



**Engineering the Future for Inhaled Therapeutics**

**2018 Annual Report**



**PULMATRIX, INC.**  
**2018 ANNUAL REPORT**  
**TABLE OF CONTENTS**

	<u>Page No.</u>
Forward-Looking Statements .....	1
<b><u>PART I</u></b>	
Item 1. Business. ....	2
Item 1A. Risk Factors. ....	16
Item 1B. Unresolved Staff Comments. ....	34
Item 2. Properties. ....	34
Item 3. Legal Proceedings. ....	34
Item 4. Mine Safety Disclosures. ....	34
<b><u>PART II</u></b>	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities. ....	35
Item 6. Selected Financial Data. ....	35
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations. ....	35
Item 7A. Quantitative and Qualitative Disclosures About Market Risk. ....	46
Item 8. Financial Statements and Supplementary Data. ....	46
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure. ....	46
Item 9A. Controls and Procedures. ....	46
Item 9B. Other Information. ....	47
<b><u>PART III</u></b>	
Item 10. Directors, Executive Officers and Corporate Governance. ....	48
Item 11. Executive Compensation. ....	54
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters. ....	60
Item 13. Certain Relationships and Related Transactions, and Director Independence. ....	68
Item 14. Principal Accounting Fees and Services\ ....	69
Financial Statements .....	F-1



## PART I

### Forward-Looking Statements

This Annual Report contains forward-looking statements. All statements other than statements of historical fact contained herein, including statements regarding our business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results, are forward-looking statements. Words such as “anticipates,” “assumes,” “believes,” “can,” “could,” “estimates,” “expects,” “forecasts,” “guides,” “intends,” “is confident that,” “may,” “plans,” “seeks,” “projects,” “targets,” and “would,” and their opposites and similar expressions, as well as statements in future tense, are intended to identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management’s good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue or complete our business objectives;
- our inability to carry out research, development and commercialization plans;
- our inability to manufacture our product candidates on a commercial scale on our own or in collaborations with third parties;
- our inability to complete preclinical testing and clinical trials as anticipated;
- our ability to adequately protect and enforce rights to intellectual property;
- difficulties in obtaining financing on commercially reasonable terms, or at all;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- adverse market and economic conditions;
- loss of one or more key executives or scientists; and
- difficulties in securing regulatory approval to market our product candidates.

For a more detailed discussion of these and other that may affect our business and that could cause our actual results to differentiate equally from those projected in these forward-looking statements, see the risk factors and uncertainties described under the heading “Risk Factors” in Part I, Item 1A of this Annual Report. The forward-looking statements contained in this Annual Report are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events, except as required by law.

---

Unless otherwise stated, references in this Annual Report to “us,” “we,” “our,” or “Company” refer to Pulmatrix, Inc., a Delaware corporation.

The Company effected a one-for-ten reverse stock split on February 3, 2019. All share and per share information in this Annual Report has been retroactively adjusted to reflect these reverse stock splits.

“iSPERSE” is one of our trademarks used in this Annual Report. Other trademarks appearing in this report are the property of their respective holders. Solely for convenience, these and other trademarks, trade names and service marks referred to in this report appear without the ®, TM and SM symbols, but those references are not intended to indicate, in any way, we or the owners of such trademarks will not assert, to the fullest extent under applicable law, their rights to these trademarks and trade names.

## **ITEM 1. BUSINESS.**

### *Overview*

We are a clinical stage biotechnology company focused on the discovery and development of novel inhaled therapeutic products intended to prevent and treat respiratory diseases and infections with significant unmet medical needs.

We design and develop inhaled therapeutic products based on our proprietary dry powder delivery technology, iSPERSE (inhaled Small Particles Easily Respirable and Emitted), which enables delivery of small or large molecule drugs to the lungs by inhalation for local or systemic applications. The iSPERSE powders are engineered to be small, dense particles with highly efficient dispersibility and delivery to airways. iSPERSE powders can be used with an array of dry powder inhaler technologies and can be formulated with a broad range of drug substances including small molecules and biologics. We believe the iSPERSE dry powder technology offers enhanced drug loading and delivery efficiency that outperforms traditional lactose-blend inhaled dry powder therapies. We believe the advantages of using the iSPERSE technology include reduced total inhaled powder mass, enhanced dosing efficiency, reduced cost of goods and improved safety and tolerability profiles. We are developing iSPERSE-based therapeutic candidates targeted at the prevention and treatment of a range of respiratory diseases, including allergic bronchopulmonary aspergillosis (“ABPA”) in asthmatics and in patients with cystic fibrosis (“CF”), chronic obstructive pulmonary disease (“COPD”) and idiopathic pulmonary fibrosis (“IPF”).

### *Corporate History*

We were incorporated in 2013 as a Nevada corporation and converted to a Delaware corporation in September 2013. On June 15, 2015, we completed a merger with Pulmatrix Operating Company, changed our name to “Pulmatrix, Inc.” and relocated our corporate headquarters to Lexington, Massachusetts. Our resources are focused on the development of novel inhaled therapeutic products intended to prevent and treat respiratory diseases and infections.

### *Business Strategy*

Our goal is to utilize our proprietary iSPERSE technology to develop breakthrough therapeutic products that are safe, convenient and more efficient than the existing therapeutic products for the treatment of respiratory diseases.

- *Focus on development of inhaled anti-fungal therapies to prevent and treat pulmonary infections and allergic/hypersensitivity responses to fungus in asthma and CF patients and other rare/orphan indications. We intend to direct resources to advance the research and development of Pulmazole for ABPA in asthmatics and CF patients. In 2018, we conducted clinical testing of Pulmazole in normal healthy volunteers and asthma patients.*
- *Focus on development of an inhaled kinase inhibitor to treat acute exacerbations in COPD patients. We completed preclinical safety studies for our lead iSPERSE formulation in 2018 and have the ability to advance our formulation and process development efforts to support clinical testing in stable moderate-severe COPD patients. We intend to direct resources to advance the research and development of PUR1800, an inhaled kinase inhibitor for the treatment of acute exacerbations in COPD patients.*

- *Capitalize on our proprietary iSPERSE technology and our expertise in inhaled therapeutics and particle engineering to identify new product candidates for prevention and treatment of respiratory diseases with significant unmet medical needs.* To add additional inhaled therapeutics to our discovery pipeline and facilitate additional discovery collaborations, we are leveraging our iSPERSE technology and our management’s expertise in inhaled therapeutics and particle engineering to identify potential product candidates that are potentially safer and more effective than the current standard of care for prevention and treatment of respiratory diseases with significant unmet medical needs.
- *Invest in protecting and expanding our intellectual property portfolio and file for additional patents to strengthen our intellectual property rights.* The status of our patent portfolio changes frequently in the ordinary course of patent prosecution. As of December 31, 2018, our patent portfolio related to iSPERSE included approximately 92 granted and allowed patents, 12 of which are granted or allowed US patents, with expiration dates from 2024 to 2034, and approximately 75 additional pending patent applications in the US and other jurisdictions. Our in-licensed portfolio related to kinase inhibitors included approximately 225 granted and allowed patents, 26 of which are granted or allowed US patents, with expiration dates from 2029 to 2035, and approximately 52 additional pending patent applications in the US and other jurisdictions.

### *iSPERSE Technology*

We use simple, safe excipients, including proprietary cationic salt formulations, to create a robust and flexible dry powder platform technology that can accommodate a wide range of drug loads in highly dispersible particles. Our initial delivery platform emerged from development of iCALM (inhaled Cationic Airway Lining Modulators), a non-steroidal anti-inflammatory therapy. The high degree of aerosol efficiency and the density profile of our dry powder iCALM formulations provided the foundation for our development of iSPERSE in 2012, using other monovalent and divalent salts.

iSPERSE particles are engineered with a small, dense and dispersible profile to exceed the performance of traditional dry powder particles as the iSPERSE particles have the dispersibility advantages of porous engineered particles. We believe this results in superior drug delivery compared to traditional oral and injectable forms of treatment for certain respiratory diseases. Unlike lactose-blended carrier formulations or low-density particles which disperse poorly, we believe that the iSPERSE technology platform offers several potential benefits, achieved through the following technological innovations:

- *Flexible drug loading for delivery of a single microgram to tens of milligrams per dose.* iSPERSE particles can be engineered to include significantly less than one percent (1%) to greater than eighty percent (80%) active pharmaceutical ingredients (“APIs”), which allows flexibility for dosing low potency and high drug load therapeutics.
- *Reproducible and one-step manufacturing.* iSPERSE powders are manufactured by a simple and reproducible one-step spray drying process with high and consistent yields. Formulations can be created independent of API physical chemistry in either crystalline or amorphous excipient matrices, as opposed to conventional dry power technologies that require the API to be in crystalline form and suitable for micronization.
- *Superior flow rate independent lung delivery without carriers.* The iSPERSE technology enables pulmonary delivery independent of lactose or other carriers, which results in significantly greater lung dose at a matched nominal dose of conventional lactose-based formulations. iSPERSE formulations are dispersible across a range of flow rates with consistent emitted dose and particle size. Performance across flow rates provides reliable dose delivery across patient populations and reduces patient-to-patient variability.
- *Delivery of macromolecules and biologics.* iSPERSE powders can be used with an array of dry powder inhaler technologies and can be formulated with a broad range of therapeutic compounds ranging from small molecules to proteins for both local and systemic drug delivery applications.

- *Homogenous combinations of multiple drugs.* iSPERSE creates homogenous particles including excipients and API, which allow for the consistent delivery of multiple APIs in a product. We have successfully formulated iSPERSE-based products with dual and triple API combinations.
- *Strong safety profile.* Current iSPERSE products and planned clinical stage products to be formulated in iSPERSE are supported by robust preclinical safety profiles. iSPERSE excipients include those with inhalation precedent and those that are generally regarded as safe (“GRAS”) by other routes of administration.

## Therapeutic Candidates

### *Pulmazole*

We are developing iSPERSE-based inhaled formulations of anti-fungal drugs for the prevention and treatment of fungal infections and allergic/hypersensitivity reactions to fungus in patients with severe lung disease, including those with asthma and CF.

*Aspergillus* colonization and infections are likely underdiagnosed and occur frequently in patients of all ages. Colonization and infection with *Aspergillus* spp. can lead to clinical disease with differing severities and complications depending on the immune status of the host. Invasive aspergillosis is a frequently fatal disease that occurs in patients that are typically immune suppressed as a result of treatment for hematologic cancers or immunosuppression prior to solid organ transplantation. In asthma and CF patients, *Aspergillus* can cause chronic infections that may be associated with worsening disease and larger declines in lung function than patients without infection. A subset of asthma and CF patients with *Aspergillus* colonization and/or infection develop ABPA, which is a complex hypersensitivity reaction to fungal antigens. ABPA is a disease resulting in mucus production, wheezing, pulmonary infiltrates, worsening bronchiectasis and fibrosis of the lung. Worldwide, approximately 5 million asthmatics suffer from ABPA.

In both asthma and CF patients, ABPA is commonly treated with oral steroids to treat inflammation and with oral antifungals to reduce fungal infection. The inhalation administration of a drug affords direct delivery of the drug to the infected parts of the lung, maximizing the dose to the affected sites and minimizing systemic exposure to the rest of the body where it could cause significant side effects. Therefore, treatment of lung infections by direct administration of anti-infective products to the lung may improve both the safety and efficacy of treatment compared to systemic administration by other routes, as well as improving patient convenience as compared to oral and injectable forms of the treatment. We believe that local lung delivery by inhalation of our iSPERSE formulation could provide convenient, effective and safe management of the debilitating and often life-threatening lung infections that are not currently addressed by inhaled therapies.

Pulmazole is our inhaled formulation of itraconazole, an anti-fungal drug commercially available as an oral drug that we are developing to treat and prevent pulmonary fungal infections. Development of Pulmazole is focused on treatment of *Aspergillus* spp. colonization and infection in patients with asthma and CF. In a Ph1/1b clinical trial, Pulmazole appeared to be safe and well tolerated in healthy normal volunteers (Parts 1 and 2) and asthmatics (Part 3). In Part 3 of the Ph1/1b study, following a single dose of Pulmazole the PK analysis of sputum samples demonstrated ~70-fold higher maximum lung concentration of itraconazole following inhalation of Pulmazole compared to oral Sporanox<sup>®</sup> despite inhaling only one tenth the dose of itraconazole (20 mg) relative to the dose of oral Sporanox (200 mg). Total systemic exposure was approximately 66-fold lower following inhalation of 20 mg Pulmazole compared to 200 mg of oral Sporanox. All objectives from the phase 1/1b study were successfully met, and we are on track to initiate a Phase 2 study in asthmatic patients with ABPA in 2019.

### *Competition and Market Opportunities*

Current treatments of pulmonary fungal infections highlight the limitations of oral or intravenous anti-infective treatments for lung infections. Itraconazole is one of the most commonly prescribed therapies for treating



Aspergillus spp. infections in patients with asthma and CF. Itraconazole is available commercially as Sporanox (Janssen Pharmaceutica) in both a capsule and oral solution form. Itraconazole is metabolized in the liver by CYP3A4 and coadministration with a large number of drugs is contraindicated due to the potential for severe drug-drug interactions.

We believe Pulmazole will achieve higher local lung itraconazole concentrations and significantly lower systemic exposure relative to oral dosing, thus allowing for the potential to improve upon both the efficacy and safety profiles observed with oral itraconazole. Furthermore, administration by inhalation may significantly reduce the exposure of the drug in the rest of the body, which may be beneficial in reducing systemic side effects and the risk of potentially toxic drug-drug interactions.

There is precedent for inhaled anti-infective therapy, dry powder and nebulized, addressing specific pulmonary infections in patients which demonstrates potential utility of inhaled drug delivery utility and market opportunity. Mylan currently markets TOBI Podhaler for treatment of Pseudomonas aeruginosa infection in the United States, and Forest Laboratories U.K. Limited (a subsidiary of Actavis PLC) markets inhaled colistin, Colobreathe, for the same infection in Europe. Savara is developing AeroVanc, an inhaled dry powder version of vancomycin, intended for treatment of methicillin-resistant Staphylococcus aureus lung infection in patients with CF, which has begun Phase III clinical trials. Insmed recently obtained approval for Amikacin Liposome Inhalation Suspension (Arikayce) for the treatment of lung disease caused by a group of bacteria, Mycobacterium avium complex (MAC) in a limited population of patients with the disease who do not respond to conventional treatment (refractory disease). Arikayce is the first drug to be approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs, or LPAD pathway, established by Congress under the 21st Century Cures Act to advance development and approval of antibacterial and antifungal drugs to treat serious or life-threatening infections in a limited population of patients with unmet need. As required for drugs approved under the LPAD pathway, labeling for Arikayce includes certain statements to convey that the drug has been shown to be safe and effective only for use in a limited population. Arikayce also was approved under the Accelerated Approval pathway. Under this approach, the U.S. Food and Drug Administration (“FDA”) may approve drugs for serious or life-threatening diseases or conditions where the drug is shown to have an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. The approval of Arikayce was based on achieving three consecutive negative monthly sputum cultures by month six of treatment. Insmed was required by the FDA to conduct an additional, post-market study to describe the clinical benefits of Arikayce. Pulmocide Ltd has recently (late 2018) initiated a Phase 2 clinical trial to investigate PC945, a novel triazole antifungal, for the treatment of Culture-positive Aspergillus Fumigatus infection in subjects with moderate to severe asthma. There are currently no products specifically approved for treatment of ABPA.

New methods to detect Aspergillus spp. infection in sputum have improved the sensitivity of diagnosis and clinical appreciation for these infections. Pulmonary Aspergillus spp. infections affect approximately 14 million patients worldwide according to the Global Action Fund for Fungal Infections (Improving Outcomes for Patients with Fungal Infections across the World: A Road Map for the Next Decade). The majority of these cases occur in asthmatics with allergic disease but also include invasive Aspergillus spp. infections that are associated with a high rate of mortality in immunocompromised patients. We believe that Pulmazole has the potential to address up to 5 million patients when all indications are considered. In addition, we believe that Pulmazole compares favorably to the products discussed above and has the potential to generate significant value based on treating and preventing pulmonary fungal infections in multiple patient populations.

### *Clinical Development*

Pulmazole is our lead iSPERSE anti-infective development program. We completed a Phase 1/1b clinical study in 2018 and plan to initiate a Phase 2 study in 2019.

## ***PUR1800***

On June 9, 2017, we entered into an exclusive, worldwide license agreement (the “License Agreement”) with RespiVert Ltd. (“RespiVert”), a wholly owned subsidiary of Janssen Biotech, Inc. (“Janssen”), for access to a portfolio of novel drug candidates in a class called kinase inhibitors. The first of which, PUR1800 (previously RV1162), we intend to develop for the treatment of acute exacerbations in patients with COPD (AECOPD). COPD is a progressive respiratory illness marked by inflammation and destruction of airways and lungs, typically brought about by longstanding smoking. Persons affected by COPD have prominent symptoms of cough, phlegm, shortness of breath and exercise limitation. AECOPDs can result from environmental, viral, or bacterial catalysts causing the patient to experience an increase in coughing, sputum production, and dyspnea. COPD exacerbations (worsening of respiratory symptoms) are a major contributor to health care costs as well disease progression that can lead to serious consequences such as hospitalization and death. AECOPD accounts for up to 62.5% of all hospital admissions related to COPD<sup>1</sup>

There are currently no therapies approved in the U.S. or the European Union (“EU”) to specifically treat AECOPD. COPD patients are commonly treated with corticosteroids to control inflammation, however AECOPDs still occur frequently. Direct delivery of PUR1800 to the lungs has the potential to control inflammation associated with AECOPD and improve the quality of life of COPD patients through improved lung function, less frequent hospitalization and lower re-hospitalization rates.

### *Clinical Development*

Studies conducted by RespiVert/Janssen for the small molecule formulated in PUR1800 (previously RV1162) demonstrated that the molecule has been well tolerated for up to 14 days of dosing in patients with COPD. Analysis of sputum collected from COPD patients treated with RV1162 showed reduced levels of p38 phosphorylation in sputum cells and decreases in the number of neutrophils recovered in sputum after 12 days of dosing suggesting the onset of anti-inflammatory benefit after a short dosing regimen.

We completed preclinical safety studies in 2018 and plan to bridge the Phase 1/1b clinical study conducted by Janssen (Janssen Study EST001, ClinicalTrials.gov NCT01970618) with our own Phase 2a study of an iSPERSE formulation, PUR1800, in stable moderate-severe COPD patients.

## ***PUR0200***

PUR0200 is a once-daily reformulation of an existing long-acting antimuscarinic agent (“LAMA”) which blocks the effects of acetylcholine on muscarinic receptors to reverse airway obstruction in COPD patients and is delivered by inhalation using the iSPERSE dry powder delivery platform.

PUR0200 is manufactured without lactose blending using the iSPERSE dry powder delivery platform. We expect that PUR0200 will deliver comparable pharmacokinetic and pharmacodynamic profiles to the reference product at significantly lower exposure doses to patients. Other potential advantages of PUR0200 include improved patient use profile and reduced cost of goods due to reduced nominal dose of the API and the availability of the abbreviated regulatory pathway (“bioequivalence”) in Europe and the 505(b)(2) regulatory pathway in the United States.

### *Clinical Development*

In December 2013, we completed a two-part Phase 1b placebo-controlled, randomized clinical trial in the United Kingdom involving moderate to severe COPD patients to assess the safety and tolerability of PUR0200 along with the pharmacodynamics and pharmacokinetics in a single dose, dose escalation trial.

<sup>1</sup> Wier et al (2011) AHRW, HCUP, Statistical Brief #106pp1-11

The goal of Part 1 was to evaluate safety and tolerability of PUR0200. Part 2 of the study tested the pharmacokinetics and pharmacodynamics of PUR0200 after single doses compared to the reference product. Part 2 of the study was a randomized, placebo-controlled 5 period cross-over study in which 38 subjects were randomized to receive a placebo, 3 dose levels of PUR0200 or a lactose-blend reference product. Data from the Phase 1b clinical study demonstrated significant bronchodilator activity at all PUR0200 doses with peak and trough increase in Forced Expiratory Volume in 1 second (FEV<sub>1</sub>, a measure of lung function) comparable to the reference product. Plasma pharmacokinetics endpoints from the Phase 1b clinical study correlated plasma drug concentrations with the pharmacodynamic effect and identified PUR0200 doses that could be similar to the reference product and targets for bioequivalent development.

A second clinical trial was completed in Europe in 2016 to further study the pharmacokinetic profile of PUR0200 compared to the reference product. In this study, 42 subjects were randomized to receive a single dose of one of five PUR0200 formulations or the reference product in a 7-period crossover design to assess the safety, tolerability and pharmacokinetics of PUR0200 and the reference product. The study aimed at defining the relationship of PUR0200 formulation characteristics to the pharmacokinetic profile of the drug to establish formulation parameters for further development towards formal bioequivalence based on peak plasma concentrations (C<sub>max</sub>) and plasma concentrations over time (Area under the curve; AUC). There were no serious adverse events and the safety profile of PUR0200 was comparable to that of the reference product. Of the 42 enrolled subjects, 41 completed all dosing periods.

PUR0200 kinetics were similar across all doses and formulations tested, with dose proportional increases in exposure for similarly sized formulations. Plasma pharmacokinetic measures were similar between selected PUR0200 formulations and the reference product. Comparisons of the pharmacokinetic profile between PUR0200 and the reference product were used to define the appropriate lung dose (C<sub>max</sub>) of PUR0200 required to match the reference product and to define the required formulation parameters to match the total drug exposure (AUC). Based on the PK profile, two PUR0200 formulations have been identified as bioequivalent drug product candidates.

On September 5, 2017, we entered into a Feasibility and Development Agreement to develop PUR0200 for COPD for the U.S. market with Vectura Limited (“Vectura”). On December 21, 2018, Vectura and Pulmatrix mutually agreed to terminate the Agreement and cease further joint development of PUR0200.

#### *Competition and Market Opportunities*

According to the World Health Organization (“WHO”), over one billion people suffer from chronic respiratory diseases. Among the most common of these afflictions is COPD, which is a progressive respiratory disease for which there is no cure. COPD is a lung disease characterized by a persistent reduction in airflow. COPD damages the airways and the lungs and leads to shortness of breath, impacting a person’s ability to perform daily activities. COPD is the third leading cause of death globally, with 384 million people worldwide suffering from the disease.<sup>2</sup> The WHO estimated that 3.17 million deaths in 2015 were caused by COPD.

There are many products currently marketed and many products that are in development to treat COPD patients. As of December 31, 2018, Pulmatrix owns the rights to PUR0200 across all geographies.

#### **PUR5700**

We received access to PUR5700, a second novel drug candidate through the License Agreement with RespiVert. The preclinical studies undertaken by RespiVert for PUR5700 demonstrated activity relevant to IPF, COPD, and asthma. Robust pre-clinical datasets demonstrated anti-inflammatory effects in steroid resistant inflammation models and pathogen induced inflammation models. A 28-day GLP (“good laboratory practice”) nonclinical safety program was completed in rats and dogs with established safety margins to support clinical dosing.

<sup>2</sup> Adeloye D, et al. Global and regional estimates of COPD prevalence: Systematic review and meta-analysis, Journal of Global Health. 2015 Dec; 5(2)

IPF is a progressive and generally fatal disease characterized by scarring of the lungs over time that thickens the tissue lining of the lungs, causing an irreversible loss of the tissue's ability to expand to transport oxygen. The cause of IPF is currently unknown.

