ARADIGM CORP
Form 10-K
March 30, 2017
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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, 2016

Or

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

For the transition period from _____ to _____,

Commission File Number: 001-36480

Aradigm Corporation

(Exact Name of Registrant as Specified in Its Charter)

California	**94-3133088**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

3929 Point Eden Way, Hayward, CA 94545

(Address of Principal Executive Offices)

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. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company

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, 2016 was: $24,277,015.

The number of shares of the registrant s common stock outstanding as of March 12, 2017 was: 14,951,089.

DOCUMENTS INCORPORATED BY REFERENCE

Parts of the Registrant s Proxy Statement for the 2017 Annual Meeting of Shareholders to be held on June 1, 2017 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 2017 Annual Meeting of Shareholders shall not be deemed to be a

part of 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 in the section entitled Risk Factors , and elsewhere in this Annual Report on Form 10-K and 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, 2016 will be sufficient to fund our operations through at least 2017, provided that we are able to earn the $5 million milestone payment from Grifols, S.A., or Grifols, upon our first regulatory filing; (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 necessary regulatory authority clearances 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 our such partnerships; (v) our strategy to commercialize certain of our unlicensed respiratory product candidates with our own focused sales and marketing force addressing pulmonary specialty doctors in the United States or in the European Union; (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; (vi) our expectations regarding future clinical trials; and (viii) 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 health care professionals 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.

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PART I

Item 1. *Business*

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of products for the treatment and prevention of severe respiratory diseases. Over the last decade, we invested a large amount of capital to develop drug delivery technologies, particularly the development of a significant amount of expertise in respiratory (pulmonary) drug delivery as incorporated in our lead product candidate that recently completed two Phase 3 clinical trials, Linhaliq inhaled ciprofloxacin, formerly known as Pulmaquin®. We also invested considerable effort into 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 formulations. We have not been profitable since inception and expect to incur additional operating losses over at least the foreseeable future as we continue product development efforts, clinical trial activities, animal toxicology and safety testing and contract manufacturing efforts for our product candidates.

Our business has focused on opportunities in the development of drugs for the treatment of severe respiratory disease that could be developed by us and commercialized in the United States and/or another significant territory, such as the European Union, or EU 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 reduced efficacy or increased 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 addition to its use in the treatment of respiratory diseases, there are opportunities for the inhalation route of delivery to administer drugs via the lung for the systemic treatment of disease elsewhere in the body. For many drugs, the large and highly absorptive area of the lung enables bioavailability and fast absorption as a result of pulmonary delivery than could otherwise only be obtained by injection.

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 non-cystic fibrosis bronchiectasis, or non-CF BE, and cystic fibrosis, or CF; 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 is a combination of the slow release liposomal formulation, Lipoquin, mixed with a small amount of unencapsulated ciprofloxacin dissolved in an aqueous medium. We received orphan drug designations for Lipoquin for both of these indications in the United States and for CF in the EU. We requested orphan drug designation from the United States Food and Drug Administration, or FDA, for Linhaliq for the management of BE and we were granted orphan drug designation for ciprofloxacin for inhalation for this indication. We may seek orphan drug designation for other eligible product candidates we develop. FDA designated Linhaliq as a Qualified Infectious Disease Product, or QIDP, for the treatment of non-CF BE patients with chronic lung infections with *Pseudomonas aeruginosa*.

In August 2013, we entered into 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, world-wide license to our inhaled liposomal ciprofloxacin product candidates for the indication of non-CF BE and other indications, as more fully described

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

Our longer term 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 cost, development time and risk 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, 2016, we had an accumulated deficit of $438.4 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 (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. By choosing to develop new applications or reformulations of FDA-approved drugs, we believe that we can substantially reduce the significant time, expenditure and risks associated with preclinical testing of new chemical entities and biologics, as well as utilize knowledge of these approved drugs to reduce the risk, time and cost of the clinical trials needed to obtain drug approval. We have already been granted

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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 data base.

Linhaliq and Lipoquin (ARD-3150 and ARD-3100) Inhaled Ciprofloxacin for the Management of Infections in Non-Cystic Fibrosis Bronchiectasis (BE) 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 and many more 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 2015, we announced that the FDA designated Linhaliq as a QIDP. The QIDP designation, granted for treatment of non-cystic fibrosis bronchiectasis patients with chronic lung infections with *Pseudomonas 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 2015, we announced that the FDA granted Fast Track designation to Linhaliq. 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.

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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 are resolved quickly, often leading to earlier drug approval and access by patients.

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, world-wide basis, our inhaled liposomal ciprofloxacin product candidates for the indication of non-CF BE 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 November 2009, the first patient was dosed in the ORBIT-2 (Once-daily Respiratory Bronchiectasis Inhalation Treatment) trial, a 168 day, multicenter, international Phase 2b clinical trial of inhaled ciprofloxacin with the Linhaliq (ARD-3150) formulation in 42 adult patients with non-cystic fibrosis bronchiectasis. The randomized, double-blind, placebo-controlled trial was conducted in Australia and New Zealand. Following a 14 day screening period, the patients were treated once-a-day for 28 days with either the active drug, or placebo, followed by a 28 day off-treatment period. This on-off sequence was repeated three times. The primary endpoint was defined as the mean change in *Pseudomonas aeruginosa* density in sputum (colony forming units CFU - per gram) from baseline to day 28 of the active treatment group versus placebo. Safety and tolerability assessments of the treatment versus placebo group were performed. Secondary efficacy endpoints assessed included long term microbiological responses, time to an exacerbation, severity of exacerbations, length of time to resolve exacerbations and changes in lung function and in quality of life measurements. ORBIT-2 explored whether the novel formulation Linhaliq, which has a different drug release profile than Lipoquin, may have additional therapeutic benefits.

In October 2010, we announced positive top line data from the ORBIT-2 study. Statistical significance was achieved in the primary endpoint the mean change in *Pseudomonas aeruginosa* density in sputum from baseline to day 28. In the full analysis population (full analysis set includes all patients who were randomized, received at least one dose and provided samples for at least two time points), there was a significant mean reduction of 4.2 $\log_{10}$ units in the Linhaliq group, reflecting an almost sixteen-thousand fold decrease in bacterial load, versus a very small mean decrease of 0.1 $\log_{10}$ units in the placebo group (p=0.004). Secondary endpoint

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

In 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 have taken 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 also obtain the initial marketing approval with a currently FDA-approved nebulizer system.

The Phase 3 clinical program for Linhaliq in non-CF BE 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 PE s 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 PE s over the 48-week double-blind period (Hazard Ratio Linhaliq/placebo: 0.73; p=0.0015), representing a 27% reduction in PE s over the period.

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When the additional analyses of combined data from both studies were conducted taking into account only PE s 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 PE s 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 PE s 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. Eighty-nine percent of the patients who completed ORBIT-3 and 91% percent of the patients who completed 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.

Lipoquin (ARD-3100) Inhaled Ciprofloxacin for the Management of Infections in CF Patients

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

This program uses our proprietary inhaled formulation of ciprofloxacin for the management of respiratory infections caused by a microorganism, *Pseudomonas aeruginosa,* common in patients with CF. CF is a genetic disease that causes thick, sticky mucus to form in the lungs, pancreas and other organs. In the lungs, the mucus tends to block the airways, causing lung damage and making these patients highly susceptible to lung infections. According to the Cystic Fibrosis Foundation, CF affects roughly 30,000 children and adults in the United States

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and roughly 70,000 children and adults worldwide. Recent reports suggest that there may be over 100,000 largely undiagnosed CF patients in India.

We believe our inhaled ciprofloxacin could also be explored for the treatment of other serious respiratory infections, such as those occurring in severe COPD, pulmonary non-tuberculous mycobacteria, or PNTM, and asthma patients.

In August 2013, we licensed to Grifols on an exclusive, world-wide basis, our inhaled liposomal ciprofloxacin product candidates for all indications with a back-license to Aradigm for biodefense applications.

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, Corvalis (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.

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

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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.

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.

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*.

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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 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, 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.

Other Programs

In August 2013, the NIH awarded us an SBIR grant in the amount of approximately $340,000 to investigate the development and validation of tests for gastro-esophageal reflux with aspirations into the respiratory tract. The Principal Investigators and co-inventors of the new diagnostic tests are Professor Homer Boushey, University of California, San Francisco (UCSF) and Dr. Igor Gonda, Aradigm Corporation. The grant is funding laboratory work and a human clinical trial being conducted at UCSF.

Aspiration of gastric contents into the respiratory tract causes significant morbidity and mortality and is accepted as the key initiating event for aspiration pneumonitis a form of acute lung injury caused by the acidity of the gastric contents, and aspiration pneumonia the consequence of the growth of pathogenic bacteria contained in the oropharynx aspirated into the tracheobronchial tree. When subclinical events of gastric aspiration occur, it is described as silent

aspiration or microaspiration. Chronic, recurrent microaspirations have been implicated in the pathogenesis and worsening of many severe chronic pulmonary diseases of unknown

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origin, such idiopathic pulmonary fibrosis, bronchiolitis obliterans after lung transplantation, pulmonary disease in conditions associated with esophageal dysfunction and delayed gastric emptying such as cystic fibrosis and scleroderma, and the very common conditions of community acquired pneumonia in the elderly, asthma and COPD.

