulations differ in the proportion of rapidly available and slow release

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

In December 2016, we announced top-line results for the Phase 3 studies for Linhaliq in NCFBE, which consisted of the two worldwide, double-blind, placebo-controlled pivotal trials, ORBIT-3 and ORBIT-4, that were identical in design except for a pharmacokinetics sub-study that was conducted in one of the trials. We held pre-NDA meetings with the FDA in December 2016 and March 2017 to discuss our Phase 3 studies.

In July 2017, we submitted a New Drug Application, or NDA, to the FDA for Linhaliq for the treatment of NCFBE patients with chronic lung infections with *P. aeruginosa*. Pursuant to the Food and Drug Administration Modernization Act of 1997 (FDAMA) Sec. 115(a) and FDA guidance, *Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* (May 1998), we submitted the Linhaliq NDA based on the positive pivotal clinical trial ARD-3150-1202 (ORBIT-4) and confirmatory evidence from Phase 3 study ARD-3150-1201 (ORBIT-3) and Phase 2b study ARD-3150-0902 (ORBIT-2), together with other supporting evidence from proprietary preclinical and clinical studies, as well as referencing other information about ciprofloxacin from publicly available sources.

In September 2017, the FDA completed the 60-day filing review period and accepted the NDA for filing. The PDUFA (Prescription Drug User Fee Act) goal date for completion of the FDA review of the Linhaliq NDA is January 26, 2018.

In August 2013, we entered into a partnership with Grifols whereby we licensed to Grifols, on an exclusive, world-wide 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.

Liposomal Ciprofloxacin for Non-Tuberculous Mycobacteria

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 mycobacteria (PNTM) infections, *Mycobacterium avium (M. avium)* and *Mycobacterium abscessus (M. abscessus)*, with Linhaliq and Lipoquin. 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.

According to a report from NIH 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 per 100,000 persons, or 8.2% per year. Forty-four percent of PNTM-affected people in the study had bronchiectasis compared to 1% in the non-PNTM cases, pointing to an important co-morbidity. PNTM infections are common also in patients with other chronic lung conditions, such as CF and emphysema.

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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.

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

In May 2015, we announced that scientists from OSU and Aradigm demonstrated that Aradigm s investigational drugs Lipoquin and Linhaliq significantly reduced the growth of PNTM after 3 weeks of once daily respiratory tract dosing in mice. The number of colony forming units (CFUs) of *Mycobacterium avium subsp hominissuis* was reduced by 79% and 77% by Lipoquin and 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 *M. 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.

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

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

In October 2016, we announced that the U.K. Defence Science and Technology Laboratory, or Dstl has 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, commenced research

related to the efficacy of Linhaliq and Lipoquin in animal models of a number of life threatening or severely debilitating infections including *Francisella tularensis* (tularemia), *Burkholderia pseudomallei* (melioidosis), *Burkholderia mallei* (glanders) and *Coxiella burnetii* (Q-fever). As 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 it there over a prolonged period of time. The liposomal formulation also facilitates intracellular uptake, essential to treat these life-threatening intracellular infections.

If we can obtain sufficient additional funding, including government grants or collaborative funding from organizations such as the Canadian DRDC and the UK Dstl, we may be able to complete the development of our liposomal ciprofloxacin for approval under FDA regulations relating to new drugs or biologics for potentially fatal diseases where human studies cannot be conducted ethically or practically. Unlike most drugs, which require large, well-controlled Phase 3 clinical trials in patients with the disease or condition being targeted, these regulations allow a drug to be evaluated and approved by the FDA on the basis of demonstrated safety in humans

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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.

Critical Accounting Policies and Estimates

We consider certain accounting policies related to revenue recognition, impairment of long-lived assets, exit/disposal activities, research and development, income taxes and stock-based compensation to be critical accounting policies that require the use of significant judgments and estimates relating to matters that are inherently uncertain and may result in materially different results under different assumptions and conditions. The preparation of financial statements in conformity with United States generally accepted accounting principles requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes to the consolidated financial statements. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization periods for payments received from product development and license agreements as they relate to the revenue recognition, and assumptions for valuing options, warrants and other stock-based compensation. Our actual results could differ from these estimates.

