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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 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)

Registrant's telephone number, including area code:
(510) 265-9000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, no par value	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or 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	☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock on June 30, 2017 was approximately $7,658,222.

The number of shares of the registrant's common stock outstanding as of March 12, 2018 was: 15,170,200.

DOCUMENTS INCORPORATED BY REFERENCE

Parts of the Registrant's Proxy Statement for the 2018 Annual Meeting of Shareholders to be held on June 27, 2018, or the 2018 Annual Meeting of Shareholders, are incorporated by reference into Part III of this Annual Report on Form 10-K. Except as expressly incorporated by reference, the Registrant's Proxy Statement for the 2018 Annual Meeting of Shareholders shall not be deemed to be a part of, or incorporated by reference in, this Annual Report on Form 10-K.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based on the current beliefs of management, as well as current assumptions made by, and information currently available to, management. All statements contained in this Annual Report on Form 10-K, other than statements that are purely historical, are forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "may," "will," "could," "continue," "seek," "estimate," or the negative thereof and similar expressions also identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause our future actual results, performance or achievements to differ materially from those expressed in, or implied by, any such forward-looking statements as a result of certain factors, including, but not limited to, those risks and uncertainties discussed in this section, as well as Item 1A—"Risk Factors", in this Annual Report on Form 10-K and in our other filings with the United States Securities and Exchange Commission, or the SEC. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements regarding: (i) our belief that our cash and cash equivalents as of December 31, 2017 will only be sufficient to fund our operations through the first quarter of 2018, (ii) our business strategies, including our intent to pursue selected opportunities for prevention and treatment of severe respiratory diseases by seeking collaborations, government grants and other non-dilutive types of financing that will fund development and commercialization; (iii) our ability to obtain any further regulatory authority clearances (EMA) or approvals for our lead development product candidate, Linhaliq™, and other product development candidates; (iv) our reliance on our collaboration partners such as Grifols and third-party contract manufacturers and our ability to maintain partnerships; (v) our strategy to commercialize certain of our unlicensed respiratory product candidates (vi) our plans to work with the US and other allied governments to supply them with our inhaled antibiotic for biodefense supplies; (vii) our intent to use our pulmonary delivery methods and formulations of drugs and biologics to improve their safety, efficacy and convenience of administration to patients; (viii) our expectations regarding future clinical trials; and (ix) our expectation that we will incur additional operating losses.

These forward-looking statements and our business are subject to significant risks such as the risks and uncertainties discussed in the section entitled "Risk Factors," including, but not limited to, our ability to maintain and/or enter into partnering agreements. Even if product candidates appear promising at various stages of development, they may not reach the market or may not be commercially successful for a number of reasons. Such reasons include, but are not limited to, the possibilities that the potential products may be found to be unsafe in animal or human trials, ineffective during clinical trials, may fail to receive necessary regulatory approvals, may be difficult to manufacture on a large scale, are uneconomical to market, may be precluded from commercialization by proprietary rights of third parties, may not be purchased by government organizations for biodefense, or may not gain acceptance from healthcare professionals, health insurance companies, third party payors and patients.

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

PART I

Item 1. *Business*

Overview

Aradigm Corporation (the "Company," "our company," "we," "our," or "us") 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 recently completed two Phase 3 clinical trials, Linhaliq inhaled ciprofloxacin, formerly known as Pulmaquin®. The key asset we have focused our efforts on in recent years is our inhaled ciprofloxacin formulations.

We believe that our cash and cash equivalents of approximately $7.1 million as of December 31, 2017, will only be sufficient to fund our operations for the first quarter of 2018. We will not be able to maintain our current level of regulatory and product development activity and there is substantial doubt about our company's ability to continue as a going concern unless we raise additional capital in early 2018. Accordingly, we need to raise additional capital through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise to enable us to maintain our business operations and to continue development of our lead product candidate Linhaliq and other products, and if we are unable to do so we will need to dispose of our assets or technology or cease operations. The discussion of future prospects of our business below is based on the assumption that we are able to obtain the necessary capital to continue to operate our business as described below.

On February 9, 2018, our Board of Directors approved temporary measures intended to preserve our cash resources until additional sources of capital can be identified. These cash preservation measures include, among other things, the termination of the Amended and Restated Aradigm Corporation Executive Officer Severance Benefit Plan, the reduction of the annual base salary of certain executive officers to 50% of their then current annual base salaries, and the reduction of cash compensation paid to members of the Board for services on the Board or committees of the Board to 50% of the then current cash compensation.

Effective February 11, 2018, each of Igor Gonda, President and Chief Executive Officer; Juergen Froehlich, Chief Medical Officer; and Nancy Pecota, Vice President, Finance, Chief Financial Officer and Corporate Secretary resigned all offices and positions held by him or her with Aradigm. In February, 2018, the Board appointed Dr. John Siebert, Chairman of the Board, to serve as Executive Chairman, Interim Principal Executive Officer, Acting Principal Financial Officer and Corporate Secretary. In addition, in February 2018, Dr. Gonda and David Bell resigned from the Board of Directors.

In July 2017, we submitted a New Drug Application, or NDA, to the U.S. Food & Drug Administration, or FDA, for Linhaliq for the treatment of non-cystic fibrosis bronchiectasis, or NCFBE, patients with chronic lung infections with *Pseudomonas aeruginosa*. In January 2018, we announced that the FDA provided a Complete Response Letter, or CRL, regarding the NDA stating that it cannot approve the NDA in its present form and providing specific reasons for this action along with recommendations needed for resubmission; the areas of concern include clinical data, human factors validation study and product quality. The recommendations in the CRL include an independent third party verification of the Phase 3 results via analyses of source data as per the statistical analysis plan, or SAP, and an additional Phase 3 clinical trial that demonstrates a significant treatment effect on clinically meaningful endpoints which could evaluate the co-primary endpoints of frequency and severity of exacerbations to assess for evidence of durable efficacy over a period of two years (or more, if scientifically justified). The CRL also included a request to conduct another Human Factors Study to demonstrate that the product packaging and instructions for use are effective, and the CRL requested, among other things, additional product quality information with respect to microbiology and a new in vitro drug release method development report. We plan to request a Type A post-action meeting with the FDA to discuss the topics covered

in the CRL as well as a potential path forward using the "limited population pathway" that was enacted in the 21st Century Cures Act.

In March 2018, we submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking approval for Linhaliq for the treatment of NCFBE patients with chronic lung infection with *P. aeruginosa*. Our submission is based on the positive Phase 3 clinical trials ARD-3150-1202 or Orbit 4 with a primary endpoint of frequency of exacerbations which differs from the U.S. FDA primary endpoint of time to first exacerbation and supporting evidence from proprietary preclinical and clinical studies, as well as referencing additional information about ciprofloxacin from publicly available sources. The company had pre-submission meetings with EMA in October and November of 2017 to discuss the results of these studies. The submission is expected to be validated by EMA at the end of March 2018 at which time Day 1 of the MAA review procedure will commence. The company expects to receive comments or questions 120 days after validation.

In addition, although our shares are currently listed on The Nasdaq Capital Market, or Nasdaq, on February 28, 2018, we received a notice from Nasdaq that, effective as of the appointment of Dr. John Siebert as our Executive Chairman and Interim Principal Executive Officer on February 11, 2018, we are no longer in compliance with Nasdaq's independent director and audit committee requirements as set forth in Nasdaq Listing Rule 5605. On March 9, 2018 we received a notice from Nasdaq, stating that based on information regarding the appointment of a new independent director to the Board and the Audit Committee, the staff of Nasdaq has determined that we now comply with Nasdaq Listing Rule 5605.

On March 7, 2018 we received a notice from Nasdaq that we are not in compliance with Nasdaq Listing Rule 5550(b)(1), as we have not maintained a minimum Market Value of Listed Securities of $35 million or shareholder's equity of at least $2.5 million among other requirements for continued listing. Pursuant to the Nasdaq Listing Rules, we have 180 days or until September 4, 2018, to regain compliance with the minimum shareholder's equity requirement. (For more information, see Item 1A—Risk Factors—"Nasdaq has notified us that we are no longer in compliance with Nasdaq's continued listing requirements. If we fail to regain compliance, we will be subject to delisting by Nasdaq. If we are delisted, our stock price may decline and the liquidity of our securities and our ability to raise capital could be significantly impaired.") We cannot assure you that we will be successful in regaining compliance with Nasdaq continued listing requirements or that we will be able to meet Nasdaq listing standards going forward.

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 still are significant unmet medical needs in the respiratory disease market, both to replace existing therapies that demonstrate suboptimal efficacy or undesired side effects over prolonged use in patients, as well as to provide novel treatments to patient populations and for disease conditions that are inadequately treated.

In selecting our proprietary development programs, we seek drugs approved by the FDA that can be reformulated for both existing and new indications in respiratory disease, or drugs that have been developed 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 costs, development times and risks of failure, when compared to the discovery of new drugs.

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 severe respiratory diseases such as NCFBE, cystic fibrosis, or CF, and

non-tuberculosis mycobacterium, or NTM. These product candidates are also tested for prophylaxis and treatment against potential bioterrorism infections. The formulations differ in the proportion of rapidly available and slow release ciprofloxacin. Linhaliq uses the slow release liposomal formulation (Lipoquin) mixed with a smaller amount of ciprofloxacin dissolved in an aqueous medium. We have been granted orphan drug designation from the FDA for Linhaliq for the management of Bronchiectasis (BE). We received orphan drug designations for Lipoquin for both CF and NCFBE in the United States and for CF in the EU. 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 was granted for the treatment of NCFBE patients with chronic lung infections with *P. aeruginosa*.

In August 2013, we entered into a collaboration with Grifols as part of our inhaled ciprofloxacin program for non-biodefense indications. We partnered with Grifols via a license and collaboration agreement, or the Grifols License Agreement, under which we granted Grifols an exclusive, worldwide license to our inhaled liposomal ciprofloxacin product candidates for the indication of non-NCFBE and other indications, as more fully described in Note 9 to the consolidated financial statements included in this Annual Report on Form 10-K. 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.

Additionally, we also entered into a governance agreement with Grifols, or the Grifols Governance Agreement, that sets forth certain rights and obligations of us and Grifols concerning, among other things, certain corporate governance matters, certain limitations on future acquisitions of shares of common stock by Grifols, and certain rights by Grifols to maintain a target level of ownership in us, as more fully described in Note 9 to the consolidated financial statements included in this Annual Report on Form 10-K.

Our strategy is to develop and commercialize products for the treatment of rare, severe respiratory diseases with unmet or poorly met patients' needs. Our goal is to use our pulmonary delivery methods and formulations to optimize the safety, efficacy, and convenience of administration to patients of already approved drugs or those discovered by others. We believe that this strategy will allow us to reduce costs, development times and risks of failure when compared to the discovery of new drugs.

We believe that our proprietary formulation and delivery technologies and our experience in the development and management of pulmonary clinical programs uniquely position us to benefit from opportunities in the respiratory disease market, as well as other disease markets that would benefit from the efficient, non-invasive inhalation delivery of drugs.

To date, we have not had any significant product sales and do not anticipate receiving revenues from the sale of any of our products in the near term. As of December 31, 2017, we had an accumulated deficit of $455.2 million. In 2016, we sold $23,000,000 in aggregate principal amount of our 9% senior notes convertible into shares of common stock due 2021, or the Convertible Notes, and 263,436 related warrants to purchase our common stock, or the Note Financing. Historically, we have primarily funded our operations through convertible debt such as the Note Financing, development expense reimbursements, license fees, milestone payments from collaborators, public offerings and private placements of our capital stock, the milestone and royalty payments associated with the sale of assets to a third party, a royalty financing transaction and interest earned on cash equivalents and short-term investments.

Our Strategy

We are a specialty pharmaceutical company, and our strategy is to develop and commercialize products for the treatment and prevention of severe respiratory diseases. We have a portfolio of proprietary technologies that may potentially address significant unmet medical needs for unique or significantly improved products in the global respiratory market. There are three key elements of our strategy:

- *Develop proprietary products for the treatment of respiratory diseases.* We believe our expertise in the development and delivery of pulmonary pharmaceutical products should enable us to advance and commercialize respiratory products for a variety of indications. We select for development those product candidates that can benefit from our experience in pulmonary delivery and that we believe are likely to provide a superior therapeutic profile or other valuable benefits to patients when compared to existing products.
- *Accelerate the regulatory approval process.* We believe that our management team's expertise in pharmaceutical inhalation products, new indications, and reformulations of existing drugs will enable us to pursue the most appropriate regulatory pathway for our product candidates. Because our current product candidates incorporate FDA-approved drugs, we believe that the most expedient review and approval pathway for these product candidates in the United States will be under Section 505(b)(2) of the Food, Drug and Cosmetic Act, or the FDCA. Section 505(b)(2) permits the FDA to rely on scientific literature or on the FDA's prior findings of safety and/or effectiveness for approved drug products. We have already been granted or intend to pursue orphan drug designation for our products when appropriate. Orphan drug designation may be granted to drugs and biologics that treat rare, life-threatening diseases that affect fewer than 200,000 persons in the United States. Such designation provides a company with the possibility of market exclusivity for 7 years as well as regulatory assistance, reduced filing fees, and possible tax credits. Similar legislation exists in the EU with a market exclusivity of 10 years. We also seek other special designations by FDA such as QIDP. Under the Generating Antibiotic Incentives Now Act, or the GAIN Act, QIDP provides incentives including priority review and eligibility for fast-track status. Further, if ultimately approved by the FDA, the product is eligible for an additional five-year extension of Hatch-Waxman exclusivity.
- *Outsource manufacturing activities.* We outsource the late-stage clinical and commercial scale manufacturing of our products to conserve our capital for product development. We believe that the required late-stage clinical and commercial manufacturing capacity can be obtained from contract manufacturers. With this approach, we seek manufacturers whose expertise should allow us to reduce risk and the costs normally incurred if we were to build, operate and maintain large-scale production facilities ourselves.

Partnered Programs Under Development

Inhaled Ciprofloxacin

See Part 1, Item 1 of the 2014 Annual Report on Form 10-K for additional information and discussion regarding earlier development efforts on Inhaled Ciprofloxacin.

We have been developing several disease indications for our inhaled ciprofloxacin that share much of the laboratory and product development efforts, as well as a common safety database.

Linhaliq and Lipoquin (ARD-3150 and ARD-3100)—Inhaled Ciprofloxacin for the Management of Infections in Non-Cystic Fibrosis Bronchiectasis (NCFBE) Patients

BE is a chronic condition characterized by abnormal dilatation of the bronchi and bronchioles associated with chronic infection. The patient's lung function is often irreversibly reduced compared to that in healthy individuals. BE is frequently observed in patients with CF. However, it is a condition that affects over 150,000 people without CF in the United States with a higher incidence seen in other countries, and results from a cycle

of inflammation, recurrent infection, and bronchial wall damage. There is currently no drug specifically approved for the treatment of BE in the U.S. The FDA granted orphan drug designation for Linhaliq for the management of BE in June 2011.

In May 2014, we announced that the FDA designated Linhaliq as a QIDP. The QIDP designation, granted for treatment of NCFBE patients with chronic lung infections with *P. aeruginosa*, will make Linhaliq eligible to benefit from certain incentives for the development of new antibiotics provided under the GAIN Act. These incentives include priority review and eligibility for fast-track status. Further, if ultimately approved by the FDA, Linhaliq is eligible for an additional five-year extension of Hatch-Waxman exclusivity.

In September 2014, we announced that the FDA granted Fast Track designation to Linhaliq for NCFBE patients with chronic lung infections with *P. aeruginosa*. The FDA gives Fast Track status to facilitate the development of new drugs intended to treat serious or life-threatening conditions and which demonstrate the potential to address unmet medical needs, with the goal of getting important new drugs to patients earlier. According to the FDA, determining whether a condition is serious is a matter of judgment, but generally is based on whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one.

A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- Eligibility for *Priority Review,* if relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of its New Drug Application, or NDA, for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire application to the FDA

According to the FDA, once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues may be resolved quickly, often leading to earlier drug approval and access by patients.

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.

We believe we have the preclinical development, clinical and regulatory expertise to advance this product through development. In August 2013, we licensed to Grifols on an exclusive, worldwide basis, our inhaled liposomal ciprofloxacin product candidates for the indication of NCFBE and other indications. We also obtained a royalty-bearing license for biodefense applications from Grifols.

Development of Inhaled Ciprofloxacin for BE

See Part 1, Item 1 of the 2014 Annual Report on Form 10-K for additional information and discussion regarding earlier efforts on the Development of Inhaled Ciprofloxacin for BE.

We had been testing two formulations of inhaled ciprofloxacin (Linhaliq and Lipoquin) that differ in the proportion of rapidly available and slow release ciprofloxacin. Linhaliq (also called Dual Release Ciprofloxacin

for Inhalation—DRCFI) uses the slow release liposomal formulation (Lipoquin, also called Ciprofloxacin for Inhalation—CFI) mixed with a small amount of ciprofloxacin dissolved in an aqueous medium. The clinical activities described below for Lipoquin also support the Linhaliq program.

In December 2011, we completed the analysis of all preclinical and clinical data from the two different formulations of inhaled ciprofloxacin (Lipoquin and Linhaliq) and determined that Linhaliq showed superior performance; therefore, we took Linhaliq forward into Phase 3 clinical trials. In order to expedite anticipated time to market and increase market acceptance, we have elected to deliver our formulations via an approved, widely-accepted nebulizer system in many countries including US and EU, for each of our clinical trials and we intend to continue using this approach and obtain the initial marketing approval with this currently FDA-approved nebulizer system.

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

In December 2016, we announced top-line results for both studies. In ORBIT-4 the median time to first mild, moderate or severe pulmonary exacerbation, or PE, was 230 days in the Linhaliq treatment group as compared to 163 days in the placebo group. This increase in the median time to first PE was statistically significant (p=0.0462) using non-stratified log-rank analysis. In the key secondary efficacy endpoint, there was a 37% reduction in the frequency of PE's over the 48-week treatment period in the Linhaliq treatment group as compared to the placebo group. This result was statistically significant (p=0.0007) with a Hazard Ratio of Linhaliq/placebo of 0.63 using non-stratified binomial regression.