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

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, 2017, we had 36 issued United States patents, with 9 additional United States patent applications pending. In addition, we had 44 issued foreign patents and an additional 40 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 2017 and 2031. 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

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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 would 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, is testing a ciprofloxacin dry powder inhaler for the management of BE in two Phase 3 studies and an experimental oral drug, BAY85-8501, which completed 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. There are also a number of other inhaled products under development to treat respiratory infections in CF, including a nebulized levofloxacin by Raptor Pharmaceutical Corp. (acquired by Horizon Pharma Plc) and a 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.

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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 Food, Drug and Cosmetic Act (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 delay in approval or refusal by the FDA to approve pending applications, injunctions ordering us to stop sale of any products we develop, seizure of our products, warning letters, 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.

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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 may also be needed to support approval for marketing this product for BE in the U.S. and the EU. We have taken the initiative to conduct this study 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 end points, 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

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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 about 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 non-CF BE, 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.

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 sue 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

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continuing GMP. In addition, 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 for this indication. In June 2012, we received orphan drug designation in the U.S. for liposomal ciprofloxacin plus ciprofloxacin for cystic fibrosis.

We may seek orphan drug designation for other eligible product candidates we develop. 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 a 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

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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 $24.4 million for the year ended December 31, 2016 and $35.3 million for the year ended December 31, 2015. 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
Peter R. Byron, Ph.D.	Medical College of Virginia, Virginia Commonwealth University	Aerosol Science/Pharmaceutics
Stephen J. Farr, Ph.D.	Zogenix, Inc.	Pulmonary Delivery/Pharmaceutics
Babatunde Otulana, M.D.	Mallinckrodt Pharmaceuticals	Pulmonary Diseases/Cystic Fibrosis/Regulatory
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, 2016, 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.

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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). 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.

Risks Related to Our Business

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

Our independent registered public accounting firm for the fiscal year ended December 31, 2016 has indicated in its audit opinion, contained in our 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.

While we believe that our cash and cash equivalents as of December 31, 2016 will be sufficient to fund our operations through at least 2017 provided that we are able to earn the $5 million milestone payment from Grifols upon our first regulatory filing, we will not be able to maintain our current level of product development activity unless we raise additional capital in 2017. Accordingly, we intend to raise additional capital through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund our operations and to continue the development of our leading product candidate Linhaliq. We cannot assure you that we will be successful in raising 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 assets or technology, and we may not be able to continue as a going concern.

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

We and our products are subject to extensive and rigorous regulation by the federal government, principally the FDA, and by state and local government agencies. Both before and after regulatory approval, the development, testing, manufacture, quality control, labeling, storage, approval, advertising, promotion, sale, distribution and export of our

potential products are subject to regulation. Pharmaceutical products that are marketed abroad are also subject to regulation by foreign governments. Our products cannot be marketed in the United States without FDA approval.

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The process for obtaining FDA approval for drug products is generally lengthy, expensive and uncertain. The FDA and other foreign regulatory agencies can delay approval of, or refuse to approve, our product candidates for a variety of reasons, including failure to meet safety and/or efficacy endpoints in our clinical trials. For example, the FDA may conclude that our ORBIT-3 and ORBIT-4 studies in the Phase 3 clinical program for Linhaliq in non-CF BE did not meet a finding of superiority based on the pre-specified endpoints and therefore do not support the filing of an NDA. We held pre-NDA meetings with the FDA in December 2016 and March 2017 to discuss our Phase 3 studies. While we believe that our Phase 3 studies for Linhaliq support the filing of an NDA, we cannot assure you that the FDA will agree with our conclusions and, even if the FDA accepts the NDA, there is no guarantee that the FDA will approve Linhaliq for the treatment of non-CF BE.

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 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 may not be able to maintain compliance with the continued listing requirements of the NASDAQ Capital Market.

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 shareholders equity of at least

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$2.5 million, among other requirements for continued listing. Based on our current share price, our market value of listed securities is below $35 million and based on our financial statements included in this Annual Report on Form 10-K, our shareholders equity is $987,000 as of December 31, 2016, which is less than the requirement of $2.5 million. Accordingly, we are not currently in compliance with the continued listing standards of NASDAQ, and we may be notified by the Listing Qualifications Department of NASDAQ, or the Staff, indicating that the Staff has determined to delist our securities due to such noncompliance. While we may be able to request a stay of any delisting action, there is no assurance that the Staff will grant such a stay. There is also no assurance that we will be able to demonstrate compliance with the continued listing standards in the future. If NASDAQ delists our common stock, the delisting could adversely affect the market liquidity of our common stock and our ability to fund our operations.

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

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

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

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

We compete with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of drugs and therapies for the disease indications we are targeting. Our competitors may succeed, and many already have succeeded, in developing competing technologies for the same disease indications, obtaining FDA approval for products or gaining acceptance

for the same markets that we are targeting. If we are not first to market, it may be more difficult for us and our present and future collaborators to enter markets as second or subsequent competitors and become commercially successful.

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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. While the FDA has granted orphan drug designation for our liposomal ciprofloxacin product candidate and the designation provides the opportunity to obtain market exclusivity for seven years from the date of the FDA s approval, our ability to launch our product in the United States could be blocked if another similar product developed by our competitors is approved by the FDA for the same indication before our product, unless we are able to demonstrate to the FDA clinical superiority of our product on the basis of safety or efficacy. For example, Bayer is developing an inhaled dry powder formulation of ciprofloxacin for the treatment of respiratory infections in CF and BE and 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 recently announced the results of their first Phase 3 clinical trial and is currently conducting another Phase 3 clinical trial of their inhaled ciprofloxacin dry powder formulation in non-CF BE patients. There are also a number of other inhaled products under development to treat respiratory infections , including a nebulized levofloxacin by Raptor (acquired by Horizon) for CF and BE, and a nebulized liposomal amikacin by Insmed for the treatment of *Mycobacterium avium* (a PNTM 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 for the management of bronchiectasis. FDA also granted orphan drug designation to our proprietary drug product of liposomal ciprofloxacin for the management of CF. Orphan drug designation is intended to encourage research and development of new therapies for diseases that affect fewer than 200,000 patients in the United States. The designation provides the opportunity to obtain market exclusivity, even in the absence of a granted patent or other intellectual property protection, for seven years from the date of the FDA s approval of an NDA. However, the market exclusivity is granted only to the first chemical entity to be approved by the FDA for a given indication. Therefore, if another similar inhaled ciprofloxacin product were to be approved by the FDA for a CF or BE indication before our product, then we may be blocked from launching our product in the United States for seven years, unless we are able to demonstrate to the FDA clinical superiority of our product on the basis of safety or efficacy. For the BE indication, Bayer recently announced the results of their first Phase 3 clinical trial with an inhaled dry powder formulation of ciprofloxacin for the treatment of respiratory infections in non-CF BE. Bayer has obtained orphan drug status for their inhaled powder formulation of ciprofloxacin in the United States for the treatment of BE and in the United States and European Union for the treatment of CF.

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

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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 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. If our contract research organizations are delayed in their activities or issues are uncovered regarding the quality of the data provided by the contract research organizations it could result in significant delays in our Linhaliq program and adversely impact our ability to file for regulatory approval of 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 non-CF BE, and we have limited ability to terminate that agreement.

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

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

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

We do not have the ability to manufacture the materials we use in our pre-clinical and clinical trials and commercial operations. Rather, we rely on various third-party contract manufacturers to produce our products. There may be long lead times to obtain materials. There can be no assurance that we will be able to identify, contract with, qualify and

obtain prior regulatory approval for additional sources of materials. We may also not be able to maintain satisfactory contract manufacturing arrangements with our current contract manufacturers. If we are not, there may be a significant delay before we find an alternative contract manufacturer or we may not find an alternative contract manufacturer at all. If there are any interruptions in this supply for any reason,

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including a decision by the third parties to discontinue manufacturing, technical difficulties, labor disputes, natural or other disasters, or a failure of the third parties to follow regulations, we may not be able to obtain regulatory approvals for our investigational drug candidates and may not be able to successfully commercialize these investigational drug candidates.

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

Further, we, our contract manufacturers and our collaborators are required to comply with the FDA s GMP requirements that relate to product testing, quality assurance, manufacturing and maintaining records and documentation. We and our contract manufacturers or our collaborators may not be able to comply with the applicable GMP and other FDA regulatory requirements for manufacturing, which could result in an enforcement or other action, prevent commercialization of our product candidates and impair our reputation and results of operations.

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

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

- the demonstration of efficacy and safety in clinical trials;
- the existence, prevalence and severity of any side effects;
- the potential or perceived advantages or disadvantages compared to alternative treatments;
- the timing of market entry relative to competitive treatments;

the pricing relative to competitive products;

the relative cost, convenience, product dependability and ease of administration;

the strength of marketing and distribution support;

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

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

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

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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.