Revenue Recognition

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.

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. We have both fixed and variable consideration. Non-refundable upfront fees and funding of research and development activities are considered fixed, while milestone payments are identified as variable consideration.

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) satisfies each performance obligation.

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. 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. 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.

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. We use key assumptions to

determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

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. 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.

Licenses of intellectual property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined

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performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone payments: 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.

Royalties: 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). To date, we have not recognized any royalty revenue resulting from any of our current licensing arrangements.

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 discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any additional payments are recorded in license, collaboration, and other revenues when the customer obtains control of the goods, which is upon delivery.

Impairment of Long-Lived Assets

We review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, we write down the assets to their estimated fair values and recognize the loss in the consolidated statements of operations.

Research and Development

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

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.

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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 10 to the consolidated financial statements included in our 2016 Annual Report on Form 10-K.

Income Taxes

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

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including our historical levels of income and losses, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If we do not consider it more likely than not that we will recover our deferred tax assets, we will record a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. At September 30, 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 the accompanying unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for information on recent accounting pronouncements.

Adopting ASU No. 201-09, *Revenue from Contracts with Customers*, or the new revenue standard, involves significant estimates and judgments related to variable consideration and the constraint on variable consideration, including an estimate of returns and the probability of development and regulatory milestones. Another significant area of judgment relates to the estimates of standalone selling prices and the allocation of discounts and variable consideration in allocating the transaction price. We expect that revenue will be recognized earlier under the new standard and may have more variability due to significant estimates involved in the new accounting.

Results of Operations

Three and nine months ended September 30, 2017 and 2016

Our net loss decreased by $4.3 million for the three months ended September 30, 2017 as compared with the three months ended September 30, 2016. For the quarter ended September 30, 2017, the decrease in net loss resulted primarily from an increase in revenue of $2.7 million and a decrease in operating expenses of $1.6 million.

Our net loss decreased by $18.5 million for the nine months ended September 30, 2017 as compared with the nine months ended September 30, 2016. For the nine months ended September 30, 2017, the decrease in our net loss resulted primarily from an increase in revenue of $12.0 million, a decrease in operating expenses of $7.2 million offset by an increase in interest and other expense of $0.7 million.

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For both the three and nine months ended September 30, 2017, the increase in revenue resulted from the adoption of ASU No. 2014-09 and the recognition of revenue allocated to partially satisfied performance obligations which are being recognized over time based on a cost-plus reasonable margin method. During the nine months ended September 30, 2017, we made a change in estimated variable consideration and included the $5.0 million milestone for filing the U.S. NDA in the transaction price. Of the $5 million, we recognized $4.5 million that was allocated to performance obligations satisfied in prior periods. During the three and nine months ended September 30, 2017, 20% and 98% of the total program spend for regulatory submission services were recognized, respectively, as compared to 0% for the three and nine months ended September 30, 2016. During the three and nine months ended September 30, 2017, 31% of the total program spend for regulatory approval services was recognized, as compared to 0% for the three and nine months ended September 30, 2016.

For both the three and nine months ended September 30, 2017, the decrease in operating expense related to the completion of Phase 3 clinical trials for Linhaliq in NCFBE in the fourth quarter of 2016. During both the three and nine months ended September 30, 2017, the increase in interest expense was due to the Convertible Notes financing which took place in 2016. During both the three and nine months ended September 30, 2017, the decrease in other income /(expense) compared to the three and nine months ended September 30, 2016 resulted from the one-time financing costs allocated to the derivative liability and warrants which were expensed immediately upon the first closing of the Convertible Notes in the three months ended June 30, 2016.

Total revenue was $2.7 million for the three months ended September 30, 2017, as compared with $50,000 in the comparable period in 2016. For the three months ended September 30, 2017, we recorded $1.3 million and $1.4 million in revenue under the Grifols agreement for regulatory submission services related to the filing of the NDA, and regulatory approval services related to the NDA, respectively. No revenue was recognized for the aforementioned contract components in the comparable period.