In ORBIT-3 the median time to first mild, moderate or severe PE was 221 days in the Linhaliq treatment group as compared to 136 days in the placebo group. This increase in the median time to first PE was similar to ORBIT-4 but was not statistically significant (p=0.8488) using non-stratified log-rank analysis. In the key secondary efficacy endpoint, there was a 13% reduction in the frequency of PE's over the 48-week treatment period in the Linhaliq treatment group as compared to the placebo group. This result was not statistically significant (p=0.3125) with a Hazard Ratio of Linhaliq/placebo of 0.87 using non-stratified binomial regression.

The analyses of combined data from both studies resulted in a statistically significant reduction in the number of PEs over the 48-week double-blind period (Hazard Ratio Linhaliq/placebo: 0.73; p=0.0015), representing a 27% reduction in PEs over the period.

When the additional analyses of combined data from both studies were conducted taking into account only PEs that were moderate or severe (i.e., those that required interventions with antibiotics or hospitalization) the median time to first PE in the Linhaliq group was 302 days vs. placebo 198 days (p=0.0217). There was also a statistically significant reduction in the number of moderate and severe PEs over the 48-week double-blind period (Hazard Ratio Linhaliq/placebo: 0.67; p=0.0002) using non-stratified analysis, representing a 33% reduction in PEs over the period.

In each study, the treatment groups were stratified for gender, pre-trial frequency of exacerbations and smoking status. The Statistical Analysis Plan for the studies called for stratified analyses; however, since some strata were found to have no or very few subjects, both non-stratified and stratified analyses were conducted. We believe that due to the limited number of subjects in some strata the non-stratified analyses are more appropriate

as strata that are too small can produce highly unstable estimated treatment effects with potential outliers. Using the stratified analyses, the median time to first PE in ORBIT-3 was Linhaliq: 221 days; placebo: 136 days; p=0.7681 and for ORBIT-4 was Linhaliq: 230 days; placebo: 163 days; p=0.0885.

Both studies demonstrated a statistically significant reduction in *P. aeruginosa* density at Day 28, the end of the first on-treatment period (ORBIT-3: p=<0.0001; ORBIT-4: p=<0.0001). For each study, the magnitude of this antibiotic effect remained persistent throughout all on-treatment periods.

Linhaliq was safe and well tolerated in both studies. There were no differences in the changes of lung function (FEV1 % predicted and FVC % predicted) or symptoms of airway irritation between the Linhaliq and placebo groups in the two studies. Overall, the incidence of all treatment-emergent adverse events (TEAE) was similar between the Linhaliq and placebo groups in both ORBIT-3 (Linhaliq: 89.6%; placebo: 91.6%) and ORBIT-4 (Linhaliq: 86.4%; placebo: 96.9%). In ORBIT-3 the rates of serious TEAEs were 30.6% with Linhaliq and 25.3% with placebo while in ORBIT-4 the rates were 17.0% versus 28.6%.

For each study, the randomization rate of Linhaliq treated subjects to placebo was 2 to 1. There were 8 deaths in ORBIT-3 (Linhaliq: 5 (2.7%); placebo: 3 (3.2%)) and 6 deaths in ORBIT-4 (Linhaliq: 2 (1.0%); placebo: 4 (4.1%)). None of the deaths was related to Linhaliq or placebo. The most frequently observed treatment-related TEAEs were of respiratory/thoracic/mediastinal nature and were reported in ORBIT-3 by 25.7% of subjects with Linhaliq and in 21.1% of subjects with placebo, while the rates in ORBIT-4 were 16.5% with Linhaliq versus 19.4% with placebo.

After the completion of the 48-week double-blind period, both Linhaliq and placebo-treated patients were given the opportunity to receive Linhaliq in a 28-day open-label extension period. Ninety seven percent of the patients who completed study drug in the double blind phase of ORBIT-3 and 96% percent of the patients who completed study drug in the double blind phase of ORBIT-4 enrolled in the extension period.

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.

In January 2018, we announced that the FDA provided a Complete Response Letter ("CRL") regarding the NDA stating that it cannot approve the NDA in its present form and providing specific reasons for this action along with recommendations needed for resubmission; the areas of concern include clinical data, human factors validation study and product quality. The recommendations in the CRL include an independent third party verification of the Phase 3 results via analyses of source data as per the statistical analysis plan ("SAP") and an additional Phase 3 clinical trial that demonstrates a significant treatment effect on clinically meaningful endpoints which could evaluate the co-primary endpoints of frequency and severity of exacerbations to assess for durable evidence of efficacy over a period of two years (or more, if scientifically justified). The CRL also included a request to conduct another Human Factors Study to demonstrate that the product packaging and instructions for use are effective, and the CRL requested, among other things, additional product quality information with respect to microbiology and a new in vitro drug release method development report. We remain confident in the efficacy, safety and quality of Linhaliq and plan to request a Type A post-action meeting with

the FDA to discuss the topics covered in the CRL with the view to developing plans to move towards resubmission of the Linhaliq NDA as soon as possible. We are committed to continue working on the approval of Linhaliq in the US for NCFBE patients who have very severe disease with high morbidity and mortality and no available treatment options.

In March 2018, we submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking approval for Linhaliq for the treatment of NCFBE patients with chronic lung infection with *P. aeruginosa*. Our submission is based on the positive Phase 3 clinical trials ARD-3150-1202 or Orbit 4 with a primary endpoint of frequency of exacerbations which differs from the U.S. FDA primary endpoint of time to first exacerbation and supporting evidence from proprietary preclinical and clinical studies, as well as referencing additional information about ciprofloxacin from publicly available sources. The company had pre-submission meetings with EMA in October and November of 2017 to discuss the results of these studies. The submission is expected to be validated by EMA at the end of March 2018 at which time Day 1 of the MAA review procedure will commence. The company expects to receive comments or questions 120 days after validation.

Liposomal Ciprofloxacin for Non-Tuberculous Mycobacteria

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

According to a report from the National Institutes of Health based on an epidemiological study in U.S. adults aged 65 years or older, PNTM infections are an important cause of morbidity among older adults in the United States. From 1997 to 2007, the annual prevalence significantly increased from 20 to 47 cases/100,000 persons or 8.2% per year. Forty-four percent of PNTM-affected people in the study had bronchiectasis compared to 1% in the non-PNTM cases pointing to an important co-morbidity. A recent study from NIH reported that in 2010 they estimated 86,244 national cases, totaling to $815 million burden, of which 87% were inpatient-related ($709 million), and 13% were outpatient-related ($106 million) costs. Of all costs incurred, medications comprised 76% of nontuberculous mycobacterial disease expenditures. PNTM infections are also common in patients with other chronic lung conditions, such as cystic fibrosis and emphysema. In patients with AIDS, the infection is disseminated. These infections are particularly difficult to treat as the mycobacteria can form biofilms in the airways and they are able to cause intracellular infections, e.g., by invasion of pulmonary macrophages. The current clinical paradigm is to treat patients with lung or disseminated disease with combination therapy given orally or by IV. Unfortunately, these therapies often fail and may have significant side effects.

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

On April 15, 2015, we announced the first results from the collaboration between scientists from OSU and Aradigm funded by NIH. The research demonstrated that after 4 days of in vitro treatment of human macrophages infected with *Mycobacterium avium* and *Mycobacterium abscessus*, Aradigm's liposomal ciprofloxacin was associated with a decrease of greater than 99% of these 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 *Mycobacterium abscessus* using once daily respiratory tract dosing in mice that had established colonization with this microorganism. After 3 weeks of treatment, the number of CFUs in the lungs was significantly reduced ($p<0.05$) by 95.2% and 96.1% by Lipoquin and Linhaliq, respectively; after 6 weeks of treatment, the CFUs were further reduced ($p<0.05$) by 99.7% and 99.4% for Lipoquin and Linhaliq, respectively. In contrast, unencapsulated ciprofloxacin had no effect.

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

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

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

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

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

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

In the experiments reported by the UK scientists, mice that were infected with *C. burnetii* via inhalation and treated 24 hours later with twice-daily oral ciprofloxacin continuing for 6 additional days, or infected drug-free

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

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

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

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

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

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

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

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

Intellectual Property and Other Proprietary Rights

Our success will depend, to a significant extent, on our ability to obtain, expand and protect our intellectual property estate, enforce patents, maintain trade secret protection and operate without infringing the proprietary rights of other parties. Our most recent patents issued in the United States were an important composition of matter patent and a method of treatment patent for Linhaliq. As of February 28, 2018, we had 34 issued United States patents, with 8 additional United States patent applications pending. In addition, we had 51 issued foreign patents and an additional 30 foreign patent applications pending. The bulk of our patents and patent applications contain claims directed toward our Linhaliq and Lipoquin compositions and methods of treatment, proprietary delivery technologies, including methods for aerosol generation, devices used to generate aerosols, breath control, compliance monitoring, certain pharmaceutical formulations, design of dosage forms and their manufacturing and testing methods The bulk of our patents directed toward our proprietary delivery technologies and methods of use expire between 2018 and 2035. Because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of our patents cannot be predicted.

We continue to seek to protect our proprietary position by protecting inventions that we determine are or may be important to our business. We do this, when we are able, through the filing of patent applications with claims directed toward the devices, methods, and technologies we develop. Our ability to compete effectively will depend to a significant extent on our ability and the ability of our collaborators to obtain and enforce patents and maintain trade secret protection over our proprietary technologies. The coverage claimed in a patent application typically is significantly reduced before a patent is issued, either in the United States or abroad. Consequently, any of our pending or future patent applications may not result in the issuance of patents or, to the extent patents have been issued or will be issued, these patents may be subjected to further proceedings limiting their scope and may in any event not contain claims broad enough to provide meaningful protection. Patents that are issued to us or our collaborators may not provide significant proprietary protection or competitive advantage and may be circumvented or invalidated.

We also rely on our trade secrets and the know-how of our officers, employees, consultants and other service providers. Our policy is to require our officers, employees, consultants, and advisors to execute proprietary information and invention assignment agreements upon commencement of their relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the relationship shall be kept confidential except in specified circumstances. These agreements also provide that all inventions developed by the individual on behalf of us shall be assigned to us and that the individual will cooperate with us in connection with securing patent protection for the invention if we wish to pursue such protection. These agreements may not provide meaningful protection for our inventions, trade secrets or other proprietary information in the event of unauthorized use or disclosure of such information.

We also execute confidentiality agreements with outside collaborators and consultants. However, disputes may arise as to the ownership of proprietary rights to the extent that outside collaborators or consultants apply

technological information developed independently by them or others to our projects, or apply our technology or proprietary information to other projects, and any such disputes may not be resolved in our favor. Even if resolved in our favor, such disputes could result in substantial expense and diversion of management attention.

In addition to protecting our own intellectual property rights, we must be able to develop products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to compositions of matter, methods of use, methods of delivery and products in those markets, it may be difficult for us to develop products without infringing the proprietary rights of others. For example, we are aware of patents recently issued in the U.S. and assigned to Insmed Incorporated, or Insmed, with claims covering methods of treatment with quinolone antibiotics, which includes ciprofloxacin, against pulmonary infections.

We will incur substantial costs if we are required to defend ourselves in suits, regardless of their merit. These legal actions could seek damages and seek to enjoin development, testing, manufacturing, and marketing of the allegedly infringing product. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the allegedly infringing product and any license required under any such patent may not be available to us on acceptable terms, if at all.

We may determine that litigation is necessary to enforce our proprietary rights against others. Such litigation could result in substantial expense and diversion of management attention, regardless of its outcome and any litigation may not be resolved in our favor.

Competition

We are in a highly competitive industry. We compete with pharmaceutical and biotechnology companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of drugs and other therapies for the respiratory disease indications we are targeting. Our competitors may succeed, and many have already succeeded, in developing competing products, obtaining FDA approval for products or gaining patient and physician acceptance of products before us for the same markets and indications that we are targeting. Many of these companies, and large pharmaceutical companies, in particular have greater research and development, regulatory, manufacturing, marketing, financial and managerial resources and experience than we have and many of these companies may have products and product candidates that are in a more advanced stage of development than our product candidates. If we are not "first to market" for a particular indication, it may be more difficult for us or our collaborators to enter markets unless we can demonstrate our products are clearly superior to existing therapies.

There is no product currently approved in the United States specifically for the treatment of bronchiectasis (BE). However, Bayer HealthCare Pharmaceuticals Inc., or Bayer, completed testing of a ciprofloxacin dry powder inhaler for the management of BE in two Phase 3 studies and an experimental oral drug, BAY85-8501, in a Phase 2 study in BE patients. Bayer has obtained orphan drug status for their inhaled powder formulation of ciprofloxacin in the United States for the treatment of BE and in the United States and European Union for the treatment of CF. Bayer filed an NDA for U.S. approval and was accepted for Priority Review. In November 2017, the FDA's Advisory Committee voted not to recommend Bayer's dry powder ciprofloxacin to be approved for the treatment of bronchiectasis. Bayer announced in their 2017 Annual Report that they have decided to discontinue development of Cipro DPI in NCFB for the time being and will evaluate possible further options for this asset. There are also a number of other inhaled products under development to treat respiratory infections in CF, including nebulized levofloxacin by Raptor Pharmaceutical Corp. (acquired by Horizon Pharma Plc) and nebulized liposomal amikacin by Insmed for the treatment of *Mycobacterium avium* (a PNTM infection).

Currently marketed inhaled antibiotics for the management of infections associated with CF include several products containing tobramycin (nebulizer and dry powder formulations), marketed by multiple companies, and nebulized Cayston*, marketed by Gilead Sciences. Several of these products already have substantial current sales and long histories of effective and safe use.

There are a number of additional product candidates in various stages of development for the treatment of respiratory infections that, if approved, could compete with any future products we may develop.

We believe that our respiratory expertise and pulmonary delivery and formulation technologies provide us with an important competitive advantage for our potential products. We intend to compete by developing products that are safer, more efficacious, more convenient, less costly, earlier to market or cheaper to develop than existing products, or any combination of the foregoing.

Government Regulation

United States

The research, development, testing, manufacturing, labeling, advertising, promotion, distribution, marketing, and export, among other things, of any products we develop are subject to extensive regulation by governmental authorities in the United States and other countries. The FDA regulates drugs in the United States under the FDCA and implementing regulations thereunder.

If we fail to comply with the FDCA or FDA regulations, we and our products could be subject to regulatory actions. These may include a delay in approval or refusal by the FDA to approve pending applications, injunctions ordering us to stop the sale of any products we develop, seizure of our products, warning letters, the imposition of civil penalties or other monetary payments, criminal prosecution, and recall of our products. Any such events would harm our reputation and our results of operations.

Before any of our drugs may be marketed in the United States, it must be approved by the FDA. None of our current product candidates has received such approval. We believe that our products currently in development will be regulated by the FDA as drugs.

The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory and animal tests, and formulation studies;
- the submission to the FDA of an Investigational New Drug (IND) application for human clinical testing that must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each indication for which approval is sought;
- the submission to the FDA of a New Drug Application (NDA) and FDA's acceptance of the NDA for filing;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is to be produced to assess compliance with the FDA's Good Manufacturing Practices (GMP); and
- FDA review and approval of the NDA.

Preclinical Testing

The testing and approval process requires substantial time, effort, and financial resources, and the receipt and timing of approval, if any, is highly uncertain. Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the proposed clinical trials as outlined in the IND prior to that time. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in FDA authorization to commence clinical trials. Once an IND is in effect, the protocol for each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

In July 2009, we received clearance from the FDA for our IND for inhaled liposomal ciprofloxacin (ARD-3100, Lipoquin) for the treatment of non-cystic fibrosis bronchiectasis. In May 2010, we received clearance from the FDA for our IND for inhaled liposomal ciprofloxacin for the treatment of cystic fibrosis. However, an additional three-month toxicity study in animals with Lipoquin (ARD-3100) and Linhaliq (ARD-3150) was requested by the FDA to support longer-term human clinical trials. This study was completed, and the results were submitted to the FDA as part of our IND filing for the Phase 3 program for Linhaliq in BE patients.

In March 2012, we received clearance from the FDA for our IND to start the two Phase 3 studies of Linhaliq (ARD-3150) in BE patients. The FDA requested a 2-year carcinogenicity study in rats with inhaled Linhaliq to support the NDA for BE. In December 2016, we announced that the study was completed and we had received the final statistical analysis report from the study; there were no differences in the rate of observed tumors between the Linhaliq and control groups. The FDA indicated a 9-month inhalation safety study in dogs might also be needed to support approval for marketing this product for BE in the U.S. and the EU. We have taken the initiative to conduct this study in the interest of reducing time to approval of Linhaliq. The 9-month inhalation safety study in dogs is complete, and the study report has been submitted to the FDA.

Clinical Trials

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators and healthcare personnel. Clinical trials are conducted under protocols detailing, for example, the parameters to be used in monitoring patient safety and the safety and effectiveness criteria, or endpoints, to be evaluated. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent institutional review board overseeing the institution conducting the trial before it can begin.

These phases generally include the following:

- *Phase 1.* Phase 1 clinical trials usually involve the initial introduction of the drug into human subjects, frequently healthy volunteers. In Phase 1, the drug is usually evaluated for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion, and pharmacodynamics.
- *Phase 2.* Phase 2 usually involves studies in a limited patient population with the disease or condition for which the drug is being developed to (1) preliminarily evaluate the efficacy of the drug for specific, targeted indications; (2) determine dosage tolerance and appropriate dosage; and (3) identify possible adverse effects and safety risks.
- *Phase 3.* If a drug is found to be potentially effective and to have an acceptable safety profile in preclinical (animal), Phase 1 and Phase 2 human studies, the clinical trial program will be expanded, usually to further evaluate clinical efficacy and safety by administering the drug in its final form to an expanded patient population at geographically dispersed clinical trial sites. Phase 3 studies usually include several hundred to several thousand patients.

Upon completion of the required clinical testing, the results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or facilities at which the product is manufactured, and will not approve the product unless continuing GMP compliance is satisfactory. If the FDA determines the NDA is not acceptable, the FDA may outline the deficiencies in the NDA and often will request additional information or additional clinical trials. Notwithstanding the submission of any requested additional testing or information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If regulatory approval of a product is granted, such approval will usually entail limitations on the indicated uses for which the product may be marketed. Once approved, the FDA may withdraw the product approval if

compliance with pre- and post-marketing regulatory requirements and conditions of approvals are not maintained, if GMP compliance is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies.