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

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

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

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

We have never been profitable and have incurred significant losses in each year since our inception. As of December 31, 2016, we have an accumulated deficit of approximately $438.4 million. We have not had any

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direct product sales and do not anticipate receiving revenues from the sale of any of our products for at least the next few years, if ever. While our agreement with Grifols has resulted in reduced operating expenses and capital expenditures as a portion of our research and development expenses for the Linhaliq program was reimbursed by Grifols we expect to continue to incur losses for the foreseeable future as we:

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

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

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

Before we or any current or future collaborators can file for regulatory approval for the commercial sale of our potential products, the FDA will require extensive preclinical safety testing and clinical trials to demonstrate their safety and efficacy. Completing clinical trials in a timely manner depends on many factors. Delays in completing any future clinical trials may result in increased costs, program delays, or both, and the loss of potential revenues.

If we do not continue to attract and retain key employees, our product development efforts will be delayed and impaired.

We depend on a small number of key management and technical personnel. Our success also depends on our ability to attract and retain additional highly qualified management, clinical, regulatory and development personnel. There is a shortage of skilled personnel in our industry, we face competition in our recruiting activities, and we may not be able to attract or retain qualified personnel. Losing any of our key employees, particularly our President and Chief Executive Officer, Dr. Igor Gonda, and our Chief Medical Officer, Dr. Juergen Froehlich, could impair our product development efforts and otherwise harm our business. Any of our employees may terminate their employment with us at will.

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

If we market any approved products in foreign countries, we will be subject to different laws and regulations, particularly with respect to intellectual property rights and regulatory approval. To maintain a proprietary market position in foreign countries, we may seek to protect some of our proprietary inventions through foreign counterpart patent applications. Statutory differences in patentable subject matter may limit the protection we can obtain on some

of our inventions outside of the United States. The diversity of patent laws may make our expenses associated with the development and maintenance of intellectual property in foreign jurisdictions more expensive than we anticipate. We probably will not obtain the same patent protection in every market in which we may otherwise be able to potentially generate revenues. In addition, in order to market our products in foreign jurisdictions, we and our 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

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delayed, if we fail to receive these approvals, or if we lose previously received approvals, our business would be impaired as we could not earn revenues from sales in those countries.

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

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

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

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

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

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

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

Our laboratory and clinical testing sometimes involves the use of hazardous and toxic materials. We are subject to federal, state and local laws and regulations governing how we use, manufacture, handle, store and dispose of these materials. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with all federal, state and local regulations and standards, there is always the risk of accidental

contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result and such liability could exceed our financial resources. Compliance

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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.

Risks Related to Our Common Stock

Our stock price is likely to remain volatile.

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

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

sales of our stock by certain large institutional shareholders;

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

fluctuations in our operating results;

failure to maintain or establish collaborative relationships;

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

investor perception of us;

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

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

our ability to raise capital; and

economic and other external factors.

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

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

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

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

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

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

We have never paid dividends on our capital stock.

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

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

In August 2013, we entered into several agreements with Grifols as part of the completion of a private sale of shares of common stock to Grifols, including in particular the License Agreement, the Governance

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Agreement, and a registration rights agreement with respect to shares of common stock owned by Grifols. As a result of the various obligations under these agreements, in addition to Grifol s ownership of approximately 36% of our outstanding common stock, or 47.4% of our common stock if Grifols converts all of its Convertible Notes, conflicts of interest may arise between us and Grifols from time to time. Disagreements regarding the rights and obligation of Grifols under these agreements could create conflicts of interest for one of our directors, who has been designated by Grifols and subsequently nominated by us for election to our board of directors. Any such disagreements could also lead to actual disputes or legal proceedings that may be resolved in a manner unfavorable to us and our other shareholders. In addition, Grifols has a number of consent rights under the Governance Agreement, including the right to consent to any termination of our Chief Executive Officer or our appointment of a successor Chief Executive Officer and certain preemptive rights to participate in any future issuances of common stock (or common stock equivalents) by us or to acquire shares in the open market to maintain ownership thresholds specified in the Governance Agreement. Grifols may exercise any of these rights, or any of its other rights contained in its agreements with us, in a manner which is not necessarily in the best interest of us or our other shareholders. The result of any of these conflicts could adversely affect our business, financial condition, results of operations or the price of our common stock.

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

A small number of our shareholders own a large percentage of our common stock and can, therefore, influence the outcome of matters submitted to our shareholders for approval. Based on information known to us, our two largest shareholders, collectively, control approximately 62% of our outstanding common stock. These two shareholders purchased most of the Convertible Notes and related Warrants described in Note 7 to the consolidated financial statements included in Part II, Item 8 of this report, leading to a corresponding increase in their respective ownership on a fully-diluted basis. As a result, these shareholders have the ability to influence the outcome of matters submitted to our shareholders for approval, including certain proposed amendments to our amended and restated articles of incorporation (for example, amendments to increase the number of our authorized shares) and any other material transactions we may undertake in the future, such as a financing transaction or a merger, consolidation or sale of all or substantially all of our assets. These shareholders may support proposals and actions with which you may disagree. The concentration of ownership could delay or prevent a change in control of our company or otherwise discourage a potential acquirer from attempting to obtain control of our company, which in turn could reduce the price of our common stock.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. PROPERTIES

As of December 31, 2016 we leased a portion of one building with an aggregate of 24,000 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, 2017. We are in the process of negotiating a lease extension for this facility. Our current facility is expected to meet our requirements for the foreseeable future.

Item 3. LEGAL PROCEEDINGS

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

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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.

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
2015		
First Quarter	$ 7.95	$ 6.26
Second Quarter	7.67	6.33
Third Quarter	7.67	6.78
Fourth Quarter	7.22	3.61
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

As of March 12, 2017, 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

All information under this Item has been previously reported on our Current Reports on Form 8-K, filed with the SEC.

Item 6. ***Selected Financial Data***

The following selected financial data should be read in conjunction with 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, 2016 and 2015 from our consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

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The selected financial data for the years ended and as of December 31, 2014, 2013, and 2012 have been derived from financial statements not included in this Annual Report on Form 10-K.

	Years Ended December 31,				
	2016	2015	2014	2013	2012
	(In thousands, except per share data)				
Statements of operations data:					
Total revenues	$ 195	$ 23,429	$ 33,561	$ 9,717	$ 1,007
Total operating expenses	30,217	40,581	37,417	29,629	7,711
Loss from operations	(30,022)	(17,152)	(3,856)	(19,912)	(6,704)
Interest income (expense), net	(2,318)	29	(271)	(1,643)	(1,520)
Other income (expense), including extinguishment of debt	(598)	(86)	8,779	(9)	(2)
Net income (loss)	(32,938)	(17,209)	4,652	(21,564)	(8,226)
Basic net income (loss) per share	(2.23)	(1.17)	0.32	(2.36)	(1.63)
Diluted net income (loss) per share	(2.23)	(1.17)	0.32	(2.36)	(1.63)
Shares used in computing basic net income (loss) per share	14,779	14,747	14,700	9,154	5,032
Shares used in computing diluted net income (loss) per share	14,779	14,747	14,726	9,154	5,032

	As of December 31,				
	2016	2015	2014	2013	2012
	(In thousands)				
Balance sheet data:					
Cash, cash equivalents and short-term investments	$ 22,591	$ 31,462	$ 47,990	$ 48,131	$ 7,617
Working capital	18,953	27,730	43,736	42,394	6,479
Total assets	25,054	35,626	53,963	50,424	8,966
Deferred revenue related party, current			790	4,379	
Deferred revenue, related party, non-current	5,000	5,000	7,845		
Note payable and accrued interest net of discount				9,035	8,513
Convertible debt, net of discount	2,212				
Convertible debt related party, net of discount	11,007				
Accumulated deficit	(438,419)	(405,481)	(388,272)	(392,924)	(371,360)
Total shareholders equity (deficit)	987	23,110	39,115	33,683	(1,441)

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, 2016 will be sufficient to fund our operations through at least 2017, provided that we are able to earn the $5 million milestone payment from Grifols upon our first regulatory filing; (ii) our ability to raise funds to

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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 necessary regulatory authority clearances 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 our such collaborative partnerships; (v) our ability in future to commercialize certain of our unlicensed respiratory product candidates with our own focused sales and marketing force addressing pulmonary specialty doctors in the United States or in the European Union; (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; (vi) our expectations regarding future clinical trials; and (viii) 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 health care 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 that recently completed two Phase 3 clinical trials, Linhaliq inhaled ciprofloxacin, formerly known as Pulmaquin. We also invested considerable effort into the development of a large volume of laboratory and clinical data demonstrating the performance of our AERx pulmonary drug delivery platform and other proprietary technologies. The key asset we have focused our efforts on in recent years is our inhaled ciprofloxacin formulations.

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 patients with chronic lung infections with *Pseudomonas aeruginosa*.

Our business has focused on opportunities in the development of drugs for the treatment of severe respiratory disease. Pulmonary delivery by inhalation is an effective, widely used and well accepted method of administration of a variety of drugs for the treatment of respiratory and other diseases. Compared to other routes of administration, inhalation provides local delivery of the drug to the respiratory tract which offers a number of potential advantages, including rapid onset of action, less drug required to achieve the desired therapeutic effect, and reduced side effects because the rest of the body has lower exposure to the drug. We believe that there are significant unmet medical needs in severe

respiratory diseases, as well as opportunities to replace some of the existing therapies with products that are more efficacious, safer and more convenient to use by the patients.