### *Competition and Market Opportunities*

From 1990 — 2011, estimates of the IPF prevalence ranged from 14.0 to 27.9 cases per 100,000 population in the US (Fernández-Pérez et al., 2010; Raghu et al., 2006b; Thomeer et al., 2001; von Plessen et al., 2003) and about 30,000 new cases are being diagnosed annually according to the Fibrosis Insight Briefing by Defined Health in 2012. Two approved drugs, Ofev (nintedanib) and Esbriet (pirfenidone) offer the first therapeutic options for IPF patients in the United States. Both Ofev and Esbriet are oral therapies and commonly cause gastrointestinal side effects that could be severe depending on the patient. In addition, both approved drugs slow the progression of IPF but have not been proven to cure the disease. To the best of our knowledge, other pharmaceutical companies such as Bristol-Myers Squibb, Novartis and Biogen Idec are developing oral and injectable therapies for IPF that are in Phase 2 clinical trials. We believe that our development of an inhaled IPF therapy could offer patients with a new therapeutic treatment class with improved efficacy or reduced side effect profiles. As such, we anticipate that an iSPERSE-based inhaled therapy for IPF could compete with Ofev and Esbriet and other therapies being developed for the same or similar indications.

## **Intellectual Property**

### *Patents and Patent Applications*

We protect our intellectual property by filing and advancing patent applications and maintaining granted patents on our iSPERSE platform technology and in-licensed kinase inhibitors, which includes claims to compositions of matter and methods of use for our Pulmazole, PUR1800, PUR5700 and PUR0200 programs, as well as process, manufacturing, devices and packaging relevant to our iSPERSE platform and product candidates.

The status of our patent portfolio changes frequently in the ordinary course of patent prosecution. As of December 31, 2018, our patent portfolio related to iSPERSE included approximately 92 granted and allowed patents, 12 of which are granted or allowed US patents, with expiration dates from 2024 to 2034, and approximately 75 additional pending patent applications in the US and other jurisdictions. Our in-licensed portfolio related to kinase inhibitors included approximately 225 granted and allowed patents, 26 of which are granted or allowed US patents, with expiration dates from 2029 to 2035, and approximately 52 additional pending patent applications in the US and other jurisdictions.

There can be no assurance that the patent applications will be granted. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers a FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. We plan to seek patent term extensions to extend the patent coverage of any of our products that received regulatory approval in any jurisdiction where these extensions are available. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment on whether such extensions should be granted, and if granted, the length of such extensions.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

#### *Trade Secrets*

We also rely on trade secret protection of our confidential and proprietary information, including the iSPERSE technology. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, consultants and others, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with Pulmatrix. These confidentiality agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us must be kept confidential and not disclosed to third parties except in specific circumstances. Our confidentiality agreements with our employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

#### **Manufacturing**

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We have small-scale production capabilities and generally perform early process development for our product candidates to produce the quantities necessary to conduct preclinical studies of our investigational product candidates. We do not have, and do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical studies. We rely on contract manufacturing organizations ("CMOs") and third-party contractors to generate drug-loaded formulations and produce larger, pilot-scale amounts of drug substance and the drug product required for our clinical studies. We expect to continue to rely on CMOs to manufacture drug substances and drug products under the appropriate current Good Manufacturing Practices ("cGMP") conditions to perform clinical studies for the foreseeable future. We also contract with CMOs for the labeling, packaging, storage and distribution of investigational drug products. These arrangements allow us to maintain a more flexible infrastructure while focusing its expertise on researching and developing our products.

We expect to continue to rely on contract manufacturers to produce sufficient quantities of our product candidates in accordance with the appropriate cGMPs for the pertinent phase of clinical trials. cGMP compliance includes strict adherence to regulations for quality control, quality assurance, and the maintenance of records and documentation. The manufacturing facilities that manufacture our approved drug products, if any are approved in the future, must comply with the FDA's cGMP regulation requirements and have acquired FDA or other regulatory approval for the manufacturing of our commercial products. Our contract manufacturers may also be subject to inspections of facilities by regulatory authorities to ensure compliance with applicable regulations. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. We have little or no direct control over our manufacturers' compliance with these regulations and standards. Failure to comply with applicable regulatory requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. These actions could have a material impact on the availability of products.

## Suppliers

We also rely on third-party contract manufacturers to supply the APIs that are used to formulate our therapeutic candidates. We place purchase orders with one contract manufacturer for the APIs required for Pulmazole and PUR1800, but there are many other potential contract manufacturers that may be capable of manufacturing APIs for Pulmazole and PUR1800 or any of our other APIs in the market. We additionally rely on third-party vendors to supply raw materials for our APIs and drug products.

## Research and Development

For fiscal years ended December 31, 2018 and 2017, we spent approximately \$13.0 million and \$10.2 million, respectively on research and development activities.

## Government Regulation

Pharmaceutical companies are subject to extensive regulation by national, state and local agencies, such as the FDA, in the United States and the European Medicines Agency in Europe. The manufacture, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the United States and various foreign countries. Additionally, in the United States, we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our products are safe and efficacious and are manufactured in accordance with cGMP regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market its products, and we may be criminally prosecuted. We and our manufacturers and clinical research organizations may also be subject to regulations under other federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. Pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act, and the U.S. government has increased its enforcement activity regarding illegal marketing practices domestically and internationally.

These regulatory requirements impact our operations and differ from one country to another, such that securing the applicable regulatory approvals of one country does not imply the approval of another country. However, securing the approval of a more stringent body, e.g. the FDA, may facilitate receiving the approval by a regulatory authority in a different country where the regulatory requirements are similar or less stringent. The approval procedures involve high costs and are manpower intensive and usually extend over many years and require highly skilled and professional resources.

### *FDA Approval Process*

The steps required to be taken before a new drug may be marketed in the United States generally include:

- Completion of pre-clinical laboratory and animal testing;
- The submission to the FDA of an investigational new drug (“IND”), application, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- Performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- Submission and approval of a new drug application (“NDA”).

Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

In all the countries that are signatories of the Helsinki Declaration, the prerequisite for conducting clinical trials (on human subjects) is securing the preliminary approval of the competent authorities of that country to conduct medical experiments on human subjects in compliance with the other principles established by the Helsinki Declaration.

The clinical testing of a product candidate (also commonly referenced as a “drug product candidate” or a “therapeutic product candidate”) generally is conducted in three sequential phases prior to approval, but the phases may overlap or be combined. A fourth, or post approval, phase may include additional clinical studies. The phases are generally as follows:

*Phase 1.* In Phase 1 clinical studies, the product is tested in a small number of patients with the target condition or disease or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the product candidate in humans, side effects associated with increasing doses, and, in some cases, to gain early evidence on efficacy. The number of participants included in Phase 1 studies is generally in the range of 20 to 80.

*Phase 2.* In Phase 2 studies, in addition to safety, the sponsor evaluates the efficacy of the product candidate on targeted indications to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks. Phase 2 studies typically are larger than Phase 1 but smaller than Phase 3 studies and may involve several hundred participants.

*Phase 3.* Phase 3 studies typically involve an expanded patient population at geographically-dispersed test sites. They are performed after preliminary evidence suggesting effectiveness of the product candidate has been obtained and are designed to further evaluate clinical efficacy and safety, to establish the overall benefit-risk relationship of the product candidate and to provide an adequate basis for a potential product approval. Phase 3 studies usually involve several hundred to several thousand participants.

*Phase 4.* Phase 4 clinical trials are post marketing studies designed to collect additional safety data as well as potentially expand a product indication. Post marketing commitments are required of, or agreed to by, a sponsor after the FDA has approved a product for marketing. These studies are used to gain additional information from the treatment of patients in the intended therapeutic indication and to verify a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement. These clinical trials are often referred to as Phase 4 post-approval or post marketing commitments. Failure to promptly conduct Phase 4 clinical trials could result in the inability to deliver the product into interstate commerce, misbranding charges, and civil monetary penalties.

Clinical trials must be conducted in accordance with the FDA’s good clinical practices (“GCP”), requirements. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board (“IRB”), generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

As a product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA would generally

increases as clinical studies progress. We and the third-party manufacturers on which we rely for the manufacture of our product candidates and their respective components (including the API) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements.

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of a NDA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. A NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, control and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

If a NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act (“PDUFA”), the FDA’s goal is to complete its initial review and respond to the applicant within twelve months of submission, unless the application relates to an unmet medical need in a serious or life-threatening indication, in which case the goal may be within eight months of NDA submission. However, PDUFA goal dates are not legal mandates and FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of a NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and inspects manufacturing facilities where the drug product and/or its API will be produced, it will either approve commercial marketing of the drug product with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the complete response letter requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies (“REMS”), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include Phase 4 clinical studies and surveillance to further assess and monitor the product’s safety and efficacy after approval. Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug.

If the FDA approves one of our therapeutic candidates, we will be required to comply with a number of post-approval regulatory requirements. We will also be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain



manufacturing changes, we will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or its API, the FDA may require stability or other data from the new manufacturer, which will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in its ability to meet commercial demand, if any. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

We rely, and expect to continue to rely, on third parties for the manufacture of clinical and future commercial quantities of its therapeutic candidates. Future FDA and state inspections may identify compliance issues at these third-party facilities that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Many of the foregoing could limit the commercial value of an approved product or require us to commit substantial additional resources in connection with the approval of a product. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of its products under development.

#### *Section 505(b)(2) New Drug Applications*

As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the Food, Drug, and Cosmetic Act ("FDCA"), was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of a NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the NDA. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference product has expired. Thus, the Section 505(b)(2) applicant may invest

a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized.

### *Orphan Drug Designation*

The Orphan Drug Act of 1983 (the “Orphan Drug Act”), encourages manufacturers to seek approval of products intended to treat “rare diseases and conditions” with a prevalence of fewer than 200,000 patients in the United States or for which there is no reasonable expectation of recovering the development costs for the product. For products that receive Orphan Drug designation by the FDA, the Orphan Drug Act provides tax credits for clinical research, FDA assistance with protocol design, eligibility for FDA grants to fund clinical studies, waiver of the FDA application fee, and a period of seven years of marketing exclusivity for the product following FDA marketing approval. In limited circumstances, the FDA may approve a competing product if the product shows clinical superiority over a product with orphan drug designation exclusivity.

### *Foreign Regulation*

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of its products. Whether or not Pulmatrix obtains FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. Abridged applications for the authorization of generic versions of drugs authorized by European Medicines Agency can be submitted to the European Medicines Agency through a centralized procedure referencing the innovator’s data and demonstrating bioequivalence to the reference product, among other things. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

### **Reimbursement**

In the United States and other countries, sales of any products for which Pulmatrix receives regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers, including government payers, managed care providers, private health insurers and other organizations. Each third-party payer may have its own policy regarding what products it will cover, the conditions under which it will cover such products, and how much it will pay for such products. Third-party payers are increasingly examining the medical necessity and cost effectiveness of medical products and services in addition to safety and efficacy and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Third-party reimbursement adequate to enable us to realize an appropriate return on our investment in research and product development may not be available for our products.

The passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the “MMA”) sets forth requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, which may

affect the marketing of our products. The MMA also introduced a new reimbursement methodology. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

### **Compliance with Environmental Laws**

Compliance with applicable environmental requirements during the years ended December 31, 2018 and 2017 and subsequently has not had a material effect upon our capital expenditures, earnings or competitive position.

### **Employees**

As of December 31, 2018, we had 22 full-time employees, 15 of whom were engaged in full-time research and development activities, and 1 part-time employee. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

### **Properties**

Our corporate headquarters are located in Lexington, Massachusetts. We currently lease approximately 21,810 square feet of office space in Lexington, Massachusetts under a lease that expires on December 31, 2020. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms for our future growth.

### **Available Information**

We make available, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports on our website at [www.pulmatrix.com](http://www.pulmatrix.com) as soon as reasonably practicable after those reports and other information is electronically filed with, or furnished to, the Securities and Exchange Commission.

## **ITEM 1A. RISK FACTORS.**

*The following risk factors, together with all of the other information included or incorporated in this Annual Report, should be carefully considered. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.*

### **Risks Related to Our Business**

***We have a history of net losses and may experience future losses.***

We have yet to establish any history of profitable operations. We reported a net loss of \$20.6 million for the fiscal year ended December 31, 2018 and had a net loss of approximately \$18.1 million during the fiscal year ended December 31, 2017. As of December 31, 2018, we had an accumulated deficit of \$194.6 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

***The report of our independent registered public accounting firm contains an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms, or at all.***

Because we have had recurring losses and negative cash flows from operating activities, substantial doubt exists regarding our ability to continue as a going concern over the next twelve months from February 19, 2019, the date of issuance of our Annual Report on Form 10-K at the same level at which we are currently performing. Accordingly, the report of Marcum LLP, our independent registered public accounting firm, with respect to our financial statements for the year ended December 31, 2018, includes an explanatory paragraph as to our potential inability to continue as a going concern over the next twelve months from February 19, 2019, the date of issuance of our Annual Report on Form 10-K. The doubts regarding our ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

***We will need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute our stockholders' ownership interests.***

Our current capital will only be sufficient to enable us to continue operations for a short period of time. In order to fully realize all of our business objectives, absent any non-dilutive funding from a strategic partner or some other strategic transactions, we will need to raise additional capital within three months from February 19, 2019, the date of filing of our Annual Report on Form 10-K, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

- advancing the research and development of Pulmazole and PUR1800;
- investing in protecting and expanding our intellectual property portfolio, including filing for additional patents to strengthen our intellectual property rights;
- hiring and retaining qualified management and key employees;
- responding to competitive pressures; and
- maintaining compliance with applicable laws.

Any additional capital raised through the sale of equity or equity backed securities will dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future financing transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

Furthermore, any additional capital financing that we may need in the future may not be available on terms favorable to us, or at all. If we are unable to obtain such additional financing on a timely basis, we may have to curtail our development activities and growth plans and/or be forced to sell assets, perhaps on unfavorable terms, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately could be forced to discontinue our operations and liquidate, in which event it is unlikely that stockholders would receive any distribution on their shares. Further, we may not be able to continue operating if we do not generate sufficient revenues from operations needed to stay in business.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition and cause further dilution to our stockholders.

***We are a clinical development stage biotechnology company and have never been profitable. We expect to incur additional losses in the future and may never be profitable.***

We are a clinical development stage biotechnology company. We have not commercialized any product candidates or recognized any revenues from product sales. All of our product candidates are still in the preclinical or clinical development stage, and none have been approved for marketing or are currently being marketed or commercialized. Our product candidates will require significant additional development, clinical studies, regulatory clearances and additional investments of time and capital before they can be commercialized. We cannot be certain when or if any of our product candidates will obtain the required regulatory approval.

We have never been profitable or generated positive cash flow from operations. We have incurred net losses each year since our inception. Our losses are principally a result of research and development and general administrative expenses in support of our operations. We may incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our product candidates. Our ability to generate revenue and achieve profitability depends mainly upon our ability, alone or with others, to successfully develop our product candidates, obtain the required regulatory approvals in various territories and commercialize our product candidates. We may be unable to achieve any or all of these goals with regard to our product candidates. As a result, we may never be profitable or achieve significant and/or sustained revenues.

***All of our product candidates are still under development, and there can be no assurance of successful commercialization of any of our products.***

All of our research and development programs are in developmental stages. One or more of our product candidates may fail to meet safety and efficacy standards in human testing, even if those product candidates are found to be effective in animal studies. To develop and commercialize inhaled therapeutic treatment for chronic obstructive pulmonary disease and cystic fibrosis and other iSPERSE-based product candidates, we must provide the FDA and foreign regulatory authorities with human clinical and non-clinical animal data that demonstrate adequate safety and effectiveness. To generate these data, we will have to subject our product candidates to significant additional research and development efforts, including extensive non-clinical studies and clinical testing. Our approach to drug discovery may not be effective or may not result in the development of any drug. Currently our development efforts are primarily focused on our lead anti-fungal product candidate, Pulmazole and PUR1800, our lead anti-inflammatory candidate for COPD. Even if Pulmazole, PUR1800 or our other product candidates are successful when tested in animals, such success would not be a guarantee of the safety or effectiveness of such product candidates in humans. It can take several years for a product to be approved and we may not be successful in bringing any therapeutic candidates to the market. A new drug may appear promising at an early stage of development or after clinical trials and never reach the market, or it may reach the market and not sell, for a variety of reasons. For example, the drug may:

- be shown to be ineffective or to cause harmful side effects during preclinical testing or clinical trials;
- fail to receive regulatory approval on a timely basis or at all;

- be difficult to manufacture on a large scale;
- not be economically viable;
- not be prescribed by doctors or accepted by patients;
- fail to receive a sufficient level of reimbursement from government, insurers or other third-party payors; or
- infringe on intellectual property rights of any other party.

If our delivery platform technologies or product development efforts fail to generate product candidates that lead to the successful development and commercialization of products, our business and financial condition will be materially adversely affected.

***Drug development is a long, expensive and inherently uncertain process with a high risk of failure at every stage of development, and results of earlier studies and trials may not be predictive of future trial results.***

We have a number of proprietary drug candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical trials are long, expensive and highly uncertain processes. It will take us several years to complete clinical trials and we may not have the resources to complete the development and commercialization of any of our proposed drug candidates. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a competitor drug or required prior therapy, clinical outcomes, or financial constraints of us and our partners.

Drug development is a highly uncertain scientific and medical endeavor, and failure can unexpectedly occur at any stage of preclinical and clinical development. Typically, there is a high rate of attrition for drug candidates in preclinical and clinical trials due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The risk of failure is heightened for our drug candidates that are based on new technologies, such as the application of our dry powder delivery platform, iSPERSE, including Pulmazole, PUR1800 and other iSPERSE-based drug candidates currently in discovery research or preclinical development. The failure of one or more of our iSPERSE-based drug candidates could have a material adverse effect on our business, financial condition and results of operations.

In addition, the results of preclinical studies and clinical trials of previously published iSPERSE-based products may not necessarily be indicative of the results of our future clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of inhaled drugs used historically in the industry and if those assumptions are incorrect, the trials may not produce statistically significant results. Preliminary results may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical trials. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if, or when, we may have an approved product for commercialization or whether we will ever achieve sales of or profits on our product candidates or those we may pursue in the future.

***We may not be able to attract, retain, or manage highly qualified personnel, which could adversely impact our business.***

Our future success and ability to compete in the biotechnology industry is substantially dependent on our ability to identify, attract, and retain highly qualified key managerial, scientific, medical, and operations personnel. The market for key employees in the pharmaceutical and biotechnology industries is competitive. The loss of the services of any of our principal members of management or key employees without an adequate replacement or our inability to hire new employees as needed could delay our product development efforts, harm our ability to sell our products or otherwise negatively impact our business.

The scientific, research and development personnel upon whom we rely to operate our business have expertise in certain aspects of drug development and clinical development, and it may be difficult to retain or replace these individuals. We conduct our operations at our facilities in Lexington, Massachusetts, within the greater Boston area, and this region is headquarters to many other biotechnology, pharmaceutical, and medical technology companies, as well as many academic and research institutions, and, therefore, we face increased competition for technical and managerial personnel in this region.

In addition, we have scientific, medical and clinical advisors who assist us in designing and formulating our products and with development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

Despite our efforts to retain valuable employees, members of our management and scientific and development teams may terminate their employment with us at any time. Although we have written employment offer letter agreements with our executive officers, these employment agreements provide for at-will employment, which means that our executive officers can leave their employment at any time, for any reason, with 30 days' notice. The loss of the services of any of our executive officers or our other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

***We face substantial competition in the development of our product candidates and may not be able to compete successfully, and our product candidates may be rendered obsolete by rapid technological change.***

The pharmaceutical and biotechnology industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing therapeutic candidates or for which we may develop product candidates in the future.

Many of our existing or potential competitors have, or have access to, substantially greater financial, research and development, production, and sales and marketing resources than we do and have a greater depth and number of experienced managers. As a result, our competitors may be better equipped than us to develop, manufacture, market and sell competing products. In addition, gaining favorable reimbursement is critical to the success of our product candidates. We are aware of many established pharmaceutical companies in the United States and other parts of the world that have or are developing technologies for inhaled drug delivery for the prevention and treatment of respiratory diseases, including GlaxoSmithKline, Mereo BioPharma, Mylan, Forest Laboratories U.K. Limited, Savara, Insmad, Bristol-Meyers and Pulmocide, which we consider our potential competitors in this regard. If we are unable to compete successfully with these and other potential future competitors, we may be unable to grow or generate revenue.

The rapid rate of scientific discoveries and technological changes could result in one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our iSPERSE delivery technology and other product candidates less competitive, uneconomical or obsolete. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our drug candidates. Our future success will depend not only on our ability to develop our product candidates but to improve them and keep pace with emerging industry developments. We cannot assure you that we will be able to do so.

We also expect to face increasing competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in the areas of respiratory diseases. These institutions are becoming increasingly aware of the commercial value of their findings and are more active in seeking patent and other proprietary rights as well as licensing revenues.

The potential acceptance of therapeutics that are alternatives to ours may limit market acceptance of our product candidates, even if commercialized. Respiratory diseases, including our targeted diseases and conditions, can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our product candidates to receive widespread acceptance if commercialized.

***If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for, or to commercialize, our products.***

We do not have the ability to independently conduct our pre-clinical and clinical trials for our products and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of our control.

***We rely on third party contract vendors to manufacture and supply us with high quality active pharmaceutical ingredients and manufacture our therapeutic candidates in the quantities we require on a timely basis.***

We currently do not manufacture any APIs. Instead, we rely on third-party vendors for the manufacture and supply of our APIs that are used to formulate our therapeutic candidates. We also do not currently own or operate manufacturing facilities and therefore rely, and expect to continue to rely, on third parties to manufacture clinical and commercial quantities of our therapeutic candidates and for quality assurance related to regulatory compliance. If these suppliers or manufacturers are incapable or unwilling to meet our current or future needs at our standards or on acceptable terms, if at all, we may be unable to locate alternative suppliers or manufacturers on acceptable terms, if at all, or produce necessary materials or components on our own.

While there may be several alternative suppliers of API in the market, changing API suppliers or finding and qualifying new API suppliers can be costly and can take a significant amount of time. Many APIs require significant lead time to manufacture. There can also be challenges in maintaining similar quality or technical standards from one manufacturing batch to the next. We place purchase orders with a single supplier to supply the API, and we could experience a delay in conducting clinical trials of or obtaining regulatory approval for Pulmazole, PUR1800 or our other drug candidates and incur additional costs if we changed from this supplier for any reason. Similarly, replacing our manufacturers could cause us to incur added costs and experience delays in identifying, engaging, qualifying and training any such replacements.

If we are not able to find stable, affordable, high quality, or reliable supplies of the APIs, or if we are unable to maintain our existing or future third party manufacturing arrangements, we may not be able to produce enough supply of our therapeutic candidates or commercialize any therapeutic candidates on a timely and competitive basis, which could adversely affect our business, financial condition or results of operations.

***We may not be successful in negotiating for an appropriate price in a future sale or assignment of our rights related to our current drug candidates.***

We may seek to sell or assign our rights related to our current drug candidates. If completed, any such sale or assignment may be at a substantial discount, the consideration received may not accurately represent the value of the assets sold or assigned and our stockholders may not be entitled to participate in the future prospects of such drug candidates.



***Our failure to successfully acquire, develop and market additional drug candidates or approved drug products could impair our ability to grow.***

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market additional product candidates and technologies. However, our internal research capabilities are limited, and we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

***Our business strategy may include entry into additional collaborative or license agreements. We may not be able to enter into collaborative or license agreements or may not be able to negotiate commercially acceptable terms for these agreements.***

Our current business strategy may include the entry into additional collaborative or license agreements for the development and commercialization of our product candidates and technologies. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators or licensees and require significant time and resources. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators or licensees, we compete with numerous other third parties with product opportunities as well as the collaborators' or licensees' own internal product opportunities. We may not be able to consummate collaborative or license agreements, or we may not be able to negotiate commercially acceptable terms for these agreements.

If we do enter into such arrangements, we could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to researching our product candidates pursuant to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

If we do not consummate collaborative or license agreements, we may use our financial resources more rapidly on our product development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business prospects. Further, we may not be successful in overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative or license relationships, our business prospects could suffer.