After approval, certain changes to the approved product, such as adding new indications, certain manufacturing changes, or additional labeling claims are subject to further FDA review and approval. Post-approval use of products can lead to new findings of the safety or efficacy of the products. This information can lead to a product sponsor making, or the FDA requiring, changes in the labeling of the product or even the withdrawal of the product from the market.

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. This was followed in July 2017 by submission of the NDA for Linhaliq to the FDA. In January 2018, we received a CRL from the FDA regarding the NDA for Linhaliq which states that the FDA determined it cannot approve the NDA in its present form and provides specific reasons for this action.

Section 505(b)(2) Applications

Some of our product candidates may be eligible for submission of applications for approval under the FDA's Section 505(b)(2) approval process, which requires less information than the NDAs described above. Section 505(b)(2) applications may be submitted for drug products that represent a modification (*e.g.*, a new indication or new dosage form) of an eligible approved drug and for which investigations other than bioavailability or bioequivalence studies are essential to the drug's approval. Section 505(b)(2) applications may rely on the FDA's previous findings for the safety and effectiveness of the listed drug, scientific literature, and information obtained by the 505(b)(2) applicant needed to support the modification of the listed drug. For this reason, preparing Section 505(b)(2) applications is generally less costly and time-consuming than preparing an NDA based entirely on new data and information from a full set of clinical trials. The law governing Section 505(b)(2) or FDA's current policies may change in such a way as to adversely affect our applications for approval that seek to utilize the Section 505(b)(2) approach. Such changes could result in additional costs associated with additional studies or clinical trials and delays.

The FDCA provides that reviews and/or approvals of applications submitted under Section 505(b)(2) may be delayed in various circumstances. For example, the holder of the NDA for the listed drug may be entitled to a period of market exclusivity, during which the FDA will not approve, and may not even review a Section 505(b)(2) application from other sponsors. If the listed drug is claimed by a patent that the NDA holder has listed with the FDA, the Section 505(b)(2) applicant must submit a patent certification that: the patent information has not been filed; the patent has expired; the patent listing will expire on a given date; or that the patent is invalid, unenforceable, or not infringed by the product that is the subject of the Section 505(b)(2) application. FDA itself will determine the accuracy of the first three certification bases for purposes of application approval timing. For the fourth basis (a "Paragraph IV claim" of no validity, non-enforceability, or non-infringement), the patent holder must use the 505(b)(2) applicant within 45 days of the patent certification notice to prevent FDA approval until the earlier of a court decision favorable to the Section 505(b)(2) applicant or the expiration of 30 months. The regulations governing marketing exclusivity and patent protection are complex, and it is often unclear how they will be applied in particular circumstances.

In addition, both before and after approval is sought, we are required to comply with a number of FDA requirements. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain limitations and other requirements concerning advertising and promotion

for our products. Also, quality control and manufacturing procedures must continue to conform to continuing GMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with continuing GMP. In addition, the discovery of problems, such as safety problems, may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition" which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. A sponsor may request orphan drug designation of a previously unapproved drug, or of a new indication for an already marketed drug. Orphan drug designation must be requested before an NDA is submitted. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan status are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in or shorten the duration of, the review and approval process. If a drug which has orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the drug is entitled to orphan drug exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, unless the subsequent application is able to demonstrate clinical superiority in efficacy or safety or that it represents a major contribution to patient care. Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication, or the same drug for other indications.

We received orphan drug designations for Lipoquin for the management of cystic fibrosis and non-cystic fibrosis bronchiectasis in the U.S. We requested orphan drug designation from the FDA for Linhaliq for the management of bronchiectasis, and in June 2011 we were granted orphan drug designation for ciprofloxacin for inhalation (which includes Linhaliq) for this indication. In June 2012, we received orphan drug designation in the U.S. for liposomal ciprofloxacin plus ciprofloxacin (i.e., Linhaliq) for cystic fibrosis.

We may seek orphan drug designation for other eligible product candidates we develop. However, our inhaled ciprofloxacin may not receive orphan drug marketing exclusivity. Also, it is possible that our competitors could obtain approval, and attendant orphan drug designation or exclusivity, for products that would preclude us from marketing our inhaled ciprofloxacin for these indications for some time.

Foreign regulatory authorities may also provide for orphan drug designations in countries outside the United States. For example, under European guidelines, Orphan Medicinal Product Designation provides 10 years of potential market exclusivity if the product candidate is the first product candidate for the indication approved for marketing in the EU. Orphan drug designation also allows the candidate's sponsor to seek assistance from the European Medicines Agency, or EMA, in optimizing the candidate's clinical development through participation in designing the clinical protocol and preparing the marketing application. Additionally, a drug candidate designated by the Commission as an Orphan Medicinal Product may qualify for a reduction in regulatory fees as well as an EU-funded research grant.

In August 2009, the EMA granted Orphan Drug Designation to our inhaled liposomal ciprofloxacin drug product candidate Lipoquin (ARD-3100) for the management of lung infections associated with cystic fibrosis.

International Regulation

We are also subject to foreign regulatory requirements governing clinical trials, product manufacturing, marketing and product sales. Our ability to market and sell our products in countries outside the United States will depend upon receiving marketing authorization(s) from appropriate regulatory authorities. We will only be permitted to commercialize our products in a foreign country if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality, and efficacy. Whether or not FDA approval has been

obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. Approval of a product by the FDA does not assure approval by foreign regulators. Regulatory requirements, and the approval process vary widely from country to country, and the time, cost and data needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with the FDA process described above.

Principal Supplier

We currently contract exclusively with Exelead (formerly known as Sigma-Tau PharmaSource, Inc.) to manufacture inhaled ciprofloxacin. However, we are exploring developing a second source to manufacture inhaled ciprofloxacin. For more information on the risks associated with this arrangement, please see Item 1A—Risk Factors—"We have limited manufacturing capacity and will have to depend on contract manufacturers and collaborators; if they do not perform as expected, our revenues and customer relations will suffer."

Research and Development

Our research and development expenses were approximately $13.8 million for the year ended December 31, 2017, and $24.4 million for the year ended December 31, 2016. For more information regarding our research and development, please see Item 7—Management's Discussion and Analysis —Research and Development.

Scientific Advisory Board

We have assembled a scientific advisory board comprised of scientific and product development advisors who provide expertise, on a consulting basis from time to time, in the areas of respiratory diseases, pharmaceutical development and drug delivery, including pulmonary delivery, but are employed elsewhere on a full-time basis. As a result, they can only spend a limited amount of time on our affairs. We access scientific and medical experts in academia, as needed, to support our scientific advisory board. The scientific advisory board assists us on issues related to potential product applications, product development, and clinical testing. Its members, and their affiliations and areas of expertise include:

Name	Affiliation	Area of Expertise
Stephen J. Farr, Ph.D.	Zogenix, Inc.	Pulmonary Delivery/Pharmaceutics
Adam Wanner, M.D.	University of Miami	Chronic Obstructive Pulmonary Diseases (COPD)

In addition to our scientific advisory board, for certain indications and programs, we assemble groups of experts to assist us on issues specific to such indications and programs.

Employees

As of December 31, 2017, we had twenty-three employees. Sixteen employees are involved in research and development, and product development and seven employees are involved in finance and administration. Eight employees have advanced scientific degrees.

Our employees are not represented by any collective bargaining agreement.

We also utilize an international network of consultants and contractors, such as clinical research organizations (CROs), clinical manufacturing organizations (CMOs) and various specialists in areas, such as regulatory affairs and business and corporate development.

Corporate History and Website Information

We were incorporated in California in 1991. Our principal executive offices are located at 3929 Point Eden Way, Hayward, California 94545, and our main telephone number is (510) 265-9000. Investors can obtain access to this Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and all amendments to these reports, free of charge, on our website at http://www.aradigm.com as soon as reasonably practicable after such filings are electronically filed with the Securities and Exchange Commission (SEC). The information contained on our website is not part of this Annual Report on Form 10-K or of our other filings with the SEC. The public may read and copy any material we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.W., Washington, D.C., 20549. The public may obtain information on the operations of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site, http://www.sec.gov that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

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

Except for historical information contained herein, the discussion of this Annual Report on Form 10-K contains forward-looking statements, including, without limitation, statements regarding the preparation and filing for regulatory approvals, the maintenance and establishment of corporate partnering arrangements, the anticipated commercial introduction of our products and the timing of our cash requirements. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those expressed in, or implied by, any such forward-looking statements. Potential risks and uncertainties include, without limitation, those mentioned in this report and in particular the factors described below. The risks described below are not the only risks we face. Additional risks not presently known to us or other factors that we do not presently perceive to present significant risks to us at this time may also impair our business, financial condition, results of operations or cash flows, or the value of our common stock.

Risks Related to Our Business

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

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

We believe that our cash and cash equivalents of approximately $7.1 million as of December 31, 2017, will only be sufficient to fund our operations for the first quarter of 2018. We will not be able to maintain our current level of regulatory and product development activity and there is substantial doubt about our company's ability to continue as a going concern unless we raise additional capital in 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 lead product candidate Linhaliq. We cannot assure you that we will be successful in raising additional capital on favorable terms or at all. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. If we are unable to obtain additional funds when required, it may delay or reduce the scope of all or a portion of our development programs, or require us to dispose of our assets or technology or to cease operations, and we may not be able to continue as a going concern.

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

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

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

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

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

- disruption of our business or distraction of our employees and management;
- difficulty in recruiting, hiring, motivating and retaining talented and skilled personnel;
- stock price volatility; and
- difficulty in negotiating, maintaining or consummating business or strategic relationships or transactions.

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

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

We have never been profitable and have incurred significant net losses in each year since our inception. As of December 31, 2017, we have an accumulated deficit of approximately $455.2 million. We have not had any direct product sales and do not anticipate receiving revenues from the sale of any of our products in 2018, if ever. We expect to incur net losses over the next several years and may never become profitable. While our agreement with our partner Grifols has resulted in reduced net operating losses and capital expenditures as a portion of our research and development expenses for the Linhaliq program was reimbursed by Grifols through 2015, we expect to continue to incur losses for the foreseeable future as we:

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

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

To achieve and sustain profitability, we must, alone or with others such as Grifols, successfully develop, obtain regulatory approval for, manufacture, market and sell our products. We expect to incur substantial expenses in our efforts to develop and commercialize products, and we may never generate sufficient product or contract research revenues to become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the processes described above, we anticipate incurring significant costs associated with seeking regulatory approval for our product candidates.

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

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. We and our products are subject to extensive and rigorous regulation in the United States by the federal government, principally the FDA, by state and local government agencies, and also by governmental and regulatory agencies outside the United States, such as the EMA. Both before and after regulatory approval, the development, testing, manufacture, quality control, labeling, storage, approval, advertising, promotion, sale, distribution, and export of our potential products are subject to regulation. Pharmaceutical products that are marketed abroad are also subject to regulation by foreign governments. Our products cannot be marketed in the United States without FDA approval.

The process for obtaining FDA approval for drug products is generally lengthy, expensive and uncertain. Despite the time and expense expended, regulatory approval is never guaranteed. The FDA and foreign regulatory agencies can delay approval of, or refuse to approve, our product candidates for a variety of reasons, including failure to meet safety and/or efficacy endpoints in our clinical trials.

Regulatory authorities may delay or not approve our product candidates even if the product candidates meet safety and efficacy endpoints in clinical trials or the approvals may be too limited for us to earn sufficient revenues.

Our pharmaceutical product candidates may not be approved even if they achieve their safety and efficacy endpoints in clinical trials. Even if a product candidate is approved, it may be approved for fewer or more limited

indications than requested or the approval may be subject to the performance of significant post-marketing studies that can be long and costly. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any limitation, condition or denial of approval or label changes would have an adverse effect on our business, reputation, and results of operations.

Even if we are granted initial FDA 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 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. Any such future financing could result in dilution to shareholders or increased fixed payment obligations and could also result in restrictive covenants or other operating restrictions that could adversely impact our ability to conduct our business.

We are a development-stage company, and our ability to generate revenue and become profitable depends on our ability to successfully complete the development of our product candidates. All of our potential products are in research or development, and we will need to raise additional capital prior to approval and commercialization of our lead product candidate, Linhaliq. Our potential drug products require extensive research and development, including pre-clinical and clinical testing. Our potential products also may involve lengthy regulatory reviews before they can be sold. Because none of our product candidates has yet received approval by the FDA, we cannot assure you that our research and development efforts will be successful, any of our potential products will be proven safe and effective, or regulatory clearance or approval to sell any of our potential products will be obtained. We cannot assure you that any of our potential products can be manufactured in commercial quantities with quality systems acceptable to the regulatory authorities at an acceptable cost or marketed successfully. We may abandon the development of some or all of our product candidates at any time and without prior notice. We must incur substantial up-front expenses to develop and commercialize products and failure to achieve commercial feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or successfully manufacture and market products will negatively impact our business. Running clinical trials and developing an investigational drug for commercialization involve significant expense, and any unexpected delays or other issues in the development process can result in significant additional expense.

Until we can generate a sufficient amount of revenue, we expect to finance future cash needs through public or private equity financings, royalty or debt financings, corporate alliances, joint ventures or licensing agreements. We may sell additional equity or debt securities to fund our operations, which would result in dilution to all of our shareholders or impose restrictive covenants that may adversely impact our business. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves, or cease operations and liquidate.

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

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

We are aware of a number of companies that are developing or have developed therapies to address indications we are targeting, including major pharmaceutical companies such as Bayer. For example, Bayer has developed an inhaled dry powder formulation of ciprofloxacin for the treatment of respiratory infections in CF and NCFBE. Bayer filed an NDA for U.S. approval and was accepted for Priority Review. In November 2017, the FDA's Advisory Committee voted not to recommend Bayer's dry powder ciprofloxacin to be approved for the treatment of bronchiectasis. Bayer in its 2017 Annual Report have announced that they have decided to discontinue development of Cipro DPI in NCFBE for the time being and will evaluate possible further options for this asset.

There are a number of other inhaled products under development to treat respiratory infections, including a nebulized levofloxacin by Raptor (acquired by Horizon) for CF 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 filed an NDA for U.S. approval, however in November 2017 the FDA's Advisory Committee voted not to recommend Bayer's dry powder ciprofloxacin to be approved for the treatment of bronchiectasis.

In August 2009, the EMA granted orphan drug designation to our inhaled liposomal ciprofloxacin drug product candidate Lipoquin (ARD-3100) for the treatment of lung infections associated with CF. Under European guidelines, Orphan Medicinal Product Designation provides 10 years of potential market exclusivity if the product candidate is the first product candidate for the indication approved for marketing in the EU. We may seek to develop additional products that incorporate drugs that have received orphan drug designations for specific indications. In each case, if our product is not the first to be approved by the FDA or European Medicines Agency for a given orphan indication, we may not be able to access the target market in the United States and/or the EU, which would adversely affect our ability to earn revenues.

Our dependence on collaborators and other third parties may delay or require that we terminate certain of our programs, and any such delay or termination would harm our business prospects and stock price.

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

Our commercialization strategy for certain of our product candidates depends on our ability to enter into or maintain agreements with collaborators, such as our collaboration with Grifols, and to obtain assistance and funding for the development and potential commercialization of our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we would over a proprietary development and commercialization program. We may determine that continuing a collaboration under the terms provided is not in our best interest and, if we are able to under the terms of the agreement, we may terminate the collaboration. Our collaborators could delay or terminate their agreements with us, and our products subject to collaborative arrangements may never be successfully commercialized. Under our existing collaboration agreement with Grifols, we have granted Grifols exclusive rights with respect to inhaled

ciprofloxacin compounds for other indications besides the treatment of NCFBE, and we have limited ability to terminate that agreement.

Further, our present or future collaborators may pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our present or future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to certain other programs that we intend to commercialize ourselves, or programs that Grifols has declined its exclusive right to fund and commercialize, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary drugs will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such drugs. We may not be able to establish such arrangements on favorable terms or at all, and our future collaborative arrangements may not be successful.

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

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

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

Further, we, our contract manufacturers and our collaborators are required to comply with the FDA's GMP requirements that relate to product testing, quality assurance, manufacturing and maintaining records and documentation. We and our contract manufacturers or our collaborators may not be able to comply with the

applicable GMP and other FDA regulatory requirements for manufacturing, which could result in an enforcement or other action, prevent commercialization of our product candidates and impair our reputation and results of operations.

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

Even if we or our collaborators successfully develop one or more products, such products may not be commercially acceptable to healthcare professionals and patients, who will have to choose our products over alternative products for the same disease indications. Many of these alternative products may be more established and acceptable than ours. For our products to be commercially viable, we will need to demonstrate to healthcare professionals and patients that our products afford benefits to the patients that are cost-effective as compared to the benefits of alternative therapies. Our ability to demonstrate this depends on a variety of factors, including:

- the demonstration of efficacy and safety in clinical trials;
- the existence, prevalence, and severity of any side effects;
- the potential or perceived advantages or disadvantages compared to alternative treatments;
- the timing of market entry relative to competitive treatments;
- the pricing relative to competitive products;
- the relative cost, convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of our product candidates by governmental and other third-party payors; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

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

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

Any of our pending or future patent applications may not result in the issuance of patents and any patents issued may be subjected to further proceedings limiting their scope and may in any event not contain claims broad enough to provide meaningful protection. Any patents that are issued to us or our present and future collaborators may not provide significant proprietary protection or competitive advantage and may be circumvented or invalidated. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Further, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire and provide only a short period of protection, if any, following commercialization of products.

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

We must be able to commercialize products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to compositions of matter, methods of use and methods of drug delivery, it could be difficult for us or our collaborator Grifols to use our technologies or commercialize products without infringing

the proprietary rights of others. We may not be able to design around the patented technologies or inventions of others, and we may not be able to obtain licenses to use patented technologies on acceptable terms, or at all. If we cannot operate without infringing on the proprietary rights of others, we will not earn product revenues. For example, we are aware of patents recently issued in the U.S. and assigned to Insmed with claims covering methods of treatment with quinolone antibiotics, which includes ciprofloxacin, against pulmonary infections. We filed a PGR petition in the PTAB challenging the validity of the claims of Insmed's U.S. Patent No. 9,402,845 or the '845 Patent. In a PGR, a petitioner may request that the PTAB reconsider the validity of issued patent claims and any patent claim PTAB determines to be unpatentable is stricken from the challenged patent. In August 2017, Insmed filed a Preliminary Response to our petition. In November 2017, PTAB denied institution of our post-grant review of the '845 Patent. We are currently assessing the PTO's decision.