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

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

In August 2013, we entered into a partnership with Grifols whereby we licensed to Grifols, on an exclusive, world-wide basis, our inhaled liposomal ciprofloxacin product candidates for the indication of non-CF BE and other indications pursuant to the Grifols License Agreement. The Company is responsible for developing its lead product candidate Linhaliq for the treatment of non-CF BE, 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 a milestone payment of $5 million upon initiation of this Phase 3 program. Additionally, Grifols will pay additional development milestone payments to us for up to a total of $20 million, including a $5 million milestone payment upon the submission of the U.S. NDA and the remainder for first regulatory approvals of Linhaliq in the U.S., EU, Japan and China, along with royalty payments on net sales of the Aradigm products.

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.

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In October 2016, we announced that the U.K. Defence Science and Technology Laboratory (Dstl) have received funding of up to $6.9 million from the U.S. Defense Threat Reduction Agency (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 *Coxiella burnetii* (Q-fever). As the most likely method for infection with biowarfare agents is via the pulmonary route, the main advantage of the inhaled liposomal ciprofloxacin approach is that it delivers the antibiotic rapidly and directly in high concentrations to the respiratory tract the area of primary infection and the liposomal formulation retains it there over a prolonged period of time. The liposomal formulation also facilitates intracellular uptake, essential to treat these life-threatening intracellular infections.

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

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

Collaborative license and development agreements often require us to provide multiple deliverables, such as a license, research and development, product steering committee services and other performance obligations. These agreements

are accounted for in accordance with ASC 605-25. Under this standard, delivered items are evaluated to determine whether such items 1) have value to our collaborators on a stand-alone basis and 2) if the

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item includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the vendor.

Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price method and the appropriate revenue recognition principles are applied to each unit. We allocate non-contingent consideration to each stand-alone deliverable based upon the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, we use best estimated selling price, or BESP, for that deliverable. Significant management judgment may be required to determine the relative selling price of each element.

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

Royalty revenue may be earned in the future under the Grifols License Agreement. We recognize royalty revenue when the amounts can be determined and when collectability is probable. We anticipate recognizing revenue from quarterly royalty payments one quarter in arrears since we believe that we will not be able to determine quarterly royalty earnings until we receive our royalty statements from collaboration partners.

Impairment of Long-Lived Assets

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

Research and Development

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

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes. As part of the process of

preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax

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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, 2016 and 2015, we believed that the amount of our deferred income taxes would not be ultimately recovered. Accordingly, we recorded a full valuation allowance for deferred tax assets. However, should there be a change in our ability to recover our deferred tax assets, we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

Stock-Based Compensation

We recognize compensation expense, using a fair-value based method, for all costs related to stock-based payments including stock options, restricted stock awards and stock issued under the Employee Stock Purchase Plan, or the 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.

Recent Accounting Pronouncements

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

Adopting ASU No. 201-09, Revenue from Contracts with Customers, or the new revenue standard, will involve significant new estimates and judgments related to variable consideration and the constraint on variable consideration, including estimate 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. We expect that revenue will be recognized earlier under the new standard and may have more variability due to significant estimates involved in the new accounting.

Results of Operations

Years ended December 31, 2016 and 2015

Our net loss of $32.9 million for the year ended December 31, 2016 increased by approximately $15.7 million as compared to the net loss of $17.2 million for the year ended December 31, 2015. The increase in

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the net loss resulted primarily from the decrease in contract revenue related party of approximately $23.3 million for the reimbursement of Linhaliq project-related expenses as we utilized the full amount of the $65 million of the Grifols-funded budget provided under the License Agreement in 2015 and an increase in interest expense of $2.4 million and other expense of $0.5 million related to the Note Financing, offset by a decrease in operating expenses of $10.4 million primarily related to the completion of Phase 3 clinical trials for Linhaliq in non-CF BE in the fourth quarter of 2016.

Total revenue was approximately $195,000 for the year ended December 31, 2016, as compared to approximately $23.4 million for the year ended December 31, 2015. We recognized approximately $116,000 in government contract revenue and approximately $39,000 in government grant revenue for the year ended December 31, 2016, as compared to approximately $23.4 million for the reimbursement of Linhaliq project-related expenses under the Grifols License Agreement and approximately $57,000 in government grant revenue for the year ended December 31, 2015. Additionally, for the year ended December 31, 2016 we recorded $40,000 in contract revenue-related party 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.

Operating expenses were approximately $30.2 million for the year ended December 31, 2016, which represented an approximately $10.4 million decrease as compared to the year ended December 31, 2015. Research and development expenses decreased approximately $10.9 million for the year ended December 31, 2016, and general and administrative expenses increased approximately $0.5 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 related to the Linhaliq program as the clinical trials were completed in 2016 offset by higher consulting expenses in anticipation of a potential Linhaliq NDA filing. The increase in general and administrative expenses was primarily due to higher non-cash stock compensation expense.

Liquidity and Capital Resources

Our independent registered public accounting firm for the fiscal year ended December 31, 2016 has indicated in their audit opinion, contained in our 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. However, we believe that our cash and cash equivalents as of December 31, 2016 will be sufficient to fund our operations throughout 2017, provided that we are able to earn the $5 million milestone payment from Grifols upon our first regulatory filing. We will need to raise additional capital in 2017 to maintain our current level of product development activity. Accordingly, we anticipate raising additional capital in 2017 through the issuance of debt or equity securities, royalty financing transactions, strategic transactions or otherwise, to fund our operations and to continue the development of our leading product candidate Linhaliq. No assurance can be given that we will be successful in raising such additional capital on favorable terms or at all. If we are unable to obtain additional funds when required, it will delay or reduce the scope of all or a portion of our development programs or require us to dispose of our assets or technology.

In 2016, we sold $23,000,000 in aggregate principal amount of our Convertible Notes and 263,436 related warrants to purchase our common stock in the Note Financing. The Note Financing consisted of two closings, one on April 25, 2016 and one on July 14, 2016. The Convertible Notes bear interest at a rate of 9% per year, payable semiannually in arrears on November 1 and May 1 of each year commencing on November 1, 2016, and the Convertible Notes will mature on May 1, 2021, unless earlier redeemed or converted. The Convertible Notes are senior unsecured and unsubordinated obligations; rank equal in right of payment to our existing and future unsecured indebtedness that is not subordinated and are effectively subordinated in right of payment to our existing and future secured indebtedness. The Convertible Notes are also initially convertible into our common stock at a conversion rate of 191.9386 shares of

common stock per $1,000 principal amount of Convertible Notes, representing an initial effective conversion price of $5.21 per share of common stock.

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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. In 2015, we utilized the full $65 million of the Grifols-funded budget provided under the License Agreement.

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.

Year ended December 31, 2015

As of December 31, 2015, we had cash and cash equivalents of approximately $31.5 million, down from approximately $48.0 million at December 31, 2014. The decrease primarily resulted from the use of cash to fund our ongoing operations offset by the receipt of approximately $23.4 million from Grifols for Linhaliq program-related expenses. Receipts from Grifols for the Linhaliq program were lower in 2015 compared to 2014 because in 2015 we utilized the full $65 million of the Grifols-funded budget provided under the License Agreement.

Net cash used by operating activities for the year ended December 31, 2015 was approximately $16.7 million as a result of operating activities after adjusting our $17.2 million net loss for non-cash expenses of approximately $1.2 million in stock-based compensation expense and depreciation, and adjusting for net changes in operating assets and liabilities of approximately $0.7 million. Net cash provided by financing activities for the year ended December 31, 2015 was approximately $0.2 million from the proceeds from the issuance of common stock primarily through the ESPP.

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***

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of Aradigm Corporation

We have audited the accompanying consolidated balance sheets of Aradigm Corporation as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, shareholders equity and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Aradigm Corporation at December 31, 2016 and 2015 and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31,2016, in conformity with accounting principles generally accepted in the United States of America.

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 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.

/s/ OUM & Co. LLP

San Francisco, California

March 30, 2017

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ARADIGM CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	December 31, 2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,591	$ 31,462
Restricted cash	1,006	
Receivables	167	150
Prepaid and other current assets	1,037	3,634
Total current assets	24,801	35,246
Property and equipment, net	253	299
Other assets		81
Total assets	$ 25,054	$ 35,626
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 711	$ 1,789
Accrued clinical and cost of other studies	3,306	4,315
Accrued compensation	1,335	1,159
Deferred rent		37
Facility lease exit obligation		104
Other accrued liabilities	496	112
Total current liabilities	5,848	7,516
Deferred revenue related party, non-current	5,000	5,000
Convertible debt, net of discount	2,212	
Convertible debt related party, net of discount	11,007	
Total liabilities	24,067	12,516
Commitments and contingencies (Note 9)		
Shareholders equity:		
Preferred stock, 5,000,000 shares authorized, none outstanding		
Common stock, no par value; authorized shares: 35,045,765 at December 31, 2016; 25,045,765 at December 31, 2015; issued and outstanding shares: 14,951,089 at December 31, 2016; 14,761,351 at December 31, 2015	439,406	428,591
Accumulated deficit	(438,419)	(405,481)
Total shareholders equity	987	23,110

Total liabilities and shareholders equity	$ 25,054	$ 35,626

See accompanying Notes to Consolidated Financial Statements.