***We may be subject to claims that our employees, independent consultants or agencies have wrongfully used or inadvertently disclosed confidential information of third parties.***

We employ individuals and contract with independent consultants and agencies that may have previously worked at or conducted business with third parties; and, we may be subject to claims that we or our employees, consultants or agencies have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that our employees' former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

***Market and economic conditions may negatively impact our business, financial condition and share price.***

Concerns over inflation, low energy prices, geopolitical issues, the U.S. financial markets and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. In addition, there is a risk that one or more of our current and future service providers, manufacturers, suppliers, hospitals and other medical facilities, our third-party payors, and other partners could be negatively affected by difficult economic times, which could adversely affect our ability to attain our operating goals on schedule and on budget or meet our business and financial objectives.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.***

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls. This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock.

***Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.***

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards or other tax attributes, or NOLs, to offset future taxable income or reduce taxes. Our past issuances of stock and other changes in our stock ownership may have resulted in ownership changes within the meaning of Section 382 of the Code; accordingly, our pre-change NOLs may be subject to limitation under Section 382. If we determine that we have not undergone an ownership change, the Internal Revenue Service could challenge our analysis, and our ability to use our NOLs to offset taxable income could be limited by Section 382 of the Code. Future changes in our stock ownership, including in connection

with our initial public offering, some of which are outside of our control, could result in ownership changes under Section 382 of the Code further limiting our ability to utilize our NOLs. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability.

### **Risks Related to Regulatory Matters**

***Our product candidates must undergo rigorous nonclinical and clinical testing, and we must obtain regulatory approvals, which could be costly and time-consuming and subject us to unanticipated delays or prevent us from marketing any products. We cannot be certain that any of our current and future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.***

Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of our product candidates. We currently have no products approved for sale, and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation, including regulation for safety, efficacy and quality, by the FDA in the United States and comparable regulatory authorities in other countries, with regulations differing from country to country. The FDA regulations and the regulations of comparable foreign regulatory authorities are wide-ranging and govern, among other things:

- product design, development, manufacture and testing;
- product labeling;
- product storage and shipping;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We cannot predict whether our current or future trials and studies will adequately demonstrate the safety and efficacy of any of our product candidates or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date, including the clinical trials for Pulmazole. The clinical trials of our product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical trials may not be sufficient to support regulatory approval of our various product candidates. Even if we believe the data collected from our clinical trials are sufficient, the FDA has substantial discretion in the approval process and may disagree with our interpretation of the data.

We are not permitted to market our product candidates in the United States until we receive approval of a NDA from the FDA. Obtaining approval of a NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. We cannot be certain that any of our submissions will be accepted for filing and review by the FDA.

The requirements governing the conduct of clinical trials and manufacturing and marketing of our product candidates outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes include essentially all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries, or vice versa.

In addition, changes in regulatory policy in the United States or in foreign countries for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections.

If we are unable to obtain approval from the FDA or other regulatory agencies for our product candidates, or if, subsequent to approval, we are unable to successfully market and commercialize our product candidates, we will not be able to generate sufficient revenue to become profitable.

***We have limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain timely approvals from the FDA or foreign regulatory agencies, if at all.***

As a company, we have no experience in late-stage regulatory filings, such as preparing and submitting NDAs, which may place us at risk of delays, overspending and human resources inefficiencies. Any delay in obtaining, or inability to obtain, regulatory approval could harm our business.

***Any failure by us to comply with existing regulations could harm our reputation and operating results.***

We will be subject to extensive regulation by U.S. federal and state and foreign governments in each of the markets where we intend to sell our product candidates if and after we are approved. If we fail to comply with applicable regulations, including the FDA's pre- or post-approval cGMP requirements, then the FDA or other foreign regulatory authorities could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of the product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, our value and operating results will be adversely affected. Additionally, if we are unable to generate revenue from sales of our product candidates, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert management's attention from the operation of our business and damage our reputation. We expend significant resources on compliance efforts and such expenses are unpredictable and might adversely affect our results. Changing laws, regulations and standards might also create uncertainty, higher expenses and increase insurance costs.

***We and our third-party manufacturers are, and will be, subject to regulations of the FDA and other foreign regulatory authorities.***

We and our contract manufacturers are, and will be, required to adhere to laws, regulations and guidelines of the FDA or other foreign regulatory authorities setting forth current good manufacturing practices. These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates. We and our third-party manufacturers may not be able to comply with applicable laws, regulations and guidelines. We and our contract manufacturers are and will be subject to unannounced inspections by the FDA, state regulators and similar foreign regulatory authorities outside the United States. Our failure, or the failure of our third party manufacturers, to comply with applicable laws, regulations and guidelines could result in the imposition of sanctions on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates, and materially and adversely affect our business, financial condition and results of operations.

***Even if we obtain regulatory approvals, our therapeutic candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign laws, regulations and guidelines, we could lose those approvals, and our business would be seriously harmed.***

Even if our therapeutic candidates receive regulatory approval, we or our commercialization partners, as applicable, will be subject to ongoing reporting obligations, including pharmacovigilance, and the therapeutic candidates and the manufacturing operations will be subject to continuing regulatory review, including inspections by the FDA or other foreign regulatory authorities. The results of this ongoing review may result in the withdrawal of a therapeutic candidate from the market, the interruption of the manufacturing operations and/or the imposition of labeling and/or marketing limitations. Since many more patients are exposed to drugs following their marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the therapeutic candidate. In addition, the manufacturer and the manufacturing facilities that we or our commercialization partners use to produce any therapeutic candidate will be subject to periodic review and inspection by the FDA and other foreign regulatory authorities. Later discovery of previously unknown problems with any therapeutic candidate, manufacturer or manufacturing process, or failure to comply with rules and regulatory requirements, may result in actions, including but not limited to the following:

- restrictions on such therapeutic candidate, manufacturer or manufacturing process;
- warning letters from the FDA or other foreign regulatory authorities;
- withdrawal of the therapeutic candidate from the market;
- suspension or withdrawal of regulatory approvals;
- refusal to approve pending applications or supplements to approved applications submitted by us or our commercial partners;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our therapeutic candidates;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; or
- adverse publicity.

If we or our commercialization partners, suppliers, third party contractors or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we or our commercialization partners may lose marketing approval for any of our therapeutic candidates if any of our therapeutic candidates are approved, resulting in decreased or lost revenue from milestones, product sales or royalties.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with any regulations applicable to us, to provide accurate information to regulatory authorities, to comply with manufacturing standards we may have established, to comply with federal and state healthcare fraud and abuse laws and regulations, or to report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risk.

***If we fail to comply with federal or state “fraud and abuse” laws, the failure to comply with these laws may adversely affect our business, financial condition and results of operations.***

In the United States, we will be subject to various federal and state health care “fraud and abuse” laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse the healthcare industry, which could affect us, particularly upon successful commercialization of our products in the United States. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on our behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration in exchange for or to induce the referral of an individual for, or the purchase, order or recommendation of, any good or service, including the purchase, order or prescription of a particular drug for which payment may be made under a federal health care program, such as Medicare or Medicaid. Under federal government regulations, some arrangements, known as safe harbors, are deemed not to violate the federal Anti-Kickback Statute. However, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental health care programs. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines, penalties and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for, or purchase, order or recommendation of, goods or services reimbursed by any source, not just governmental payers. The scope and enforcement of these laws are uncertain and subject to change in the current environment of healthcare reform. We cannot predict the impact on our business, financial condition nor results of operations of any changes in these laws. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Law enforcement authorities are increasingly focused on enforcing these laws, and if we are challenged under one of these laws, we could be required to pay a fine and/or penalty and could be suspended or excluded from participation in federal or state health care programs, and our business, results of operations and financial condition may be adversely affected.

### **Risks Related to Our Financial Position and Need for Additional Capital**

*We will be required to raise additional capital to fund our operations, and we may not be able to continue as a going concern if we are unable to do so.*

Pharmaceutical product development, which includes research and development, pre-clinical and clinical studies and human clinical trials, is a time-consuming and expensive process that takes years to complete. We anticipate that our expenses will increase substantially as we advance Pulmazole into the Phase II trial and pursue development of PUR1800 or other iSPERSE-based product candidates and/or pursue development of iSPERSE-based pharmaceuticals in additional indications. Based upon our current expectations, we believe that our existing capital resources will enable us to continue planned operations into the second quarter of 2019. We cannot assure you, however, that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. We will need to raise additional funds, whether through the sale of equity or debt securities, the entry into strategic business collaborations, the establishment of other funding facilities, licensing arrangements, or asset sales or other means, in order to continue our research and development and clinical trial programs for our iSPERSE-based product candidates and to support our other ongoing activities. However, it may be difficult for us to raise additional funds through these planned measures if we are able to at all. Since inception, we have incurred losses each year and have an accumulated deficit of \$194.6 million, which may raise concerns about our solvency and affect our ability to raise additional capital.

The amount of additional funds we need will depend on a number of factors, including:

- rate of progress and costs of our clinical trials and research and development activities, including costs of procuring clinical materials and operating our manufacturing facilities;
- our success in establishing strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions we are able to establish;
- actions taken by the FDA and other regulatory authorities affecting our products and competitive products;
- our degree of success in commercializing any of our product candidates;
- the emergence of competing technologies and products and other adverse market developments;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- the level of our legal expenses; and
- the costs of discontinuing projects and technologies.

We have raised capital in the past primarily through debt and private placements of stock. We may in the future pursue the sale of additional equity and/or debt securities, or the establishment of other funding facilities including asset-based borrowings. There can be no assurances, however, that we will be able to raise additional

capital through such an offering on acceptable terms, or at all. Issuances of additional debt or equity securities could impact the rights of the holders of Company Common Stock and may dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, including Pulmazole or PUR1800 development activities, or reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be continued doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. If we are or become insolvent, investors in our stock may lose the entire value of their investment.

***Our long-term capital requirements are subject to numerous risks.***

Our long-term capital requirements are expected to depend on many potential factors, including, among others:

- the number of product candidates in development;
- the regulatory clarity and path of each of our product candidates;
- the progress, success and cost of our clinical trials and research and development programs, including manufacturing;
- the costs, timing and outcome of regulatory review and obtaining regulatory clarity and approval of our product candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of manufacturing, developing sales, marketing and distribution channels;
- our ability to successfully commercialize our product candidates, including securing commercialization agreements with third parties and favorable pricing and market share; and
- our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

**Risks Related to Our Intellectual Property**

***We may be unable to adequately protect or enforce our rights to intellectual property, causing us to lose valuable rights. Loss of patent rights may lead us to lose market share and anticipated profits.***

Our success, competitive position and future revenues depend, in part, on our ability to obtain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. Despite our efforts to protect our proprietary technologies and processes, it is possible that competitors or other unauthorized third parties may obtain, copy, use or disclose proprietary technologies and processes.

We try to protect our proprietary position by, among other things, filing U.S., European and other patent applications related to our product candidates, methods, processes and other technologies, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.



Because the patent position of pharmaceutical companies involves complex legal and factual questions, we cannot predict the validity and enforceability of patents with certainty. Our issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Our competitors may also independently develop inhaled drug delivery technologies or products similar to iSPERSE and iSPERSE-based product candidates or design around or otherwise circumvent patents issued to us. Thus, any patents that we own may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. Even if these patents are issued, they may not provide us with proprietary protection or competitive advantages. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Patent rights are territorial, and accordingly, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and the European Union. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

After the completion of prosecution and granting of our patents, third parties may still manufacture and/or market therapeutic candidates in infringement of our patent protected rights. Such manufacture and/or market of our product candidates in infringement of our patent protected rights is likely to cause us damage and lead to a reduction in the prices of our product candidates, thereby reducing our anticipated profits.

In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our therapeutic candidates, any patents that protect our product candidate may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of generic products into the market and a subsequent decline in market share and profits.

In addition, in some cases we may rely on our licensors to conduct patent prosecution, patent maintenance or patent defense on our behalf. Therefore, our ability to ensure that these patents are properly prosecuted, maintained, or defended may be limited, which may adversely affect our rights in our therapeutic products. Any failure by our licensors or development partners to properly conduct patent prosecution, patent maintenance or patent defense could harm our ability to obtain approval or to commercialize our products, thereby reducing our anticipated profits.

***If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.***

In addition to filing patents, we generally try to protect our trade secrets, know-how and technology by entering into confidentiality or non-disclosure agreements with parties that have access to us, such as our development and/or commercialization partners, employees, contractors and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while employed or engaged by us. However, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our

products, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable and a court may determine that the right belongs to a third party.

***Legal proceedings or third-party claims of intellectual property infringement and other challenges may require us to spend substantial time and money and could prevent us from developing or commercializing our product candidates.***

The development, manufacture, use, offer for sale, sale or importation of our product candidates may infringe on the claims of third-party patents or other intellectual property rights. The nature of claims contained in unpublished patent filings around the world is unknown to us, and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty or other mechanisms. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our therapeutic candidates in the event of an infringement action.

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a product candidate or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly.

***We may be subject to other patent-related litigation or proceedings that could be costly to defend and uncertain in their outcome.***

In addition to infringement claims against us, we may in the future become a party to other patent litigation or proceedings before regulatory agencies, including interference, re-examination Inter Partes review, or post grant review proceedings filed with the U.S. Patent and Trademark Office or opposition proceedings in other foreign patent offices regarding intellectual property rights with respect to our therapeutic candidates, as well as other disputes regarding intellectual property rights with development and/or commercialization partners, or others with whom we have contractual or other business relationships. Post-issuance oppositions are not uncommon and we or our development and/or commercialization partners will be required to defend these opposition procedures as a matter of course. Opposition procedures may be costly, and there is a risk that we may not prevail, which could harm our business significantly.

### **Risks Related to Company Common Stock**

***The price of Company Common Stock is subject to fluctuation and has been and may continue to be volatile.***

The stock market in general, and Nasdaq in particular, as well as biotechnology companies, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of small companies. The market price of Company Common Stock may fluctuate as a result of, among other factors:

- the announcement of new products, new developments, services or technological innovations by us or our competitors;

- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;
- announcements relating to strategic relationships, mergers, acquisitions, partnerships, collaborations, joint ventures, capital commitments, or other events by us or our competitors;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the economic performance or market valuations of other biotechnology and pharmaceutical companies;
- general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance or financial condition;
- purchase or sale of Company Common Stock by stockholders, including executives and directors;
- volatility and limitations in trading volumes of Company Common Stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our human clinical trials, and other business activities;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned pre-clinical and clinical trials;
- ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of Company Common Stock by stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- analyst research reports, recommendations and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigation related to intellectual property rights, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of Company Common Stock could fluctuate or decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

***Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management may be required to devote substantial time to compliance matters.***

As a publicly traded company, we incur significant additional legal, accounting and other expenses. The obligations of being a public reporting company require significant expenditures, including costs resulting from

public company reporting obligations under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and corporate governance practices, among many other complex rules that are often difficult and time consuming to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an “emerging growth company.” In addition, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. Compliance with such requirements also places demands on management’s time and attention.

***In the foreseeable future, we do not intend to pay cash dividends on shares of Company Common Stock so any investor gains will be limited to the value of our shares.***

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any gains to stockholders will therefore be limited to the increase, if any, in our share price.

***We are an “emerging growth company” and our election to delay adoption of new or revised accounting standards applicable to public companies may result in our financial statements not being comparable to those of other public companies. As a result of this and other reduced disclosure requirements applicable to emerging growth companies, our securities may be less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the “Securities Act”), for complying with new or revised accounting standards.

In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to delay such adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. As a result of such election, our financial statements may not be comparable to the financial statements of other public companies. We cannot predict whether investors will find our securities less attractive because it will rely on these exemptions. If some investors find the Company Common Stock less attractive as a result, there may be a less active trading market for the Company Common Stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We could remain an “emerging growth company” until the earliest to occur of earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) March 31, 2019; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

***We may be at risk of securities class action litigation.***

We may be at risk of securities class action litigation. This risk is especially relevant due to our dependence on positive clinical trial outcomes and regulatory approvals. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events

such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and result in a decline in the market price of Company Common Stock.

***In the event that we fail to satisfy any of the listing requirements of The NASDAQ Capital Market, the Company Common Stock may be delisted, which could affect our market price and liquidity.***

The Company Common Stock is listed on The NASDAQ Capital Market. For continued listing on The NASDAQ Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. In the event that we fail to satisfy any of the listing requirements of The NASDAQ Capital Market, the Company Common Stock may be delisted. If our securities are delisted from trading on The NASDAQ Stock Market, and we are not able to list our securities on another exchange or to have them quoted on The NASDAQ Stock Market, our securities could be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that Company Common Stock is a "penny stock," which would require brokers trading in Company Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

***We may issue additional equity securities in the future, which may result in dilution to existing investors.***

We may seek the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaborative and licensing arrangements. To the extent we raise additional capital by issuing equity securities, including in a debt financing where we issue convertible notes or notes with warrants and any shares of Company Common Stock to be issued in a private placement, our stockholders may experience substantial dilution. We may, from time to time, sell additional equity securities in one or more transactions at prices and in a manner we determine. If we sell additional equity securities, existing stockholders may be materially diluted. In addition, new investors could gain rights superior to existing stockholders, such as liquidation and other preferences. In addition, the exercise or conversion of outstanding options or warrants to purchase shares of capital stock may result in dilution to our stockholders upon any such exercise or conversion.

In addition, as of February 14, 2019, 521,137 shares remained available to be awarded under our 2013 Employee, Director and Consultant Equity Incentive Plan (the "2013 Plan"). Further, an aggregate of 970,291 shares of Company Common Stock could be delivered upon the exercise or conversion of outstanding stock options or restricted stock units under the Incentive Plan and other equity incentive plans we previously assumed. We may also issue additional options, warrants and other types of equity in the future as part of stock-based compensation, capital raising transactions, technology licenses, financings, strategic licenses or other strategic transactions. To the extent these options are exercised, existing stockholders would experience additional ownership dilution. In addition, the number of shares available for future grant under our equity compensation plans may be increased in the future, as our equity compensation plan contains an "evergreen" provision, pursuant to which additional shares may be authorized for issuance under the plan each year.

***Anti-takeover provisions under Delaware corporate law may make it difficult for our stockholders to replace or remove our board of directors and could deter or delay third parties from acquiring us, which may be beneficial to our stockholders.***

We are subject to the anti-takeover provisions of Delaware law, including Section 203 of the General Corporation Law of Delaware (the "DGCL"). Under these provisions, if anyone becomes an "interested

stockholder,” we may not enter into a “business combination” with that person for three (3) years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 203 of the DGCL, “interested stockholder” means, generally, someone owning fifteen percent (15%) or more of our outstanding voting stock or an affiliate that owned fifteen percent (15%) or more of our outstanding voting stock during the past three (3) years, subject to certain exceptions as described in Section 203 of the DGCL.

***Protective provisions in our charter and bylaws could prevent a takeover which could harm our stockholders.***

Our certificate of incorporation and bylaws contain a number of provisions that could impede a takeover or prevent us from being acquired, including, but not limited to, a classified board of directors and limitations on the ability of our stockholders to remove a director from office without cause. Each of these charter and bylaw provisions give our board of directors the ability to render more difficult or costly the completion of a takeover transaction that our stockholders might view as being in their best interests.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

Our corporate headquarters are located at 99 Hayden Avenue, Suite 390, Lexington, Massachusetts. We currently lease approximately 21,810 square feet of office space in Lexington, Massachusetts under a lease that expires on December 31, 2020. Base rent expense for the year ended December 31, 2018 was approximately \$654,300. The lease agreement, as amended on October 27, 2015, provides for a base monthly rent, and we are also responsible for real estate taxes, maintenance and other operating expenses applicable to the leased premises. Our future minimum lease payments under the lease are as follows (dollars in thousands):

Year	<u>Amount</u>
2019 .....	676
2020 .....	<u>698</u>
Total .....	<u>\$1,374</u>

We believe our facility is well-maintained and is both suitable and adequate for our current needs.

**ITEM 3. LEGAL PROCEEDINGS.**

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not aware of any material legal proceedings to which we or our subsidiary is a party or to which any of our property is subject, nor are we aware of any such threatened or pending litigation or proceedings known to be contemplated by governmental authorities.

There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial stockholder of more than 5% of our common stock, or any associate of any of the foregoing, is an adverse party or has a material interest adverse to our interest.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

#### Market Information

Our common stock trades on the NASDAQ Capital Market under the symbol "PULM".

On February 14, 2019 the last reported sale price of our common stock on the NASDAQ Capital Market before filing of our Annual Report on Form 10-K was \$1.06 per share.

#### Stockholders

As of February 14, 2019, there were approximately 191 stockholders of record of our common stock.

#### Dividends

We have not paid dividends to our stockholders since inception and do not plan to pay cash dividends in the foreseeable future. Any future declaration of dividends will depend on our earnings, capital requirements, financial condition, prospects and any other factors that our board of directors deems relevant, as well as compliance with the requirements of state law. In general, as a Delaware corporation, we may pay dividends out of surplus capital or, if there is no surplus capital, out of net profits for the fiscal year in which a dividend is declared and/or the preceding fiscal year. We currently intend to retain earnings, if any, for reinvestment in our business.

#### Unregistered Sales of Securities

None.

#### Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2018.

### ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

*The information set forth below should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report. This discussion and analysis contains forward-looking statements based on our current expectations, assumptions, estimates and projections. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those indicated in these forward-looking statements as a result of certain factors, including those discussed in Item 1 of this Annual Report, entitled "Business," under "Forward-Looking Statements" and Item 1A of this Annual Report, entitled "Risk Factors." References in this discussion and analysis to "us," "we," "our," or our "Company" refer to Pulmatrix, Inc., a Delaware corporation.*

#### Overview

We are a clinical stage biopharmaceutical company developing innovative inhaled therapies to address serious pulmonary disease using its patented iSPERSE (inhaled Small Particles Easily Respirable and Emitted)

technology. We are developing iSPERSE-based therapeutic candidates targeted at the prevention and treatment of a range of respiratory diseases, including allergic bronchopulmonary aspergillosis (“ABPA”) in asthmatics and in patients with cystic fibrosis (“CF”), chronic obstructive pulmonary disease (“COPD”) and idiopathic pulmonary fibrosis (“IPF”). Our product candidates are based on iSPERSE, our proprietary dry powder delivery platform, which seeks to improve delivery of small molecule drugs, macromolecules and potentially other biologics to the lungs by maximizing local concentrations and reducing systemic side effects to improve patient outcomes.

Our goal is to develop breakthrough therapeutic products that are safe, convenient and more efficient than the existing therapeutic products for the treatment of respiratory diseases. In support of this goal, we are focusing on developing inhaled anti-fungal therapies to prevent and treat pulmonary infections and allergic/hypersensitivity responses to fungus in patients with asthma, CF and other rare/orphan indications. We intend to capitalize on our iSPERSE technology platform and our expertise in inhaled therapeutics to identify new product candidates for the prevention and treatment of respiratory diseases with significant unmet medical needs to build our product pipeline beyond our existing candidates. In order to advance our clinical trials for our therapeutic candidates for asthma, CF, COPD and IPF and leverage the iSPERSE platform to enable delivery of partnered compounds, we intend to form strategic alliances with third parties, including pharmaceutical, biotechnology companies or academic or private research institutes.

We do not have any products approved for sale and have not generated any revenue from product sales. We fund our operations through proceeds from issuances of common stock, collaborations with third parties and non-dilutive grants.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years based on our drug development plans. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities, as we:

- initiate and expand clinical trials for Pulmazole for ABPA, and other indications for immunocompromised at-risk patients;
- seek regulatory approval for our product candidates;
- hire personnel to support our product development, commercialization and administrative efforts; and
- advance the research and development related activities for inhaled therapeutic products in our pipeline.

We will not generate product sales unless and until we successfully complete clinical developments and obtain regulatory approvals for our product candidates. Additionally, we currently utilize third-party contract research organizations (“CROs”) to carry out our clinical development activities and third-party contract manufacturing organizations (“CMOs”) to carry out our clinical manufacturing activities; we do not yet have a commercial organization. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. Accordingly, we anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, potentially including collaborative commercial arrangements. Likewise, we intend to seek to limit our commercialization costs by partnering with other companies with complementary capabilities or larger infrastructure including sales and marketing.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.