If we or our collaborator Grifols are required to defend an infringement lawsuit, we could incur substantial costs, and the lawsuit could divert management's attention, regardless of the lawsuit's merit or outcome. These legal actions could seek damages and seek to enjoin testing, manufacturing, and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process and any license required under any such patent may not be made available to us on acceptable terms, if at all, or we could incur significant expenses in royalty payments to a licensor.

Periodically, we review publicly available information regarding the development efforts of others in order to determine whether these efforts may violate our proprietary rights. We may determine that litigation is necessary to enforce our proprietary rights against others. Such litigation could result in substantial expense, regardless of its outcome, and may not be resolved in our favor.

Furthermore, patents already issued to us or our pending patent applications may become subject to dispute, and any disputes could be resolved against us. In addition, patent applications in the United States are currently maintained in secrecy for a period of time prior to issuance and patent applications in certain other countries generally are not published until more than 18 months after they are first filed. Publication of discoveries in scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first creator of inventions covered by our issued patents or pending patent applications or that we were the first to file patent applications on such inventions. For example, we are aware of patents recently issued in the U.S. and assigned to Insmed with claims covering methods of treatment with quinolone antibiotics, which includes ciprofloxacin, against pulmonary infections.

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. Our former President and Chief Executive Officer, Dr. Igor Gonda, our former Chief Medical Officer, Dr. Juergen Froehlich, and our former Chief Financial Officer, Nancy Pecota resigned on February 11, 2018. These resignations and losing any of our

remaining key employees could impair our product development efforts and otherwise harm our business. Any of our employees may terminate their employment with us at will.

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

If we market any approved products in foreign countries, we will be subject to different laws and regulations, particularly with respect to intellectual property rights and regulatory approval. To maintain a proprietary market position in foreign countries, we may seek to protect some of our proprietary inventions through foreign counterpart patent applications. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. The diversity of patent laws may make our expenses associated with the development and maintenance of intellectual property in foreign jurisdictions more expensive than we anticipate. We will not obtain the same patent protection in every market in which we may otherwise be able to potentially generate revenues. In addition, in order to market our products in foreign jurisdictions, we and our present and future collaborators must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety and quality. We may not be able to obtain regulatory approvals in such jurisdictions, and we may have to incur significant costs in obtaining or maintaining any foreign regulatory approvals. If approvals to market our products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our business would be impaired as we could not earn revenues from sales in those countries.

We may be exposed to product liability claims, which would hurt our reputation, market position, and operating results.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates in humans and will face an even greater risk upon commercialization of any products. These claims may be made directly by consumers or by pharmaceutical companies or others selling such products. We may be held liable if any product we develop causes injury or is found otherwise unsuitable during product testing, manufacturing or sale. Regardless of merit or eventual outcome, liability claims would likely result in negative publicity, decreased demand for any products that we may develop, injury to our reputation and suspension or withdrawal of clinical trials. Any such claim will be very costly to defend and also may result in substantial monetary awards to clinical trial participants or customers, loss of revenues and the inability to commercialize products that we develop. Although we currently have clinical trials and product liability insurance, we may not be able to maintain such insurance or obtain additional insurance on acceptable terms, in amounts sufficient to protect our business, or at all. A successful claim brought against us in excess of our insurance coverage would have a material adverse effect on our results of operations.

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

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

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

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

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that fiscal year. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Reform Act, became law. The Reform Act includes a provision that indefinitely exempts companies that qualify as either a non-accelerated filer or smaller reporting company from the auditor attestation requirement of Section 404(b) of the Sarbanes-Oxley Act of 2002. For our fiscal 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.

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

We store sensitive data, including intellectual property, our proprietary business information and personally identifiable information of our employees, on our network servers, located in our data centers. The secure maintenance of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, damage our reputation and adversely impact our operating results. Numerous United States federal and state laws and regulations and foreign laws and regulations, including data breach notification laws, health information privacy laws, and federal and consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996.

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

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

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

Risks Related to Our Common Stock

Our stock price is likely to remain volatile.

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

- the limited trading volume for shares of our common stock and the fact that a large percentage of our outstanding shares are held by a small number of shareholders;
- announcements of clinical trial results, technological innovations or new commercial products by our competitors or us;
- developments or disputes concerning patents or proprietary rights;
- delays in the development or approval of our product candidates;
- regulatory developments in both the United States and foreign countries;
- sales of our stock by certain large institutional shareholders;
- research analyst recommendations and our ability to meet or exceed quarterly performance expectations of analysts or investors;
- fluctuations in our operating results;
- failure to maintain or establish collaborative relationships;
- publicity regarding actual or potential developments relating to products under development by our competitors or us;
- investor perception of us;
- concern of the public or the medical community as to the safety or efficacy of our products, or products deemed to have similar safety risk factors or other similar characteristics to our products;
- future sales or expected sales of substantial amounts of common stock by shareholders;
- our ability to raise capital; and
- economic and other external factors.

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

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

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

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

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

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

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

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

We have adopted a shareholder rights plan, commonly known as a "poison pill." We have also adopted an executive officer severance plan (which was temporarily suspended in the first quarter of 2018) and entered into change of control agreements with our executive officers, both of which may provide for the payment of benefits to our officers and other key employees in connection with an acquisition. The provisions of our articles of

incorporation, our poison pill, our severance plan and our change of control agreements, and provisions of the California Corporations Code may discourage, delay or prevent another party from acquiring us or reduce the price that a buyer is willing to pay for our common stock.

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

We have never paid dividends on our capital stock.

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

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

In August 2013, we entered into several agreements with Grifols as part of the completion of a private sale of shares of common stock to Grifols, including in particular the License Agreement, the Governance Agreement, and a registration rights agreement with respect to shares of common stock owned by Grifols. As a result of the various obligations under these agreements, in addition to Grifols' ownership of approximately 34.6% of our outstanding common stock, or 47.8% of our common stock if Grifols converts all of its Convertible Notes, conflicts of interest may arise between Grifols and us from time to time. Disagreements regarding the rights and obligation of Grifols under these agreements could create conflicts of interest for one of our directors, who has been designated by Grifols and subsequently nominated by us for election to our board of directors. Any such disagreements could also lead to actual disputes or legal proceedings that may be resolved in a manner unfavorable to our other shareholders and us. In addition, Grifols has a number of consent rights under the Governance Agreement, including the right to consent to any termination of our Chief Executive Officer or our appointment of a successor Chief Executive Officer and certain preemptive rights to participate in any future issuances of common stock (or common stock equivalents) by us or to acquire shares in the open market to maintain ownership thresholds specified in the Governance Agreement. Grifols may exercise any of these rights, or any of its other rights contained in its agreements with us, in a manner which is not necessarily in the best interest of us or our other shareholders. The result of any of these conflicts could adversely affect our business, financial condition, results of operations or the price of our common stock.

Our principal shareholders own a large percentage of our common stock and will be able to exert significant control over matters submitted to our shareholders for approval, including delaying or preventing a change in control of our company.

A small number of our shareholders own a large percentage of our common stock and can, therefore, influence the outcome of matters submitted to our shareholders for approval. Based on information known to us, our two largest shareholders, collectively, beneficially own approximately 67% of the class of our common stock as of March 12, 2018. These two shareholders purchased most of the Convertible Notes and related Warrants described in Note 7 to the consolidated financial statements included in this Annual Report on Form 10-K, 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. Properties

As of December 31, 2017, we leased a portion of one building with an aggregate of 23,500 square feet office and laboratory facilities at 3929 Point Eden Way, Hayward, California. This building serves as our Corporate office and research and development facility, with a lease expiration of March 31, 2023. Our current facility is expected to meet our requirements for the foreseeable future.

Item 3. 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 denied institution of our post-grant review of the '845 Patent. We are currently assessing the PTO's decision.

On January 11, 2018 a putative class action lawsuit, *Kevin Kheder v. Aradigm Corporation, et al.,* No. 3:18-cv-00261, was filed in the United States District Court for the Northern District of California against the Company and two of its former officers. The suit is purportedly brought on behalf of persons and entities who acquired or otherwise purchased Aradigm common stock between July 27, 2017 and January 8, 2018 (the "Class Period"). Plaintiff alleges that defendants made false and misleading statements during the Class Period that artificially inflated the price of Aradigm stock. Plaintiff seeks to recover compensable damages he alleges to have been caused by defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The Company believes that the plaintiff's allegations are without merit and intends to defend the action vigorously.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. *Market for the Registrant's Common Stock, Related Stockholder Matters and Issuer Purchases of Equity Securities*

Market Information

Since June 11, 2014, our common stock has been traded on the Nasdaq Capital Market under the symbol "ARDM" following the Company's 1-for-40 reverse split of all outstanding shares of the Company's common stock effected on May 23, 2014.

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated as reported on the Nasdaq Capital Market.

	High	Low
2016		
First Quarter	$4.44	$2.65
Second Quarter	5.13	4.18
Third Quarter	6.88	4.13
Fourth Quarter	6.82	1.59
2017		
First Quarter	$2.08	$1.54
Second Quarter	1.59	0.80
Third Quarter	4.20	1.13
Fourth Quarter	7.05	3.30

As of March 12, 2018, there were 61 holders of record of our common stock. A greater number of holders of common stock are "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We expect to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends on our capital stock will be, subject to applicable law, at the discretion of our Board of Directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions in loan agreements or other agreements.

Recent Sales of Unregistered Securities

Not applicable.

Item 6. *Selected Financial Data*

The following selected financial data should be read in conjunction with Item 7—"Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

We have derived the selected financial data for the years ended and as of December 31, 2017, and 2016 from our consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

The selected financial data for the years ended and as of December 31, 2015, 2014, and 2013 have been derived from financial statements not included in this Annual Report on Form 10-K.

	Years Ended December 31,				
	2017	2016	2015	2014	2013
	(In thousands, except per share data)				
Statements of operations data:					
Total revenues	$ 14,465	$ 195	$ 23,429	$ 33,561	$ 9,717
Total operating expenses	21,407	30,217	40,581	37,417	29,629
Loss from operations	(6,942)	(30,022)	(17,152)	(3,856)	(19,912)
Interest income (expense), net	(3,778)	(2,318)	29	(271)	(1,643)
Other income (expense), including extinguishment of debt	15	(598)	(86)	8,779	(9)
Net income (loss)	(10,705)	(32,938)	(17,209)	4,652	(21,564)
Basic net income (loss) per share	(0.72)	(2.23)	(1.17)	0.32	(2.36)
Diluted net income (loss) per share	(0.72)	(2.23)	(1.17)	0.32	(2.36)
Shares used in computing basic net income (loss) per share	14,860	14,779	14,747	14,700	9,154
Shares used in computing diluted net income (loss) per share	14,860	14,779	14,747	14,726	9,154

	As of December 31,				
	2017	2016	2015	2014	2013
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents and short-term investments	$ 7,095	$ 22,591	$ 31,462	$ 47,990	$ 48,131
Working capital	2,218	18,953	27,730	43,736	42,394
Total assets	8,065	25,054	35,626	53,963	50,424
Deferred revenue—related party, current	1,900	—	—	790	4,379
Deferred revenue, —related party, non-current	90	5,000	5,000	7,845	—
Note payable and accrued interest net of discount	—	—	—	—	9,035
Convertible debt, net of discount	2,382	2,212	—	—	—
Convertible debt related party, net of discount	12,626	11,007	—	—	—
Accumulated deficit	(455,170)	(438,419)	(405,481)	(388,272)	(392,924)
Total shareholders' equity (deficit)	(12,531)	987	23,110	39,115	33,683

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 8 to the consolidated financial statements included in this Annual Report on Form 10-K.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Note Regarding Forward-Looking Statements

The discussion below contains forward-looking statements that are based on the current beliefs of our management, as well as current assumptions made by, and information currently available to, our management. All statements contained in the discussion below, other than statements that are purely historical, are forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause our future actual results, performance or achievements to differ materially from those expressed in, or implied by, any such forward-looking statements as a result of certain factors, including, but not limited to, those risks and uncertainties discussed in this section, as well as in the section entitled "Risk Factors", and elsewhere in our other filings with the SEC. Forward-looking statements contained in this Annual Report on Form 10-K include,

but are not limited to, statements regarding(i) our belief that our cash and cash equivalents as of December 31, 2017 will be sufficient to fund our operations through the first quarter of 2018, (ii) our ability to raise funds to execute on our business strategy to develop therapeutic products for prevention and treatment of severe respiratory diseases, or to obtain the funding for such programs by collaborations, government grants and other non-dilutive types of financing; (iii) our ability to obtain any further regulatory authority clearances (EMA) or approvals for our lead development product candidate, Linhaliq, and to comply with any regulatory standards for such product development candidates; (iv) our reliance on our collaborative partners such as Grifols, S.A., or Grifols, and third-party contract manufacturers and our ability to maintain collaborative partnerships; (v) our ability in future to commercialize certain of our unlicensed respiratory product candidates; (vi) our plans to work with the US and other allied governments to develop and, once approved, to supply them with our inhaled antibiotic for biodefense; (vii) our intent to use our pulmonary delivery methods and formulations of drugs and biologics to improve their safety, efficacy and convenience of administration to patients; (viii) our expectations regarding future clinical trials; and (ix) our expectation that we will incur additional operating losses.

Our business is subject to significant risks including, but not limited to, our ability to maintain our collaboration agreement with Grifols, our ability to implement our product development strategy, the success of product development efforts, obtaining and enforcing patents important to our business, clearing the lengthy and expensive regulatory approval process and possible competition from other products. Even if product candidates appear promising at various stages of development, they may not reach the market or may not be commercially successful for a number of reasons. Such reasons include, but are not limited to, the possibilities that the potential products may be found to be ineffective during clinical trials, may fail to receive necessary regulatory approvals, may be difficult to manufacture on a large scale, are uneconomical to market, may be precluded from commercialization by proprietary rights of third parties or may not gain acceptance from healthcare professionals and patients.

Investors are cautioned not to place undue reliance on the forward-looking statements contained herein. We undertake no obligation to update these forward-looking statements in light of events or circumstances occurring after the date hereof or to reflect the occurrence of unanticipated events.

Overview

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

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

In March 2018, we submitted a marketing authorization application, or MAA, to the European Medicines Agency, or EMA, seeking approval for Linhaliq for the treatment of NCFBE patients with chronic lung infection with *P. aeruginosa*. Our submission is based on the positive Phase 3 clinical trials ARD-3150-1202 or Orbit 4 with a primary endpoint of frequency of exacerbations which differs from the U.S. FDA primary endpoint of time to first exacerbation and supporting evidence from proprietary preclinical and clinical studies, as well as referencing additional information about ciprofloxacin from publicly available sources. The company had pre-submission meetings with EMA in October and November of 2017 to discuss the results of these studies. The submission is expected to be validated by EMA at the end of March 2018 at which time Day 1 of the MAA review procedure will commence. The company expects to receive comments or questions 120 days after validation.

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

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.

In April 2015, we announced the first results from the collaboration between scientists from OSU and Aradigm funded by NIH. 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. 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.

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 Dstl has received funding of up to $6.9 million from 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. 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 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. See Note 8 to the consolidated financial statements presented in this report.

Our contract revenues consist of revenues from grants, collaboration agreements, and feasibility studies. License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreement typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of milestones and royalties on net product sales. 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) we satisfy 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. For performance obligations that are services, revenue is recognized over time proportionate to the costs that the Company has incurred to perform the services using the input 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 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. When our assessment of probability of achievement changes and variable consideration becomes probable, any additional estimated consideration is allocated to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation and recorded in license, collaboration, and other revenues based upon when the customer obtains control of each element.

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).

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, the material rights are accounted for as separate performance obligations. Payments associated with optional items are allocated to the performance obligations in the separate contract. If we are entitled to additional payments for performance obligations in the original arrangement when the customer exercises these options, any additional payments are allocated to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation and recorded in license, collaboration, and other revenues when the customer obtains control of the goods or services.

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. We expense research and development costs as incurred.

We are eligible under the AusIndustry research and development tax incentive program to obtain a cash amount from the Australian Taxation Office. The tax incentive is available to us on the basis of specific criteria

with which we must comply. Specifically, we must have revenue of less than AUD $20.0 million and cannot be controlled by income tax exempt entities. These research and development tax incentives are recognized as contra research and development expense when the right to receive has been attained, and funds are considered to be collectible. The tax incentive is denominated in Australian dollars and, therefore, the related receivable is remeasured into U.S. dollars as of each reporting date.

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

Stock-Based Compensation

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

We use the Black-Scholes option pricing model to estimate the fair value of stock-based awards as of the grant date. The Black-Scholes model is complex and dependent upon key data input estimates. The primary data inputs with the greatest degree of judgment are the expected terms of the stock options and the estimated volatility of our stock price. The Black-Scholes model is highly sensitive to changes in these two inputs. The expected term of the options represents the period of time that options granted are expected to be outstanding. We use the simplified method to estimate the expected term as an input into the Black-Scholes option pricing model. We determine expected volatility using the historical method, which is based on the historical daily trading data of our common stock over the expected term of the option. For more information about our accounting for stock-based compensation, see Note 10 to the consolidated financial statements included in this 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 December 31, 2017, and December 31, 2016, we believed that the amount of our deferred income taxes would not be ultimately recovered. Accordingly, we recorded a full valuation allowance for deferred tax assets. However, should there be a change in our ability to recover our deferred tax

assets, we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

Recent Accounting Pronouncements

See Note 1 to our consolidated financial statements included in this Annual Report on Form 10-K for information on recent accounting pronouncements.

Accounting for revenues under the guidance of ASC Topic 606, Revenue from Contracts with Customers, or the new revenue standard, involves significant new estimates and judgments related to variable consideration and the constraint on variable consideration, including estimates of returns and the probability of development 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. Significant judgment is also 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. As a result, the timing of recognition of revenue has more variability under the new revenue standard due to significant estimates involved in the new accounting.

Results of Operations

Years ended December 31, 2017, and 2016

Our net loss of $10.7 million for the year ended December 31, 2017, decreased by approximately $22.2 million as compared to the net loss of $32.9 million for the year ended December 31, 2016. The decrease in the net loss resulted primarily from an increase in revenue of $14.3 million, a decrease in operating expenditure of $8.8 million primarily related to the completion of Phase 3 clinical trials for Linhaliq in NCFBE in the fourth quarter of 2016 and a decrease in other expense of $0.6 million in 2017, offset by an increase in interest expense of $1.5 million related to the Note Financing.