Total revenue was $12.1 million for the nine months ended September 30, 2017, as compared with $70,000 in the comparable period in 2016. For the nine months ended September 30, 2017, we updated our expected consideration associated with milestone payments resulting in the addition of $5.0 million to the transaction price for the Grifols agreement, and we recorded $3.9 million, $6.2 million, $1.4 million and $0.4 million in revenue under the Grifols agreement for the increase in variable consideration allocated to research and development services performed in prior periods, regulatory submission services related to the filing of the NDA performed in the period, regulatory approval services related to the NDA performed in the period and the increase in variable consideration allocated to the previously delivered license, respectively. No revenue was recognized for the aforementioned contract components in the comparable period. Contract revenue related party was zero for both the three and nine months ended September 30, 2016, as we had fully utilized the $65 million of the Grifols-funded budget provided under the License Agreement for the Linhaliq NCFBE program. However, due to the modified retrospective adoption of ASU 2014-09, there has been a reallocation amongst the contract elements which resulted in a deferral of revenue that had previously been recognized for the reimbursement of Phase 3 clinical studies and is now being recognized in 2017 as regulatory submission and approval services are performed.

Operating expenses were $5.7 million for the three months ended September 30, 2017, which represented a $1.6 million decrease from the three months ended September 30, 2016. Research and development expenses decreased $2.3 million and general and administrative expenses increased approximately $0.7 million as compared with the three months ended September 30, 2016. The decrease in research and development expenses was due to lower contract testing and clinical trial costs because the testing, labeling and packaging expenses for clinical supplies and the patient activities of the Linhaliq Phase 3 clinical trials were completed in 2016, offset by higher employee-related expenses, higher consulting expenses in support of the Linhaliq bronchiectasis regulatory process for US and EU approvals for market authorization and higher stock compensation expense. The increase in general

and administrative expenses was primarily related to higher performance bonus expense, higher legal expense, higher non-cash stock compensation expense and higher consulting expenses.

Operating expenses were approximately $15.8 million for the nine months ended September 30, 2017, which represented a $7.2 million decrease from the nine months ended September 30, 2016. Research and development expenses decreased approximately $8.4 million and general and administrative expenses increased approximately $1.2 million. The decrease in research and development expenses was due to lower contract testing and clinical trial costs because the testing, labeling and packaging expenses for clinical supplies and the patient activities of the Linhaliq Phase 3 clinical trials were completed in 2016, the receipt and recording of the Australian research and development credit, offset by higher employee-related expenses, higher consulting expenses in support of the Linhaliq bronchiectasis regulatory process for US and EU approvals for market authorization and higher non-cash stock compensation expenses. The increase in general and administrative expenses was primarily related to higher performance bonus expense, higher legal expense, higher non-cash stock compensation expense, higher consulting expenses and higher corporate insurance expense.

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Liquidity and Capital Resources

As reflected in the accompanying condensed consolidated financial statements, we had an accumulated deficit of $451.0 million as of September 30, 2017, that included a net loss of $6.5 million for the nine months ended September 30, 2017, which raises doubt about our ability to continue as a going concern. We believe that our cash and cash equivalents as of September 30, 2017, will be sufficient to fund our operations at least through 2017. We will need to raise additional capital in 2017 or early 2018 to maintain our current level of product development activity. Accordingly, we anticipate raising additional capital in 2017 or early 2018 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 leading 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.

In 2016, we sold $23,000,000 in aggregate principal amount of our Convertible Notes and 263,436 related warrants to purchase our common stock in the Note Financing. The Note Financing consisted of two closings, one on April 25, 2016, and one on July 14, 2016. 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, and the Convertible Notes will 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 our existing and future unsecured indebtedness that is not subordinated and are effectively subordinated in right of payment to our existing and future secured indebtedness. The Convertible Notes are also initially convertible into our common stock at a conversion rate of 191.9386 shares of common stock per $1,000 principal amount of Convertible Notes, representing an initial effective conversion price of $5.21 per share of common stock.

We have funded our operations with a variety of financing arrangements including 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.

Nine months ended September 30, 2017

Total cash and cash equivalents decreased by approximately $10.0 million for the nine months ended September 30, 2017. The decrease primarily resulted from the use of cash to fund our ongoing operations in support of our Linhaliq program, offset by the receipt of $670,000 from the Australian Tax Office related to the Australian research and development program and the receipt of the $5.0 million milestone payment related to the submission of the U.S. NDA under the Grifols contract.