## **Financial Overview**

The following information is reported in thousands.

To date, we have not generated any product sales. Our 2018 and 2017 revenue resulted from an award from Cystic Fibrosis Foundation Therapeutics (“CFFT”), the nonprofit drug discovery and development affiliate of the Cystic Fibrosis Foundation, to support the development of Pulmazole for the treatment of ABPA in patients with asthma and cystic fibrosis.

### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for the research and development of our preclinical and clinical candidates, and include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with CROs or CMOs, and consultants that conduct our clinical trials and preclinical activities;
- the cost of acquiring, developing and manufacturing clinical trial materials and lab supplies;
- facility, depreciation and other expenses, which include direct and allocated expenses for rent, maintenance of our facility, insurance and other supplies; and
- costs associated with preclinical activities and regulatory operations.

We expense research and development costs to operations as incurred. We recognize costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or information provided to us by our vendors.

Research and development activities are central to our business model. We utilize a combination of internal and external efforts to advance product development from early stage work to clinical trial manufacturing and clinical trial support. External efforts include work with consultants and substantial work at CROs and CMOs. We support an internal research and development team and facility for our pipeline programs. To move these programs forward along our development timelines, a large portion, approximately 67%, of our staff are research and development employees. In addition, we maintain a 12,000 square foot research and development facility which includes capital equipment for the manufacture and characterization of our iSPERSE powders for our pipeline programs. As we identify opportunities for iSPERSE in respiratory indications, we anticipate additional head count, capital, and development costs will be incurred to support these programs.

Because of the numerous risks and uncertainties associated with product development, however, we cannot determine with certainty the duration and completion costs of these or other current or future preclinical studies and clinical trials. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

### ***General and Administrative Expenses***

General and administrative expenses consist principally of salaries and related costs such as stock-based compensation for personnel and consultants in executive, finance, business development, corporate communications and human resource functions, facility costs not otherwise included in research and development expenses, patent filing fees and professional legal fees. Other general and administrative expenses include travel expenses, expenses related to being a publicly-traded company and professional fees for consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission requirements, director and officer liability insurance, investor relations costs and other costs associated with being a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in staffing and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

### ***Impairment of Goodwill***

Goodwill is not amortized but evaluated at December 31, 2018 and 2017 for impairment. As of December 31, 2018 and 2017, goodwill is impaired by \$69 and \$0, respectively.

### ***Interest Expense***

Interest expense primarily reflects the amortization of debt discounts and interest expense accrued in connection with a term loan that was outstanding during the period. We incurred interest expense associated with the \$7 million term loan, or Term loan, from Hercules Technology Growth Capital, Inc., or Hercules, until its maturity date of July 1, 2018. The loan was paid in its entirety and as of June 30, 2018, there was no further liability.

### ***Other Income/(Expense), Net***

Other income/(expense), net is comprised primarily of interest income on cash deposits.

### **Critical Accounting Policies**

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

### ***Revenue Recognition***

Our principal sources of revenue during the reporting period were income from reimbursement of clinical study costs. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, and collectability of the resulting receivable is reasonably assured.

### *Milestones*

Contingent consideration from research and development activities that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. At the inception of each arrangement that includes milestone payments, we evaluate whether each milestone is substantive. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

### *Research and Development Costs*

Costs incurred in the research and development of our product candidates are expensed as incurred. Research and development costs that are paid in advance of performance are capitalized as prepaid expenses and amortized over the service period as the services are provided.

### *Stock-Based Compensation*

Stock-based compensation expense is recognized on the grant-date fair value of the stock-based awards using the Black-Scholes valuation model. The fair value measurement date for non-employee awards is generally the date the performance of services is completed. We recognize compensation expense only for those stock-based awards expected to vest after considering expected forfeitures of the stock-based awards. Stock-based compensation expense is recognized on a straight-line basis over the service period related to each award.

Stock-based payments to non-employees are re-measured at each reporting date and recognized as services are rendered, generally on a straight-line basis. We believe that the fair values of these awards are more reliably measurable than the fair values of the services rendered.

### *Basic and Diluted Net Loss Per Share*

Basic net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding during the period. Diluted net loss per share is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. In periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share because common stock equivalents are excluded as their inclusion would be anti-dilutive.

### *Income Taxes*

Income taxes are recorded in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than

not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of December 31, 2018 and 2017, we did not have any significant uncertain tax positions. We recognize interest and penalties related to uncertain tax positions in income tax expense.

On December 22, 2017, the Tax Cuts and Jobs Act (“the Act”) was enacted in the United States. The Act reduces the U.S. federal corporate tax rate from 34% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. At December 31, 2017, we have completed our accounting for the tax effects of enactment of the Act, including the effects on our existing deferred tax balances and the one-time transition tax. For the year ended December 31, 2017, we recognized no transition tax.

### **Goodwill**

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired, and liabilities assumed under the acquisition method of accounting for push-down accounting. Goodwill is not amortized but is evaluated for impairment within our single reporting unit on an annual basis during the fourth quarter, or more frequently if an event occurs or circumstances change that would more likely than not reduce the fair value of our reporting unit below our carrying amount. When performing the impairment assessment, the accounting standard for testing goodwill for impairment permits a company to first assess the qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the goodwill is impaired. If we believe, as a result of the qualitative assessment, that it is more likely than not that the fair value of goodwill is impaired, we must perform a quantitative analysis to determine if the carrying value of the goodwill exceeds the fair value of the Company. Based on the quantitative analysis, goodwill was determined not to be impaired as of December 31, 2017. As of December 31, 2018, we determined that goodwill was impaired, and a charge of \$69 was recorded.

### **Results of Operations**

#### **Year Ended December 31, 2018 Compared with Year ended December 31, 2017**

The following table sets forth our results of operations for each of the periods set forth below (in thousands):

	<b>Year ended December 31,</b>		<b>Change</b>
	<b>2018</b>	<b>2017</b>	
Revenues .....	\$ 153	\$ 335	\$ (182)
<b>Operating expenses</b>			
Research and development .....	12,966	10,243	2,723
General and administrative .....	7,518	7,567	(49)
Total operating expenses .....	<u>20,484</u>	<u>17,810</u>	<u>2,674</u>
Loss from operations .....	(20,331)	(17,475)	(2,856)
Interest expense .....	(186)	(643)	457
Impairment of Goodwill .....	(69)	—	(69)
Fair value adjustment of derivative liability .....	1	34	(33)
Other income, net .....	22	28	(6)
Loss before income taxes .....	<u>(20,563)</u>	<u>(18,056)</u>	<u>(2,507)</u>
Net loss .....	<u><u>\$(20,563)</u></u>	<u><u>\$(18,056)</u></u>	<u><u>\$(2,507)</u></u>

**Revenue** — Revenue was \$0.1 million for the year ended December 31, 2018, compared to \$0.3 million for the year ended December 31, 2017, a decrease of \$0.2 million. The decrease was the result of the conclusion of the CFFT award that began in 2017.

**Research and development expenses** — Research and development expense was \$13.0 million for the year ended December 31, 2018, compared to \$10.2 million for the year ended December 31, 2017, and increase of \$2.7 million. The increase was primarily due to increased spend of \$1.9 million on the Pulmazole project, \$0.5 million on the PUR1800 project and \$0.3 million in employment costs.

**General and administrative expenses** — General and administrative expense was \$7.5 million for the year ended December 31, 2018, compared to \$7.6 million for the year ended December 31, 2017. The decrease was primarily due to decreases of \$0.5 million in professional consulting expense and \$0.1 million in employment cost, partially offset by \$0.5 million increase in patent expense.

**Interest expense** — Interest expense was \$0.2 million for the year ended December 31, 2018, compared to \$0.6 million for the year ended December 31, 2017, a decrease of \$0.5 million. For both years, interest expense incurred related to the term loan agreement that we entered into in June 2015. Final payments were made in June 2018 and, as of June 30, 2018, the term loan was paid in full.

**Impairment of goodwill** — For the year ended December 31, 2018, the goodwill impairment charge was \$0.1 million. In 2018, the Company performed an impairment assessment and concluded that the carrying amount of the goodwill exceeded its fair value and recorded a resulting impairment charge. There was no impairment in 2017.

### **Liquidity and Capital Resources**

At December 31, 2018, the Company had unrestricted cash of \$2.6 million and working capital of \$0.4 million. The Company had incurred recurring losses and as of December 31, 2018 had an accumulated deficit of \$194.6 million. During the year ended December 31, 2018, the Company had used approximately \$16.8 million in its operating activities. The Company has primarily financed operations to date through the sale of equity securities and a term loan. The Company will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. These conditions raise substantial doubt about the Company's ability to continue as a going concern over the next twelve months from February 19, 2019, the date of issuance of our Annual Report on Form 10-K and meet its obligations.

During the year ended December 31, 2018, the Company raised an aggregate of \$19.3 million in net proceeds through the sale of its common stock (note 8 of the accompanying consolidated financial statements). Subsequent to December 31, 2018, the Company further raised an aggregate of \$3.7 million in gross proceeds through the sale of its common stock (note 8 of the accompanying consolidated financial statements). The accompanying financial statements have been prepared under the assumption the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements as of December 31, 2018, do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern over the next twelve months from February 19, 2019, the date of issuance of our Annual Report on Form 10-K.

The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company raises additional funds by issuing equity securities, the Company's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company's ability to conduct business. If unable to raise additional capital when required or on acceptable terms, the Company may have to (i) delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. The Company's ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing and, ultimately, to generate revenue. There will be continued doubt about the Company's ability to continue as a going concern if the Company is unable to do so.

As of June 30, 2018, the \$7.0 million term loan agreement that we entered into in 2015 was paid in full.

We believe that our existing resources will be sufficient to fund our planned operations into the second quarter of 2019. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our preclinical studies and clinical trials. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials or obtain approval of any product candidates from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities.

The following table sets forth the major sources and uses of cash for each of the periods set forth below (in thousands):

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Net cash used in operating activities . . . . .	\$(16,761)	\$(14,477)
Net cash used in investing activities . . . . .	(19)	(74)
Net cash provided by financing activities . . . . .	15,793	13,919
Net decrease in cash and cash equivalents . . . . .	<u>\$ (987)</u>	<u>\$ (632)</u>

***Cash Flows from Operating Activities***

Net cash used in operating activities for the year ended December 31, 2018 was \$16.8 million, which was primarily the result of a net loss of \$20.6 million, partially offset by \$3.3 million of net non-cash adjustments and \$0.5 million in cash inflows associated with changes in operating assets and liabilities. Our non-cash adjustments were primarily comprised of \$3.0 million of stock-based compensation expense, \$0.2 million of depreciation and amortization, \$0.1 million of goodwill impairment. The net cash inflows associated with changes in operating assets and liabilities was primarily due to a \$0.7 million increase in accounts payable, partially offset by a \$0.2 million decrease in accrued expenses.

Net cash used in operating activities for the year ended December 31, 2017 was \$14.5 million, which was primarily the result of a net loss of \$18.0 million, partially offset by \$3.2 million of net non-cash adjustments and \$0.3 million in cash inflows associated with changes in operating assets and liabilities. Our non-cash adjustments were primarily comprised of \$2.8 million of stock-based compensation expense, \$0.2 million of depreciation and amortization, and \$0.2 million of non-cash interest and rent expense. The net cash inflows associated with changes in operating assets and liabilities was primarily due to a \$0.7 million increase in accrued expenses, partially offset by a \$0.3 million decrease in accounts payable and a \$0.1 million decrease in prepaid expenses and other current assets.

***Cash Flows from Investing Activities***

Net cash used in investing activities for the year ended December 31, 2018 was less than \$0.1 million, compared to net cash used in investing activities of \$0.1 million for the year ended December 31, 2017. Net cash used in investing activities in both years was primarily due to purchases of property and equipment.

### ***Cash Flows from Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2018 was \$15.8 million. Net cash provided by financing activities for the year ended December 31, 2018 was due to the issuance of common stock that resulted in net proceeds of \$19.3 million, partially offset by principle and end of term loan payments of \$3.5 million required by the loan and security agreement with Hercules, the holder of the term loan.

Net cash provided by financing activities for the year ended December 31, 2017 was \$13.9 million. Net cash provided by financing activities for the year ended December 31, 2017 was due to the issuance of common stock that resulted in net proceeds of \$16.3 million and \$0.3 million from the exercise of stock options, partially offset by \$2.7 million of principle payments as required by the loan and security agreement with Hercules, the holder of the term loan.

### ***Financings***

Based on our planned use for our existing cash resources, we believe that our available funds will enable us to support chemistry manufacturing and control activities in support of the Pulmazole program into the second quarter of 2019. The current available funds will not allow us to complete additional clinical work for any of the pipeline programs. We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical studies for existing and new pipeline programs based on iSPERSE;
- the outcome, timing and cost of regulatory approvals by the FDA and European regulatory authorities, including the potential for these agencies to require that we perform studies in addition to those that we currently have planned;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need to expand our research and development activities;
- our need and ability to hire additional personnel;
- our need to implement additional infrastructure and internal systems;
- the cost of establishing and maintaining a commercial-scale manufacturing line; and
- the cost of establishing sales, marketing and distribution capabilities for any products for which we may receive regulatory approval.

If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

### ***Reverse Stock Split***

On February 3, 2019, the Board approved a 1-for-10 reverse stock split of our issued and outstanding shares of common stock (the “Reverse Stock Split”) and the Company’s common stock began trading on a split-adjusted basis when the market opened on February 6, 2019. With the Reverse Stock Split, every 10 shares of the Company’s issued and outstanding common stock (and such shares held in treasury) were automatically converted into one share of common stock, without any change in the par value per share. Any fraction of a share

of common stock that would otherwise have resulted from the Reverse Stock Split will be rounded up to the nearest whole share. Accordingly, all common share and per share data are retrospectively restated to give effect of the split for all periods presented herein.

### *2019 Financings*

On January 31, 2019 and February 5, 2019, we closed confidentially marketed public offerings. In the two offerings, we sold a total of 688,471 shares of our common stock at a price of \$1.70 per share that resulted in gross proceeds of \$1.2 million.

On February 12, 2019, we closed a registered direct offering of 1,706,484 shares of our common stock at \$1.465 per share that resulted in gross proceeds of \$2.5 million.

### *2018 Financings*

#### *Registered Direct Offering*

On November 29, 2018, the Company entered into a Securities Purchase Agreement with an institutional investor (the “Purchaser”), pursuant to which the Company agreed to issue and sell an aggregate of 240,000 shares of common stock, par value \$0.0001 per share, of the Company common stock at an offering price of \$3.20 per share for gross proceeds of \$768 before the deduction of offering expenses. In addition, the Company sold pre-funded warrants (the “Pre-Funded Warrants”) to purchase 697,500 shares of common stock (and the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants). The Pre-Funded Warrants were sold at an offering price of \$3.10 per share for gross proceeds of \$2.2 million before deduction of offering expenses.

In a concurrent private placement, the Company agreed to issue to the Purchaser, for each share of common stock and pre-funded warrant purchased in the Offering, a common warrant, each to purchase one share of Common Stock (the “Common Warrants”). The Common Warrants are initially exercisable six months following issuance and terminate five and one-half years following issuance. The Common Warrants have an exercise price of \$3.90 per share and are exercisable to purchase an aggregate of 937,500 shares of Common Stock.

The closing of the sale of the shares and the prefunded warrants occurred on December 3, 2018 and the company recorded gross proceeds of \$2.9 million.

During January 2019, 697,500 pre-funded warrants were exercised, and the company recorded proceeds of \$0.1 million.

#### *Public Offering*

On April 3, 2018, the Company closed its firm commitment underwritten public offering in which, pursuant to the underwriting agreement (the “Underwriting Agreement”) entered into between the Company and Oppenheimer & Co. Inc., as representative of the underwriters (the “Underwriters”), dated March 28, 2018, the Company issued and sold (i) 1,566,000 common units (“Common Units”), with each Common Unit being comprised of one share of the Company’s common stock, par value \$0.0001 per share, one Series A warrant (collectively, the “Series A Warrants”) to purchase one share of common stock and one Series B warrant (collectively, the “Series B Warrants”) to purchase one share of common stock, and (ii) 784,000 pre-funded units (the “Pre-Funded Units” and, together with the Common Units, the “Units”), with each Pre-Funded Unit being comprised of one pre-funded warrant to purchase one share of common stock, one Series A Warrant and one Series B Warrant. The public offering price was \$6.50 per Common Unit and \$6.40 per Pre-Funded Unit, and the gross proceeds received by the Company on April 3, 2018 pursuant to such sales were \$15,197, prior to deducting underwriting discounts and commissions and other estimated offering expenses.



In addition, on April 4, 2018, the Company closed on the sale of 115,000 additional Common Units pursuant to the Underwriters' option to purchase up to an additional 115,000 Units, which were exercised in full. After giving effect to the exercise of the Underwriters' overallotment option, the gross aggregate proceeds from the offering on April 3 and 4 were \$15,944, prior to deducting underwriting discounts and commissions and other estimated offering expenses.

All pre-funded warrants issued in the offering were exercised in April 2018 and, as 15,000 were exercised on a cashless basis, resulted in the issuance of an additional 783,707 shares of common stock with gross proceeds of \$78 in Q3.

The Series A Warrants included in the Common Units and the Pre-Funded Units were immediately exercisable at a price of \$6.50 per share of common stock, subject to adjustment in certain circumstances, and expired according to their terms on October 3, 2018 and October 4, 2018, respectively. The Series B Warrants included in the Common Units and the Pre-Funded Units were immediately exercisable at a price of \$7.50 per share of common stock, subject to adjustment in certain circumstances, and will expire five years from the date of issuance. The shares of common stock, or Pre-Funded Warrants in the case of the Pre-Funded Units, and the Series A Warrants and Series B Warrants were offered together, but the securities contained in the Common Units and the Pre-Funded Units were issued separately.

The Company agreed to pay Oppenheimer a commission of (a) 7% of the gross proceeds raised up to \$5,000 and (b) 6.5% of the gross proceeds raised in excess of \$5,000. The Company also agreed to pay or reimburse certain expenses on behalf of Oppenheimer. A total of \$1,501 of commissions and other issuance costs were associated with the public offering.

The net proceeds to the Company from the Offering were approximately \$14,520, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the Offering for research and development of its therapeutic candidates, particularly the development of Pulmazole, as well as for working capital and general corporate purposes.

#### *At-the-Market Offering — 2017 and 2018*

On March 17, 2017, we entered into an At-The-Market Sales Agreement (the "Sales Agreement") with BTIG, LLC ("BTIG") to act as our sales agent with respect to the issuance and sale of up to \$11,000,000 of shares of our common stock, from time to time in an at-the-market public offering (the "Offering"). Sales of common stock under the Sales Agreement are made pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on July 15, 2016, and subsequently declared effective on August 3, 2016 (File No. 333-212546), and a related prospectus. BTIG acts as our sales agent on a commercially reasonable efforts basis, consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The NASDAQ Capital Market. If expressly authorized by us, BTIG may also sell the Company's common stock in privately negotiated transactions. There is no specific date on which the Offering will end, there are no minimum sale requirements and there are no arrangements to place any of the proceeds of this offering in an escrow, trust or similar account.

BTIG is entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of the Company's common stock pursuant to the Sales Agreement.

During 2017, we sold 310,336 shares of common stock under the Sales Agreement at an average selling price of approximately \$29.30 per share which resulted in gross proceeds of approximately \$9,096 and net proceeds of approximately \$8,712 after payment of 3% commission to BTIG and other issuance costs.

During 2018, we sold 123,266 shares of common stock under the Sales Agreement at an average selling price of approximately \$15.40 per share which resulted in gross proceeds of approximately \$1,904 and net proceeds of approximately \$1,847 after payment of 3% commission to BTIG and other issuance costs.

### *Term Loan and Warrant*

On June 11, 2015, Pulmatrix Operating entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc., for a term loan in a principal amount of \$7,000 (“Term Loan”). The term loan was secured by substantially all of the Company’s assets, excluding intellectual property. Final payments were made in June 2018 and, as of June 30, 2018, the term loan was paid in full and there is no further liability.

### *Commitments*

We contract with various other organizations to conduct research and development activities. As of December 31, 2018, we had aggregate commitments to pay approximately \$2.9 million remaining on these contracts. The scope of the services under contracts for research and development activities may be modified and the contracts, subject to certain conditions, may generally be cancelled by us upon written notice. In some instances, the contracts, subject to certain conditions, may be cancelled by the third party.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not applicable.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The information required by this Item 8 is included at the end of this Annual Report beginning on page F-1.

### **Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

Not applicable.

### **Item 9A. CONTROLS AND PROCEDURES.**

#### **Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officers as appropriate to allow timely decisions regarding required disclosure.

#### **Internal Control over Financial Reporting**

##### *Management’s Annual Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a

process designed by, or under the supervision of, our Principal Executive Officer and Principal Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the disposition of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP and that receipts and expenditures are being made only in accordance with authorizations of our management and board of directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2018.

#### *Changes in Internal Controls over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during our last fiscal quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. OTHER INFORMATION.**

None.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table sets forth information regarding our executive officers and the members of our board of directors.

<u>Name</u>	<u>Age</u>	<u>Position with the Company</u>
Robert W. Clarke, Ph.D . . . . .	50	Chief Executive Officer and Director
William E. Duke, Jr. . . . .	46	Chief Financial Officer
Teofilo Raad . . . . .	49	Chief Business Officer
James Roach, M.D. . . . .	59	Chief Medical Officer
Steven Gillis, Ph.D . . . . .	65	Director
Michael J. Higgins . . . . .	56	Director
Mark Iwicki . . . . .	53	Director
Terrance McGuire . . . . .	62	Director
Amit D. Munshi . . . . .	50	Director
Matthew L. Sherman, M.D. . . . .	63	Director

Our Board is classified into three classes, with the term of office of one class expiring each year. The term of Class I directors expires at the Company’s annual meeting of stockholders to be held in 2021, the term of Class II directors expires at the Company’s annual meeting of stockholders to be held in 2019, and the term of office of Class III directors expires at the Company’s annual meeting of stockholders to be held in 2020. Stockholders vote to elect directors of the class with a term then expiring each year at our annual meeting. Officers are appointed by our Board and serve at the discretion of the Board.

#### Biographical Information

**Robert W. Clarke, Ph.D.** Dr. Clarke has served as our chief executive officer and director since June 15, 2015, and he has been the chief executive officer and director of Pulmatrix Operating Company, Inc., previously known as “Pulmatrix Inc.” (“Pulmatrix Operating”) since July 2012. Dr. Clarke joined Pulmatrix Operating in April 2004 as its first Ph.D. scientist and served as Chief Scientific Officer from May 2011 to September 2012, where he oversaw the research and development efforts focused on the iCALM and iSPERSE technologies. Prior to joining our Company, Mr. Clarke served as an Associate Director of Life Sciences at Alkermes, Inc. focusing on the development of inhaled therapeutic products based on the Advanced Inhalation Research (AIR) technology. Dr. Clarke holds a B.Sc. in Biomedical Engineering from Boston University and received his Ph.D. in Physiology from Johns Hopkins University. Dr. Clarke also completed post-doctoral training in Respiratory Biology at Brigham and Women’s Hospital and Harvard University. As a result of Dr. Clarke’s more than 25 years of experience in the healthcare industry and his focus on pulmonary drug delivery and the role of inhaled particles in respiratory biology and medicine, including co-authorship of over eighty (80) chapters, papers, and abstracts, we believe that Dr. Clarke is qualified to serve as a member of the Board.