Total revenue was approximately $14.5 million for the year ended December 31, 2017, as compared to approximately $195 thousand for the year ended December 31, 2016. We recognized approximately $268,000 in government contract revenue and approximately $122,000 in government grant revenue for the year ended December 31, 2017, as compared to approximately $116,000 in government contract revenue and approximately $39,000 in government grant revenue for the year ended December 31, 2016. Additionally, for the year ended December 31, 2017, we recorded $14.1 million in contract revenue-related party for regulatory submission and approval services (which included $80,000 for the reimbursement of separate projects), as compared to $40,000 for the year ended December 31, 2016 for the reimbursement of a separate project involving biofilms that was not part of the original $65 million of Grifols-funded budget provided under the License Agreement. The increase in contract revenue—related party, was primarily due to the adoption of ASC 606 which resulted in a cumulative increase in deferred revenue upon adoption of approximately $6 million for revenue that was previously recorded and is now being recognized in 2017 and future periods as performance obligations are satisfied. Of the $14.5 million increase in contract revenue due to the adoption of ASC 606, revenue increased by $9.4 million for services performed in the period which under prior milestone recognition methodology, would not have been recognized until the milestones were substantially achieved. In addition, revenue increased by an additional $4.5 million for research and development services milestone payments received in 2017 that were allocated to regulatory submission and approval services performed in the period.

Operating expenses were approximately $21.4 million for the year ended December 31, 2017, which represented an approximately $8.8 million decrease as compared to the year ended December 31, 2016. Research and development expenses decreased approximately $10.6 million for the year ended December 31, 2017, and general and administrative expenses increased approximately $1.8 million for the year ended December 31, 2016. The decrease in research and development expenses was due to lower contract manufacturing, 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, meeting and travel expenses in support of the Linhaliq bronchiectasis regulatory process for US and EU approvals for market authorization and higher non-cash stock compensation expense. The increase in general and administrative expenses was primarily related to higher performance bonus expense, higher legal expense, higher corporate insurance expense, higher non-cash stock compensation expense and higher consulting expenses.

Liquidity and Capital Resources

Our independent registered public accounting firm for the fiscal year ended December 31, 2017 has indicated in their audit opinion, contained in our consolidated financial statements included in this Annual Report on Form 10-K that our current liquidity position raises substantial doubt about our ability to continue as a going concern due to our recurring losses from operations and net capital deficiency. We believe that our cash and cash equivalents as of December 31, 2017 of approximately $7.1 million will only be sufficient to fund our operations through the first quarter of 2018. As of December 31, 2017, we had working capital of approximately $2.2 million. We will not be able to maintain our current level of regulatory and product development activity in 2018 or in future fiscal years unless we raise additional capital in early 2018. We intend to raise additional capital through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund our operations and to continue the development of our lead product candidate Linhaliq in early 2018. No assurance can be given that we will be successful in raising such additional capital on favorable terms or at all. If we are unable to obtain additional funds when required, it will delay or reduce the scope of all or a portion of our development programs or require us to dispose of our assets or technology or to cease operations. See also Item 1A.—Risk Factors —"Although our financial statements have been prepared on a going concern basis, we will require additional financing to finance our operating expenses. Additional funds may not be available on terms that are acceptable to us or at all." Changing circumstances may cause us to expend cash significantly faster that we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

In 2016, we sold $23 million 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. Management expects operating losses to continue for the forseeable future including the year ended December 31, 2018. In 2015, we completed utilization of the full $65 million of the Grifols-funded budget provided under the License Agreement.

Year ended December 31, 2017

As of December 31, 2017, we had cash and cash equivalents of approximately $7.1 million, down from approximately $22.6 million at December 31, 2016. The decrease primarily resulted from the use of cash to fund

our ongoing operations in support of our Linhaliq program, partially offset by the receipt of $930,000 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 License Agreement.

Net cash used by operating activities for the year ended December 31, 2017 was approximately $16.5 million as a result of operating activities after adjusting our $10.7 million net loss for non-cash expenses of approximately $2.7 million in stock-based compensation expense and depreciation, $1.8 million amortization of convertible debt discount and related financing costs, and adjusting for net changes in operating assets and liabilities of approximately $10.4 million. Net cash provided by investing activities for the year ended December 31, 2017, was $0.9 million from the transfer of restricted cash used to pay interest expense on the Note which was offset by $154 thousand used to purchase capital expenditures. Net cash provided by financing activities for the year ended December 31, 2017, was approximately $150 thousand from proceeds received in connection with the issuance of common stock and exercise of stock options.

Year ended December 31, 2016

As of December 31, 2016, we had cash and cash equivalents of approximately $22.6 million, down from approximately $31.5 million at December 31, 2015. The decrease primarily resulted from the use of cash to fund our ongoing operations, offset by the receipt of $23.0 million in gross proceeds from the Note financing.

Net cash used by operating activities for the year ended December 31, 2016 was approximately $28.5 million as a result of operating activities after adjusting our $32.9 million net loss for non-cash expenses of approximately $1.8 million in stock-based compensation expense and depreciation, $1.7 million amortization of convertible debt discount and related financing costs, and adjusting for net changes in operating assets and liabilities of approximately $1.0 million. Net cash provided by financing activities for the year ended December 31, 2016, was approximately $20.7 million from the proceeds of the Note financing of $23.0 million (of which approximately $20.0 million was from a related party) partially offset by debt issuance costs of $2.4 million. Refer to Note 7 in the Notes to Consolidated Financial Statements for details of this debt issuance.

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 7A. ***Quantitative and Qualitative Disclosure About Market Risk***

The disclosures in this section are not required since we qualify as a smaller reporting company.

Item 8. ***Financial Statements and Supplementary Data***

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Aradigm Corporation
Hayward, California

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aradigm Corporation (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Notes 1 and 15 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Notes 1 and 15. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ OUM & Co. LLP

San Francisco, California
March 23, 2018
We have served as the Company's auditor since 2007.

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

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,095	$ 22,591
Restricted cash	—	1,006
Receivables	200	167
Prepaid and other current assets	389	1,037
Total current assets	7,684	24,801
Property and equipment, net	289	253
Other assets	92	—
Total assets	$ 8,065	$ 25,054
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 903	$ 711
Accrued clinical and cost of other studies	274	3,306
Accrued compensation	1,643	1,335
Deferred revenue—related party, current	1,900	—
Deferred revenue—other	183	—
Other accrued liabilities	563	496
Total current liabilities	5,466	5,848
Deferred rent	32	—
Deferred revenue—related party, non-current	90	5,000
Convertible debt, net of discount	2,382	2,212
Convertible debt—related party, net of discount	12,626	11,007
Total liabilities	20,596	24,067
Commitments and contingencies (Note 16)		
Shareholders' equity (deficit):		
Preferred stock, 5,000,000 shares authorized, none outstanding		
Common stock, no par value; authorized shares: 35,045,765 at December 31, 2017; 35,045,765 at December 31, 2016; issued and outstanding shares: 15,170,200 at December 31, 2017; 14,951,089 at December 31, 2016	442,639	439,406
Accumulated deficit	(455,170)	(438,419)
Total shareholders' equity (deficit)	(12,531)	987
Total liabilities and shareholders' equity (deficit)	$ 8,065	$ 25,054

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 8.

See accompanying Notes to Consolidated Financial Statements.

ARADIGM CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)

	Years Ended December 31,	
	2017	2016
Revenue:		
Contract revenue—related party (Note 9)	$ 14,075	$ 40
Contract revenue	268	116
Grant revenue	122	39
Total revenues	14,465	195
Operating expenses:		
Research and development	13,815	24,387
General and administrative	7,592	5,828
Restructuring and asset impairment	—	2
Total operating expenses	21,407	30,217
Loss from operations	(6,942)	(30,022)
Interest income	92	88
Interest expense	(3,870)	(2,406)
Other income (expense), net	15	(598)
Net loss and comprehensive loss	$ (10,705)	$ (32,938)
Basic and diluted net loss per common share	$ (0.72)	$ (2.23)
Shares used in computing basic and diluted net loss per common share	14,860	14,779

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 8.

See accompanying Notes to Consolidated Financial Statements.

ARADIGM CORPORATION
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)

	Common Stock		Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount		
Balances at December 31, 2015	14,761,351	$428,591	$ (405,481)	23,110
Issuance of common stock under the employee stock purchase plan	23,738	104	—	104
Issuance of restricted stock	166,000	—	—	—
Reclassification of derivative liability to equity	—	8,362	—	8,362
Reclassification of warrants to equity	—	11	—	11
Issuance of warrants with convertible notes	—	662	—	662
Stock-based compensation expense for stock options, restricted stock and restricted stock units	—	1,676	—	1,676
Net loss	—	—	(32,938)	(32,938)
Balances at December 31, 2016	14,951,089	439,406	(438,419)	$ 987
Cumulative Effect of Adopting New Accounting Standards				
Adoption of ASU 2016-09, Note 1	—	21	(21)	—
Adoption of ASC 606, Note 8	—	—	(6,025)	(6,025)
Issuance of common stock under the employee stock purchase plan	78,949	103	—	103
Issuance of restricted stock	118,100	—	—	—
Exercise of options	22,062	47	—	47
Stock issued in payment of officer bonus	—	444	—	444
Stock-based compensation expense for stock options, restricted stock and restricted stock units	—	2,618	—	2,618
Net loss	—	—	(10,705)	(10,705)
Balances at December 31, 2017	15,170,200	$442,639	$ (455,170)	$ (12,531)

See accompanying Notes to Consolidated Financial Statements.

ARADIGM CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (10,705)	$ (32,938)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	118	121
Stock-based compensation expense	2,618	1,676
Amortization of convertible debt discount	1,788	1,057
Financing costs, derivative liability and warrants	—	997
Change in value of derivative liability	—	(386)
Changes in operating assets and liabilities:		
Receivables	(33)	(17)
Prepaid and other current assets	648	2,597
Other assets	(92)	81
Accounts payable	193	(1,078)
Accrued compensation	752	176
Current deferred revenue—related party	(8,852)	—
Accrued liabilities	(2,965)	(625)
Deferred rent	32	(37)
Deferred revenue—related party, non-current	—	—
Facility lease exit obligation	—	(104)
Net cash used in operating activities	(16,498)	(28,480)
Cash flows from investing activities:		
Transfer to/from restricted cash, net	1,006	(1,006)
Capital expenditures	(154)	(75)
Net cash provided by (used in) investing activities	852	(1,081)
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	150	104
Payments for financing costs	—	(2,414)
Net cash provided by financing activities	150	20,690
Net decrease in cash and cash equivalents	(15,496)	(8,871)
Cash and cash equivalents at beginning of year	22,591	31,462
Cash and cash equivalents at end of year	$ 7,095	$ 22,591
Supplemental disclosure of cash flow information:		
Cash paid for interest	2,070	1,005
Non-cash disclosure of financing activities:		
Reclassification of derivative liability to equity	—	8,362
Reclassification of warrants to equity	—	11
Debt discount from warrants	—	662
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 Consolidated Financial Statements.

ARADIGM CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization

Aradigm Corporation (the "Company," "we," "our," or "us") is a California corporation, incorporated in 1991, focused on the development and commercialization of drugs delivered by inhalation for the treatment and prevention of severe respiratory diseases. The Company's principal activities to date have included conducting research and development and developing collaborations. Management does not anticipate receiving revenues from the sale of any of its products during the upcoming year. The Company operates as a single operating segment.

Basis of Presentation and Consolidation

The accompanying 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. Certain prior period amounts have been conformed to the current period's presentation.

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 1: Summary of Significant Accounting Policies-Accounting Changes." All amounts and disclosures set forth in this Form 10-K reflect these changes.

Liquidity and Financial Condition

The Company has incurred significant operating losses and negative cash flows from operations. At December 31, 2017, the Company had an accumulated deficit of approximately $455.2 million, working capital of approximately $2.2 million and shareholders' deficit of approximately $12.5 million. Management expects operating losses to continue for the foreseeable future. As a result of expected losses and negative cash flows from operations, along with the Company's cash position of $7.1 million at December 31, 2017, the Company will have sufficient resources to fund operations for the first quarter of 2018. The Company will need to raise additional capital through issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund the Company's operations and continue development of the Company's lead product candidate Linhaliq in early 2018. No assurance can be given that the Company will be successful in raising such additional capital on favorable terms or at all. If the Company is unable to obtain additional funds when required, it will delay or reduce the scope of all or a portion of its development programs or dispose of assets or technology, and if not achieved on a timely basis would materially harm its business, financial condition and results of operations or require the Company to dispose of its assets or technology or to cease operations, and the Company may not be able to continue as a going concern. For more information, see "Note 15: Going Concern."

Use of Estimates

The preparation of financial statements, in conformity with generally accepted accounting principles or 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 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 the restricted cash balance in the Consolidated Statement of Cash Flows based on the nature of the restriction. As of December 31, 2016, the Company had $1.0 million in restricted cash held in an interest-bearing escrow account for the purpose of making interest payments on the Convertible Notes, as outlined in Note 7 below. The Company was required to maintain such deposits sufficient to pay all required payments of interest through May 1, 2017. On December 31, 2017, the restricted cash balance is zero.

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 include external costs incurred for validation of the equipment. The Company does not capitalize internal validation expense. Computer equipment and software include capitalized computer software. All of the Company's capitalized software is purchased; the Company has no internally developed computer software. Leasehold improvements are amortized over the shorter of the term of the lease or useful life of the improvement.

The standard estimated useful lives of property and equipment are as follows:

Computer equipment and software	3 years
Furniture and fixtures	7 years
Lab equipment	5 years
Machinery and equipment	5 years
Leasehold improvements	5 years

Impairment of Long-Lived Assets

The Company reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values, and the loss is recognized in the Consolidated Statements of Operations and Comprehensive Loss.

Convertible Instruments

The Company accounts for hybrid contracts that feature conversion options in accordance with GAAP. 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 upon 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 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. For performance obligations that are services, revenue is recognized over time proportionate to the costs that the Company has incurred to perform the services using the input 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.

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. When our assessment of probability of achievement changes and variable consideration becomes probable, any additional estimated consideration is allocated to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation and recorded in license, collaboration, and other revenues based upon when the customer obtains control of each element.

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).

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 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. The Company assesses if these options provide a material right to the licensee and if so, the material rights are accounted for as separate performance obligations. Payments associated with optional items are allocated to the performance obligations in the separate contract. If the Company is entitled to additional payments for performance obligations in the original arrangement when the customer exercises these options, any additional payments are allocated to each performance obligation based on the estimated relative standalone selling prices of the promised goods or service underlying each performance obligation and recorded in license, collaboration, and other revenues when the customer obtains control of the goods or services.

Research and Development

Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and research-related overhead expenses. The Company expenses research and development costs as such costs are incurred.

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 year ended December 31, 2017, the Company offset its research and development costs by approximately $1 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 or ESPP. 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 10 for further discussion of the Company's stock-based compensation plans.

Income Taxes

The Company makes certain estimates and judgments in determining income tax expense for 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 the 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 its income taxes in each of the jurisdictions in which it operates. This process involves the estimation of the current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities which are included in the Company's consolidated balance sheets.

The Company 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 its 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, it will record a valuation allowance against the deferred tax assets that it estimates will not ultimately be recoverable. At December 31, 2017 and 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, it 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 shares subject to repurchase. Diluted net income/(loss) per common share is based on the weighted average number of common and common share equivalents, such as stock options and unvested restricted stock shares outstanding during the period. Potentially dilutive securities were not included in the net loss per common share calculation for the years ended December 31, 2017 and 2016 because the inclusion of such shares would have had an anti-dilutive effect. Refer to Note 11 for a summary of the anti-dilutive securities.

Significant Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and short-term investments. Risks associated with these instruments are mitigated by banking with, and only purchasing commercial paper and corporate notes from, creditworthy institutions. The maximum amount of loss due to credit risk associated with these financial instruments is their respective fair values as stated in the accompanying Consolidated Balance Sheets.

Comprehensive Income (Loss)

ASC 220, *Comprehensive Income* requires that an entity's change in equity or net assets during a period from transactions and other events from non-owner sources be reported. The Company reports unrealized gains or losses on its available-for-sale securities as other comprehensive income (loss). Total comprehensive income (loss) has been disclosed on the Consolidated Statement of Operations and Comprehensive Income (Loss).

Accounting Changes

In May 2014, the Financial Accounting Standards Board or 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 8 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 $21,000, 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.

2. Cash and Cash Equivalents

At December 31, 2017 and 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.

3. Fair Value Measurements

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

The Company's cash and cash equivalents at December 31, 2017 and 2016, consist of cash and money market funds. Money market funds are valued using quoted market prices.

4. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2017	2016
Machinery and equipment	$ 4,382	$ 4,363
Furniture and fixtures	592	578
Lab equipment	1,449	1,446
Computer equipment and software	1,874	1,821
Leasehold improvements	1,799	1,734
Property and equipment	10,096	9,942
Less accumulated depreciation and amortization	(9,807)	(9,689)
Property and equipment, net	$ 289	$ 253

Depreciation expense was $118,000 and $121,000 for the years ended December 31, 2017 and 2016, respectively. In 2016, the Company retired $2.7 million in assets that were no longer in service.

5. Sublease Agreement and Lease Exit Liability:

On July 18, 2007, the Company entered into a sublease agreement with Mendel, to lease approximately 48,000 square feet of the Company's 72,000 square foot headquarters facility located in Hayward, California which ended in July 2016.

During the year ended December 31, 2007, the Company recorded a $2.1 million lease exit liability and related expense for the expected loss on the sublease, in accordance with ASC 420 *Exit or Disposal Cost*

Obligations, because the monthly payments the Company expects to receive under the sublease are less than the amounts that the Company will owe the lessor for the sublease space. The fair value of the lease exit liability was determined using a credit-adjusted risk-free rate to discount the estimated future net cash flows, consisting of the minimum lease payments to the lessor for the sublease space and payments the Company will receive under the sublease. The sublease loss and ongoing accretion expense required to record the lease exit liability at its fair value using the interest method were recorded as part of restructuring and asset impairment expense in the Consolidated Statement of Operations and Comprehensive Loss in the year ended December 31, 2007. The lease exit liability activity for the years ended December 31, 2017 and 2016 is as follows (in thousands):

	Year Ended December 31,	
	2017	2016
Balance at the beginning of year	$ —	$ 104
Accretion expense	—	2
Lease payments	—	(106)
Balance at the end of the year	$ —	$ —

As of December 31, 2017 and 2016, the Company had no lease liability.