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ARADIGM CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

	Years Ended December 31,	
	2016	2015
Revenue:		
Contract revenue related party (Note 8)	$ 40	$ 23,372
Contract revenue	116	
Grant revenue	39	57
Total revenues	195	23,429
Operating expenses:		
Research and development	24,387	35,276
General and administrative	5,828	5,294
Restructuring and asset impairment	2	11
Total operating expenses	30,217	40,581
Loss from operations	(30,022)	(17,152)
Interest income	88	29
Interest expense	(2,406)	
Other expense, net	(598)	(86)
Net loss and comprehensive loss	$ (32,938)	$ (17,209)
Basic and diluted net loss per common share	$ (2.23)	$ (1.17)
Shares used in computing basic and diluted net loss per common share	14,779	14,747

See accompanying Notes to Consolidated Financial Statements.

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ARADIGM CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(In thousands, except share data)

	Common Stock			Total Shareholders Equity
	Shares	Amount	Accumulated Deficit	
Balances at December 31, 2014	14,726,960	$ 427,387	$ (388,272)	39,115
Issuance of common stock under the employee stock purchase plan	30,891	154		154
Exercise of options	3,500	21		21
Stock-based compensation expense for stock options, restricted stock and restricted stock units		1,029		1,029
Net loss			(17,209)	(17,209)
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

See accompanying Notes to Consolidated Financial Statements.

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ARADIGM CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Years Ended December 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (32,938)	$ (17,209)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	121	203
Stock-based compensation expense	1,676	1,029
Amortization of convertible debt discount	1,057	
Financing costs, derivative liability and warrants	997	
Change in value of derivative liability	(386)	
Changes in operating assets and liabilities:		
Restricted cash		250
Receivables	(17)	908
Prepaid and other current assets	2,597	(2,427)
Other assets	81	2,875
Accounts payable	(1,078)	(917)
Accrued compensation	176	340
Current deferred revenue related party		(790)
Accrued liabilities	(625)	2,133
Deferred rent	(37)	(60)
Deferred revenue related party, non-current		(2,845)
Facility lease exit obligation	(104)	(193)
Net cash used in operating activities	(28,480)	(16,703)
Cash flows from investing activities:		
Transfer to/from restricted cash, net	(1,006)	
Capital expenditures	(75)	
Net cash used in investing activities	(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	104	175
Payments for financing costs	(2,414)	
Net cash provided by financing activities	20,690	175

Net decrease in cash and cash equivalents	(8,871)	(16,528)
Cash and cash equivalents at beginning of year	31,462	47,990
Cash and cash equivalents at end of year	$ 22,591	$ 31,462
Supplemental disclosure of cash flow information:		
Cash paid for interest	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	

See accompanying Notes to Consolidated Financial Statements.

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ARADIGM CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization

Aradigm Corporation, or the Company, is a California corporation, incorporated in 1991, focused on the development and commercialization of drugs delivered by inhalation for the prevention and treatment of severe respiratory diseases. The Company s principal activities to date have included conducting research and development and developing collaborations. Management does not anticipate receiving revenues from the sale of any of its products in 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.

Liquidity and Financial Condition

The Company has incurred significant operating losses and negative cash flows from operations. At December 31, 2016, the Company had an accumulated deficit of approximately $438.4 million, working capital of approximately $19.0 million and shareholders equity of approximately $1.0 million. The Company believes that its cash and cash equivalents totaling approximately $22.6 million as of December 31, 2016 will be sufficient to fund its operations at least through 2017, provided the Company is able to earn the $5 million milestone payment from Grifols upon the first regulatory filing. However, the Company will need to raise additional capital in 2017 to maintain the Company s current level of product development activity. Accordingly, the Company anticipates raising additional capital in 2017, 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 leading product candidate Linhaliq. No assurance can be given that the Company will be successful in raising such additional capital on favorable terms or at all. If the Company is unable to obtain additional funds when required it will, delay or reduce the scope of all or a portion of its development programs or dispose of assets or technology.

Use of Estimates

The preparation of financial statements, in conformity with United States generally accepted accounting principles, requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates include useful lives for property and equipment and related depreciation calculations, assumptions for valuing options and warrants, and income taxes. Actual results could differ from these estimates.

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 statement of cash flows based on the nature of the restriction. At December 31, 2016, the Company has $1.0 million in restricted cash held in an interest bearing escrow account for the purpose of making future interest payments on the Convertible Notes, as outlined in Note 7 below. The Company is required to maintain such deposits sufficient to pay all required payments of interest through May 1, 2017.

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Property and Equipment

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

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 to 17 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 generally accepted accounting principles in the United States. ASC 815, *Derivatives and Hedging Activities*, or ASC 815, requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Company accounts for convertible instruments (when it has determined that the embedded conversion options should be bifurcated from their host instruments) in accordance with ASC 815. Under ASC 815, a portion of the proceeds received 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

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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

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. License and collaboration revenue is primarily generated through agreements with strategic partners for the development and commercialization of our product candidates. The terms of the agreement typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of milestones and royalties on net product sales. The Company recognizes revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin 104, Topic 13, *Revenue Recognition Revised and Updated*, or SAB Topic 13, and ASC 605-25. Revenue for arrangements not having multiple deliverables, as outlined in ASC 605-25, is recognized once costs are incurred and collectability is reasonably assured.

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

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

The Company prospectively adopted the provisions of Accounting Standards Update No. 2009-13, Revenue Recognition (Topic 605); *Multiple-Deliverable Revenue Arrangements*, or ASU 2009-13, for new and materially modified arrangements originating on or after January 1, 2010. ASU 2009-13 provides updated guidance on how the deliverables in an arrangement should be separated, and how consideration should be allocated, and it changes the level of evidence of standalone selling price required to separate deliverables by allowing a vendor to make its best

estimate of the standalone selling price of deliverables when vendor-specific objective evidence or third-party evidence of selling price is not available.

The Company allocates non-contingent consideration to each stand-alone deliverable based upon the relative selling price of each element. When applying the relative selling price method, the Company determines

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the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, the Company uses best estimated selling price, or BESP, for that deliverable.

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

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

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

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

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

Research and Development

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

Stock-Based Compensation

The Company accounts for share-based payment arrangements in accordance with ASC 718, *Compensation-Stock Compensation* and *ASC 505-50, Equity-Equity Based Payments to Non-Employees* which requires the recognition of

compensation expense, using a fair-value based method, for all costs related to share-based payments including stock options and restricted stock awards and stock issued under the ESPP. These standards

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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, 2016 and 2015, the Company believed that the amount of its deferred income taxes would not be ultimately recovered. Accordingly, the Company recorded a full valuation allowance for deferred tax assets. However, should there be a change in the Company s ability to recover its deferred tax assets, 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 equivalent shares, such as stock options and unvested restricted stock shares outstanding during the period.

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).

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU 2014-09, and has subsequently issued various amendments in 2015 and 2016 (ASU No. s 2015-14, 2016-08, 2016-10, 2016-11, 2016-12, and 2016-20). The standard provides companies with a single model for

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use in accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The new revenue guidance ASU 2014-09, as amended, is effective for annual reporting periods beginning after December 15, 2017, but allows the Company to elect to adopt one year early. The Company plans to adopt the new revenue standard effective January 1, 2018. The Company has not yet determined if it will apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment to equity. While the Company is still in the process of evaluating the impact of adoption of the new revenue standard on its historical financial statements, the Company has identified that transactions which under current guidance are recognized at the time substantive milestones are achieved will be recorded under the new standard as variable consideration for which the outcomes cannot be estimated at the outset of the arrangement. These substantive milestones will be included in variable consideration when it is no longer probable that such estimations will not significantly reverse, and such estimations will be reassessed every reporting period. As a result, the Company anticipates that revenue for such milestones may be recorded in an earlier period than under the existing guidance. In addition, the Company has identified that once commercial sales of an approved product commence, product revenue will be recognized when goods are transferred to the control of the customer subject to estimations for product returns. This is a change from the current guidance which would delay recognition of product revenue until customers sell through to patients, since there is no history for returns for newly approved pharmaceutical products. The Company is still evaluating the performance obligations under the Grifols collaboration agreement, the allocation of consideration under this agreement including estimated variable consideration, and the pattern of recognition for each performance obligation under the new standard. The Company is still in clinical trials, has not achieved the substantive milestones under the Grifols collaboration agreement, does not expect to achieve any substantive milestones prior to adoption of the new standard, and does not expect to commence commercial product sales prior to adoption of the new standard. The next steps in the Company s implementation efforts are to (i) complete the evaluation of the Grifols collaboration agreement, (ii) assess the accounting impact to the financial statements, (iii) prepare the accounting entries for adoption, and (iv) write supplemental footnote disclosures. The Company expects to complete these efforts by the fourth quarter of 2017.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern, or ASU 2014-15. This ASU provides guidance about management s responsibility to evaluate whether there is substantial doubt about the organization s ability to continue as a going concern and provides principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted. The Company adopted this guidance as of December 31, 2016. The adoption of ASU 201-15 impacted the Company s disclosures only and did not have an effect on its consolidated financial statements.