**William E. Duke, Jr.** Mr. Duke has served as our chief financial officer since June 2015. Prior to joining our company, Mr. Duke served as the chief financial officer of Valeritas, a medical technology company, from January 2014 until June 2015 and from July 2011 until January 2014, he served as Valeritas’ vice president and corporate controller. At Valeritas, Mr. Duke led the controller relationship, financial planning and analysis, investor relations and information technology functions. Prior to joining Valeritas, Mr. Duke was senior director, finance for Genzyme Corporation, a biopharmaceutical company, from January 2010 to July 2011, where he had oversight responsibility for external reporting to the Securities and Exchange Commission, internal management reporting and worldwide financial consolidation. Prior to Genzyme, he was the director of finance and accounting of Haemonetics Corporation, a medical device company, from May 2008 to January 2010 and held various senior financial roles with consulting services and emerging growth organizations. Mr. Duke holds a B.S. in Accounting from Stonehill College and a M.B.A. with a concentration in Finance from Bentley University and is a Certified Public Accountant.

**Ted Raad.** Mr. Raad has served as our chief business officer since May 2017 and leads our commercial and business development efforts. He has more than 20 years of commercial health care and life science leadership experience and most recently served as chief commercial officer at Option Care, where he helped separate the specialty home infusion business unit from Walgreens to create the nation's largest independent home infusion provider. Prior to that, he was a business unit head at Sunovion with overall responsibility for CNS and respiratory products, including assets in asthma and COPD. During his time at Sunovion, Mr. Raad led multiple products through clinical development to commercialization and implemented new strategic alliances in the US and Japan. Earlier in his career he also gained direct launch experience with Sporanox, Janssen's oral itraconazole product to treat fungal infections, and brings that experience to the Pulmatrix Pulmazole program. Mr. Raad holds a BS in Business Administration from University of Colorado at Boulder and an MBA from Thunderbird Global School of Global Management.

**James Roach, M.D., FACP, FCCP.** Dr. Roach has served as our chief medical officer since November 2017. For the year prior to joining Pulmatrix, Jim was the chief medical officer at Veristat, Inc. (a contract research organization), and also served as the senior vice president, development and chief medical officer at Momenta Pharmaceuticals, Inc. from 2008-2016, where he was responsible for preclinical and clinical development and medical and regulatory affairs. Dr. Roach was the senior vice president, medical affairs at Sepracor, Inc, where he led the medical affairs group from 2002 to 2008. Dr. Roach has also held senior clinical research and/or medical affairs positions at Millennium Pharmaceuticals, Inc., LeukoSite, Inc., Medical and Technical Research Associates, Inc. (a contract research organization), and Astra USA. Dr. Roach held an academic appointment at Harvard Medical School for close to 25 years and has been an associate physician at Brigham and Women's Hospital (BWH) and member of the BWH pulmonary and critical care medicine division since 1993. He received his B.A. in biology and philosophy from the College of the Holy Cross and his M.D. from Georgetown University School of Medicine. Dr. Roach completed his residency in internal medicine and fellowships in pulmonary disease and critical care medicine at Walter Reed Army Medical Center in Washington, D.C., and served in the U.S. Army Medical Corps for ten years. Dr. Roach is board certified in internal medicine and pulmonary disease and is a fellow of the American College of Physicians (ACP) and the American College of Chest Physicians (ACCP).

**Steven Gillis, Ph.D.** Dr. Gillis has been a director of our Company since his appointment effective June 15, 2015. Dr. Gillis was previously a director of Pulmatrix Operating from October 2009 until the date of the Merger. Since 2005, Dr. Gillis has been a managing director at ARCH Venture Fund, a venture capital firm. From 1994 to 2005, Dr. Gillis served as chief executive officer and chairman of the board of directors of Corixa Corporation, which he co-founded in October 1994. Previously, Dr. Gillis served as a director, head of research and development, chief scientific officer and acting chief executive officer of Immunex Corporation, which he co-founded in 1981. As a former director and chairman of Trubion Pharmaceuticals, Inc., Dr. Gillis led its acquisition by Emergent BioSolutions in the fall of 2010. Dr. Gillis currently serves as a director of Takeda Pharmaceutical Company and Homology Medicines, Inc. and serves as director and chairman of VBI Vaccines, Inc. Dr. Gillis received his B.A. in Biology and English from Williams College and his Ph.D. in Biological Science from Dartmouth College. We believe that Dr. Gillis's experience in the venture capital industry, particularly with biotechnology and pharmaceutical companies, qualifies him to serve as a member of the Board.

**Michael J. Higgins.** Mr. Higgins has been a director of our Company since his appointment effective June 15, 2015. Mr. Higgins was previously a director of Pulmatrix Operating from March 2015 until June 15, 2015. Mr. Higgins is currently an Entrepreneur-in-residence at Polaris Partners and is a board member at Genocoea Biosciences, Voyager Therapeutics, Kindex Pharmaceuticals, Camp4 Therapeutics, Sea Pharmaceuticals and Private Equity Access Fund, II. Mr. Higgins served as senior vice president, chief operating officer and chief financial officer of Ironwood Pharmaceuticals Inc. and led its finance, operations and strategy efforts from 2003 to 2014 and through its initial public offering and the launch of its first commercial product. Prior to 2003, Mr. Higgins spent seven (7) years and held a variety of senior business positions at Genzyme Corporation, including vice president of corporate finance and vice president of business development. Prior to joining Genzyme Corporation, Mr. Higgins led Procept, Inc.'s financial team from founding through its initial public

offering. Mr. Higgins earned a B.S. from Cornell University and an M.B.A. from the Amos Tuck Tuck School of Business Administration at Dartmouth College.

**Mark Iwicki.** Mr. Iwicki has served as chairman of the Board and as a director of our Company since his appointment in December 2015. Mr. Iwicki currently serves as chairman of the board of directors and chief executive officer of Kala Pharmaceuticals. Prior to joining Kala, he was president and chief executive officer of Civitas Therapeutics, Inc., which was acquired by Acorda Therapeutics, Inc. in October 2014. Prior to joining Civitas, he served as president and chief executive officer at Blend Therapeutics, Inc., or Blend, from December 2012 to January 2014. Prior to Blend, Mr. Iwicki was president and chief executive officer of Sunovion Pharmaceuticals Inc. (formerly Sepracor Inc.), or Sunovion. Mr. Iwicki was at Sepracor/Sunovion from October 2007 to June 2012. Prior to joining Sepracor Inc., Mr. Iwicki was at Novartis Pharmaceuticals Corporation from March 1998 to October 2007, where he was vice president and business unit head. Before that, he held management positions at Astra Merck Inc. and Merck & Co., Inc. In addition to serving on our Board, Mr. Iwicki is currently a director at Kala Pharmaceuticals, Merus, Aimmune Therapeutics, Nimbus Therapeutics, and Oxeia Biopharmaceuticals. He previously served on the boards of Civitas, Sunovion, Blend and Taris Biomedical, all privately held companies. Mr. Iwicki holds a B.S. in Business Administration from Ball State University and an M.B.A. from Loyola University. We believe that Mr. Iwicki's more than 25 years of experience as a biopharmaceutical industry leader, managing all stages of drug development and commercialization in multiple therapeutic areas, qualifies him to serve as our chairman of the Board.

**Terrance G. McGuire.** Mr. McGuire has been a director of our Company since his appointment effective June 15, 2015. Mr. McGuire was previously a director of Pulmatrix Operating from May 2006 until June 15, 2015. Mr. McGuire co-founded Polaris in 1996 and is currently one of their general partners. Prior to starting Polaris, Mr. McGuire spent 7 years at Burr, Egan, Deleage & Co., investing in early stage medical and information technology companies. He currently serves on the board of directors of one other public company: Ironwood Pharmaceuticals Inc. Mr. McGuire also serves on the boards of several private companies, including Adimab, Alector, Quantum Designs, Inc., Arsenal Medical, and Iora Health. Mr. McGuire has formerly served on the board of directors of Editas, Life Line Screening, NextCode, and Saga, among others. Mr. McGuire is the former chairman of the National Venture Capital Association, chairman of the board of the Thayer School of Engineering at Dartmouth College, and a member of the boards of The David H. Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology and The Arthur Rock Center for Entrepreneurship at Harvard Business School. Mr. McGuire earned a B.S. in physics and economics from Hobart College, an M.S. in engineering from The Thayer School at Dartmouth College, and an M.B.A. from Harvard Business School. We believe that Mr. McGuire's extensive experience as a venture capitalist focused on the biotechnology industry, as well as Mr. McGuire's many years of experience helping companies evolve from the start-up phase to successful public companies, qualifies him to serve as a member of the Board.

**Amit D. Munshi.** Mr. Munshi was appointed to serve as a director of Pulmatrix in June 2017. He is currently the president and chief executive officer of Arena Pharmaceuticals, Inc. Previously, Mr. Munshi served as president and chief executive officer and a director of Epirus Biopharmaceuticals, Inc. from May 2012 to May 2016. Prior to Epirus, Mr. Munshi served as chief executive officer of Percivia LLC, a biotechnology company, from 2011 to 2012, was a co-founder and served as chief business officer of Kythera Biopharmaceuticals, Inc., from 2005 to 2010, and held multiple leadership positions at Amgen Inc. from 1997 to 2005, including general manager, Nephrology Europe. Mr. Munshi has more than 25 years of global biopharmaceutical industry experience in executive management, business development, product development and portfolio management. Mr. Munshi holds a B.S. in Economics and a B.A. in History from the University of California, Riverside, and an M.B.A. from the Peter F. Drucker Graduate School of Management at Claremont Graduate University. Mr. Munshi previously served on the board of Cytrellis Biosystems, Inc.

**Matthew L. Sherman, M.D.** Dr. Sherman became a director of our Company in September 2016. Most recently, Dr. Sherman was chief medical officer of Acceleron Pharma Inc. from May 2006 to July 2018 and executive vice president from March 2015 to July 2018. Prior to joining Acceleron, he served as senior vice president and chief

medical officer at Synta Pharmaceuticals where he was responsible for clinical research, clinical operations, biostatistics, data management, regulatory affairs, quality assurance and program management. Prior to that, Dr. Sherman worked at Genetics Institute and Wyeth Pharmaceuticals in various capacities including therapeutic area director for oncology. While at Wyeth Pharmaceuticals, Dr. Sherman provided senior oncology and hematology leadership for worldwide clinical development for both small molecule and biologic therapeutics, including the submission and approval of Mylotarg® by the U.S. Food and Drug Administration. Dr. Sherman has published numerous papers and book chapters in the field of oncology and clinical development and is named as an inventor of several patents. Dr. Sherman is board certified in medical oncology and internal medicine and held various clinical positions at Harvard Medical School with corresponding hospital appointments at the Dana-Farber Cancer Institute and Brigham and Women's Hospital. Dr. Sherman received an S.B. in chemistry from the Massachusetts Institute of Technology and an M.D. from Dartmouth Medical School. We believe that Dr. Sherman brings to the Board his medical background and extensive experience as a biopharmaceutical industry leader in clinical research and development.

### **Family Relationships**

There are no family relationships among any of our officers or executive officers.

### **Involvement in Certain Legal Proceedings**

There have been no material legal proceedings that would require disclosure under the federal securities laws that are material to an evaluation of the ability or integrity of our directors or executive officers, or in which any director, officer, nominee or principal stockholder, or any affiliate thereof, is a party adverse to us or has a material interest adverse to us.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who own more than 10% of a registered class of our equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater-than-10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of copies of such reports furnished to us and written representations that no other reports were required, each of our directors, officers and ten percent stockholders complied with all Section 16(a) filing requirements applicable to them for the fiscal year ended December 31, 2018.

### **Independent Directors**

We are currently listed on the NASDAQ Capital Market and therefore rely on the definition of independence set forth in the NASDAQ Listing Rules ("NASDAQ Rules"). Under the NASDAQ Rules, a director will only qualify as an "independent director" if, in the opinion of our Board, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Based upon information requested from and provided by each director concerning his background, employment, and affiliations, including family relationships, we have determined that Drs. Gillis and Sherman and Messrs. Iwicki, Higgins, McGuire and Munshi have no material relationships with us that would interfere with the exercise of independent judgment and are "independent directors" as that term is defined in the NASDAQ Listing Rules.

Three of our directors are employed by venture capital investors that own our Company's common stock through a series of private placements, rounds of venture capital financing and a recapitalization since its formation, including: (i) Polaris Venture Partners V, L.P., Polaris Venture Partners Founders' Fund V, L.P., Polaris Venture Partners Special Founders' Fund V, L.P., Polaris Venture Partners Entrepreneurs' Fund V, L.P., Polaris Venture

Partners IV, L.P., Polaris Venture Partners Entrepreneurs' Fund IV, L.P. (collectively, "Polaris") and (ii) ARCH Venture Fund VII, L.P. ("ARCH Venture Fund"). In making the independence determinations, the Board considered that Mr. Higgins is currently an Entrepreneur-in-Residence at Polaris, Mr. McGuire co-founded Polaris in 1996 and is currently one of its General Partners and Dr. Gillis has served as a Managing Director at ARCH Venture Partners since 2005. As of February 14, 2019, Polaris beneficially owned 7.78% of our common stock and ARCH Venture Partners beneficially owned 5.63% of our common stock.

### Committees of the Board of Directors

The Board delegates various responsibilities and authority to different Board committees. Committees regularly report on their activities and actions to the full Board. Currently, the Board has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Committee assignments are re-evaluated annually. Each of these committees operates under a charter that has been approved by our Board. The current charter of each of these committees is available on our website at [www.pulmatrix.com](http://www.pulmatrix.com) in the "Corporate Governance" section under "Investors."

As of February 14, 2019, the following table sets forth the membership of each of the Board committees listed above.

Name	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
Robert W. Clarke, Ph.D.			
Steven Gillis, Ph.D.		Chairman	
Michael J. Higgins	Chairman		Member
Mark Iwicki*		Member	Member
Terrance G. McGuire	Member		Chairman
Amit D. Munshi	Member		
Matthew L. Sherman, M.D.		Member	

\* Chairman of the Board of Directors

### *Audit Committee*

Our Audit Committee is responsible for, among other matters:

- approving and retaining the independent auditors to conduct the annual audit of our financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approving audit and non-audit fees and services;
- reviewing accounting and financial controls with the independent auditors and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- recognizing and preventing prohibited non-audit services;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the SEC require to be included in our annual meeting proxy statement.



Our Audit Committee is composed of Michael J. Higgins (chairman), Terrance G. McGuire and Amit D. Munshi. Our Board has determined that Mr. Higgins, Mr. McGuire and Mr. Munshi are independent in accordance with NASDAQ Rules and Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Our Board has also reviewed the education, experience and other qualifications of each member of the Audit Committee. Based upon that review, our Board has determined that Michael J. Higgins qualifies as an “audit committee financial expert,” as defined by the rules of the SEC.

### ***Compensation Committee***

Our Compensation Committee is responsible for, among other matters:

- reviewing and recommending the compensation arrangements for management, including the compensation for our president and chief executive officer;
- appointing, compensating and overseeing the work of any compensation consultant, legal counsel or other advisor retained by the Compensation Committee;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Our Compensation Committee is composed of Dr. Steven Gillis (chairman), Mark Iwicki and Dr. Matthew L. Sherman. Our Board has determined that Dr. Gillis, Mr. Iwicki and Dr. Sherman are independent in accordance with NASDAQ Rules. The Compensation Committee has the authority to delegate to subcommittees of the Compensation Committee any of the responsibilities of the full committee.

### ***Nominating and Corporate Governance Committee***

Our Nominating and Corporate Governance Committee is responsible for, among other matters:

- evaluating the current composition, organization and governance of the Board and its committees, and making recommendations for changes thereto;
- reviewing each director and nominee annually;
- determining desired Board member skills and attributes and conducting searches for prospective members accordingly;
- evaluating nominees, and making recommendations to the Board concerning the appointment of directors to Board committees, the selection of Board committee chairs, proposal of the slate of directors for election to the Board, and the termination of membership of individual directors in accordance with the Board’s governance principles;
- overseeing the process of succession planning for the chief executive officer and, as warranted, other senior officers of the Company;
- developing, adopting and overseeing the implementation of a code of business conduct and ethics; and
- administering the annual Board performance evaluation process.

Our Nominating and Corporate Governance Committee is composed of Terrance G. McGuire (chairman), Michael Higgins and Mark Iwicki.

**Code of Ethics**

We have adopted a Corporate Code of Conduct and Ethics and Whistleblower Policy (the “Corporate Code”) that applies to all of our directors and employees, including the principal executive officer and the principal financial officer. The full text of our Corporate Code is published on the Investor section of our website at www.pulmatrix.com. We intend to disclose any future amendments to certain provisions of the Corporate Code, or any waivers of such provisions granted to executive officers and directors, on this website promptly following the date of any such amendment or waiver.

**ITEM 11. EXECUTIVE COMPENSATION.**

**Compensation Information**

The following table sets forth the names and positions of: (i) each person who served as our principal executive officer during the last completed fiscal year; and (ii) our two most highly compensated executive officers, other than our principal executive officer, who were serving as executive officers, as determined in accordance with the rules and regulations promulgated by the SEC, as of December 31, 2018, with compensation of \$100,000 or more (our “Named Executive Officers”) for the year ended December 31, 2018:

Name	Position
Robert W. Clarke, Ph.D.	President, Chief Executive Officer, Director
William Duke, Jr.	Chief Financial Officer
Teofilo David Raad	Chief Business Officer

**Summary Compensation Table**

The following table sets forth information regarding compensation awarded to, earned by or paid to the Named Executive Officers for the fiscal year ended December 31, 2018 and the fiscal year ended December 31, 2017.

Name and Principal Position	Year	Salary (\$)	Incentive Compensation (\$)	Stock Awards (\$)	Option Awards (\$)(1)	Non-equity incentive plan compensation	Nonqualified deferred compensation earnings	All Other Compensation (\$)	Total (\$)
						(\$)	(\$)		
Robert W. Clarke, Ph.D. (Chief Executive Officer)	2018	434,074	176,516 (2)		634,012			6,022 (3)	1,250,624
	2017	407,862	82,484 (4)		305,011			5,776 (5)	801,133
William Duke, Jr. (Chief Financial Officer)	2018	338,226	120,874 (2)		269,455			6,022 (3)	734,577
	2017	313,337	55,447 (4)		144,013			5,776 (5)	518,573
Teofilo Raad (6) (Chief Business Officer)	2018	345,135	121,396 (2)		234,904			6,022 (3)	707,457
	2017	215,769	39,938 (4)		594,589			4,663 (7)	854,959

- (1) In accordance with SEC rules, this column reflects the aggregate fair value of the stock awards and option awards granted during the respective fiscal year computed as of their respective grant dates in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions. The assumptions made in the valuation of the share-based payments are contained in Note 10 to our consolidated financial statements for the fiscal year ended December 31, 2018 in our Annual Report for the year ended December 31, 2018.
- (2) Represents incentive compensation earned.
- (3) Represents Company 401(k) plan contributions of \$5,500 and payment made by the Company for life, AD&D and LTD premiums in the amount of \$522.
- (4) Represents incentive compensation payments made.
- (5) Represents Company 401(k) plan contributions of \$5,300 and payment made by the Company for life, AD&D and LTD premiums in the amount of \$476.
- (6) Began to serve on May 1, 2017.
- (7) Represents Company 401(k) plan contributions of \$4,315 and payment made by the Company for life, AD&D and LTD premiums in the amount of \$348.

## **Narrative Disclosure to Summary Compensation Table**

### ***Executive Employment Agreements***

We have entered into executive employment agreements with each of our Named Executive Officers. The executive employment agreements provide for “at will” employment and set forth the terms and conditions of employment, including annual base salary, discretionary bonus opportunities, benefits and eligibility to participate in our employee benefit plans and programs. As a condition of their employment, our Named Executive Officers were each required to execute our standard proprietary information, inventions and non-competition agreement. The material terms of these executive employment agreements are summarized below.

### ***Retirement Plans***

As part of our overall compensation program, we provide all full-time employees, including our Named Executive Officers, with the opportunity to participate in a defined contribution 401(k) plan. Our 401(k) plan is intended to qualify under Section 401 of the Internal Revenue Code so that employee pre-tax contributions and income earned on such contributions are not taxable to employees until withdrawn. Employees may elect to defer up to 100 percent of their eligible compensation (not to exceed the statutorily prescribed annual limit) in the form of elective deferral contributions to our 401(k) plan. Our 401(k) plan also has a “catch-up contribution” feature for employees aged 50 or older (including those who qualify as “highly compensated” employees) who can defer amounts over the statutory limit that applies to all other employees.

### ***Employee Benefits and Perquisites***

Dr. Clarke and Messrs. Duke and Raad are eligible to participate in our health and welfare plans, including: medical and dental benefits, short-term and long-term disability insurance, and life insurance.

### ***No Tax Gross-Ups***

We do not make gross-up payments to cover our executives’ personal income taxes that may pertain to any of the compensation or perquisites paid or provided by us.

### ***Dr. Clarke***

In June 2015, we entered into an employment agreement with Dr. Clarke to serve as our president and chief executive officer. Dr. Clarke’s employment with us is “at-will,” and the agreement does not include a specified term. Both Dr. Clarke’s salary and bonus are subject to review and adjustment by the Board or an appropriate committee thereof. The actual bonus amount is based on both the Company and individual performance during the year.

### ***Termination Benefits***

If Dr. Clarke’s employment is terminated (i) by the Company without cause or (ii) by Dr. Clarke for good reason, then the Company must pay Dr. Clarke, in addition to any then-accrued and unpaid obligations owed to him, (x) twelve (12) months of his then-current base salary, (y) fifty percent (50%) of a pro rata portion of the bonus for the year in which the termination occurs, based on year-to-date performance as determined by the Company’s Board, or a committee thereof, and (z) up to twelve (12) months of COBRA health insurance premiums at the Company’s then-normal rate of contribution. In addition, all unvested equity awards held by Dr. Clarke that would have vested during the twenty-four (24) months following the termination date will immediately vest and become exercisable. If Dr. Clarke’s employment is terminated (i) by the Company without cause or (ii) by Dr. Clarke for good reason, within twelve (12) months following a change in control, then Dr. Clarke shall be entitled to receive, in addition to any then-accrued and unpaid obligations owed to him, (x) a lump sum payment

equal to twelve (12) months of his then-current base salary and a pro rata portion of the target bonus for the year in which the termination occurs, and (y) up to twelve (12) months of COBRA health insurance premiums at the Company's then-normal rate of contribution. In addition, in that case, all unvested equity awards will immediately vest and become exercisable. Receipt of Dr. Clarke's severance and other termination benefits is subject to his execution of a release of claims and his compliance with the restrictive covenants contained in his agreements with the Company.

Under Dr. Clarke's employment agreement, "good reason" is defined as (i) relocation of Dr. Clarke's principal business location to a location more than fifty (50) miles from his then-current business location; (ii) a material diminution in Dr. Clarke's duties, authority or responsibilities; or (iii) a material reduction in Dr. Clarke's base salary; provided that (A) Dr. Clarke provides the Company with written notice that he intends to terminate his employment for good reason within thirty (30) days of such circumstance occurring, (B) if such circumstance is capable of being cured, the Company has failed to cure such circumstance within a period of thirty (30) days from the date of such written notice, and (C) Dr. Clarke terminates his employment within sixty five (65) days from the date that good reason first occurs.

#### ***Mr. Duke***

In June 2015, we entered into an employment agreement with Mr. Duke to serve as our chief financial officer. Mr. Duke's employment with us is "at-will," and the agreement does not include a specified term. Both Mr. Duke's salary and bonus are subject to review and adjustment by the Board or an appropriate committee thereof. The actual bonus amount is based on both the Company and individual performance during the year.