Nine months ended September 30, 2016

Total cash and cash equivalents decreased by approximately $3.0 million for the nine months ended September 30, 2016. The decrease reflects cash used in operating activities totaling $21.7 million and cash used in investing activities totaling $2.1 million during the nine months ended September 30, 2016. The cash burn from operating and investing activities was offset by the receipt of $20.9 million in net proceeds from the Note Financing.

Off-Balance Sheet Financings and Liabilities

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

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.

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Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of the end of the period covered by this report, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the, Exchange Act)) were effective as of the end of the period covered by this report to ensure that information that we are required to disclose in reports that management files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our Chief Executive Officer and Chief Financial Officer have concluded that these controls and procedures are effective at the reasonable assurance level. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

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

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 Lipoid-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 will decide whether to institute post grant review of the 845 Patent. If the PGR is instituted, PTAB should issue a Final Written Decision addressing validity of patent claim(s) within 18 months of the filing date.

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 timing and results of clinical trials, the maintenance and establishment of corporate partnering arrangements, the anticipated commercial introduction of our products and the timing of our cash requirements. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those expressed in, or implied by, any such

forward-looking statements. Potential risks and uncertainties include, without limitation, those mentioned in this report and in particular the factors described below.

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 2016 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 2016 Annual Report on Form 10-K.

Risks Related to Our Business

Although our financial statements have been prepared on a going concern basis, we will require additional financing to finance our operating expenses and fulfill our business plan.

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Our independent registered public accounting firm for the fiscal year ended December 31, 2016 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 $12.6 million as of September 30, 2017 will be sufficient to fund our operations through at least 2017. We will not be able to maintain our current level of regulatory and product development activity unless we raise additional capital in 2017 or early 2018. 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 leading product candidate Linhaliq. We cannot assure you that we will be successful in raising additional capital on favorable terms or at all. 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 potentially require disposal of assets or technology, and we may not be able to continue as a going concern.

*****The FDA may not approve Linhaliq for marketing.***

We have focused primarily on the development of our leading 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. While the FDA accepted our NDA submission for filing, the FDA retains complete discretion in deciding whether or not to approve the NDA. Additionally, the FDA has indicated that it plans to convene an Advisory Committee of independent experts, including clinicians and other scientific experts, to review, evaluate and provide recommendations as to whether the NDA should be approved and under what conditions. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions. 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 they may identify related to our development of Linhaliq for the treatment of NCFBE.

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

We and our products are subject to extensive and rigorous regulation by the federal government, principally the FDA, and by state and local government agencies. Both before and after regulatory approval, the development, testing, manufacture, quality control, labeling, storage, approval, advertising, promotion, sale, distribution and export of our potential products are subject to regulation. Pharmaceutical products that are marketed abroad are also subject to regulation by foreign governments. Our products cannot be marketed in the United States without FDA approval.

The process for obtaining FDA approval for drug products is generally lengthy, expensive and uncertain. The FDA and other foreign regulatory agencies can delay approval of, or refuse to approve, our product candidates for a variety of reasons, including failure to meet safety and/or efficacy endpoints in our clinical trials.

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 approval for any of our product candidates, we may not be able to maintain such approval, which would reduce our revenues.

Even if we are granted initial regulatory approval for a product candidate, the FDA and similar foreign regulatory agencies can limit or withdraw product approvals for a variety of reasons, including failure to comply with regulatory requirements, changes in regulatory requirements, problems with manufacturing facilities or processes or the occurrence of unforeseen problems, such as the discovery of previously undiscovered side effects. 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

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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 review and approval. Advertising and other promotional material must comply with FDA requirements. We, our collaborators and our manufacturers will be subject to continuing review and periodic inspections by the FDA and other authorities, where applicable, and must comply with ongoing requirements, including the FDA s GMP requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA and make certain other required reports. Product approvals may be withdrawn if regulatory requirements are not complied with or if problems concerning safety or efficacy of the product occur following approval. Any limitation or withdrawal of approval of any of our products could delay or prevent sales of our products, which would adversely affect our revenues. Further continuing regulatory requirements may involve expensive ongoing monitoring and testing requirements.