In April 2015, the FASB issued AUS No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs*, which requires companies to present debt financing costs as a direct deduction from the carrying amount of the associated debt liability rather than as an asset, consistent with the presentation of debt discounts on the consolidated balance sheets. The new standard became effective for the Company beginning on January 1, 2016. The Company adopted this standard as of January 1, 2016 and, as required by this standard, debt issuance costs are presented net of the associated debt liability.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), requiring lessee s to recognize assets and liabilities for the rights and obligations created by leases with lease terms of more than 12 months on the entity s balance sheet Leases will be classified as either finance or operating, with classification affecting the pattern of

expense recognition in the income statement. The new Leases standard will require new disclosures that depict the amount, timing, and uncertainty of cash flows pertaining to an entity s leases. The new guidance is

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effective for fiscal years and for interim periods within those fiscal years, beginning after December 15, 2018, and the Company expects to adopt as of January 1, 2019. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of the adoption on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230) Restricted Cash. The standard addresses diversity in the classification and presentation of restricted cash transfers in the statement of cash flows by requiring that amounts generally described as restricted cash be included in cash and cash equivalents. The new guidance is effective for fiscal years beginning after December 15, 2017 and early adoption is permitted. A retrospective transition method should be applied in the period of transition. Upon adoption, the Company s presentation of restricted cash in the consolidated statement of cash flows will be updated accordingly.

2. Cash and Cash Equivalents

At December 31, 2016 and December 31, 2015, 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, 2016 and December 31, 2015 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,	
	2016	**2015**
Machinery and equipment	$ 4,363	$ 4,783
Furniture and fixtures	578	1,144
Lab equipment	1,446	2,138
Computer equipment and software	1,821	2,679
Leasehold improvements	1,734	1,844
Property and equipment	9,942	12,588
Less accumulated depreciation and amortization	(9,689)	(12,289)
Property and equipment, net	$ 253	$ 299

Depreciation expense was $121,000 and $203,000 for the years ended December 31, 2016 and 2015, 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 Biotechnology, Inc., or 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.

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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, 2016 and 2015 are as follows (in thousands):

	Year Ended December 31,	
	2016	2015
Balance at beginning of year	$ 104	$ 297
Accretion expense	2	11
Lease payments	(106)	(204)
Balance at end of the year	$	$ 104

As of December 31, 2016, the Company had no lease liability. The Company classified all of the $104,000 lease exit liability in current liabilities in the accompanying Consolidated Balance Sheet at December 31, 2015.

6. Other Accrued Liabilities

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. The liability for accrued interest of $340,000 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, 2016. At December 31, 2015, other accrued liabilities consisted of accrued expenses for services of $73,000 and payroll withholding liabilities of $39,000.

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.

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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.

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On April 25, 2016, the initial closing of the Convertible Notes took place under which the Company raised $20 million from a total of two investors and issued 4,319 Warrants to one investor. Of the $20 million, $19.9 million was financed by Grifols, a related party to the Company, as described in Note 8 below. 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, 2016.

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, 2016.

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.

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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, 2016, the Convertible Notes consisted of the following:

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

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

	Year ended December 31, 2016 (in thousands)
Cash Interest Expense	
Coupon interest expense	$ 1,349
Noncash Interest Expense	
Amortization of debt discount	920
Amortization of transaction costs	137
	$ 2,406

As of December 31, 2016, the unamortized debt discount will be amortized over a remaining period of approximately 4.34 years. The if converted value as of December 31, 2016 does not exceed the principal balance of the Convertible

Notes. Accrued interest payable at December 31, 2016 is $340,000 and is included in other accrued liabilities.

8. Collaboration Agreement

Grifols License and Collaboration Agreement

On May 20, 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 a total of 5,244,363 shares of the Company s common stock, or Common Stock, to Grifols and an additional 3,104,838 shares of Common Stock to the Investors, for a total sale of 8,349,201 shares of Common Stock, or the

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Company Stock Sale, for a purchase price of $4.96 per share. The aggregate gross consideration paid to the Company in August 2013 in the Company Stock Sale was approximately $41.4 million.

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 will be 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.

On July 15, 2013 shareholders of the Company (i) approved certain amendments to the Company s charter including amendments necessary to increase the total number of shares of Common Stock authorized to be issued by the Company to at least 17,670,765 shares, including the 8,349,201 shares to be sold in the Company Stock Sale, or the Charter Amendment, and (ii) approved the Company s closing of the Company Stock Sale and entering into the License Agreement, Governance Agreement and other agreements described below and in the Stock Purchase Agreement, or the Transactions. Shareholders of the Company holding more than 50% of the outstanding shares of the Company s Common Stock voted in favor of these proposals at a special meeting.

The closing of the Transactions was subject to certain closing conditions, including, among others the Company s entering into binding terms with a third party to commercially manufacture Products to permit the Company to satisfy its obligation to commercially supply Grifols with Products. All conditions to the closing of the Transactions were met as of August 27, 2013 and the Company Stock Sale was completed on August 27, 2013.

In August of 2013 Grifols paid approximately $26.0 million for the shares of the Company s common stock at a purchase price of $4.96 per share, which reflected the contractual price for the Company s common stock as stated in the Stock Purchase Agreement on May 20, 2013. Following the announcement of the collaboration, execution of a supply agreement and satisfaction of the other conditions of closing, the stock price rose to $8.00 per share at the time of closing. Consequently, the contractual price of $4.96 per share resulted in a $3.04 per share discount from the August 27, 2013 closing price of $8.00 per share, a discount of approximately $15.9 million from the fair market value of the common stock on the effective date of the Grifols License and Collaboration Agreement. The Company determined this transaction was not within the scope of ASC 605-25 and, accordingly, the Company recorded the sale of common stock to Grifols at fair value based on the closing price of the Company s stock on August 27, 2013 at $8.00 per share. This discount, which is a non-cash charge, has been recorded as Collaboration Arrangement Acquisition Cost in the Company s Consolidated Statement of Operations and Comprehensive Loss for the year ended December 31, 2013.

License Agreement

The License Agreement was signed simultaneously with the closing of the Company Stock Sale. 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

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will develop the Product for additional indications at Grifols sole expense if Grifols elects to pursue such development. Pursuant to the License Agreement, the Company recognized reimbursements of development costs from Grifols as Contract revenue related party totaling $23.4 million for the year ended December 31, 2015, for the reimbursement of fully burdened development expenses for collaboration services performed and costs incurred related to the development of Linhaliq for non-cystic fibrosis bronchiectasis. 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 to use 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.

The Company s deliverables included an exclusive license for inhaled ciprofloxacin compounds for the indication of non-cystic fibrosis bronchiectasis and other indications, payment of development costs over $65 million for the non-cystic fibrosis bronchiectasis indication and participation on a Joint Steering Committee, or JSC. Having determined that both the development and JSC do not have standalone value from the license, the Company combined these deliverables into a single unit of accounting. The Company is recognizing reimbursements of development expenses as collaboration services are performed and costs are incurred. During the years ended December 31, 2016 and December 31, 2015, the Company recognized zero and $23.4 million, respectively, in contract revenue related party relating to services performed and costs incurred during the period under the License Agreement. In addition, the Company has a current deferred revenue balance at December 31, 2016 of $5.0 million representing a milestone payment which was received upon the dosing of the first patient in a Phase III clinical trial. The $5.0 million milestone payment will be recognized as revenue upon receiving the first regulatory approval.

As of December 31, 2015, the Company had utilized the full amount of the $65 million of Grifols-funded budget provided under the License Agreement and will not be recognizing any future revenue related to the $65 million Grifols-funded budget.

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Costs incurred under the Grifols License Agreement in the quarters ended December 31, 2016 and 2015 are zero. Costs incurred under the Grifols License Agreement for the years ended December 31, 2016 and 2015 are zero and $23.4 million, respectively. Research and development expenses incurred under the Grifols License Agreement for the years ended December 31, 2016 and 2015 are zero and $22.2 million, respectively. General and administrative expenses incurred under the Grifols License Agreement for the years ended December 31, 2016 and 2015 are zero and $1.2 million, respectively. Research and development expenses under the Grifols License Agreement decreased approximately $22.2 million and general and administrative expenses decreased approximately $1.2 million as the $65 million expense reimbursement cap was reached in 2015. Development expenses are fully burdened and include direct costs reported as research and development expenses and collaboration-related general and administrative expenses.

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

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the Company agreed to provide registration rights to Grifols with respect to the shares of Common Stock to be acquired in the Company Stock Sale. Under such agreement, Grifols will be entitled to require the Company to file with the SEC certain registration statements under the Securities Act of 1933, as amended, 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.

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

9. Leases, Commitments and Contingencies

The Company has a lease for a building containing offices, laboratory and manufacturing facilities, which will expire in 2017. The Company s monthly rent payments fluctuated under the master lease. In accordance with U.S. generally accepted accounting principles, the Company recognized rent expense on a straight-line basis. The Company recorded deferred rent for the difference between the amounts paid and recorded as expense. At December 31, 2016 and 2015, the Company had zero and $37,000 of deferred rent, respectively.

For the years ended December 31, 2016 and 2015, building rent expense under operating leases totaled $587,000 and $591,000, respectively.

Indemnification

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, 2016 or 2015.