#### ***Termination Benefits***

If Mr. Duke's employment is terminated (i) by the Company without cause or (ii) by Mr. Duke for good reason, then the Company must pay Mr. Duke, in addition to any then-accrued and unpaid obligations owed to him, (x) nine (9) months of his then-current base salary, (y) seventy-five percent (75%) of a pro rata portion of the bonus for the year in which the termination occurs, based on year-to-date performance as determined by the Company's Board, or a committee thereof, and (z) up to nine (9) months of COBRA health insurance premiums at the Company's then-normal rate of contribution. In addition, all unvested equity awards held by Mr. Duke that would have vested during the nine (9) months following the termination date will immediately vest and become exercisable. If Mr. Duke's employment is terminated (i) by the Company without cause or (ii) by Mr. Duke for good reason, within twelve (12) months following a change in control, then Mr. Duke shall be entitled to receive, in addition to any then-accrued and unpaid obligations owed to him, (x) a lump sum payment equal to twelve (12) months of his then-current base salary and a pro rata portion of the target bonus for the year in which the termination occurs, and (y) up to twelve (12) months of COBRA health insurance premiums at the Company's then-normal rate of contribution. In addition, in that case, all unvested equity awards will immediately vest and become exercisable. Receipt of Mr. Duke's severance and other termination benefits is subject to his execution of a release of claims and his compliance with the restrictive covenants contained in his agreements with the Company.

Under Mr. Duke's employment agreement, "good reason" is defined as (i) relocation of Mr. Duke's principal business location to a location more than fifty (50) miles from his then-current business location; (ii) a material diminution in Mr. Duke's duties, authority or responsibilities; or (iii) a material reduction in Mr. Duke's base salary; provided that (A) Mr. Duke provides the Company with written notice that he intends to terminate his employment for good reason within thirty (30) days of such circumstance occurring, (B) if such circumstance is capable of being cured, the Company has failed to cure such circumstance within a period of thirty (30) days from the date of such written notice, and (C) Mr. Duke terminates his employment within sixty five (65) days from the date that good reason first occurs.

### ***Mr. Raad***

In May 2017, we entered into an employment agreement with Mr. Raad to serve as our chief business officer. Mr. Raad's employment with us is "at-will," and the agreement does not include a specified term. Both Mr. Raad's salary and bonus are subject to review and adjustment by the Board or an appropriate committee thereof. The actual bonus amount is based on both the Company and individual performance during the year.

### ***Termination Benefits***

If Mr. Raad's employment is terminated (i) by the Company without cause or (ii) by Mr. Raad for good reason, then the Company must pay Mr. Raad, in addition to any then-accrued and unpaid obligations owed to him, (x) nine (9) months of his then-current base salary, (y) seventy-five percent (75%) of a pro rata portion of the bonus for the year in which the termination occurs, based on year-to-date performance as determined by the Company's Board, or a committee thereof, and (z) up to nine (9) months of COBRA health insurance premiums at the Company's then-normal rate of contribution. In addition, all unvested equity awards held by Mr. Raad that would have vested during the nine (9) months following the termination date will immediately vest and become exercisable. If Mr. Raad's employment is terminated (i) by the Company without cause or (ii) by Mr. Raad for good reason, within twelve (12) months following a change in control, then Mr. Raad shall be entitled to receive, in addition to any then-accrued and unpaid obligations owed to him, (x) a lump sum payment equal to twelve (12) months of his then-current base salary and a pro rata portion of the target bonus for the year in which the termination occurs, and (y) up to twelve (12) months of COBRA health insurance premiums at the Company's then-normal rate of contribution. In addition, in that case, all unvested equity awards will immediately vest and become exercisable. Receipt of Mr. Raad's severance and other termination benefits is subject to his execution of a release of claims and his compliance with the restrictive covenants contained in his agreements with the Company.

Under Mr. Raad's employment agreement, "good reason" is defined as (i) relocation of Mr. Raad's principal business location to a location more than fifty (50) miles from his then-current business location; (ii) a material diminution in Mr. Raad's duties, authority or responsibilities; or (iii) a material reduction in Mr. Raad's base salary; provided that (A) Mr. Raad provides the Company with written notice that he intends to terminate his employment for good reason within thirty (30) days of such circumstance occurring, (B) if such circumstance is capable of being cured, the Company has failed to cure such circumstance within a period of thirty (30) days from the date of such written notice, and (C) Mr. Raad terminates his employment within sixty five (65) days from the date that good reason first occurs.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning the outstanding equity awards that have been previously awarded to each of our Named Executive Officers and which remain outstanding as of December 31, 2018:

### Outstanding Equity Awards at Fiscal Year End Table 2018 Option Awards

<u>Name</u>	<u>Number of securities underlying unexercised options (#) exercisable</u>	<u>Number of securities underlying unexercised options (#) unexercisable</u>	<u>Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)</u>	<u>Option exercise price (\$)</u>	<u>Option expiration date</u>
Robert W. Clarke, Ph.D. . . . . .	267 (1)	—	—	22.10	02/10/2020
	242 (1)	—	—	22.10	05/24/2020
	1,186 (1)	—	—	22.10	06/15/2021
	2,371 (1)	—	—	20.30	06/08/2022
	17,101 (1)	—	—	20.30	09/18/2022
	6,563 (1)	—	—	18.80	10/11/2023
	40,791 (1)	—	—	118.00	06/16/2025
	4,435 (1)	—	—	110.00	06/24/2025
	22,525 (2)	9,276	—	28.00	02/03/2026
	6,956 (2)	8,945	—	27.80	03/20/2027
	74,996 (3)	125,004	—	4.68	06/05/2028
William Duke, Jr. . .	20,582 (3)	2,941	—	110.00	06/24/2025
	10,639 (3)	4,381	—	28.00	02/03/2026
	3,286 (3)	4,225	—	27.80	03/20/2027
	31,874 (3)	53,127	—	4.68	06/05/2028
Teofilo Raad . . . . .	13,086 (2)	19,965	—	27.00	05/01/2027
	27,789 (3)	46,312	—	4.68	06/05/2028

- (1) Fully vested.
- (2) Each of these options vests over a four (4) year period, with twenty-five percent (25%) vesting on the first anniversary of the date of grant and 2.083% vesting each month thereafter for the next thirty-six (36) months.
- (3) Each of these options vests over a three (3) year period, with twenty-five percent (25%) vesting on the grant date and 2.083% vesting each month thereafter for the next thirty-six (36) months.

## Director Compensation

The following table presents the total compensation for each person who served as a member of our Board during 2018. Other than as set forth in the table and described more fully below, we did not pay any compensation, reimburse any expense of, make any equity awards or non-equity awards to, or pay any other compensation to any of the other members of our Board in such period.

**Director Compensation Table  
2018**

<u>Name</u>	<u>Fees earned or paid in cash (\$)</u>	<u>Stock awards (\$)</u>	<u>Option awards (\$)</u>	<u>All other compensation (\$)</u>	<u>Total (\$)</u>
Steven Gillis, Ph.D . . . . .	30,000	—	39,703 (1)	—	69,703
Michael J. Higgins . . . . .	50,000	—	39,703 (2)	—	89,703
Mark Iwicki . . . . .	68,000	—	49,629 (3)	—	117,629
Terrance G. McGuire . . . . .	47,000	—	39,703 (4)	—	86,703
Amit D. Munshi . . . . .	37,000	—	39,703 (5)	—	76,703
Matthew L. Sherman, M.D. . . . .	33,000	—	39,703 (6)	—	72,703

- (1) As of December 31, 2018, Dr. Gillis had outstanding options representing the right to purchase 15,602 shares of our common stock.
- (2) As of December 31, 2018, Mr. Higgins had outstanding options representing the right to purchase 17,484 shares of our common stock
- (3) As of December 31, 2018, Mr. Iwicki had outstanding options representing the right to purchase 23,289 shares of our common stock.
- (4) As of December 31, 2018, Mr. McGuire had outstanding options representing the right to purchase 15,602 shares of our common stock.
- (5) As of December 31, 2018, Mr. Munshi had outstanding options representing the right to purchase 13,280 shares of our common stock.
- (6) As of December 31, 2018, Dr. Sherman had outstanding options representing the right to purchase 13,720 shares of our common stock.

We have entered into a director’s agreement with each of our non-employee directors. In 2018, under these agreements, non-employee directors were paid cash compensation payable in four quarterly payments as set forth in the table below.

	<u>Annual Retainer</u>
<b>Board of Directors:</b>	
All Non-Employee Members . . . . .	\$30,000
Chairperson . . . . .	\$60,000
<b>Audit Committee:</b>	
Members . . . . .	\$ 7,000
Chairperson . . . . .	\$15,000
<b>Compensation Committee:</b>	
Members . . . . .	\$ 3,000
Chairperson . . . . .	\$ 7,000
<b>Nominating and Corporate Governance Committee:</b>	
Members . . . . .	\$ 5,000
Chairperson . . . . .	\$10,000

The agreements also provide that such directors will be reimbursed for reasonable out-of-pocket expenses incurred in connection with the attendance of board meetings.

During 2018, we issued stock options to non-employee members of our Board with an exercise price equal to the fair market value of our common stock on the date of grant. On June 5, 2018, each of Messrs. Higgins, McGuire, Munshi and Drs. Gillis and Sherman received an option to purchase 12,400 shares of the Company’s common stock and Mr. Iwicki received an option to purchase 15,500 shares of the Company’s common stock. All option awards had an exercise price of \$4.68 per share, which was the closing price on June 5, 2018, the grant date.

For all stock options issued to non-employee members of our Board in 2015, 2.08333% of the options vest in 48 equal installments on a monthly basis. For the grants made on March 20, 2017 and June 13, 2017, 25% of the options vest on the first anniversary of the date of grant, and the remaining options vest in 36 equal monthly installments thereafter. For the grants made on June 5, 2018, 25% of the options vest immediately on the grant date and the remaining shares vest in 36 equal monthly installments thereafter.

We did not pay any compensation or award any stock options to Dr. Clarke for his service as a director.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

**Equity Compensation Plan Information**

The following table provides information regarding the number of securities to be issued under the 2013 Plan and Old Pulmatrix Equity Plans (as defined below), the weighted-average exercise price of options issued under the 2013 Plan and Old Pulmatrix Equity Plans and the number of securities remaining available for future issuance under the 2013 Plan and Old Pulmatrix Equity Plans, in each case as of December 31, 2018:

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (3)</u>
Equity compensation plans approved by security holders (1) . . . . .	975,569	\$24.14	272,222
Equity compensation plans not approved by security holders (2) . . . . .	—	—	—
Total . . . . .	975,569	\$24.14	272,222

- (1) Represents shares available for issuance under the 2013 Plan.
- (2) Excludes 49,108 shares of our common stock issuable upon outstanding options granted under equity compensation plans granted under the Original 2013 Plan and the 2003 plan. No additional awards may be issued under the Original 2013 Plan nor the 2003 Plan. As of December 31, 2018, there were 9,521 options with a weighted average exercise price of \$18.75 per share outstanding pursuant to the Original 2013 Plan. As of December 31, 2018, there were 39,587 options with a weighted average exercise price of \$21.02 per share outstanding pursuant to the 2003 Plan.
- (3) The number of authorized shares under the 2013 Plan is subject to annual increases based upon an “evergreen” provision, which allows for an annual increase in the number of shares of our common stock available for issuance under the plan on the first day of each fiscal year beginning in calendar year 2016. The annual increase in the number of shares shall be equal to: (i) five percent (5%) of the number of shares of our common stock outstanding as of such date; or (ii) an amount determined by our Board. On January 1, 2019, under the 2013 Plan’s “evergreen” provision, the number of shares of our common stock available for issuance increased by 246,637 shares to a total of 1,496,637 shares.



## **Incentive Plans**

We sponsor the 2013 Plan. The 2013 Plan was amended and restated as of June 15, 2015 to, among other things, (i) increase the number of shares of our common stock authorized under the plan, (ii) comply with the requirements imposed by Section 162(m) of the Code, and (iii) provide an increase in the number of shares of our common stock available for issuance under the 2013 Plan's "evergreen" provision. The 2013 Plan was amended and restated as of June 7, 2018 to increase the number of shares of our common stock authorized under the plan and as of December 31, 2018, the 2013 Plan provided for the grant of up to 1,250,000 shares of our common stock, of which 272,219 shares remained available for future grant. Effective January 1, 2019, under the 2013 Plan's "evergreen" provision, the number of shares of our common stock available for issuance was increased by 246,636. As of February 14, 2019, the total authorized shares under the 2013 Plan were 1,496,636 shares of which 521,137 shares were available for future issuance.

At the effective time of the merger with Pulmatrix operating, we assumed Pulmatrix Operating's 2013 Employee, Director and Consultant Equity Incentive Plan (the "Original 2013 Plan") and Pulmatrix Operating's 2003 Employee, Director, and Consultant Stock Plan (the "2003 Plan"), and terminated the Original 2013 Plan as to future awards. The 2003 Plan expired on August 1, 2013; however, awards previously granted and outstanding prior to that date continue to remain in full force and effect according to their respective terms. A total of 9,522 and 39,588 shares of our common stock may be delivered under options outstanding as of December 31, 2018 under the Original 2013 Plan and the 2003 Plan, respectively, however, no additional awards may be granted under the Original 2013 Plan or the 2003 Plan. The 2003 Plan and Original 2013 Plan are collectively referred to as the "Old Pulmatrix Equity Plans."

### **2013 Plan**

In connection with the merger agreement with Pulmatrix Operating, our compensation committee, our Board and stockholders approved the 2013 Plan.

*Eligibility.* The 2013 Plan allows our Company, under the direction of our compensation committee, to make grants of stock options, restricted and unrestricted stock awards and other stock-based awards to employees, consultants and directors who, in the opinion of our compensation committee, are in a position to make a significant contribution to our long-term success. The purpose of these awards is to attract and retain key individuals, further align employee and stockholder interests, and to closely link compensation with Company performance. All employees, directors and consultants of the Company and its affiliates are eligible to participate in the 2013 Plan.

*Shares Available for Issuance.* As of February 14, 2019, the total authorized shares under the 2013 Plan were 1,496,636 shares of which 521,137 shares were available for future issuance. The 2013 Plan contains an "evergreen" provision, which allows for an annual increase in the number of shares of our common stock available for issuance under the plan on the first day of each fiscal year beginning in calendar year 2016. The annual increase in the number of shares shall be equal to: (i) five percent (5%) of the number of shares of our common stock outstanding as of such date; or (ii) an amount determined by our Board.

Generally, shares of common stock subject to awards under the 2013 Plan that lapse, are forfeited or are canceled will be added back to the share reserve available for future awards. However, shares of common stock tendered in payment for an award or shares of common stock withheld for taxes will not be available again for grant.

*Plan Administration.* In accordance with the terms of the 2013 Plan, our Board has authorized our compensation committee to administer the 2013 Plan. The compensation committee may delegate part of its authority and powers under the 2013 Plan to one or more of our directors and/or officers, but only the compensation committee can make awards to participants who are directors or executive officers of the Company. In accordance with the provisions of the 2013 Plan, our compensation committee determines the terms of awards, including:

- which employees, directors and consultants will be granted awards;
- the number of shares subject to each award;
- the vesting provisions of each award;
- the termination or cancellation provisions applicable to awards; and
- all other terms and conditions upon which each award may be granted in accordance with the 2013 Plan.

In addition, our compensation committee may, in its discretion, amend any term or condition of an outstanding award provided (i) such term or condition as amended is permitted by the 2013 Plan, and (ii) any such amendment shall be made only with the consent of the participant to whom such award was made, if the amendment is adverse to the participant; and provided, further, that, without the prior approval of our stockholders, options will not be repriced, replaced or regranted through cancellation or by lowering the exercise price of a previously granted award and will not be exchanged for another type of award or cash.

*Performance Goals.* In order for the Company to have the ability to grant awards under the 2013 Plan that qualify as “performance-based compensation” under Section 162(m) of the Code, the 2013 Plan provides that our compensation committee may require that the vesting of certain awards be conditioned on the satisfaction of performance criteria related to objectives of the Company, an affiliate of the Company or a division or strategic business unit of the Company in which the relevant participant is employed, such as: (i) pre-tax income or after-tax income; (ii) income or earnings including operating income, earnings before or after taxes, interest, depreciation, amortization, and/or extraordinary or special items; (iii) net income excluding amortization of intangible assets, depreciation and impairment of goodwill and intangible assets and/or excluding charges attributable to the adoption of new accounting pronouncements; (iv) earnings or book value per share (basic or diluted); (v) return on assets (gross or net), return on investment, return on capital, return on invested capital or return on equity; (vi) return on revenues; (vii) cash flow, free cash flow, cash flow return on investment (discounted or otherwise), net cash provided by operations, or cash flow in excess of cost of capital; (viii) economic value created; (ix) operating margin or profit margin; (x) stock price or total stockholder return; (xi) income or earnings from continuing operations; (xii) cost targets, reductions and savings, expense management, productivity and efficiencies; (xiii) operational objectives, consisting of one or more objectives based on achieving progress in research and development programs or achieving regulatory milestones related to development and or approval of products; or (xiv) strategic business criteria, consisting of one or more objectives based on meeting specified market penetration or market share of one or more products or customers, geographical business expansion, customer satisfaction, employee satisfaction, human resources management, supervision of litigation, information technology, and goals relating to acquisitions, divestitures, joint ventures and similar transactions. As discussed above, if we determine to make awards under the 2013 Plan subject to the attainment of performance goals relating to any of the foregoing performance criteria, the compensation committee intends that compensation paid under the 2013 Plan will not be subject to the deductibility limitation imposed under Section 162(m) of the Code.

*Stock Options.* Stock options granted under the 2013 Plan may either be incentive stock options, which are intended to satisfy the requirements of Section 422 of the Code, or non-qualified stock options, which are not intended to meet those requirements. Incentive stock options may be granted to employees of the Company and its affiliates that are corporations. Non-qualified stock options may be granted to employees, directors and consultants of the Company and its affiliates. The exercise price of a stock option may not be less than 100% of

the fair market value of our common stock on the date of grant. If an incentive stock option is granted to an individual who owns more than 10% of the combined voting power of all classes of our capital stock, the exercise price may not be less than 110% of the fair market value of our common stock on the date of grant and the term of the incentive stock option may not be longer than five years. Non-qualified stock options may not have a term longer than ten years.

Award agreements for stock options will include rules for exercise of the stock options after termination of service. Stock options may not be exercised unless they are vested, and no stock option may be exercised after the end of the term set forth in the award agreement. Unless otherwise provided in an award agreement, in general, stock options will be exercisable for three months after termination of service for any reason other than death or total and permanent disability, and for twelve (12) months after termination of service on account of death or total and permanent disability.

*Restricted Stock.* Restricted stock is common stock that is subject to restrictions, including a prohibition against transfer and a substantial risk of forfeiture, until the end of a “restricted period” during which the participant must satisfy certain vesting conditions (including, continued service with the Company through the restricted period and/or the achievement of performance goals). If the participant does not satisfy the vesting conditions by the end of the restricted period, the restricted stock is forfeited. During the restricted period, the holder of restricted stock has the rights and privileges of a regular stockholder, except that the restrictions set forth in the applicable award agreement apply. For example, the holder of restricted stock may vote and receive dividends on the restricted shares; but he or she may not sell the shares until the restrictions are lifted.

*Other Stock-Based Awards.* The 2013 Plan also authorizes the grant of other types of stock-based compensation including, but not limited to phantom stock awards, stock appreciation rights and stock unit awards. Our compensation committee may award such stock-based awards subject to such conditions and restrictions as it may determine; provided, however, each stock appreciation right shall have an exercise price which shall not be less than the fair market value of our common stock on the date of grant and shall terminate no more than ten years from the date of grant. These conditions and restrictions may include continued service with our Company through a specified restricted period and/or the achievement of performance goals.

*Stock Dividends and Stock Splits.* If our common stock shall be subdivided or combined into a greater or smaller number of shares or if we issue any shares of common stock as a stock dividend, the number of shares of our common stock deliverable upon exercise of an option issued or upon issuance of an award shall be appropriately increased or decreased proportionately, and appropriate adjustments shall be made in the purchase price per share to reflect such subdivision, combination or stock dividend.

*Corporate Transactions.* Upon a merger, consolidation, sale of all or substantially all of the Company’s assets, or such other corporate transaction event, our Board, may, in its sole discretion, take any one or more of the following actions pursuant to the 2013 Plan, as to some or all of the outstanding awards:

- provide that all outstanding stock options shall be assumed or substituted by the successor corporation;
- upon written notice to a participant provide that the participant’s unexercised options will terminate immediately prior to the consummation of such transaction unless exercised by the participant;
- in the event of a merger pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the merger, make or provide for a cash payment to the participants equal to the difference between the merger price times the number of shares of our common stock subject to such outstanding options, and the aggregate exercise price of all such outstanding options, in exchange for the termination of such options;
- provide that outstanding awards shall be assumed or substituted by the successor corporation, become realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the merger or reorganization event; and

- with respect to stock grants, in lieu of any of the foregoing, the Board or an authorized committee may provide that, upon consummation of the transaction, each outstanding stock grant shall be terminated in exchange for payment of an amount equal to the consideration payable upon consummation of such transaction to a holder of the number of shares of common stock comprising such award (to the extent such stock grant is no longer subject to any forfeiture or repurchase rights then in effect or, at the discretion of the Board or an authorized committee, all forfeiture and repurchase rights being waived upon such transaction).

*Amendment and Termination.* The 2013 Plan may be amended by our stockholders. It may also be amended by our Board, provided that any amendment approved by our Board which is of a scope that requires stockholder approval as required by the NASDAQ Rules, in order to ensure favorable federal income tax treatment for any incentive stock options under Code Section 422, or for any other reason is subject to obtaining such stockholder approval. However, no such action may adversely affect any rights under any outstanding award without the participant's consent.

*Duration of Plan.* The 2013 Plan will expire by its terms ten (10) years from the earlier of the date of its adoption by our Board and its approval by our stockholders.

### ***2003 Plan and Original 2013 Plan***

On August 1, 2003, Pulmatrix Operating adopted the 2003 Plan, which provided for awards of stock options and shares of Pulmatrix Operating common stock to certain employees, directors, and consultants who were selected for participation by the 2003 Plan's administrator. The 2003 Plan expired on August 1, 2013; however, awards previously granted and outstanding prior to that date continued to remain in full force and effect according to their respective terms. As of February 14, 2019, 39,588 shares of our common stock may be issued pursuant to outstanding stock options under the 2003 Plan and no additional awards may be granted under the 2003 Plan.

On August 26, 2013, Pulmatrix Operating adopted the Original 2013 Plan, which provides for awards of stock options, stock grants, and other stock-based awards to certain employees, directors, and consultants who were selected for participation by the Original 2013 Plan's administrator. Immediately prior to the adoption of the 2013 Plan, we terminated the Original 2013 Plan as to future awards. As of February 14, 2019, 9,522 shares of our common stock may be issued pursuant to outstanding stock options under the Original 2013 Plan and no additional awards may be granted under the Original 2013 Plan.

The Old Pulmatrix Equity Plans are administered by our compensation committee, which has been delegated to act on the Board's behalf. The administrator has discretion to, among other things, interpret the Old Pulmatrix Equity Plans and make all rules and determinations necessary to administer the Old Pulmatrix Equity Plans, select those persons eligible to receive awards under the Old Pulmatrix Equity Plans, determine the number of shares of our stock subject to, and the terms and conditions of, awards under the Old Pulmatrix Equity Plans, amend outstanding awards and adopt any sub-plans applicable to residents of a specified jurisdiction in order to comply with or take advantage of such jurisdiction's tax or other applicable laws.

Stock options granted under the Old Pulmatrix Equity Plans could either be "incentive stock options" within the meaning of Section 422 of the Code or "nonqualified stock options." Incentive stock options may not have an exercise price per share of less than 100% (110% in the case of a participant who owns more than 10% of the combined voting power of Pulmatrix or an affiliate (a "10% Stockholder")) of the fair market value of a share of our stock on the date of grant or a term longer than ten years (five years in the case of a 10% Stockholder). The exercise price per share of a nonqualified stock option granted under the Original 2013 Plan may not be less than 100% of the fair market value of a share of our stock on the date of grant, unless the option complies with Section 409A of the Code or is granted to a consultant to whom Section 409A of the Code does not apply. A stock grant awarded under the Old Pulmatrix Equity Plans will state the purchase price per share, if any, and may include the right for us to restrict or reacquire the shares covered by the award, subject to the terms and

conditions of the applicable award agreement. Other stock-based awards permitted under the Original 2013 Plan include securities convertible into our stock, stock appreciation rights, phantom stock awards and stock units, and are intended to be exempt from or comply with Section 409A of the Code.