6. Other Accrued Liabilities

At December 31, 2017, other accrued liabilities consisted of accrued expenses for interest of $345,000, expenses for services of $132,000 and payroll withholding liabilities of $86,000. The liability for accrued interest of $345,000 is related to the Convertible Notes as outlined in Note 7 and represents the interest on the Convertible Notes that is accrued but unpaid as of December 31, 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.

7. 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.

The Convertible Notes are initially convertible into the Company's 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. The conversion rate may be subject to adjustment upon the occurrence of certain specified events as provided in the indenture governing the Convertible Notes, dated April 25, 2016, between the Company and U.S. Bank National Association, as trustee, or the Indenture, but will not be adjusted for accrued but unpaid interest. Upon conversion of a Convertible Note, the Company will settle the conversion obligation in common stock equal to the conversion rate, together with a cash payment, if applicable.

The Convertible Notes are convertible at the option of the holders at any time prior to April 29, 2021. Holders of the Convertible Notes who convert their Convertible Notes in connection with a make-whole

fundamental change, as defined in the Indenture, may be entitled to a make-whole premium in the form of an increase to the conversion rate during a specified period following the effective date of the make-whole fundamental change. In addition, upon the occurrence of a fundamental change prior to the maturity date of the Convertible Notes, as defined in the Indenture, holders of the Convertible Notes may require the Company to purchase all or a portion of their Convertible Notes for cash at a price equal to 100% of the principal amount of the Convertible Notes to be purchased plus any accrued but unpaid interest to, but excluding, the fundamental change purchase date.

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 aggregate principal amount of the then outstanding Convertible Notes may declare all of 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. The Warrants are exercisable commencing on the later of October 25, 2016, and the date of the public release of top-line data related to the conclusion of the ORBIT-3 and ORBIT-4 Phase 3 pivotal clinical trials for the Company's investigational product Linhaliq inhaled ciprofloxacin. The Warrants became exercisable on December 1, 2016, following the Company's announcement of the top-line data from the Phase 3 clinical trials. If, at any time from and after October 25, 2016, the daily volume-weighted average price of the shares of the Company's common stock for each of ten consecutive trading days exceeds 150% of the Exercise Price, the Company will have the right to call all or a portion of the Warrants for redemption upon twenty business days prior notice to the holders, at a redemption price of $0.01 per Warrant; provided that the holders of the Warrants may elect to exercise their Warrants upon receipt of any redemption notice from the Company.

In accounting for the Convertible Notes and Warrants in the first closing, the Company bifurcated a derivative liability from the debt host and discounted the Convertible Notes for the estimated fair value of the conversion feature and the freestanding Warrants issued in connection with the Convertible Notes. The liability components were measured by estimating their fair value as of the commitment date. On June 9, 2016, the Company obtained Shareholder Approval for the Convertible Notes, the Warrants and the underlying shares, at which point the Conversion Share Cap on the Convertible Notes was lifted. As a result, the bifurcated derivative and warrant liability met the equity classification criteria under ASC 815-40-25, and the liabilities were remeasured at fair value on June 9, 2016, and reclassified to permanent equity. The equity component will not be remeasured in subsequent periods provided that the component continues to meet the conditions necessary for equity classification. The excess of the aggregate face value of the Convertible Notes over the estimated fair value of the liability components is recognized as a debt discount which will be amortized over the term of the Convertible Notes using the effective interest rate method. Amortization of the debt discount is recognized as non-cash interest expense.

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 9 below. 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 Company deposited $1.8 million of the net proceeds into an escrow account after the initial closing to fund, when due, the first two scheduled semi-annual interest payments on the Notes. The effective interest rate of the liability component was equal to 22.9% for the year ended December 31, 2017.

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 Company deposited $215,000 of the net proceeds into an escrow account after the second closing to fund, when due, the first two scheduled semi-annual interest payments on the Convertible Notes. The effective interest rate of the liability component was equal to 16.24% for the year ended December 31, 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 year ended December 31, 2016, financing costs of $997,000, allocated to the derivative liability and Warrant components were expensed and are included in other expense in the Consolidated Statement of Operations and Comprehensive Loss.

In connection with the first closing, the derivative and warrant liabilities were measured at fair value using certain estimated inputs, which are classified within Level 3 of the valuation hierarchy. The following assumptions were used in the Black-Scholes Model to measure the fair value of the derivative and warrant liability as of June 9, 2016 (the date of the shareholder vote) and April 21, 2016 (the date of the first closing):

	June 9, 2016	April 21, 2016
Fair value of underlying stock—per share	$ 4.48	$ 4.55
Risk-free interest rate	1.20%	1.35%
Expected life (years)	4.9	5
Expected volatility	73.16%	73.95%
Dividend yield	0.0%	0.0%

The following table summarizes the activity in the derivative liability and the warrant liability for the year ended December 31, 2016:

	Year Ended December 31, 2016 (in thousands)				
	Fair Value December 31, 2015	Fair Value of Instruments Issued	Change in Fair value	Reclassifications to Equity	Fair Value December 31, 2016
Derivative liability	$ —	$ 8,748	$ (386)	$ (8,362)	$ —
Warrant liability	—	11	—	(11)	—
Total	$ —	$ 8,759	$ (386)	$ (8,373)	$ —

For the year December 31, 2016, the Company recognized a gain of $386,000 and $500 on the derivative and warrant liabilities, respectively, related to the change in fair value from the date of commitment to the date the instruments met the equity classification criteria on June 9, 2016, at which point $8.4 million was reclassified from liabilities to equity. The gain has been recorded in other expense in the Consolidated Statement of Operations and Comprehensive Loss.

In connection with the second closing, the Warrants issued as a component of equity were measured at fair value using certain estimated inputs, which are classified within Level 3 of the valuation hierarchy. The

following assumptions were used in the Black-Scholes Model to measure the fair value of the Warrants as of July 14, 2016:

	July 14, 2016
Fair value of underlying stock—per share	$ 4.58
Risk-free interest rate	1.07%
Expected life (years)	4.78
Expected volatility	72.87%
Dividend yield	0.0%

As of December 31, 2017 and 2016, the Convertible Notes consisted of the following:

	December 31, 2017	December 31, 2016
	(in thousands, except conversion rate and conversion price)	
Principal value	$ 23,000	$ 23,000
Unamortized debt discount	(6,948)	(8,501)
Unamortized debt issuance costs	(1,044)	(1,280)
Carrying value of the convertible notes	$ 15,008	$ 13,219
Conversion rate (shares of common stock per $1,000 principal amount of notes)	191.9386	191.9386
Conversion price (per share of common stock)	$ 5.21	$ 5.21

For the years ended December 31, 2017 and 2016, the Company recognized interest expense associated with its Convertible Notes as follows:

	Year ended December 31, 2017	Year ended December 31, 2016
	(in thousands)	
Cash Interest Expense		
Coupon interest expense	$ 2,070	$ 1,349
Other interest expense	12	—
Noncash Interest Expense		
Amortization of debt discount	1,552	920
Amortization of transaction costs	236	137
	$ 3,870	$ 2,406

As of December 31, 2017, the unamortized debt discount will be amortized over a remaining period of approximately 3.34 years. The if-converted value as of December 31, 2017, exceeds the principal balance of the Convertible Notes by $6.6 million. Accrued interest payable at December 31, 2017 and 2016 is $345,000 and $340,000, respectively and is included in other accrued liabilities. For the twelve months ended December 31, 2017 interest expense on the Company's Consolidated Statement of Operations and Comprehensive Loss is primarily composed of interest expense associated with the Convertible Notes but also includes $12,000 of other miscellaneous interest expense.

8. Revenue Recognition

Adoption of ASC Topic 606, "Revenue from Contracts with Customers"

On January 1, 2017, the Company adopted ASC 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 ASC Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historical accounting under ASC Topic 605.

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 year ended December 31, 2017, revenue increased by $9.4 million for services performed in the period which under the prior milestone recognition methodology, would not be recognized until the milestones are substantively achieved. In addition, revenue increased by an additional $4.5 million for research and development services milestone payments received in the period that were allocated to regulatory submission and approval services performed in the period. For the year ended December 31, 2017, net loss decreased by $13.9 million and basic and diluted net loss per share decreased by $0.94 per share as a result of the adoption of Topic 606.

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 giving 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 1 above.

The following table presents changes in the Company's contract assets and liabilities for the year ended December 31, 2017.

	Balance at Beginning of the Year	Additions	Deductions	Balance at the end of the Year
		(in thousands)		
Contract Assets	$ —	$ 67	$ —	$ 67
Contract Liabilities: Deferred Revenue	$ 11,026	$ 5,411	$ (14,264)	$ 2,173

Deferred revenues allocated to unsatisfied performance obligations will be recognized over time as the services are performed, which is expected to take place in 2018 and 2019.

Sales-based royalties, including milestone payments based on the level of sales, related to license arrangements are excluded from variable consideration and will be recognized 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 elected to exclude providing further disclosure about sales-based royalties in accordance with ASC Topic 606-10-50-14A.

Milestone payments that are not considered probable of being achieved are excluded from the transaction price until those approvals are received. As a result, amounts that would be allocated to unsatisfied performance obligations for such milestone payments are excluded from Contract Assets and Contract Liabilities.

During the year ended December 31, 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	$ 9,167
New activities in the period:	
Changes in the estimated transaction price allocated to performance obligations satisfied in prior periods	4,527
Performance obligations satisfied from new activities in the current period—contract revenue	649
Performance obligations satisfied from new activities in the current period—grant revenue	122
Total revenue	$14,465

9. Collaboration Agreement

Grifols License and Collaboration Agreement

In 2013, the Company and Grifols, S.A., or Grifols and certain other investors, or the Investors, entered into a Stock Purchase Agreement, or the Grifols Stock Purchase Agreement, pursuant to which the Company agreed, subject to the terms and conditions set forth in the Stock Purchase Agreement, to issue and sell shares of the Company's common stock, or Common Stock, to Grifols and additional shares of Common Stock to the Investors.

In conjunction with signing the Grifols Stock Purchase Agreement, the Company and Grifols agreed to enter into a License and Collaboration Agreement, or the Grifols License Agreement, at the closing of the Company Stock Sale; Grifols and the Company are considered to be related parties, and as a result, all transactions between the two entities are recognized as related party transactions. The License Agreement exclusively licenses the Company's inhaled liposomal ciprofloxacin compounds for the indication of non-cystic fibrosis bronchiectasis and other indications (the "Program") to Grifols on a worldwide basis. Grifols has funded development expenses of $65 million for the first indication of non-cystic fibrosis bronchiectasis with all other indications fully funded by Grifols if Grifols elects to pursue such development, and will commercialize products from the Program, or the Products, and pay development milestones and royalties on future commercial sales of Products. The License Agreement is described further below.

The Company determined this transaction was not within the scope of ASC 605-25.

License Agreement

The License Agreement was signed simultaneously with the closing of the Company Stock Sale in 2013. Under the License Agreement, the Company granted to Grifols an exclusive license to the Program, the lead product candidate of which is named Linhaliq. The license permits Grifols to commercialize Products throughout the world and grants Grifols a back-up manufacturing right to produce Products.

The Company is responsible for developing the Product for non-cystic fibrosis bronchiectasis or pulmonary infections associated with non-cystic fibrosis bronchiectasis, in accordance with an agreed upon development plan and pursuant to a Grifols-funded budget of $65 million (which includes allocations for the Company's internal, fully-burdened expenses). Any excess expenses are the responsibility of the Company. The Company will develop the Product for additional indications at Grifols' sole expense if Grifols elects to pursue such development. The Grifols-funded budget was fully utilized by the year ended December 31, 2015.

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

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

The collaboration between Grifols and the Company is governed by a joint committee comprised of equal representation by the Company and Grifols and operated on a consensus basis. In the event that the parties do not agree, Grifols has deciding authority, except with respect to specific matters specified in the License Agreement. The Company has no obligation to participate in the joint committee after the first commercial sale of the product but may do so at its discretion. Accordingly, the Company determined that it can separate performance obligations that occur over the development period from performance obligations that will occur during the commercialization period.

With respect to the US and EU development and approval of Linhaliq for non-cystic fibrosis bronchiectasis management, Grifols has paid to Aradigm reimbursements of development costs of $65 million and will pay development milestone payments of up to a total of $25 million. Additionally, royalty payments on a country-by-country basis on net sales at a rate of either 12.5% or 20% (depending on the amount of net sales) for so long as there is patent coverage or orphan drug designation (or, if longer, 10 years), except that payments will be reduced by half on a country-by-country basis in the event that another inhaled liposomal product containing ciprofloxacin is being sold for an indication for which the Aradigm product has regulatory approval. Royalty payments may also be reduced by 50% if Aradigm has no valid patent claim or orphan drug protection in that country.

Prior to the adoption of ASC Topic 606, under ASC Topic 605, the Company recognized reimbursements of development expenses as collaboration services were performed and costs were incurred. During the year ended December 31, 2016, the Company recognized no contract revenue – related party relating to services performed and costs incurred during the period under the License Agreement as the Company had utilized the full $65 million of the Grifols-funded budget provided under the License Agreement. In addition, the Company's current deferred revenue balance at December 31, 2016, was $5.0 million, representing a milestone payment which was received upon the dosing of the first patient in a Phase III clinical trial.

Upon adoption of ASC Topic 606 as of January 1, 2017, the Company deferred $6.0 million for the portion of the Grifols 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 a result of adoption, an additional $14.0 million of Grifols contract revenue was recognized for performance obligations satisfied during the year ended December 31, 2017, including the $5.0 million milestone payment received during 2017, which under the prior milestone recognition methodology would not have been recognized since the milestone is not considered to be substantively achieved until regulatory approval is achieved.

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 did not include a material right.

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 December 31, 2017, the Company has achieved two of the six milestones and has received $10.0 million in payments. Milestone payments related to regulatory submission and approval services are considered variable consideration and excluded from the transaction price 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 year ended December 31, 2017 due to the constraint on variable consideration.

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 $2.0 million of the transaction price in the Grifols' arrangement that is allocated to the performance obligations that are unsatisfied (or partially unsatisfied) as of December 31, 2017.

Governance Agreement

The Grifols Governance Agreement sets forth certain rights and obligations of the Company and Grifols concerning, among other things, certain corporate governance matters, certain limitations on future acquisitions of shares of Common Stock by Grifols, and certain rights by Grifols to maintain a target level of ownership in the Company.

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

The Grifols Governance Agreement also provides that during the period beginning on the date of Closing and ending 12 months after the first commercial sale of a Product, or the Restricted Period, Grifols will not directly or indirectly acquire or offer to acquire any shares of Common Stock except (i) with the approval of the Company's board of directors and a majority of its independent directors, (ii) effected solely to the extent necessary to maintain the beneficial ownership of Grifols and its affiliates at an amount equal to 35%, or the Target Percentage, of the shares of Common Stock on a Fully Diluted Basis (as defined in the Governance Agreement), or (iii) in order to maintain its ownership percentage in the event that the Company issues new securities, in accordance with the provisions of the Governance Agreement. In conjunction with the Note Financing, the Grifols Governance Agreement was amended to raise the Target Percentage to 43.3%. The Restricted Period terminates upon the occurrence of certain events, including a change in control of the Company and a third party publicly proposing to acquire the Company. The Governance Agreement further imposes certain "standstill" obligations on Grifols during the Restricted Period, pursuant to which Grifols and certain related persons are prohibited from soliciting proxies from the Company's shareholders, granting proxies or entering into voting agreements and seeking additional representation on the Company's Board of Directors.

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

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

Registration Rights Agreements

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

10. Shareholders' Equity

Shareholder Rights Plan

In September 2008, the Company adopted an amended and restated shareholder rights plan, which replaced the rights plan originally adopted in August 1998. Pursuant to the rights plan, as amended and restated, the Company distributes rights to purchase shares of Series A Junior Participating Preferred Stock as a dividend at the rate of one right for each share of common stock outstanding. Until the rights are distributed, the rights trade with, and are not separable from, the Company's common stock and are not exercisable. The rights are designed to guard against partial tender offers and other abusive and coercive tactics that might be used in an attempt to gain control of the Company or to deprive the Company's shareholders of their interest in the Company's long-term value. The shareholder rights plan seeks to achieve these goals by encouraging a potential acquirer to negotiate with the Company's Board of Directors. The rights will expire at the close of business on September 8, 2018.

Stock Option Plans: 2005 Equity Incentive Plan, and 2015 Equity Incentive Plan

On March 13, 2015 the Board adopted and, on May 14, 2015 the Company's shareholders approved, the 2015 Equity Incentive Plan, or the 2015 Plan. The 2015 Plan replaces the Company's 2005 Equity Incentive Plan, or 2005 Plan, which expired in March 2015. The 2015 Plan is intended to promote our long-term success and increase shareholder value by attracting, motivating, and retaining non-employee directors, officers, employees, advisors, consultants and independent contractors, and allows the flexibility to grant a variety of awards to eligible individuals, thereby strengthening their commitment to the Company's success and aligning their interests with those of the Company's shareholders. The Company did not request that shareholders authorize any new shares of Common Stock in connection with the approval of the 2015 Plan; rather, the shares authorized for issuance under the 2005 Plan are now available for issuance under the 2015 Plan. In March 2016, the Company's Board of Directors amended, and in June 2016 the Company's shareholders approved, an amendment to the 2015 Plan increasing the shares of common stock authorized for issuance by 2,400,000 shares. In April of 2017, the Company's Board of Directors amended, and in June 2017 the Company's shareholders approved an amendment to the 2015 Plan increasing the shares of common stock authorized for issuance by 2,500,000 shares.

Options granted under the 2005 Plan and the 2015 Plan expire no later than 10 years from the date of grant and may be either incentive or non-statutory stock options. For incentive and non-statutory stock option grants, the option price shall be at least 100% and 85%, respectively, of the fair value on the date of grant, as determined by the Company's Board of Directors. If at any time the Company grants an option, and the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant.