Legal Matters

From time to time, the Company is involved in litigation arising out of the ordinary course of its business. Currently there are no known claims or pending litigation expected to have a material effect on the Company s overall financial position, results of operations, or liquidity.

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

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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 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.

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, 2016 and 2015, 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 under the 2005 Plan and the 2015 Plan for the year ended December 31, 2016:

	Shares Available for Future Grant
Balance at January 1, 2016	252,725
Increase in authorized shares	2,400,000
Options granted	(1,005,323)

Options cancelled	28,870
Restricted stock awards granted	(166,000)
Balance at December 31, 2016	1,510,272

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Stock Options	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2016	947,142	$ 11.40		
Options granted	1,005,323	$ 4.45		
Options cancelled	(28,870)	$ 72.10		
Outstanding at December 31, 2016	1,923,595	$ 6.86	8.31	$
Ending vested and expected to vest	1,895,273	$ 6.87	8.30	$
Ending exercisable	588,585	$ 9.63	7.01	$

The weighted-average grant-date fair value of options granted during the years ended December 31, 2016 and 2015 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 2016 and 2015 was zero and $2,100, respectively.

A summary of the activity of the Company s unvested restricted stock and performance bonus stock award activities for the year ending December 31, 2016 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, 2016	300	$ 57.60
Restricted stock awards granted	166,000	3.87
Restricted stock awards vested	(14,062)	4.04
Outstanding at December 31, 2016	152,238	$ 3.96

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, 2016 and 2015 was $53,000 and zero, respectively.

Restricted Stock Units

	Number of Shares	Weighted Average Grant Date Fair Value

Outstanding at January 1, 2016	10,306	$	5.34
Restricted stock units granted			
Restricted stock units vested			
Outstanding at December 31, 2016	10,306	$	5.34

As of December 31, 2016, 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, 2016 and 2015 was zero for both years.

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Performance-based Stock Options

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 year ended December 31, 2016, as none of the performance-based goals was 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, 2016, a total of 286,250 shares have been reserved for issuance under the ESPP, of which 195,695 shares have been issued to participants leaving a remaining balance of 90,555 available authorized shares. Compensation expense related to the ESPP was $73,000 and $104,000 for the years ended December 31, 2016 and 2015, 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, 2016 and 2015, (in thousands, except per share amounts):

	2016	2015
Costs and Expenses		
Research and development	$ 826	$ 522
General and administrative	850	507
Total stock-based compensation expense	$ 1,676	$ 1,029
Impact on basic and diluted net loss per common share	$ (0.11)	$ (0.07)

There was no capitalized stock-based compensation expense as of December 31, 2016. Since the Company has cumulative net losses through December 31, 2016, 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, net of forfeitures, was $2,051,000 as of December 31, 2016.This amount will be recognized over a

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weighted average period of 1.0 year. As of December 31, 2016, there was $397,000 of unrecognized compensation expense, net of forfeitures, related to unvested restricted stock awards that is expected to be recognized over a weighted average period of 1.9 years. There also was $25,000 of unrecognized compensation expense related to the current ESPP offering period as of December 31, 2016, which is expected to be through March 31, 2017.

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	
	2016	**2015**
Dividend yield	0.0%	0.0%
Volatility factor	74.0%	83.9%
Risk-free interest rate	1.4%	1.7%
Expected term (in years)	5.5	5.7
Weighted-average fair value of options granted during the periods	$ 3.13	$ 4.95

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

	Year Ended December 31, 2016
Dividend yield	0.0%
Volatility factor	77.1%

Risk-free interest rate		1.5%
Expected term (in years)		5.7
Weighted-average fair value of options granted during the period	$	2.68

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

	Years Ended December 31,	
	2016	2015
Dividend yield	N/A	0.0%
Volatility factor	N/A	65.6%
Risk-free interest rate	N/A	0.06%
Expected life (years)	N/A	2.00
Weighted-average fair value of purchase rights granted during the period	N/A	$ 3.38

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

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, 2016 and 2015.

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

	Year ended December 31,	
	2016	2015
Common shares underlying convertible notes ..	4,269	
Outstanding stock options ..	1,924	947
Common shares underlying warrants	263	71
Unvested restricted stock ..	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 2016 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 $88,000 and $47,000 in 2016 and 2015, respectively.

13. Income Taxes

In 2016 and 2015, 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.

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

	December 31,	
	2016	2015
Net operating loss carryforwards	$ 25,536	$ 18,406
Research and development credits	6,509	6,509
Federal orphan drug credits	18,599	11,011
Other	3,572	2,130
Total deferred tax assets	54,216	38,056
Valuation allowance	(54,216)	(38,056)
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, 2016 and 2015, 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 increased by $16.2 million during the year ended December 31, 2016 and increased by $8.2 million during the year ended December 31, 2015. In accordance with ASC 718 *Compensation-Stock Compensation*, the Company has excluded from deferred tax assets those tax benefits attributable to employee stock option exercises.

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,	
	2016	2015
Income tax benefit at federal statutory rate	$ (11,531)	$ (6,016)
State taxes (net of federal)	(391)	(17)
Credits	(4,932)	(2,466)
Other	694	276
Change in valuation allowance	16,160	8,223
Total	$	$

As of December 31, 2016, the Company had federal net operating loss carryforwards of approximately $63.8 million and federal orphan drug credit carryforwards of approximately $18.6 million, which expire in the years 2028 through 2036. The Company also had California net operating loss carryforwards of approximately $44.1 million, which expire in the years 2017 through 2036, and California research and development tax credit carryforwards of approximately $9.9 million, which do not expire. None of the federal and state net operating loss carryforwards represent stock option deductions arising from activity under the Company s stock option plan.

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, 2016, 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.

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The Company does not have any unrecognized tax benefits, or interest and penalties accrued on unrecognized tax benefits, at December 31, 2016, 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, 2016 and 2015 (in thousands, except per share data):

	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Total revenue	$ 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

	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Total revenues	$ 8,768	$ 9,952	$ 4,674	$ 35
Operating expenses:				
Research and development	8,361	9,754	8,880	8,281
General and administrative	1,542	1,339	1,320	1,093
Restructuring and asset impairment	4	3	2	2

Total expenses	9,907	11,096	10,202	9,376
Loss from operations	(1,139)	(1,144)	(5,528)	(9,341)
Interest income	8	7	7	7
Other expense	(32)	(8)	(28)	(18)
Loss before income taxes	(1,163)	(1,145)	(5,549)	(9,352)
Income tax provision				
Net loss and comprehensive loss	$ (1,163)	$ (1,145)	$ (5,549)	$ (9,352)
Basic and diluted net loss per common share	$ (0.08)	$ (0.08)	$ (0.38)	$ (0.63)
Shares used in computing basic and diluted net loss per common share	14,727	14,749	14,751	14,761

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15. Going Concern

As reflected in the accompanying consolidated financial statements, the Company has an accumulated deficit of $438.4 million as of December 31, 2016 that includes a net loss of $32.9 million for the year ended December 31, 2016 which raises doubt about the Company s ability to continue as a going concern. The Company s current assets of $24.8 million exceed current liabilities of $5.8 million by $19.0 million. The Company believes that its cash and cash equivalents of approximately $19.5 million as of February 28, 2017 are sufficient to fund its operations through 2017 provided the Company is able to earn the $5 million milestone payment from Grifols upon the first regulatory filing. However, the Company will need to raise additional capital in 2017 to maintain the Company s current level of product development activity. Accordingly the Company anticipates raising additional capital in 2017 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 leading 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. Subsequent Events

The Company has evaluated subsequent events that have occurred after December 31, 2016 and determined that there were no events that occurred during this reporting period which require recognition or disclosure in the consolidated financial statements except as follows: in February 2017, the Company received a cash rebate under the Australian R&D Tax Incentive Program of approximately $675,000 for qualified research and development expenses incurred in Australia during the period of July 1, 2015 through June 30, 2016. At December 31, 2016, the Company had not completed and filed the application for the R&D rebate and as the Company had no previous experience with filing for and receiving such a rebate did not consider the receipt of the rebate to be probable.

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

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our chief executive officer and chief financial officer have concluded that these controls and procedures are effective at the reasonable assurance level. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide

absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

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Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. 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, 2016. 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, 2016.

As a result of the enactment of the Reform Act, Exemption for Non-accelerated Filer, and in accordance with Section 989G 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 our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

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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 the 2017 Annual Meeting of Shareholders to be filed by the Company with the SEC, or the 2017 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 2017 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 2017 Proxy Statement.

Item 11. ***Executive Compensation***

The information required by this Item is incorporated by reference from the section captioned Compensation contained in the 2017 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 2017 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 2017 Proxy Statement.

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

The information required by this item is incorporated by reference from the section titled Ratification of Selection of Independent Registered Public Accounting Firm contained in the 2017 Proxy Statement.

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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:

(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.
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.
3.8(6)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.9(14)	Certificate of Correction to Certificate of Amendment of Articles of Incorporation of the Company.

3.10(19)	Certificate of Amendment of Articles of Incorporation of the Company.
3.11(22)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.12(2)	Amended and Restated Bylaws of the Company, as amended.
3.13(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 and 3.13.
4.2(1)	Specimen common stock certificate.