Participants in the Old Pulmatrix Equity Plans do not have any voting or other rights as a stockholder of Pulmatrix until the exercise of the award, payment of the aggregate exercise or purchase price, if any, and registration of the acquired shares in the participant's name. Except as otherwise permitted by the administrator, awards granted under the Old Pulmatrix Equity Plans are transferable only by will or through the laws of descent and distribution, and are exercisable during the participant's lifetime only by the participant (or his or her legal representative).

Except as otherwise provided in an award agreement, if a participant's employment with us or an affiliate is terminated for any reason, all unvested stock options granted under the Old Pulmatrix Equity Plans will expire and be forfeited and all stock grants and stock-based awards granted under the Old Pulmatrix Equity Plans that have not been accepted by the participant, and the purchase price, if any, not paid, shall terminate. If the participant's employment with us or an affiliate is terminated for any reason other than by us for cause or due to the participant's death or total and permanent disability, then vested stock options granted under the Old Pulmatrix Equity Plans remain exercisable for the duration of the term specified in the award agreement, which cannot exceed three months in the case of an incentive stock option, and all stock grants under the Old Pulmatrix Equity Plans that remain subject to forfeiture or our repurchase rights shall be cancelled or repurchased, as applicable. If the termination of employment is due to the participant's death or total and permanent disability (or the participant dies or becomes disabled within three months of the participant's termination of employment other than for cause), then outstanding, vested stock options granted under the Old Pulmatrix Equity Plans may be exercised for up to one year following the participant's termination date and the forfeiture provisions of, or our repurchase rights in, outstanding stock grants under the Old Pulmatrix Equity Plans shall lapse, provided that, to the extent such forfeiture provisions or repurchase rights otherwise lapse over time, such provisions or rights shall lapse only as to the pro rata number of shares of stock subject to such provisions or rights, based on the number of days in the relevant time period prior to the date of death or total and permanent disability. If a participant's employment with us or an affiliate is terminated for cause, or a participant subsequently commits an act constituting cause, then all outstanding, unexercised stock options granted under the Old Pulmatrix Equity Plans will be immediately forfeited and any shares of stock subject to any stock grant under the Old Pulmatrix Equity Plans, whether or not then subject to forfeiture or right of repurchase, shall be immediately subject to repurchase by us, with the repurchase price determined as provided in the 2003 Plan or the Original 2013 Plan, as applicable.

Pursuant to the Old Pulmatrix Equity Plans, all unexercised stock options and any stock grants or stock-based awards that have not been accepted by the participant, to the extent required by the applicable award agreement, will terminate immediately prior to our dissolution or liquidation. Unless otherwise determined by the administrator or specifically provided in the applicable award agreement, all outstanding stock-based awards shall immediately terminate upon our dissolution or liquidation.

In the event of a "Corporate Transaction" (as defined in the Old Pulmatrix Equity Plans), all outstanding stock options shall be (i) substituted, on an equitable basis, for stock options in the successor or acquiring entity, (ii) terminated, if not exercised by the participant upon receiving advance written notice that such options, to the extent exercisable or made exercisable at the discretion of the administrator, must be exercised by a specific date or (iii) terminated in exchange for payment of an amount equal to the consideration payable upon consummation of the Corporate Transaction for the number of shares covered by the stock options then exercisable or made exercisable at the discretion of the administrator, less the stock options' aggregate exercise price. In the event of a Corporate Transaction, all outstanding stock grants shall either be (x) substituted for stock grants, with the same terms and conditions, but in securities of the successor or acquiring entity or (y) terminated in exchange for a payment of an amount equal to the consideration payable upon consummation of the Corporate Transaction for the number of shares covered by the stock grant that are no longer subject to any forfeiture or repurchase rights,

whether by their terms or that were waived in the administrator's discretion. In the event of a Corporate Transaction, the administrator or the Board of the successor or acquiring entity shall determine the specific adjustments to be made to any outstanding stock-based awards, which determination shall be conclusive.

The administrator or our stockholders may amend the Old Pulmatrix Equity Plans, provided that no such amendment shall adversely affect the rights of any participant without the participant's consent.

## STOCK OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of our common stock as of February 14, 2019 by (i) each person known to us to beneficially own five percent (5%) or more of our common stock, (ii) each director and Named Executive Officer and (iii) all of our directors and executive officers as a group. The persons named in the table have sole voting and investment power with respect to all shares of common stock owned by them and have an address of c/o Pulmatrix Inc., 99 Hayden Avenue, Suite 390, Lexington, MA 02421, unless otherwise noted. Percentage of ownership is based on 8,027,895 shares of common stock issued and outstanding as of February 14, 2019.

Beneficial ownership is determined in accordance with the rules of the SEC. For the purpose of calculating the number of shares beneficially owned by a stockholder and the percentage ownership of that stockholder, shares of common stock subject to options or warrants that are currently exercisable or exercisable within sixty (60) days of February 14, 2019 by that stockholder are deemed outstanding.

<u>Name</u>	<u>Number of Shares Beneficially Owned (1)(2)</u>	<u>Percentage of Shares Outstanding (1)(2)</u>	<u>Beneficially Owned as a result of stock ownership (1)(2)</u>	<u>Beneficially Owned as a result of stock option ownership (1)(2)</u>	<u>Beneficially Owned as a result of warrant ownership (1)(2)</u>
<b><i>Directors and Officers</i></b>					
Robert W. Clarke, Ph.D. ....	200,065	2.43%	2,320	197,745	—
William E. Duke, Jr. ....	76,654	*	—	76,654	—
Steven Gillis, Ph.D. ....	467,011	5.73%	343,646	8,365	115,000
Michael J. Higgins (3) ....	10,129	*	—	10,129	—
Mark Iwicki ....	74,848	*	30,700	13,448	30,700
Terrance G. McGuire (4) ....	641,392	7.87%	518,025	8,365	115,002
Amit D. Munshi ....	6,087	*	—	6,087	—
Teofilo Raad ....	49,796	*	—	49,796	—
James Roach, M.D. ....	49,460	*	—	49,460	—
Matthew L. Sherman, M.D. ....	10,453	*	2,000	6,453	2,000
<b>All directors and executive officers as a group of ten persons</b>					
	1,585,895	18.19%	896,691	426,502	262,702
<b><i>Five Percent (5%) Stockholders</i></b>					
Polaris (5) ....	633,027	7.78%	518,025	—	115,002
ARCH Venture Fund ....	458,646	5.63%	343,646	—	115,000

\* Less than 1%.

- (1) Beneficial ownership as reported in the above table has been determined in accordance with Rule 13d-3 promulgated under the Exchange Act and is not necessarily indicative of beneficial ownership for any other purpose. The number of shares of common stock shown as beneficially owned includes shares of common stock issuable upon the exercise of stock options that will become exercisable within sixty (60) days of February 14, 2019.
- (2) Exercisable as of February 14, 2019 or will become exercisable within 60 days after such date.

- (3) Mr. Higgins is affiliated with the investment manager of the PVP IV Funds and PVP V Funds (each defined below) but does not have any voting or dispositive power with respect to the shares owned by the PVP IV Funds and PVP V Funds referenced in footnote (4) below.
- (4) Consists of 518,025 shares of our common stock of which (i) 155,668 shares are held by Polaris Venture Partners IV, L.P. (“PVP IV”), 2,918 shares are held by Polaris Venture Partners Entrepreneurs’ Fund IV, L.P. (“PVPEF IV” and, together with PVP IV, the “PVP IV Funds”), 346,819 shares are held by Polaris Venture Partners V, L.P. (“PVP V”), 6,773 shares are held by Polaris Venture Partners Entrepreneurs’ Fund V, L.P. (“PVPEF V”), 2,388 shares are held by Polaris Venture Partners Founders’ Fund V, L.P. (“PVPEF V”) and 3,459 shares are held by Polaris Venture Partners Special Founders’ Fund V, L.P. (“PVPSFF V” and, together with PVP V, PVPEF V and PVPEF V, the “PVP V Funds”) and (ii) 115,002 shares of our common stock issuable upon the exercise of warrants within 60 days of February 14, 2019. Of such 115,002 shares, 34,556 are held by PVP IV, 648 are held by PVPEF IV, 76,999 are held by PVP V, 1,501 are held by PVPEF V, 528 are held by PVPEF V and 770 are held by PVPSFF V. Excluded are 116,965 shares issuable upon the exercise of warrants (of such 116,965 shares 35,145 are held by PVP IV, 659 are held by PVPEF IV, 78,313 are held by PVP V, 1,527 are held by PVPEF V, 537 are held by PVPEF V and 784 are held by PVPSFF V), which shares were excluded because exercisability of such warrants is conditioned upon the occurrence of events outside the holder’s control and not deemed to be or become exercisable within sixty (60) days of February 14, 2019. Polaris Venture Management Co. IV, L.L.C. (“PVM IV”) is the general partner of the PVP IV Funds and Polaris Venture Management Co. V, L.L.C. (“PVM V”) is the general partner of the PVP V Funds. Each of Mr. McGuire and Jonathan Flint are the managing members of each of PVM IV and PVM V and may be deemed to have shared voting and dispositive power with respect to the shares held by each of the PVP IV Funds and the PVP V Funds. Each of PVM IV and Messrs. McGuire and Flint disclaim beneficial ownership of the shares held by each of the PVP IV Funds and each of PVM V and Messrs. McGuire and Flint disclaim beneficial ownership of the shares held by each of the PVM V Funds. This report shall not be deemed an admission that any of PVM IV, PVM V or Messrs. McGuire or Flint is the beneficial owner of any of the shares owned by the PVP IV Funds and PVP V Funds for any purpose, except to the extent of their respective pecuniary interests therein.
- (4) The business address of Polaris is One Marina Park Dr., Boston, Massachusetts 02210.
- (5) Consists of the shares held by the PVP IV Funds and PVP V Funds and described in footnote (3) above.
- (6) Includes the following shares which are also reported on this table as being beneficially owned by ARCH Venture Fund: (i) 343,646 shares of Pulmatrix common stock and (ii) 115,000 shares of Pulmatrix common stock issuable upon the exercise of warrants within 60 days of February 14, 2019. Excluded are 79,751 shares issuable upon the exercise of warrants, which shares were excluded because exercisability of such warrants is conditioned upon the occurrence of events outside the holder’s control. The sole general partner of ARCH Venture Fund is ARCH Venture Partners VII, L.P. (“ARCH Partners VII”). The sole general partner of ARCH Partners VII is ARCH Venture Partners VII, LLC (“ARCH VII LLC”). Each of the Managing Directors of ARCH VII LLC, Robert T. Nelsen, Keith Crandell and Clinton Bybee, may be deemed to have voting and dispositive power over the shares and may be deemed to beneficially own shares held by ARCH Venture Fund. Dr. Gillis owns an interest in ARCH Venture Fund but does not have voting or investment control over the shares held by ARCH Venture Fund. Each of Robert T. Nelsen, Keith Crandell, Clinton Bybee and Dr. Gillis disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein, and this disclosure shall not be deemed an admission that Robert T. Nelsen, Keith Crandell, Clinton Bybee or Dr. Gillis are the beneficial owners of such securities for purposes of Section 13(d) of the Exchange Act or any other purpose.
- (7) The business address of ARCH Venture Fund is 8725 W. Higgins Rd., Suite 290, Chicago, IL 60631.

## **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.**

### **General**

Transactions with related persons are governed by our Code of Corporate Conduct and Ethics and Whistleblower Policy, which applies to all of our associates, as well as each of our directors and certain persons performing services for us. This code covers a wide range of potential activities, including, among others, conflicts of interest, self-dealing and related party transactions. Waiver of the policies set forth in this code will only be permitted when circumstances warrant. Such waivers for directors and executive officers, or that provide a benefit to a director or executive officer, may be made only by our Board, as a whole, or the Audit Committee and must be promptly disclosed as required by applicable law or regulation. Absent such a review and approval process in conformity with the applicable guidelines relating to the particular transaction under consideration, such arrangements are not permitted. All related party transactions for which disclosure is required to be provided herein were approved in accordance with our Code of Corporate Conduct and Ethics and Whistleblower Policy.

### **Certain Relationships**

Three of our directors are employed by venture capital investors that beneficially own the majority of our Company's common stock through a series of private placements, rounds of venture capital financing and a recapitalization since its formation, Polaris and ARCH Venture Fund. Terrance G. McGuire is a General Partner of and owns an interest in Polaris Venture Management Co. IV, L.L.C., which is the sole general partner of Polaris Venture Partners IV, L.P., and Polaris Venture Partners Entrepreneurs' Fund IV, L.P. and Polaris Venture Management Co. V, L.L.C., which is the sole general partner of Polaris Venture Partners V, L.P., Polaris Venture Partners Founders' Fund V, L.P., Polaris Venture Partners Special Founders' Fund V, L.P. and Polaris Venture Partners Entrepreneurs' Fund V, L.P. In addition, Michael J. Higgins is an Entrepreneur-in-Residence at Polaris. As of February 14, 2019, Polaris beneficially owns approximately 7.78% of our Company's outstanding common stock. Dr. Steven Gillis is a Managing Director of and owns an interest in ARCH Venture Fund, a venture capital firm. As of February 14, 2019, ARCH Venture Fund beneficially owns approximately 5.63 % of our Company's outstanding common stock.

### **Transactions with Related Persons**

On April 3, 2018, we completed an underwritten public offering for a total of (i) 1,566,000 common units, with each common unit being comprised of one share of our common stock, one Series A Warrant to purchase one share of common stock and one Series B Warrant to purchase one share of common stock, and (ii) 784,000 pre-funded units, with each pre-funded unit being comprised of one Pre-funded Warrant to purchase one share of common stock, one Series A Warrant and one Series B Warrant. The offering price to the public was \$6.50 per common unit and \$6.40 per pre-funded unit. The Series A Warrants included in the common units and the pre-funded units were immediately exercisable at a price of \$6.50 per share of common stock, subject to adjustment in certain circumstances, and expired six months from the date of issuance. The Series B Warrants included in the common units and the pre-funded units are immediately exercisable at a price of \$7.50 per share of common stock, subject to adjustment in certain circumstances, and will expire five years from the date of issuance. The pre-funded units were issued and sold to purchasers whose purchase of units in the offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of the offering, if the purchaser so chooses in lieu of common units that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock (or at the election of the purchaser, 9.99%). Each Pre-Funded Warrant contained in a pre-funded unit is exercisable for one share of our common stock at an exercise price of \$0.10 per share. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full.



The purchasers in the offering included the following related persons:

(1) Mark Iwicki, the chairman of our board of directors, purchased 30,700 units, for a purchase price of \$199,550.

(2) PVP V, PVPEF V, PVPFF V, PVPSFF V, PVP IV and PVPEF IV purchased 76,999, 1,501, 528, 770, 34,556 and 648 common units, respectively, for an aggregate purchase price of \$747,500. At the time of the underwritten public offering, Polaris funds beneficial owned more than 5% of our common stock. Mr. McGuire, our director, is one of the managing members of each of PVM IV and PVM V.

(3) ARCH Venture Fund VII purchased 115,000 common units for an aggregate purchase price of \$747,500. At the time of the underwritten public offering, ARCH Venture Fund VII beneficial owned more than 5% of our common stock. Dr. Gillis, our director, owns an interest in ARCH Venture Fund VII. Partners Entrepreneurs' Fund V, L.P. In addition, Michael J. Higgins is an Entrepreneur-in-Residence at Polaris. As of February 14, 2019, Polaris beneficially owns approximately 7.78% of our Company's outstanding common stock. Dr. Steven Gillis is a Managing Director of and owns an interest in ARCH Venture Fund, a venture capital firm. As of February 14, 2019, ARCH Venture Fund beneficially owns approximately 5.63 % of our Company's outstanding common stock.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.**

**Fees to Independent Registered Public Accounting Firm**

The following is a summary of the fees billed to us by Marcum LLP for professional services rendered in the years ended December 31, 2018 and 2017:

	<u>2018</u>	<u>2017</u>
Audit Fees .....	\$ 185,018	\$155,778
Audit-Related Fees .....	75,576	61,850
Tax Fees .....	—	—
All Other Fees .....	—	—
Total Fees .....	<u>\$ 260,594</u>	<u>\$217,628</u>

*Audit Fees.* This category includes the audit of our annual consolidated financial statements, reviews of our financial statements included in our Form 10-Qs and services that are normally provided by our independent registered public accounting firm in connection with its engagements for those years. This category also includes advice on audit and accounting matters that arose during, or as a result of, the audit or the review of our interim financial statements.

*Audit-Related Fees.* This category consists of assurance and related services by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and are not reported above under “Audit Fees.” The services for the fees disclosed under this category include consents regarding equity issuances.

*Tax Fees.* This category typically consists of professional services rendered by our independent registered public accounting firm for tax compliance and tax advice.

*All Other Fees.* This category includes aggregate fees billed in each of the last two fiscal years for products and services provided by the Marcum LLP, other than the services reported in the categories above.

### **Pre-Approval Policies and Procedures**

Under the Audit Committee's pre-approval policies and procedures, the Audit Committee is required to pre-approve the audit and non-audit services performed by our independent registered public accounting firm. On an annual basis, the Audit Committee pre-approves a list of services that may be provided by the independent registered public accounting firm without obtaining specific pre-approval from the Audit Committee. In addition, the Audit Committee sets pre-approved fee levels for each of the listed services. Any type of service that is not included on the list of pre-approved services must be specifically approved by the Audit Committee or its designee. Any proposed service that is included on the list of pre-approved services but will cause the pre-approved fee level to be exceeded will also require specific pre-approval by the Audit Committee or its designee.

The Audit Committee has delegated pre-approval authority to the Audit Committee chairman and any pre-approved actions by the Audit Committee chairman as designee are reported to the Audit Committee for approval at its next scheduled meeting.

All services rendered by Marcum LLP in 2018 were pre-approved by the Audit Committee.

**PULMATRIX, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b><u>Page</u></b>
Report of Independent Registered Public Accounting Firm .....	F-2
Consolidated Balance Sheets .....	F-3
Consolidated Statements of Operations .....	F-4
Consolidated Statements of Stockholders' Equity .....	F-5
Consolidated Statements of Cash Flows .....	F-6
Notes to Consolidated Financial Statements .....	F-7

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors  
and Shareholders of Pulmatrix, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pulmatrix, Inc. and Subsidiary (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders’ equity and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

### Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company continues to have negative cash flow from its operations, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

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

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

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

/s/ Marcum LLP

Marcum LLP

We have served as the Company’s auditor since 2015.

New York, NY  
February 19, 2019

**PULMATRIX, INC.**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share data)

	December 31,	
	2018	2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$ 2,563	\$ 3,550
Prepaid expenses and other current assets .....	717	696
Total current assets .....	3,280	4,246
Property and equipment, net .....	394	614
Long-term restricted cash .....	204	204
Goodwill .....	10,845	10,914
Total assets .....	\$ 14,723	\$ 15,978
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Loan Payable, net of debt discount and issuance costs .....	\$ —	\$ 3,221
Accounts payable .....	1,183	457
Accrued expenses .....	1,696	2,162
Total current liabilities .....	2,879	5,840
Derivative liability .....	—	1
Total liabilities .....	2,879	5,841
Stockholders' Equity:		
Common stock, \$0.0001 par value — 200,000,000 and 100,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 4,932,723 and 2,104,750 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively .....	—	—
Additional paid-in capital .....	206,409	184,139
Accumulated deficit .....	(194,565)	(174,002)
Total stockholders' equity .....	11,844	10,137
Total liabilities and stockholders' equity .....	\$ 14,723	\$ 15,978

*See accompanying notes to consolidated financial statements.*

**PULMATRIX, INC.**  
**Consolidated Statements of Operations**  
(in thousands, except share and per share data)

	<u>Years ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Revenues .....	\$ 153	\$ 335
Operating expenses		
Research and development .....	12,966	10,243
General and administrative .....	7,518	7,567
Total operating expenses .....	<u>20,484</u>	<u>17,810</u>
Loss from operations .....	(20,331)	(17,475)
Other (expense)/income		
Interest expense .....	(186)	(643)
Impairment of Goodwill .....	(69)	—
Fair value adjustment of derivative liability .....	1	34
Other income, net .....	22	28
Total other (expense)/income .....	<u>(232)</u>	<u>(581)</u>
Net loss .....	<u>\$ (20,563)</u>	<u>\$ (18,056)</u>
Net loss per share attributable to common stockholders, basic and diluted .....	<u>\$ (4.98)</u>	<u>\$ (9.32)</u>
Weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders .....	<u>4,126,393</u>	<u>1,937,161</u>

*See accompanying notes to consolidated financial statements.*

**PULMATRIX, INC.**  
**Consolidated Statements of**  
**Stockholders' Equity**  
(in thousands, except share data and per share data)

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
Balance — January 1, 2017 . . . . .	1,485,053	\$ —	\$164,707	\$(155,946)	\$ 8,761
Issuance of common stock, net of issuance costs . . . . .	605,336	—	16,310	—	16,310
Exercise of common stock options . . . . .	13,843	—	304	—	304
Vesting of restricted stock units . . . . .	518	—	—	—	—
Stock-based compensation . . . . .	—	—	2,818	—	2,818
Net loss . . . . .	—	—	—	(18,056)	(18,056)
Balance — December 31, 2017 . . . . .	<u>2,104,750</u>	<u>\$ —</u>	<u>\$184,139</u>	<u>\$(174,002)</u>	<u>\$ 10,137</u>
Issuance of common stock, net of issuance costs . . . . .	2,827,973	—	19,297	—	19,297
Stock-based compensation . . . . .	—	—	2,973	—	2,973
Net loss . . . . .	—	—	—	(20,563)	(20,563)
Balance — December 31, 2018 . . . . .	<u><u>4,932,723</u></u>	<u><u>\$ —</u></u>	<u><u>\$206,409</u></u>	<u><u>\$(194,565)</u></u>	<u><u>\$ 11,844</u></u>

*See accompanying notes to consolidated financial statements.*

**PULMATRIX, INC.**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Year Ended December 31,	
	2018	2017
<b>Cash flows from operating activities:</b>		
Net loss .....	\$( 20,563)	\$(18,056)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization .....	231	246
Stock-based compensation .....	2,973	2,818
Impairment of Goodwill .....	69	—
Non-cash rent expense .....	—	21
Non-cash interest expense .....	35	171
Non-cash debt issuance expense .....	3	12
Fair value adjustment on derivative liability .....	(1)	(34)
Loss on disposal of property and equipment .....	8	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets .....	(21)	(119)
Accounts payable .....	726	(290)
Accrued expenses .....	(221)	754
Net cash used in operating activities .....	(16,761)	(14,477)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment .....	(19)	(74)
Net cash used in investing activities .....	(19)	(74)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock and warrants, net .....	19,297	16,310
Proceeds from exercise of stock options .....	—	304
Principal payments term loan .....	(3,259)	(2,695)
End of term loan payment .....	(245)	—
Net cash provided by financing activities .....	15,793	13,919
<b>Net decrease in cash and cash equivalents .....</b>	<b>(987)</b>	<b>(632)</b>
<b>Cash and cash equivalents — beginning of period .....</b>	<b>3,550</b>	<b>4,182</b>
<b>Cash and cash equivalents — end of period .....</b>	<b>\$ 2,563</b>	<b>\$ 3,550</b>
<b>Supplemental disclosures of cash flow information</b>		
Cash paid for Interest .....	\$ 131	\$ 472

*See accompanying notes to consolidated financial statements*



**PULMATRIX, INC.**  
**Notes to Consolidated Financial Statements**  
**(in thousands, except share and per share data)**

**1. Organization**

Pulmatrix, Inc. (the “Company”) was incorporated in 2013 as a Nevada corporation and converted to a Delaware corporation in September 2013. On June 15, 2015, the Company completed a merger with Pulmatrix Operating Company, changed its name from Ruthigen, Inc. to “Pulmatrix, Inc.” and relocated its corporate headquarters to Lexington, Massachusetts. The Company is a clinical stage biotechnological company and is focused on the development of novel inhaled therapeutic products intended to prevent and treat respiratory diseases and infections.