Options granted under the 2005 Plan and the 2015 Plan may be immediately exercisable if permitted in the specific grant approved by the Board of Directors and, if exercised early may be subject to repurchase provisions. The shares acquired generally vest over a period of four years from the date of grant. Both Plans also provides for

a transition from employee to consultant status without termination of the vesting period as a result of such transition. Under both Plans, employees may exercise options in exchange for a note payable to the Company, if permitted under the applicable grant. As of December 31, 2017 and 2016, there were no outstanding notes receivable from shareholders. Any unvested stock issued is subject to repurchase agreements whereby the Company has the option to repurchase unvested shares upon termination of employment at the original issue price. The common stock subject to repurchase has voting rights, but cannot be resold prior to vesting. No grants with early exercise provisions have been made under the 2005 Plan or 2015 Plan and no shares have been repurchased.

The following is a summary of activity (time- and performance-based) under the 2005 Plan and the 2015 Plan for the year ended December 31, 2017:

	Shares Available for Future Grant
Balance at January 1, 2017	1,510,272
Increase in authorized shares	2,500,000
Options granted	(2,041,901)
Options cancelled	215,853
Restricted stock awards granted	(539,100)
Balance at December 31, 2017	1,645,124

Stock Options	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2017	1,923,595	$ 6.86		
Options granted	2,041,901	$ 3.29		
Options exercised	(22,062)	$ 2.12		
Options cancelled	(215,853)	$ 10.53		
Outstanding at December 31, 2017	3,727,581	$ 4.72	8.27	$8,763,440
Ending exercisable	1,634,831	$ 4.76	7.30	$3,909,557

The weighted-average grant-date fair value of options granted during the years ended December 31, 2017 and 2016 is discussed below under "*Valuation Assumptions*". The intrinsic value of exercised stock options is calculated based on the excess, if any, of the quoted market price of our common stock as of the close of business on the exercise date over the exercise price. The total intrinsic value of stock options exercised in fiscal years 2017 and 2016 was $69,000 and zero, respectively.

A summary of the activity of the Company's unvested restricted stock and performance-based restricted stock award activities for the year ended December 31, 2017 is presented below. The ending balance represents the maximum number of shares that could be earned or vested under the 2005 Plan and 2015 Plan:

Restricted Stock Awards

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2017	152,238	$ 3.96
Restricted stock awards granted	539,100	1.39
Restricted stock awards vested	(77,800)	2.03
Outstanding at December 31, 2017	613,538	$ 1.95

Recipients of restricted stock do not pay cash consideration for the shares and have the right to vote all shares subject to the grant. The weighted average grant date fair value of restricted stock awards is based on the closing price of the Company's common stock on the date of grant. The total fair value of restricted stock awards that vested during the years ended December 31, 2017 and 2016 was $213,000 and $53,000 respectively.

Restricted Stock Units

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2017	10,306	$ 5.34
Restricted stock units granted	—	—
Restricted stock units vested	—	—
Outstanding at December 31, 2017	10,306	$ 5.34

As of December 31, 2017, there was no unrecognized compensation cost related to restricted stock unit arrangements granted under the Plans. The total fair value of shares vested during the years ended December 31, 2017 and 2016 was zero for both years.

Performance-based Stock Options

During the year ended December 31, 2017, the Company granted to certain executives 460,000 performance-based stock options with a weighted average exercise price of $4.02. These performance-based stock options have a contractual term of ten years and vesting is dependent upon meeting certain specified company-wide performance goals. The weighted average grant date fair value of these performance-based stock options is discussed below under "*Valuation Assumptions*". No stock-based compensation expense related to these performance-based stock options has been recognized during the year ended December 31, 2017, as none of the performance-based goals was deemed to have been probable of being achieved during the period. Subsequent to December 31, 2017; 440,000 performance-based stock options were cancelled due to not meeting certain specified performance goals and the resignations of the officers and a vice president.

During the year ended December 31, 2016, the Company granted to certain executives 595,000 performance-based stock options with a weighted average exercise price of $4.09 (contingent upon shareholder approval which was received in June 2016). These performance-based stock options have a contractual term of ten years and vesting is dependent upon meeting certain specified company-wide performance goals. The weighted average grant date fair value of these performance-based stock options is discussed below under "*Valuation Assumptions*". No stock-based compensation expense related to these performance-based stock options has been recognized during the years ended December 31, 2017 and 2016, as none of the performance-based goals was deemed to have been probable of being achieved during the period. During the year ended December 31, 2017; 170,000 performance-based stock options were cancelled due to not meeting certain specified performance goals. Subsequent to December 31, 2017; 395,000 stock options were cancelled due to the resignations of certain officers and a vice president and the Company's failure to meet specified performance goals.

Performance-based Restricted Stock Awards

During the year ended December 31, 2017, the Company granted to certain executives 421,000 performance-based restricted stock awards or PRSAs with a weighted average fair value of $1.39. Vesting in these PRSAs is dependent upon meeting a certain specified company-wide performance goal. No stock-based compensation expense related to these PRSAs has been recognized during the year ended December 31, 2017, as the performance-based goal was not deemed to have been probable of being achieved during the period.

Employee Stock Purchase Plan

Employees generally are eligible to participate in the ESPP if they have been continuously employed by the Company for at least 10 days prior to the first day of the offering period and are customarily employed at least 20 hours per week and at least five months per calendar year and are not a 5% or greater shareholder. Shares may be purchased under the ESPP at 85% of the lesser of the fair market value of the common stock on the grant date or purchase date. Employee contributions, through payroll deductions, are limited to the lesser of 15% of earnings or $25,000.

As of December 31, 2017, a total of 486,250 shares have been reserved for issuance under the ESPP, of which 274,644 shares have been issued to participants leaving a remaining balance of 211,606 available authorized shares. Compensation expense related to the ESPP was $105,000 and $73,000 for the years ended December 31, 2017 and 2016, respectively. The fair value of employee stock purchase rights under the ESPP is discussed below under "*Valuation Assumptions*".

Stock-Based Compensation Expense

The Company recognizes stock-based compensation expense based on the fair value of that portion of stock options and restricted stock awards that are ultimately expected to vest during the period. Stock-based compensation expense recognized in the Consolidated Statement of Operations and Comprehensive Loss includes compensation expense for stock-based awards based on the estimated grant date fair value over the requisite service period.

The following table shows stock-based compensation expense included in the Consolidated Statement of Operations and Comprehensive loss for the years ended December 31, 2017 and 2016, (in thousands, except per share amounts):

	2017	2016
Costs and Expenses		
Research and development	$1,317	$ 826
General and administrative	1,301	850
Total stock-based compensation expense	$2,618	$1,676
Impact on basic and diluted net loss per common share	$ (0.18)	$ (0.11)

There was no capitalized stock-based compensation expense as of December 31, 2017. Since the Company has cumulative net losses through December 31, 2017, there was no tax benefit associated with stock-based compensation expense.

The total amount of unrecognized compensation expense related to unvested stock options and stock purchases was $3,049,000 as of December 31, 2017. This amount will be recognized over a weighted average period of 1.3 years. As of December 31, 2017, there was $249,000 of unrecognized compensation expense related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 0.3 years. There also was $184,000 of unrecognized compensation expense related to the current ESPP offering period as of December 31, 2017, which is expected to be recognized through March 31, 2019.

Valuation Assumptions

The fair value of stock options and employee stock purchase rights are estimated at the date of grant using the Black-Scholes option pricing model based on the following assumptions:

Expected term represents the period of time that options are expected to be outstanding. Because we do not have sufficient history of exercise behavior, we determine the expected term assumption for options using the

simplified method, which is an average of the contractual term of the option and its vesting period. For performance-based stock options, the expected term is based on a combination of the Company's probability assessment that the performance targets will be achieved and use of the simplified method. For non-employee options, the expected term is the contractual term of the option. For ESPP stock purchase rights, the expected term is generally the two-year offering period.

Expected volatility is based on the historical volatility of the Company's common stock at the time of grant for the time period approximately equal to the expected term.

Risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for the time period approximately equal to the expected term.

Expected dividend yield is 0% based on the fact that the Company does not anticipate paying dividends in the foreseeable future.

The weighted average assumptions for employee service-based options (which for purposes of this table includes members of the board of directors) were as follows:

	Years Ended December 31	
	2017	2016
Dividend yield	0.0%	0.0%
Volatility factor	81.1%	74.0%
Risk-free interest rate	2.0%	1.4%
Expected term (in years)	5.6	5.5
Weighted-average fair value of options granted during the periods	$ 2.24	$ 3.13

The weighted average assumptions for performance-based options were as follows:

	Years Ended December 31,	
	2017	2016
Dividend yield	0.0%	0.0%
Volatility factor	80.4%	77.1%
Risk-free interest rate	2.1%	1.5%
Expected term (in years)	5.2	5.7
Weighted-average fair value of options granted during the period	$ 2.64	$ 2.68

The weighted average assumptions for employee stock purchase rights under the ESPP were as follows:

	Years Ended December 31,	
	2017	2016
Dividend yield	0.0%	N/A
Volatility factor	81.7%	N/A
Risk-free interest rate	1.2%	N/A
Expected life (years)	2.0	N/A
Weighted-average fair value of purchase rights granted during the period	$ 0.90	N/A

There were no employee stock purchase rights valued during the year ended December 31, 2016 as the previous offering period was valued on April 1, 2015 and was over a two-year period.

The Company accounts for options issued to non-employees under ASC 505-50, Equity-Equity Based Payments to Non-Employees, using the Black-Scholes option pricing model. The value of such non-employee options are periodically re-measured over their vesting terms.

11. Net Loss Per Common Share

The Company computes basic net loss per common share using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of shares of common stock subject to repurchase. The effects of including the incremental shares associated with options, warrants and unvested restrictive are anti-dilutive and are not included in the diluted weighted average number of shares of common stock outstanding for the years ending December 31, 2017 and 2016.

The Company excluded the following securities from the calculation of diluted net loss per common share for the years ended December 31, 2017 and 2016, as their effect would be anti-dilutive (in thousands):

	Year ended December 31,	
	2017	2016
Common shares underlying convertible notes	4,415	4,415
Outstanding stock options	3,728	1,924
Common shares underlying warrants	263	263
Unvested restricted stock	613	152
Unvested restricted stock units	10	10

12. Employee Benefit Plans

The Company provides a 401(k) Plan for all full-time employees. Employees can contribute on a pretax basis up to the 2017 statutory limit of $18,000 (plus an additional $6,000 for employees that are 50 years and older). The Company matches employees' contributions up to a maximum of three percent of an employee's annual salary based upon the employee's contribution and certain other limitations. The Company's employer matching contribution expense was $106,000 and $88,000 in 2017 and 2016, respectively.

13. Income Taxes

In 2017 and 2016, the Company recorded an income tax benefit of zero. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and the amounts used for tax purposes as well as net operating loss and tax credit carryforwards.

Income (loss) before provision for income taxes consists as follows (in thousands)

	December 31,	
	2017	2016
United Sates	$(11,465)	$(31,594)
International	760	(1,344)
Total	$(10,705)	$(32,938)

Significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2017	2016
Net operating loss carryforwards	$ 18,267	$ 25,536
Research and development credits	7,898	6,509
Federal orphan drug credits	23,881	18,599
Other	1,483	3,572
Total deferred tax assets	51,529	54,216
Valuation allowance	(51,529)	(54,216)
Net deferred tax assets	$ —	$ —

The Company considers all available evidence, both positive and negative, including historical levels of taxable income, 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. At December 31, 2017 and 2016, based on the Company's analysis of all available evidence, both positive and negative, it was considered more likely than not that the Company's deferred tax assets would not be realized, and as a result, the Company recorded a valuation allowance for its deferred tax assets. The valuation allowance decreased by $2.7 million during the year ended December 31, 2017 and increased by $16.2 million during the year ended December 31, 2016.

The difference between the income tax benefit and the amount computed by applying the federal statutory income tax rate to loss before income taxes is as follows (in thousands):

	Year Ended December 31,	
	2017	2016
Income tax benefit at federal statutory rate	$ (3,746)	$ (11,531)
State taxes (net of federal)	(8)	(391)
Credits	(3,434)	(4,932)
Other	67	694
Change in valuation allowance	(1,931)	16,160
Tax Rate Change	9,052	—
Total	$ —	$ —

On December 22, 2017, H.R.1, known as the "Tax Cuts and Jobs Act," was signed into law. Among other things, the Tax Cuts and Jobs Act permanently lowers the corporate tax rate to 21% from the existing minimum rate of 35%, effective for tax years including or commencing January 1, 2018. As a result of this reduction of the corporate tax rate to 21% U.S. generally accepted accounting principles require companies to re-value their deferred tax assets and liabilities as of the date of enactment, with resulting tax effects accounted for in the reporting period of enactment. The difference in the net change in the valuation allowance is due to the tax rate change that is separately stated in the rate reconciliation.

The Company has revalued its deferred tax assets and liabilities as of December 31, 2017, at the new rate of 21% based upon balances in existence at date of enactment. Based upon preliminary estimates, it is currently expected that the Company's net deferred tax assets before valuation allowance will be written down by approximately $9 million in the fourth quarter of 2017. This estimate is based upon a review and analysis of the Company's net deferred tax assets. The Company's actual write-down may vary materially from the estimated range due to a number of uncertainties and factors and is subject to further clarification of the new law that cannot be reasonably estimated at this time.

As of December 31, 2017, the Company had federal net operating loss carryforwards of approximately $71.5 million and federal orphan drug credit carryforwards of approximately $23.9 million, which expire in the years 2019 through 2037. The Company also had California net operating loss carryforwards of approximately $44.1 million, which expire in the years 2028 through 2037, and California research and development tax credit carryforwards of approximately $9.9 million, which do not expire.

Utilization of the Company's NOL and credit carryforwards may be subject to additional annual limitations based on future stock issuances or ownership changes. Such future limitations could result in the expiration of the net operating loss and credit carryforwards before utilization. Based on the analyses performed on ownership changes that have occurred from inception through December 31, 2017, the Company expects to be able to use the NOL and tax credit carryforwards as noted above.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is subject to U.S. federal and state income tax examinations by tax authorities for tax years from 1998 due to net operating losses and tax credits that are being carried forward for tax purposes. As of December 31, 2017, the Company does not believe that it is reasonably possible that its unrecognized benefits would significantly change in the following 12 months.

The Company does not have any unrecognized tax benefits, or interest and penalties accrued on unrecognized tax benefits, at December 31, 2017, or during the two years then ended. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

14. Quarterly Results of Operations (unaudited)

Following is a summary of the quarterly results of operations for the years ended December 31, 2017 and 2016 (in thousands, except per share data):

	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Total revenue	$ 1,693	$ 7,675	$ 2,728	$ 2,369
Operating expenses:				
Research and development	2,774	3,794	3,543	3,704
General and administrative	1,678	1,911	2,133	1,870
Restructuring and asset impairment	—	—	—	—
Total expenses	4,452	5,705	5,676	5,574
Loss from operations	(2,759)	1,970	(2,948)	(3,205)
Interest income (expense), net	(925)	(937)	(947)	(969)
Other income (expense)	6	2	9	(2)
Income (loss) before income taxes	(3,678)	1,035	(3,886)	(4,176)
Income tax provision	—	—	—	—
Income (net loss and comprehensive loss)	$ (3,678)	$ 1,035	$ (3,886)	$ (4,176)
Basic and diluted net income (loss) per common share	$ (0.25)	$ 0.07	$ (0.26)	$ (0.28)
Shares used in computing basic net income (loss) per common share	14,800	14,847	14,860	14,931
Shares used in computing diluted net income (loss) per common share	14,800	14,848	14,860	14,931

	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Total revenues	$ 6	$ 14	$ 50	$ 125
Operating expenses:				
Research and development	6,451	6,235	5,836	5,865
General and administrative	1,644	1,385	1,460	1,339
Restructuring and asset impairment	1	1	—	—
Total expenses	8,096	7,621	7,296	7,204
Loss from operations	(8,090)	(7,607)	(7,246)	(7,079)
Interest income (expense), net	4	(551)	(864)	(913)
Other income (expense)	—	(571)	(76)	55
Loss before income taxes	(8,086)	(8,729)	(8,186)	(7,937)
Income tax provision	—	—	—	—
Net loss and comprehensive loss	$ (8,086)	$ (8,729)	$ (8,186)	$ (7,937)
Basic and diluted net loss per common share	$ (0.55)	$ (0.59)	$ (0.55)	$ (0.54)
Shares used in computing basic and diluted net loss per common share	14,761	14,778	14,782	14,795

15. Going Concern

As reflected in the accompanying consolidated financial statements, the Company has an accumulated deficit of $455.2 million as of December 31, 2017 that includes a net loss of $10.7 million for the year ended December 31, 2017 which raises doubt about the Company's ability to continue as a going concern. As of December 31, 2017, the Company's current assets of $7.7 million exceed current liabilities of $5.5 million by $2.2 million. In February 2018, the Board of Directors (the "Board") implemented temporary measures intended to preserve the Company's cash resources until additional sources of capital can be identified, including the reduction of cash compensation and severance benefits for officers and the reduction of cash compensation for members of the Board. The Company believes that its cash and cash equivalents of approximately $7.1 million as of December 31, 2017 will only be sufficient to fund its operations through the first quarter of 2018. Therefore, the Company will continue to require additional capital through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund the Company's operations and continue the development of the Company's lead product candidate Linhaliq.

Since cash and cash equivalents are insufficient to fund the Company's operations for the ensuing twelve months from the filing of this report, there is substantial doubt about the Company's ability to continue to operate as a going concern. While recoverability of the recorded asset amounts shown in the accompanying balance sheet is dependent upon continued operations of the Company, the 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.

16. Commitments and Contingencies

Leases

On April 1, 2017, the Company entered into an amendment of the current lease for a building containing offices, laboratory, and manufacturing facilities, through March 31, 2023. The lease calls for annual minimum rental payments that increase at the rate of 3.5% per annum throughout the lease term. In accordance with 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 December 31, 2017 and 2016, the Company had $32,000 and zero in deferred rent, respectively.

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 December 31, 2017, are as follows:

For the year ended December 31,	(in thousands)
2018	$ 482
2019	499
2020	516
2021	535
2022	553
Thereafter	140
Total	**$ 2,725**

For the twelve months ended December 31, 2017 and 2016, base rental expense was approximately $492,000 and $587,000, respectively.