We are a development-stage company and will require substantial capital to complete the development of our product candidates and commercialize them.

We are a development-stage company and our ability to generate revenue and become profitable depends on our ability to successfully complete the development of our product candidates. All of our potential products are in research or development, and we will need to raise additional capital prior to approval and commercialization of our leading product candidate, 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, 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.

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

We compete with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of drugs and therapies for the disease indications we are targeting. Our competitors may succeed, and many already have succeeded, in developing competing technologies for the same disease indications, obtaining FDA approval for products or gaining acceptance for the same markets that we are targeting. If we are not first to market, it may be more difficult for us and our present and future collaborators to enter markets as second or subsequent competitors and become commercially successful.

We are aware of a number of companies that are developing or have developed therapies to address indications we are targeting, including major pharmaceutical companies such as Bayer. The FDA has granted orphan drug designation for our liposomal ciprofloxacin product candidate and the designation provides the opportunity to obtain market exclusivity for seven years from the date of the FDA s approval. Our ability to launch our product in the United States could be blocked if another similar product developed by our competitors is approved by the FDA for the same indication before our product, unless we are able to demonstrate to the FDA clinical superiority of our product on the basis of safety or efficacy. For example, Bayer is developing an inhaled dry powder

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formulation of ciprofloxacin for the treatment of respiratory infections in CF and NCFBE and 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 has filed an NDA for U.S. approval and was granted Priority Review. The FDA has scheduled an Advisory Committee for review of Bayer s dry powder ciprofloxacin for the treatment of bronchiectasis for November 16, 2017.

There are also a number of other inhaled products under development to treat respiratory infections, including a nebulized levofloxacin by Raptor (acquired by Horizon) for CF and 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.

*****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 has filed an NDA for U.S. approval and the FDA has scheduled an Advisory Committee for review of Bayer s dry powder ciprofloxacin for the treatment of bronchiectasis for November 16, 2017.

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

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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.

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 will have 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 may 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.

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

Even if we or our collaborators successfully develop one or more products, such products may not be commercially acceptable to healthcare professionals and patients, who will have to choose our products over alternative products for the same disease indications. 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;
- 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 and have filed a PGR petition in the PTAB challenging the validity of the claims of the Insmed 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 will decide whether to institute post grant review of the 845 Patent. We cannot assure you that the PTAB will decide to institute a review and, even if such review were to occur, PTAB may not decide the petition in our favor.

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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.

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

We have never been profitable and have incurred significant losses in each year since our inception. As of September 30, 2017, we have an accumulated deficit of approximately $451.0 million. We have not had any direct product sales and do not anticipate receiving revenues from the sale of any of our products in 2017, if ever. While our agreement with Grifols has resulted in reduced operating expenses and capital expenditures as a portion of our research and development expenses for the Linhaliq program was reimbursed by Grifols we expect to continue to incur losses for the foreseeable future as we:

- continue drug product development efforts;
- conduct preclinical testing and clinical trials;
- pursue additional applications for our existing delivery technologies; and
- outsource the commercial-scale production of our products.

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

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 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. Losing any of our key employees, particularly our President and Chief Executive Officer, Dr. Igor Gonda, our Chief Medical Officer, Dr. Juergen Froehlich, or Nancy Pecota, our Chief Financial Officer, could impair our product development efforts and otherwise harm our business. Any of our employees may terminate their employment with us at will.

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

If we market any approved products in foreign countries, we will be subject to different laws and regulations, particularly with respect to intellectual property rights and regulatory approval. To maintain a proprietary market position in foreign countries, we may seek to protect some of our proprietary inventions through foreign counterpart patent applications. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. The diversity of patent laws may make our expenses associated with the development and maintenance of intellectual property in foreign jurisdictions more expensive than we anticipate. We 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 adequate reimbursement status of newly approved health care products. Any products we are able to successfully develop may not be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. If any products we develop do not receive adequate reimbursement, our revenues will be severely limited.