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Exhibit No.	Description
10.1(1)+	Form of Indemnity Agreement between the Company and each of 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 as of August 10, 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 between the Company and Mendel Biotechnology, Inc., dated July 11, 2007, under the Lease Agreement by and between the Company and Hayward Point Eden I Limited Partnership, a Delaware limited partnership, as successor-in-interest to Britannia Point Eden, LLC, as amended, for 3929 Point Eden Way, Hayward, California.
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)+	Amended and Restated Executive Officer Severance Benefit Plan.
10.15(15)	Amended and Restated Change of Control Agreement entered into between the Company and certain of the Company s senior officers.
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.
10.19(16)	Securities Purchase Agreement, dated as of December 11, 2012, among the Company and the investors party thereto.
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 listed on the signature page thereto.

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Exhibit No.	Description
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 November 5, 2013, by and between the Company and Dr. Juergen Froehlich.
10.28(20)	Offer Letter, dated November 5, 2013, between the Company and Dr. Juergen Froehlich.
10.29(21)	Assignment, Assumption, Waiver and Consent, effective February 28, 2015, by and among the 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 September 1, 2015, between the Company and Grifols, S.A.
10.32(26)+	Aradigm Corporation 2015 Equity Incentive Plan.
10.33(26)+	Form of Stock Option Agreement pursuant to Aradigm Corporation 2015 Equity Incentive Plan.
10.34(26)+	Aradigm Corporation Employee Stock Purchase Plan.
10.35(27)+	Form of Amendment to the Stock Option Agreement.
10.36(27)	Supply Agreement between the Company and Grifols, S.A. dated October 22, 2015.
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. Reference is made to the signature page.
31.1	Section 302 Certification of the Chief Executive Officer.
31.2	Section 302 Certification of the Chief Financial Officer.
32.1	Section 906 Certification of the Chief Executive Officer and the Chief Financial Officer.
101	The following materials from the Registrant s Annual Report on Form 10-K for the year ended December 31, 2016 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.

(1) Incorporated by reference to the Company s Form S-1 (No. 333-4236) filed on April 30, 1996, as amended.
(2) Incorporated by reference to the Company s Form 10-Q filed on August 14, 1998.
(3) Incorporated by reference to the Company s Form 10-K filed on March 29, 2002.

(4) Incorporated by reference to the Company s Form S-3 (No. 333-76584) filed on January 11, 2002, as amended.
(5) Incorporated by reference to the Company s Form 10-Q filed on August 13, 2004.
(6) Incorporated by reference to the Company s Form 10-K 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 filed on March 24, 1998, as amended.

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(9) Incorporated by reference to the Company s Form 8-K filed on July 24, 2007.
(10) Incorporated by reference to the Company s definitive proxy statement filed on April 7, 2008.
(11) Incorporated by reference to the Company s Form 8-K filed on May 21, 2009.
(12) Incorporated by reference to the Company s Form 10-Q filed on November 12, 2008.
(13) Incorporated by reference to the Company s Form 8-K filed on January 8, 2009.
(14) Incorporated by reference to the Company s Form 8-K filed on September 20, 2010.
(15) Incorporated by reference to the Company s Form 8-K filed on April 18, 2011.
(16) Incorporated by reference to the Company s Form 8-K filed on December 13, 2012.
(17) Incorporated by reference to the Company s Form 8-K filed on May 24, 2013.
(18) Incorporated by reference to the Company s Form 10-Q filed on October 28, 2013.
(19) Incorporated by reference to the Company s Form 8-K filed on February 4, 2015.
(20) Incorporated by reference to the Company s Form S-1 (No. 333-193751) filed on February 4, 2015, as amended.
(21) Incorporated by reference to the Company s Form 8-K filed on February 4, 2015, as amended.
(22) Incorporated by reference to the Company s Form 10-Q filed on May 14, 2015.
(23) Incorporated by reference to the Company s Form 10-K filed on March 17, 2015.
(24) Incorporated by reference to the Company s Form 8-K filed on September 4, 2015.
(25) Incorporated by reference to the Company s Form 10-Q 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 filed on March 30, 2016.
(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.

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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 30th day of March 2017.

ARADIGM CORPORATION

By: /s/ Igor Gonda
Igor Gonda
President and Chief Executive Officer

KNOWN ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints, jointly and severally, Igor Gonda and Nancy E. Pecota, 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/ Igor Gonda Igor Gonda	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2017
/s/ Nancy E. Pecota Nancy E. Pecota	Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2017
/s/ Virgil D. Thompson Virgil D. Thompson	Chairman of the Board and Director	March 30, 2017
/s/ David Bell David Bell	Director	March 30, 2017
/s/ Frederick Hudson Frederick Hudson	Director	March 30, 2017

/s/ John M. Siebert John M. Siebert	Director	March 30, 2017

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EXHIBIT INDEX

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.
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.
3.8(6)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.9(14)	Certificate of Correction to Certificate of Amendment of Articles of Incorporation of the Company.
3.10(19)	Certificate of Amendment of Articles of Incorporation of the Company.
3.11(22)	Certificate of Amendment of Amended and Restated Articles of Incorporation of the Company.
3.12(2)	Amended and Restated Bylaws of the Company, as amended.
3.13(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 and 3.13.
4.2(1)	Specimen common stock certificate.
10.1(1)+	Form of Indemnity Agreement between the Company and each of 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 as of August 10, 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 between the Company and Mendel Biotechnology, Inc., dated July 11, 2007, under the Lease Agreement by and between the Company and Hayward Point Eden I Limited Partnership, a Delaware limited partnership, as successor-in-interest to Britannia Point Eden, LLC, as amended, for 3929 Point Eden Way, Hayward, California.

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Exhibit No.	Description
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)+	Amended and Restated Executive Officer Severance Benefit Plan.
10.15(15)	Amended and Restated Change of Control Agreement entered into between the Company and certain of the Company s senior officers.
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.
10.19(16)	Securities Purchase Agreement, dated as of December 11, 2012, among the Company and the investors party thereto.
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 listed on the signature page 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 November 5, 2013, by and between the Company and Dr. Juergen Froehlich.
10.28(20)	Offer Letter, dated November 5, 2013, between the Company and Dr. Juergen Froehlich.
10.29(21)	Assignment, Assumption, Waiver and Consent, effective February 28, 2015, by and among the 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 September 1, 2015, between the Company and Grifols, S.A.
10.32(26)+	Aradigm Corporation 2015 Equity Incentive Plan.
10.33(26)+	Form of Stock Option Agreement pursuant to Aradigm Corporation 2015 Equity Incentive Plan.

10.34(26)+	Aradigm Corporation Employee Stock Purchase Plan.
10.35(27)+	Form of Amendment to the Stock Option Agreement.
10.36(27)	Supply Agreement between the Company and Grifols, S.A. dated October 22, 2015.

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Exhibit

No.	Description
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. Reference is made to the signature page.
31.1	Section 302 Certification of the Chief Executive Officer.
31.2	Section 302 Certification of the Chief Financial Officer.
32.1	Section 906 Certification of the Chief Executive Officer and the Chief Financial Officer.
101	The following materials from the Registrant s Annual Report on Form 10-K for the year ended December 31, 2016 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.

(1) Incorporated by reference to the Company s Form S-1 (No. 333-4236) filed on April 30, 1996, as amended.
(2) Incorporated by reference to the Company s Form 10-Q filed on August 14, 1998.
(3) Incorporated by reference to the Company s Form 10-K filed on March 29, 2002.
(4) Incorporated by reference to the Company s Form S-3 (No. 333-76584) filed on January 11, 2002, as amended.
(5) Incorporated by reference to the Company s Form 10-Q filed on August 13, 2004.
(6) Incorporated by reference to the Company s Form 10-K 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 filed on March 24, 1998, as amended.
(9) Incorporated by reference to the Company s Form 8-K filed on July 24, 2007.
(10) Incorporated by reference to the Company s definitive proxy statement filed on April 7, 2008.
(11) Incorporated by reference to the Company s Form 8-K filed on May 21, 2009.
(12) Incorporated by reference to the Company s Form 10-Q filed on November 12, 2008.
(13) Incorporated by reference to the Company s Form 8-K filed on January 8, 2009.
(14) Incorporated by reference to the Company s Form 8-K filed on September 20, 2010.
(15) Incorporated by reference to the Company s Form 8-K filed on April 18, 2011.
(16) Incorporated by reference to the Company s Form 8-K filed on December 13, 2012.
(17) Incorporated by reference to the Company s Form 8-K filed on May 24, 2013.
(18) Incorporated by reference to the Company s Form 10-Q filed on October 28, 2013.
(19) Incorporated by reference to the Company s Form 8-K filed on February 4, 2015.
(20) Incorporated by reference to the Company s Form S-1 (No. 333-193751) filed on February 4, 2015 as amended.
(21) Incorporated by reference to the Company s Form 8-K filed on February 4, 2015, as amended.
(22) Incorporated by reference to the Company s Form 10-Q filed on May 14, 2015.
(23) Incorporated by reference to the Company s Form 10-K filed on March 17, 2015.
(24) Incorporated by reference to the Company s Form 8-K filed on September 4, 2015.
(25) Incorporated by reference to the Company s Form 10-Q 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 filed on March 30, 2016.