Indemnification

On May The Company from time to time enters into contracts that contingently require the Company to indemnify parties against third party claims. These contracts primarily relate to: (i) real estate leases, under which the Company may be required to indemnify property owners for environmental and other liabilities, and other claims arising from the Company's use of the applicable premises, and (ii) agreements with the Company's officers, directors and employees, under which the Company may be required to indemnify such persons from certain liabilities arising out of such persons' relationships with the Company. To date, the Company has made no payments related to such indemnifications and no liabilities have been recorded for these obligations on the balance sheets at December 31, 2017 or 2016.

Legal Matters

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

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

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

On January 11, 2018 a putative class action lawsuit, *Kevin Kheder v. Aradigm Corporation, et al.,* No. 3:18-cv-00261, was filed in the United States District Court for the Northern District of California against the Company and two of its former officers. The suit is purportedly brought on behalf of persons and entities who acquired or otherwise purchased Aradigm common stock between July 27, 2017 and January 8, 2018 (the

"Class Period"). Plaintiff alleges that defendants made false and misleading statements during the Class Period that artificially inflated the price of Aradigm stock. The Company believes that the plaintiff's allegations are without merit and intends to defend the action vigorously. In addition, from time to time, the Company is involved in litigation arising out of the ordinary course of its business. Due to inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of the litigation described above, and we are unable at this time to determine whether the outcome of the litigation would have a material effect on our business, financial condition, results of operations or cash flows.

17. Subsequent Events

On February 9, 2018, the Board of Directors approved temporary measures intended to preserve the Company's cash resources until additional sources of capital can be identified. These cash preservation measures include, among other things:

- the termination of the Amended and Restated Aradigm Corporation Executive Officer Severance Benefit Plan,
- the reduction of the annual base salary of certain executive officers to 50% of their then current annual base salaries, and
- the reduction of cash compensation paid to members of the Board for services on the Board or committees of the Board to 50% of the then current cash compensation.

Effective February 11, 2018, each of Igor Gonda, President and Chief Executive Officer; Juergen Froehlich, Chief Medical Officer; and Nancy Pecota, Vice President, Finance, Chief Financial Officer and Corporate Secretary resigned all offices and positions held by him or her with Aradigm. In addition, in February, 2018, Dr. Gonda and David Bell resigned from the Board of Directors. Dr. John Siebert, Chairman of the Board of Aradigm was appointed Executive Chairman and Interim Principal Executive Officer effective February 11, 2018. Additionally, on March 1, 2018, the Board appointed Dr. John Siebert as Acting Principal Financial Officer of the Company. Dr. Gonda and Dr. Juergen have been retained as consultants by the Company.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Based on his evaluation as of the end of the period covered by this report our Executive Chairman, Interim Principal Executive Officer and Acting Principal Financial Officer has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the 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 we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

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

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

There are inherent limitations in the effectiveness of any system of internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurances with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal control may vary over time.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission in *Internal Control—Integrated Framework* (2013 framework). Based on its assessment using the COSO criteria, management concluded that our internal control over financial reporting was effective as of December 31, 2017.

As a result of the enactment of the Reform Act, and in accordance with Section 989G ("Exemption for Nonaccelerated Filers") of that act, we are not required to provide an attestation report of our independent registered public accounting firm regarding internal control over financial reporting for this fiscal year or thereafter, until such time as we are no longer eligible for the exemption set forth therein.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of our fiscal year ending December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information required by this Item concerning (i) identification and business experience of the Company's directors, as well as legal proceedings involving such directors and any family relationships between directors and executive officers of the Company, (ii) the identification of the members of the Company's audit committee and (iii) the identification of the Audit Committee Financial Expert is incorporated by reference from the section captioned "Proposal 1: Election of Directors" contained in the Company's Proxy Statement related to our 2018 Annual Meeting of Shareholders to be held June 27, 2018 to be filed by the Company with the SEC, or the 2018 Proxy Statement.

We have adopted a code of ethics, which is part of our Code of Business Conduct and Ethics that applies to all of our employees, including our principal executive officer and our principal financial and accounting officer. This code of ethics is posted on our website. If we amend or waive a provision of our Code of Business Conduct and Ethics, we intend to post such amendment or waiver on our website, as required by applicable rules.

Identification of Executive Officers

The information required by this Item is incorporated by reference from the section captioned "Compensation" contained in the 2018 Proxy Statement.

Section 16(a) Beneficial Ownership Reporting Compliance

The information regarding compliance with Section 16(a) of the Securities Exchange Act of 1934, as amended, required by this Item is incorporated by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" in the 2018 Proxy Statement.

Item 11. ***Executive Compensation***

The information required by this Item is incorporated by reference from the section captioned "Compensation" contained in the 2018 Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this Item is incorporated by reference from the section captioned "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the 2018 Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions and Director Independence***

The information required by this Item is incorporated by reference from the section captioned "Certain Transactions" contained in the 2018 Proxy Statement.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is incorporated by reference from the section titled "Proposal 2—Ratification of Selection of Independent Registered Public Accounting Firm" contained in the 2018 Proxy Statement.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a)(1) *Financial Statements.*

Included in Part II of this Annual Report on Form 10-K:

	Page in Form 10-K
Report of Independent Registered Public Accounting Firm	47
Consolidated Balance Sheets — December 31, 2017 and 2016	48
Consolidated Statements of Operations and Comprehensive Loss — Years ended December 31, 2017 and 2016	49
Consolidated Statements of Shareholders' Equity — Years ended December 31, 2017 and 2016	50
Consolidated Statements of Cash Flows — Years ended December 31, 2017 and 2016	51
Notes to Consolidated Financial Statements	52

(2) *Financial Statement Schedules.*

All financial statement schedules are omitted because they are not applicable or not required or because any required information is included in the financial statements or notes thereto.

(3) *Exhibits.*

Exhibit No.	Description
3.1(1)	Amended and Restated Articles of Incorporation of the Company.
3.2(3)	Certificate of Determination of Series A Junior Participating Preferred Stock of the Company.
3.3(4)	Amended and Restated Certificate of Determination of Preferences of Series A Convertible Preferred Stock.
3.4(3)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.5(3)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock.
3.6(5)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.7(5)	Certificate of Amendment of Certificate of Determination of Series A Junior Participating Preferred Stock of the Company.
3.8(6)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.9(33)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.10(14)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.11(19)	Certificate of Amendment of Articles of Incorporation of the Company.
3.12(34)	Certificate of Correction to Certificate of Amendment of Articles of Incorporation of the Company.
3.13(22)	Certificate of Amendment to Amended and Restated Articles of Incorporation.
3.14(30)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.15(2)	Amended and Restated Bylaws of the Company, as amended.

Exhibit No.	Description
3.16(24)	Certificate of Amendment to the Amended and Restated Bylaws of the Company.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 , 3.5, 3.6, 3.7 , 3.8, 3.9, 3.10 , 3.11, 3.12, 3.13 and 3.14.
4.2(35)	Specimen common stock certificate.
4.3(31)	Indenture, dated as of April 25, 2016, between the Company and U.S. Bank National Association, as trustee.
4.4	Form of 9.0% Senior Convertible Note due May 1, 2021 (included in Exhibit 4.3).
4.5	Form of Warrant (included in Exhibit 10.37).
10.1(1)+	Form of Indemnity Agreement between the Company and its directors and officers.
10.2(1)+	Form of the Company's Incentive Stock Option Agreement under the 2005 Equity Incentive Plan.
10.3(1)+	Form of the Company's Non-statutory Stock Option Agreement under the 2005 Equity Incentive Plan.
10.4(1)+	1996 Non-Employee Directors' Stock Option Plan.
10.5(1)+	Form of the Company's Non-statutory Stock Option Agreement under the 1996 Non-Employee Directors' Stock Option Plan.
10.6(1)+	Form of the Company's Employee Stock Purchase Plan Offering Document.
10.7(6)+	Form of the Company's Restricted Stock Bonus Agreement under the 2005 Equity Incentive Plan.
10.8(7)+	Employment Agreement, dated July 14, 2006, with Dr. Igor Gonda.
10.9(8)	Lease Agreement for the property located in Phase V of the Britannia Point Eden Business Park in Hayward, California, dated January 28, 1998, between the Company and Britannia Point Eden, LLC.
10.10(9)	Sublease, dated July 11, 2007, by and between the Company and Mendel Biotechnology, Inc. under the Lease Agreement by and between the Company and Hayward Point Eden I Limited Partnership, as successor-in-interest to Britannia Point Eden, LLC, as amended.
10.11(10)+	2005 Equity Incentive Plan, as amended.
10.12(11)+	Employee Stock Purchase Plan, as amended.
10.13(12)	Amended and Restated Rights Agreement, dated as of September 5, 2008 by and between the Company and ComputerShare Trust Company, N.A.
10.14(13)+	Aradigm Corporation Executive Officer Severance Benefit Plan (amended and restated).
10.15(15)+	Aradigm Corporation Executive Officer Severance Benefit Plan (amended and restated).
10.16(15)+	Amended and Restated Change of Control Agreement, dated as of April 5, 2011, by and between the Company and Igor Gonda.
10.17(15)+	Amended and Restated Change of Control Agreement, dated as of April 5, 2011, by and between the Company and Nancy Pecota.
10.18(15)+	Form of Indemnification Agreement between the Company and its directors and senior officers.
10.19(16)	Securities Purchase Agreement, dated as of December 11, 2012, among the Company and the investors party thereto.

Exhibit No.	Description
10.20(16)	Registration Rights Agreement, dated as of December 11, 2012 among the Company and the buyers party thereto.
10.21(17)	Form of License and Collaboration Agreement by and among the Company and Grifols, S.A.
10.22(17)	Form of Option Agreement by and among the Company and Grifols, S.A.
10.23(17)	Form of Governance Agreement by and among the Company and Grifols, S.A.
10.24(17)	Form of Registration Rights Agreement by and among the Company and Grifols, S.A.
10.25(17)	Form of Registration Rights Agreement by and among the Company and the buyers party thereto.
10.26(18)‡	Clinical Supply and Commercial Manufacturing Services Agreement, dated as of August 27, 2013, by and between SIGMA-TAU Pharmasource Inc. and the Company.
10.27(20)+	Change of Control Agreement, dated as of November 5, 2013, by and between the Company and Dr. Juergen Froehlich.
10.28(20)+	Offer Letter, dated November 5, 2013, by and between the Company and Dr. Juergen Froehlich.
10.29(21)	Assignment, Assumption, Waiver and Consent, effective as of February 28, 2014, by and among Aradigm Royalty Financing LLC, the Company, R&D Bauer Ventures, LP and SG-PBS LLC.
10.30(23)+	Form of Non-statutory Stock Option Agreement, by and between the Company and Igor Gonda.
10.31(25)	Board Observer Rights Agreement, dated July 20, 2015, between the Company and Grifols, S.A.
10.32(28)+	Aradigm Corporation 2015 Equity Incentive Plan.
10.33(26)+	Form of Stock Option Agreement pursuant to Aradigm Corporation 2015 Equity Incentive Plan.
10.34(29)+	Aradigm Corporation Employee Stock Purchase Plan.
10.35(27)+	Form of Amendment to the Stock Option Agreement.
10.36(27)	Supply Agreement by and between the Company and Grifols, S.A., dated October 22, 2015.
10.37(31)	Securities Purchase Agreement, dated as of April 21, 2016.
10.38(31)	Amendment to Governance Agreement, dated as of April 21, 2016, by and between the Company, and Grifols, S.A.
10.39(31)	Escrow Agreement, dated as of April 25, 2016, by and between the Company and U.S. Bank National Association, as Escrow Agent, and U.S. Bank National Association, as Trustee.
10.40(32)	Fifth Amendment to Lease, dated as of July 18, 2017, by and between Hayward Point Eden I Limited Partnership and the Company.
21.1(23)	List of Subsidiaries of the Company.
23.1*	Consent of OUM & Co. LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included in signature page to this Annual Report on Form 10-K).
31.1*	Section 302 Certification of the Executive Chairman, Interim Principal Executive Officer and Acting Principal Financial Officer.
32.1**	Section 906 Certification of the Executive Chairman, Interim Principal Executive Officer and Acting Principal Financial Officer.
101*	The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017 are formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive Loss, (iii) the Consolidated Statements of Cash Flows, and (iv) Notes to the Consolidated Financial Statements.

+ Represents a management contract or compensatory plan or arrangement.
‡ Portions of this exhibit have been omitted pursuant to a request for confidential treatment and the non-public information has been filed separately with the Securities and Exchange Commission.
* Filed with this Annual Report on Form 10-K.
** Furnished with this Annual Report on Form 10-K.
(1) Incorporated by reference to the Company's Form S-1 (No. 333-04236) filed on April 30, 1996.
(2) Incorporated by reference to the Company's Form 10-Q (No. 000-28402) filed on August 14, 1998.
(3) Incorporated by reference to the Company's Form 10-K (No. 333-72037) filed on March 29, 2002.
(4) Incorporated by reference to the Company's Form S-3 (No. 333-76584) filed on January 11, 2002.
(5) Incorporated by reference to the Company's Form 10-Q (No. 333-72037) filed on August 13, 2004.
(6) Incorporated by reference to the Company's Form 10-K (No. 000-28402) filed on March 31, 2006.
(7) Incorporated by reference to the Company's Form S-1 (No. 333-138169) filed on October 24, 2006, as amended.
(8) Incorporated by reference to the Company's Form 10-K (No. 000-28402) filed on March 24, 1998, as amended.
(9) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on July 24, 2007.
(10) Incorporated by reference to the Company's Form S-8 (No. 333-187947) filed on April 16, 2013.
(11) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on May 21, 2009.
(12) Incorporated by reference to the Company's Form 10-Q (No. 000-28402) filed on November 12, 2008.
(13) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on January 8, 2009.
(14) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on September 20, 2010.
(15) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on April 18, 2011.
(16) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on December 13, 2012.
(17) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on May 24, 2013.
(18) Incorporated by reference to the Company's Form 10-Q (No. 000-28402) filed on October 28, 2013.
(19) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on February 4, 2014.
(20) Incorporated by reference to the Company's Form S-1 (No. 333-193751) filed on February 4, 2014.
(21) Incorporated by reference to the Company's Form 8-K (No. 000-28402) filed on March 10, 2014.
(22) Incorporated by reference to the Company's Form 10-Q (No. 000-28402) filed on May 14, 2014.
(23) Incorporated by reference to the Company's Form 10-K (No. 001-36480) filed on March 13, 2014.
(24) Incorporated by reference to the Company's Form 8-K (No. 001-36480) filed on September 4, 2015.
(25) Incorporated by reference to the Company's Form 10-Q (No. 001-36480) filed on November 12, 2015.
(26) Incorporated by reference to the Company's Form S-8 (No. 333-205613) filed on July 10, 2015.
(27) Incorporated by reference to the Company's Form 10-K (No. 001-36480) filed on March 30, 2016.
(28) Incorporated by reference to the Company's Proxy Statement (No. 001-36480) filed on April 19, 2017, as Exhibit B.
(29) Incorporated by reference to the Company's Proxy Statement (No. 001-36480) filed on April 19, 2017, as Exhibit A.
(30) Incorporated by reference to the Company's Form S-1/A (No. 333-211329) filed on July 7, 2016.
(31) Incorporated by reference to the Company's Form 8-K/A (No. 001-36480) filed on April 28, 2016.
(32) Incorporated by reference to the Company's Form 10-Q (No. 001-36480) filed on November 3, 2017.
(33) Incorporated by reference to the Company's Form 10-Q (No. 000-28402) filed on August 8, 2008.
(34) Incorporated by reference to the Company's Form 8-K/A (No. 000-28402) filed on February 18, 2014.
(35) Incorporated by reference to the Company's Form S-1/A (No. 333-04236) filed on June 11, 1996.

(b) *Index to Exhibits.*

See Exhibits listed under Item 15(a) (3).

(c) *Financial Statement Schedules.*

All financial statement schedules are omitted because they are not applicable or not required or because the required information is included in the financial statements or notes thereto.

Aradigm, Lipoquin, Pulmaquin and AERx are registered trademarks of the Company. Linhaliq is a registered trademark of Grifols.

* Other names and brands may be claimed as the property of others.

Item 16. ***Form 10–K Summary.***

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Hayward, State of California, on the 23rd day of March 2018.

ARADIGM CORPORATION

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

KNOWN ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, jointly and severally, John Siebert and Lisa Thomas, and each one of them, attorneys-in-fact for the undersigned, each with power of substitution, for the undersigned in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or their substitutes, may do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated opposite his or her name.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ John Siebert John Siebert	Executive Chairman, Interim Principal Executive Officer, Acting Principal Financial Officer and Director	March 23, 2018
/s/ Lisa Thomas Lisa Thomas	Corporate Controller	March 23, 2018
/s/ Virgil D. Thompson Virgil D. Thompson	Director	March 23, 2018
/s/ Frederick Hudson Frederick Hudson	Director	March 23, 2018
/s/ Edwin H. Gordon Edwin H. Gordon	Director	March 23, 2018

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-15947, No. 333-62039, No. 333-92169, No. 333-43152, No. 333-63116, No. 333-85244, No. 333-107157, No. 333-128525, No. 333-135122, No. 333-148226, No. 333-152501, No. 333-161142, No. 333-169580, No. 333-187947, No. 333-205613 and No. 333-223387), on Form S-3 (No. 333-148263 and No. 333-122223) and on Form S-1 (No. 333-221352), of our report dated March 23, 2018, which expresses an unqualified opinion and contains an explanatory paragraph regarding the Company's ability to continue as a going concern, relating to the consolidated financial statements of Aradigm Corporation, which appears in this Annual Report on Form 10-K.

/s/ OUM & Co LLP

San Francisco, California
March 23, 2018

EXHIBIT 31.1

CERTIFICATION

I, John Siebert, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aradigm Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Date: March 23, 2018

EXHIBIT 32.1

CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code, John Siebert, Executive Chairman, Interim Principal Executive Officer and Acting Principal Financial Officer of Aradigm Corporation (the "Company") hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2017, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Annual Report and results of operations of the Company for the period covered by the Annual Report.

IN WITNESS WHEREOF, the undersigned has set his hand hereto as of the 23rd day of March 2018.

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

Dated: March 23, 2018

** This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and will not be deemed to be incorporated by reference into any filing of Aradigm Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report on Form 10-K), irrespective of any general incorporation language contained in such filing.