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

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

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal year. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, 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 2016 and subsequent foreseeable fiscal years, we expect to be exempt from such requirement. However, our ability to comply with the annual internal control report requirements will depend on the effectiveness of our financial reporting and data systems and controls across our company. We expect these systems and controls to involve significant expenditures and to become increasingly complex as our business grows. To effectively manage this complexity, we will need to continue to improve our operational, financial and management controls and our reporting systems and procedures. Any failure to implement required new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Risks Related to Our Common Stock

Our stock price is likely to remain volatile.

The market prices for securities of many companies in the drug delivery and pharmaceutical industries, including ours, have historically been highly volatile, and the market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. The market prices for our common stock may also be influenced by many factors, including:

- the limited trading volume for shares of our common stock and the fact that a large percentage of our outstanding shares are held by a small number of shareholders;
- announcements of clinical trial results, technological innovations or new commercial products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- delays in the development or approval of our product candidates;
- regulatory developments in both the United States and foreign countries;
- sales of our stock by certain large institutional shareholders;

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

fluctuations in our operating results;

failure to maintain or establish collaborative relationships;

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

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.

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

In addition, although our shares are currently listed by NASDAQ, we cannot assure you that we will be successful in maintaining a NASDAQ listing continuously or that we will be able to meet NASDAQ listing standards going forward.

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

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

We have adopted a shareholder rights plan, commonly known as a poison pill. We have also adopted an executive officer severance plan and entered into change of control agreements with our executive officers, both of which may provide for the payment of benefits to our officers and other key employees in connection with an acquisition. The provisions of our articles of incorporation, our poison pill, our severance plan and our change of control agreements, and provisions of the California Corporations Code may discourage, delay or prevent another party from acquiring us or reduce the price that a buyer is willing to pay for our common stock.

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

We have never paid dividends on our capital stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and growth of our business. Therefore, our shareholders may not receive any funds absent a sale of their shares. We cannot assure shareholders of a positive return on their investment if they sell their shares, nor can we assure that shareholders will not lose the entire amount of their investment.

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

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

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

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Our principal shareholders own a large percentage of our common stock and will be able to exert a significant control over matters submitted to our shareholders for approval.

A small number of our shareholders own a large percentage of our common stock and can, therefore, influence the outcome of matters submitted to our shareholders for approval. Based on information known to us, our two largest shareholders, collectively, control approximately 62% of our outstanding common stock. These two shareholders purchased most of the Convertible Notes and related Warrants described in Note 6 to the unaudited condensed consolidated financial statements included in Item 1 of this report, leading to a corresponding increase in their respective ownership on a fully-diluted basis. As a result, these shareholders have the ability to influence the outcome of matters submitted to our shareholders for approval, including certain proposed amendments to our amended and restated articles of incorporation (for example, amendments to increase the number of our authorized shares) and any other material transactions we may undertake in the future, such 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.

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.

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Item 6. EXHIBITS

Exhibit Number	Description
3.1 (1)	Amended and Restated Articles of Incorporation of the Company.
3.2 (2)	Certificate of Determination of Series A Junior Participating Preferred Stock.
3.3 (3)	Amended and Restated Certificate of Determination of Preferences of Series A Convertible Preferred Stock.
3.4 (2)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.5 (2)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.6 (4)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.7 (4)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.8 (5)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.9 (6)	Certificate of Correction to Certificate of Amendment of Articles of Incorporation of the Company.
3.10 (7)	Certificate of Amendment of Articles of Incorporation of the Company.
3.11 (2)	Amended and Restated Bylaws of the Company, as amended.
3.12 (8)	Certificate of Amendment of the Amended and Restated Bylaws of the Company.
3.13	Fifth Amendment to Lease with HCP Estates USA Inc.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10, 3.11, and 3.12.
4.2 (1)	Specimen common stock certificate.
31.1	Certification of the Principal Executive Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.1	The following materials from the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 are formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

(1) Incorporated by reference to the Company s Form S-1 (No. 333-04236) filed on April 30, 1996, as amended.
(2) Incorporated by reference to the Company s Form 10-Q filed on August 14, 1998.
(3) Incorporated by reference to the Company s Form S-3 (No. 333-76584) filed on January 11, 2002, as amended.

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

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SIGNATURES

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

ARADIGM CORPORATION

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

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

Dated: November 3, 2017