*Reverse Stock Split*

On February 3, 2019, the Board approved a 1-for-10 reverse stock split of our issued and outstanding shares of common stock (the “Reverse Stock Split”) and the Company’s common stock began trading on a split-adjusted basis when the market opened on February 6, 2019. With the Reverse Stock Split, every 10 shares of the Company’s issued and outstanding common stock were automatically converted into one share of common stock, without any change in the par value per share. Any fraction of a share of common stock that would otherwise have resulted from the Reverse Stock Split will be rounded up to the nearest whole share. Accordingly, all common share and per share data are retrospectively restated to give effect of the split for all periods presented herein.

*Liquidity, Going Concerns and Management Plans*

At December 31, 2018, the Company had unrestricted cash of \$2.6 million and working capital of \$0.4 million. The Company had incurred recurring losses and as of December 31, 2018 had an accumulated deficit of \$194.6 million. During the year ended December 31, 2018, the Company had used approximately \$16.8 million in its operating activities. The Company has primarily financed operations to date through the sale of equity securities and a term loan. The Company will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. These conditions raise substantial doubt about the Company’s ability to continue as a going concern over the next twelve months from the date of issuance of this Annual Report on Form 10-K and meet its obligations.

During the year ended December 31, 2018, the Company raised an aggregate of \$19.3 million in net proceeds through the sale of its common stock (note 8). Subsequent to December 31, 2018, the Company further raised an aggregate of \$3.7 million in gross proceeds through the sale of its common stock (note 8). The accompanying financial statements have been prepared under the assumption the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements as of December 31, 2018, do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company’s ability to continue as a going concern over the next twelve months from the date of issuance of this Annual Report on Form 10-K.

The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company raises additional funds by issuing equity securities, the Company’s stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company’s ability to conduct business. If unable to raise additional capital when required or on acceptable terms, the Company may have to (i) delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or

(iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. The Company's ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing and, ultimately, to generate revenue. There will be continued doubt about the Company's ability to continue as a going concern if the Company is unable to do so.

## **2. Significant Accounting Policies**

### **Basis of Presentation**

#### **Principles of Consolidation**

The consolidated financial statements represent the consolidation of the accounts of the Company and its subsidiary in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP"). All intercompany accounts and transactions have been eliminated in consolidation.

#### **Recent Accounting Standards**

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-13, Fair Value Measurement. ASU 2018-13 modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The amendments in ASU 2018-13 will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU No. 2018-13 and delay adoption of the additional disclosures until their effective date. The Company has not yet evaluated the impact of adoption of this ASU on its consolidated financial statements disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. Subtopic 505-50, Equity — Equity-Based Payments to Non-Employees, addresses aspects of the accounting for nonemployee share based compensation. The amendments are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company is currently evaluating the potential impact of adopting this guidance on its consolidated financial statements.

In March 2018, the FASB issued ASU No. 2018-05, "*Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*", ("ASU 2018-05") to add various SEC paragraphs pursuant to the issuance of SEC Staff Accounting Bulletin No. 118 ("SAB 118"), to ASC 740 "Income Taxes". SAB 118 was issued by the SEC in December 2017 to provide immediate guidance for accounting implications of U.S. tax reform under the "*Tax Cuts and Jobs Act*" (the "Tax Act"), which became effective for the Company on January 1, 2018. The Company has adopted ASU 2018-05 and adoption of this ASU has no significant impact on its consolidated financial statements.

In February 2018, the FASB issued ASU No. 2018-02, "*Income Statement — Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*" ("ASU 2018-02"), which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Act and requires certain disclosures about stranded tax effects. ASU 2018-02 is effective for the Company beginning December 1, 2019 (with early adoption permitted) and shall be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the corporate income tax rate in the Tax Act is recognized. The Company is currently evaluating the potential impact of adopting this guidance on its consolidated financial statements.

In July 2017, FASB issued ASU No. 2017-11, Earnings per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). ASU 2017-11 consists of two parts. The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The amendments in Part II of this Update do not require any transition guidance because those amendments do not have an accounting effect. The Company is in the process of evaluating this ASU and adoption of this ASU is not expected to have a material impact on its consolidated financial position and results of operations.

In February 2016, the FASB issued authoritative guidance under ASU 2016-02, Leases (Topic 842). ASU 2016-02 provides new comprehensive lease accounting guidance that supersedes existing lease guidance. Upon adoption of ASU 2016-02, the Company will be required to recognize most leases on its balance sheet at the beginning of the earliest comparative period presented with a corresponding adjustment to stockholders' equity. ASU 2016-02 requires the Company to capitalize most current operating lease obligations as right-of-use assets with a corresponding liability based on the present value of future operating lease obligations. Criteria for distinguishing leases between finance and operating are substantially similar to criteria for distinguishing between capital leases and operating leases in existing lease guidance. Lease agreements that are 12 months or less are permitted to be excluded from the balance sheet. Topic 842 includes a number of optional practical expedients that the Company may elect to apply. Expanded disclosures with additional qualitative and quantitative information will also be required. The adoption will include updates as provided under ASU 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842 and ASU 2018-10, Codification Improvements to Topic 842, Leases. The Company is required to adopt this new guidance in the first quarter of fiscal 2020. The Company is currently evaluating the potential impact of adoption of this standard on its consolidated financial statements and the additional transition method under ASU 2018-11, which allows the Company to recognize Topic 842's cumulative effect within retained earnings in the period of adoption.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements in ASC Topic 605, "Revenue Recognition" and some cost guidance included in ASC Subtopic 605-35, "Revenue Recognition - Construction-Type and Production-Type Contracts." The core principle of ASU 2014-09 is that revenue is recognized when the transfer of control of goods or services to customers occurs in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. ASU 2014-09 requires the disclosure of sufficient information to enable readers of the Company's financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. ASU 2014-09

also requires disclosure of information regarding significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 provides two methods of retrospective application. The first method would require the Company to apply ASU 2014-09 to each prior reporting period presented. The second method would require the Company to retrospectively apply ASU 2014-09 with the cumulative effect recognized at the date of initial application. Since the Company is an emerging growth company and elected to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act, this ASU 2014-09 will be effective for the Company beginning in fiscal 2019 as a result of ASU 2015-14, “*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*,” which was issued by the FASB in August 2015 and extended the original effective date by one year. The Company has evaluated this ASU and does not expect it to have significant impact on its consolidated financial statements in future reporting periods.

### **Use of Estimates**

In preparing consolidated financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results may differ from these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include valuing equity securities in share-based payments, estimating the useful lives of depreciable and amortizable assets, valuation allowance against deferred tax assets, goodwill impairment, and estimating the fair value of long-lived assets to assess whether impairment charges may apply.

### **Concentrations of Credit Risk**

Cash is a financial instrument that potentially subjects the Company to concentrations of credit risk. For all periods presented, substantially all of the Company’s cash was deposited in an account at a single financial institution that management believes is creditworthy. The Company is exposed to credit risk in the event of default by these financial institutions for amounts in excess of the Federal Deposit Insurance Corporation insured limits. The Company maintains its cash at a high-quality financial institution and has not incurred any losses to date.

### **Fair Value of Financial Instruments**

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurements and Disclosures* (“ASC 820”), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company’s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 — Valuations based on quoted prices for similar assets or liabilities in markets that are not active, or for which all significant inputs are observable, either directly or indirectly.

Level 3 — Valuations that require inputs that reflect the Company’s own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The fair value of the Company’s convertible notes was determined using current applicable rates for similar instruments with similar conversion and settlement features as of the balance sheet dates. The carrying value of the Company’s convertible notes payable approximated their fair value considering their short-term maturity dates and that the stated interest rate was near current market rates for instruments with similar conversion and settlement features. The fair value of the Company’s convertible notes and warrant liabilities were determined using “Level 3” inputs.

### **Common Stock Warrants**

The Company classifies as equity any warrants that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any warrants that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company’s control), (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement) or (iii) that contain reset provisions that do not qualify for the scope exception. The Company assesses classification of its common stock warrants and other freestanding derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required. The Company’s freestanding derivatives consist of warrants to purchase common stock that were issued in connection with its (i) convertible preferred stock, (ii) private placement, (iii) term loan, (iv) consulting services and (v) underwriting and representative services. The Company evaluated these warrants to assess their proper classification and determined that the common stock warrants meet the criteria for equity or liability classification in the balance sheet. The warrants classified as liability are initially recorded at fair value, with gains and losses arising from changes in fair value recognized in other income (expense) in the statements of operations at each period end while such instruments remain outstanding.

### **Cash and Cash Equivalents**

Cash and cash equivalents are held in U.S. banks and consist of liquid investments and money market funds with a maturity from date of purchase of 90 days or less that are readily convertible into cash.

### **Restricted Cash**

Restricted cash represents cash held in a depository account at a financial institution to collateralize a conditional stand-by letter of credit related to the Company’s Lexington, Massachusetts, office and laboratory facility lease agreement. Restricted cash is reported as non-current unless the restrictions are expected to be released in the next 12 months.

At December 31, 2018 and 2017 the Company had a \$153 letter of credit as a security deposit on its leased office and laboratory facility that carries an automatic annual extension until February 21, 2021 at which time it will expire. The letter of credit is secured by a deposit in a money market account, as well as \$51 deposited in a money market account as security for a credit card.

## Property and Equipment, net

Property and equipment are recorded at cost less accumulated depreciation and amortization. Property and equipment are depreciated over their estimated useful lives using the straight-line method. Leasehold improvements are amortized over the shorter of the estimated remaining lease term or the useful lives of the related assets. Repairs and maintenance costs are expensed as incurred, whereas major improvements are capitalized as additions to property and equipment.

Depreciation is provided over the following estimated useful lives:

<u>Asset Description</u>	<u>Estimated Useful Lives</u>
Laboratory equipment	5 years
Computer equipment	3 years
Office furniture and equipment	5 years
Leasehold improvements	Shorter of estimated useful life or remaining lease term

Upon retirement or sale, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations.

## Deferred Rent

Deferred rent, included within accrued expenses in the consolidated balance sheet, consists of the difference between cash payments and the recognition of rent expense on a straight-line basis for the facilities the Company occupies. The Company's lease for its Lexington, Massachusetts, facility provides for a rent-free period as well as fixed increases in minimum annual rental payments. The total amount of rental payments due over the lease term is being charged to rent expense ratably over the life of the lease.

## Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with ASC 360. Long-lived assets, other than goodwill, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or any other significant adverse change that would indicate that the carrying amount of an asset or group of assets may not be recoverable. Application of alternative assumptions, such as changes in estimate of future cash flows, could produce significantly different results. Because of the significance of the judgments and estimation processes, it is likely that materially different amounts could be recorded if we used different assumptions or if the underlying circumstances were to change.

For long-lived assets used in operations, impairment losses are only recorded if the asset's carrying amount is not recoverable through its undiscounted, probability-weighted future cash flows. The Company measures the impairment loss based on the difference between the carrying amount and estimated fair value.

## Revenue Recognition

The Company's principal sources of revenue during the reporting period were income from reimbursement of clinical study costs. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, and collectability of the resulting receivable is reasonably assured.

## *Milestones*

Contingent consideration from research and development activities that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone

is substantive. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

#### *Service revenues*

The Company recognized upfront non-refundable fees ratably over the estimated non-contingent portion of the arrangement when the research and development activities related to the initial clinical studies were performed as there is no other discernible pattern of revenue recognition. At the end of each reporting period, the Company reviews and adjusts, if necessary, the amounts recognized in revenue for any change in the estimated non-contingent period over which the research and development activities were performed.

#### **Research and Development Costs**

Research and development costs are expensed as incurred and include: salaries, benefits, bonus, stock-based compensation, license fees, milestone payments due under license agreements, costs paid to third-party contractors to perform research, conduct clinical trials, and develop drug materials and delivery devices; and associated overhead and facilities costs. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors, clinical research organizations ("CROs") and clinical manufacturing organizations ("CMOs"). Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of fees and costs associated with the contract that were rendered during the period.

#### **Stock-Based Compensation**

The Company recognizes all employee share-based compensation as a cost in the consolidated financial statements. Equity-classified awards principally related to stock options and restricted stock units ("RSUs") which are measured at the grant date fair value of the award. The Company determines grant date fair value of stock option awards using the Black-Scholes option-pricing model. The fair value of restricted stock awards are determined using the closing price of the Company's common stock on the grant date. For service based vesting grants, expense is recognized over the requisite service period based on the number of options or shares expected to ultimately vest. For performance-based vesting grants, expense is recognized over the requisite period until the performance obligation is met, assuming that it is probable. No expense is recognized for performance-based grants until it is probable the vesting criteria will be satisfied. Forfeitures are estimated at the date of grant and revised when actual or expected forfeiture activity differs from original estimates.

Stock-based payments to non-employees are re-measured at each reporting date and recognized as services are rendered, generally on a straight-line basis. The Company believes that the fair values of these awards are more reliably measurable than the fair values of the services rendered.

#### **Basic and Diluted Net Loss Per Share**

Basic net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding during the period. Diluted net loss per share is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. In periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share because common stock equivalents are excluded as their inclusion would be anti-dilutive.

## Income Taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, *Income Taxes* (“ASC 740”), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances.

On December 22, 2017, the Tax Cuts and Jobs Act (“the Act”) was enacted in the United States. The Act reduces the U.S. federal corporate tax rate from 34% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. At December 31, 2017, we have completed our accounting for the tax effects of enactment of the Act, including the effects on our existing deferred tax balances and the one-time transition tax. For the year ended December 31, 2017, due to the reduction of the corporate tax rate from 34% to 21%, the Company reduced its deferred tax assets by \$17.6 million, with a corresponding decrease to its valuation allowance of \$17.6 million, for which the net effect of the Act was zero (Note 12).

## Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired, and liabilities assumed under the acquisition method of accounting for push-down accounting. Goodwill is not amortized but is evaluated for impairment within the Company’s single reporting unit on an annual basis during the fourth quarter, or more frequently if an event occurs or circumstances change that would more likely than not reduce the fair value of the Company’s reporting unit below its carrying amount. When performing the impairment assessment, the accounting standard for testing goodwill for impairment permits a company to first assess the qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the goodwill is impaired. If the Company believes, as a result of the qualitative assessment, that it is more likely than not that the fair value of goodwill is impaired, the Company then must perform a quantitative analysis to determine if the carrying value of the goodwill exceeds the fair value of the Company. Based on the quantitative analysis, goodwill was determined not to be impaired as of December 31, 2017. As of December 31, 2018, the Company determined that goodwill was impaired, and a charge of \$69 was recorded.

## 3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	For the year ended December 31,	
	2018	2017
Prepaid Insurance . . . . .	\$243	\$203
Prepaid Clinical Trials . . . . .	419	421
Prepaid Other . . . . .	27	44
Accounts receivable . . . . .	—	1
Deferred Operating Costs . . . . .	28	27
Total Prepaid Expenses and Other Current Assets . . . . .	<u>\$717</u>	<u>\$696</u>



#### 4. Property and Equipment, Net

Property and equipment consisted of the following:

	<b>For the Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Laboratory equipment . . . . .	\$ 1,529	\$ 2,476
Computer equipment . . . . .	185	216
Office furniture and equipment . . . . .	217	214
Leasehold improvements . . . . .	579	578
Total property and equipment . . . . .	2,510	3,484
Less accumulated depreciation and amortization . . . . .	(2,116)	(2,870)
Property and equipment — net . . . . .	<u>\$ 394</u>	<u>\$ 614</u>

Depreciation and amortization expense for the years ended December 31, 2018 and 2017 was \$231 and \$246, respectively. During the years ended 2018 and 2017, the Company recorded gross fixed asset disposals of \$993 and \$47 and their related accumulated depreciation of \$985 and \$47, respectively.

#### 5. Significant Agreements

##### *Feasibility and Development Agreement*

On September 5, 2017, the Company entered into a Feasibility and Development Agreement to develop its drug candidate, PUR0200, for chronic obstructive pulmonary disease (COPD) for the U.S. market with Vectura Limited (“Vectura”). During the term of the agreement, Vectura and/or its partners were responsible for all future development costs to advance the product for the U.S. market, while the Company provided the data package for PUR0200 and assisted with the transfer of development and manufacturing activities to Vectura. On December 21, 2018, the Company and Vectura mutually agreed to terminate the Feasibility and Development Agreement and cease further joint development of PUR0200. The Company did not incur any termination fees or penalties in connection with the termination of the agreement. As of December 31, 2018, Pulmatrix owns the rights to PUR0200 across all geographies.

##### *License, Development and Commercialization Agreement*

On June 9, 2017, the Company entered into a License Agreement with RespiVert, a wholly owned subsidiary of Janssen Biotech, Inc., pursuant to which RespiVert granted the Company an exclusive, royalty-bearing license to its Licensed IP, to develop and commercialize products worldwide that incorporate the Licensed IP. The development, application, design and marketing of the Licensed IP for PUR1800 and PUR5700 and any licensed products will be managed exclusively by the Company.

Under the terms of the License Agreement, the Company paid RespiVert an up-front, non-refundable license fee of \$1,000,000 in partial consideration for the rights granted by RespiVert to the Company and will pay RespiVert designated amounts when any licensed product achieves certain developmental milestones. Following the commencement of commercial sales of the licensed products, the Company will pay RespiVert designated amounts when certain milestone events occur. The development milestones and commercial milestones range from \$1,000,000 to \$80,000,000 depending upon the significance of the particular milestone. The Company is also required to pay RespiVert royalties on all sales of licensed products, with such royalties ranging from 6%—10% of sales. As of December 31, 2018, PUR1800 and PUR5700 remain in pharmaceutical development.

The License Agreement terminates upon the expiration of the Company’s obligation to pay royalties for all licensed products, unless earlier terminated. In addition, the License Agreement may be terminated (i) by the Company for any reason upon 120 days’ advance notice to RespiVert; (ii) by RespiVert upon receipt of notice

from the Company of either voluntary or involuntary insolvency proceedings of the Company; and (iii) by either party for a material breach which remains uncured following the applicable cure period.

The Company recorded \$1,000,000 in research and development expense for the upfront license fee during 2017. The next development milestone payment would be \$1,000,000 and result from first dosing of a patient in a Phase 2b Clinical Trial for a licensed product. The payment will be made within 10 days of the first dosing of a patient in a Phase 2b Clinical Trial. No milestone payments were made during 2018.

## 6. Debt

### *Loan and Security Agreement and Warrant Agreement*

On June 11, 2015, Pulmatrix Operating entered into a Loan and Security Agreement (“LSA”) with Hercules Technology Growth Capital, Inc. (“Hercules”), for a term loan in a principal amount of \$7,000 (the “Term Loan”). The Term Loan is secured by substantially all of the Company’s assets, excluding intellectual property. Final payments were made in June 2018 and, as of June 30, 2018, the term loan was paid in full.

On June 16, 2015, in connection with the LSA, the Company granted to Hercules a warrant to purchase 2,515 shares of the Company’s common stock at an exercise price of \$83.50 per share. The warrants are exercisable in whole or in part any time prior to the expiration date of June 16, 2020. At any point prior to the expiration of the warrants, Hercules may elect to convert all or a portion of the warrants into Company Common Stock on a net basis. In the event the warrants are not fully exercised and the fair market value of one share of Company Common Stock is greater than the exercise price of the warrant, upon the expiration date any outstanding warrants will be automatically exercised for shares of Company Common Stock on a net basis.

The Term Loan bore interest at a floating annual rate equal to the greater of (i) 9.50% and (ii) the sum of (a) the prime rate as reported by The Wall Street Journal minus 3.25% plus (b) 9.50%. The Term Loan interest rate was 10.75% and 10.00% at December 31, 2017 and 2016, respectively. Upon repayment of the Term Loan, the Company paid an end of term charge to the lenders equal to \$245. As of June 30, 2018, the Company has no further liability to Hercules.

The Company incurred interest expense of \$186 during the year ended December 31, 2018, which included accretion of debt discount of \$35. Of the remaining \$151 interest expense, \$131 was payable in cash and \$20 relates to the Hercules end of term fee. For the year ended December 31, 2018, the Company also accreted debt issuance costs of \$3 recorded to general and administrative expenses in accompanying consolidated statement of operations.

The Company incurred interest expense of \$643 during the year ended December 31, 2017, which includes accretion of debt discount of \$101. Of the remaining \$542 interest expense, \$472 was payable in cash and \$70 relates to the Hercules end of term fee. For the year ended December 31, 2017, the Company also accreted debt issuance costs of \$12 recorded to general and administrative expenses in accompanying consolidated statement of operations.

The carrying amounts of the Company’s Notes as of December 31, 2018 and December 31, 2017 were as follows:

	<u>Hercules Term Loan</u>	<u>Debt Discount</u>	<u>Issuance Costs</u>	<u>Total</u>
Balance — January 1, 2018 .....	\$ 3,259	\$ (35)	\$ (3)	\$ 3,221
Accretion of debt discount .....		35		35
Accretion of issuance costs .....			3	3
Principal payments .....	<u>(3,259)</u>			<u>(3,259)</u>
Balance — December 31, 2018 .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

## 7. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following:

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
Accrued vacation . . . . .	\$ 59	\$ 57
Accrued wages and incentive . . . . .	915	1,113
Accrued clinical & consulting . . . . .	517	568
Accrued legal & patent . . . . .	67	61
End of term fee . . . . .	—	225
Deferred rent . . . . .	67	68
Accrued other expenses . . . . .	71	70
Total accrued expenses . . . . .	<u>\$1,696</u>	<u>\$2,162</u>

## 8. Common Stock

### *2018 Registered Direct Offering*

On November 29, 2018, the Company entered into a Securities Purchase Agreement with an institutional investor (the “Purchaser”), pursuant to which the Company agreed to issue and sell an aggregate of 240,000 shares of common stock, par value \$0.0001 per share, of the Company common stock at an offering price of \$3.20 per share for gross proceeds of \$768 before the deduction of offering expenses. In addition, the Company sold pre-funded warrants (the “Pre-Funded Warrants”) to purchase 697,500 shares of common stock (and the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants). The Pre-Funded Warrants were sold at an offering price of \$3.10 per share for gross proceeds of \$2,162 before deduction of offering expenses.

In a concurrent private placement, the Company agreed to issue to the Purchaser, for each share of common stock and pre-funded warrant purchased in the Offering, a common warrant, each to purchase one share of Common Stock (the “Common Warrants”). The Common Warrants are initially exercisable six months following issuance and terminate five and one-half years following issuance. The Common Warrants have an exercise price of \$3.90 per share and are exercisable to purchase an aggregate of 937,500 shares of Common Stock.

The closing of the sale of the shares and the prefunded warrants occurred on December 3, 2018 and the company recorded gross proceeds of \$2,930.

The Shares were offered and sold by the Company pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on July 15, 2016, and subsequently declared effective on August 3, 2016 (File No. 333-212546), and a related prospectus.

### *Public Offering*

On April 3, 2018, the Company closed its firm commitment underwritten public offering in which, pursuant to the underwriting agreement (the “Underwriting Agreement”) entered into between the Company and Oppenheimer & Co. Inc., as representative of the underwriters (the “Underwriters”), dated March 28, 2018, the Company issued and sold (i) 1,566,000 common units (“Common Units”), with each Common Unit being comprised of one share of the Company’s common stock, par value \$0.0001 per share, one Series A warrant (collectively, the “Series A Warrants”) to purchase one share of common stock and one Series B warrant (collectively, the “Series B Warrants”) to purchase one share of common stock, and (ii) 784,000 pre-funded units (the “Pre-Funded Units” and, together with the Common Units, the “Units”), with each Pre-Funded Unit being comprised of one pre-funded warrant to purchase one share of common stock, one Series A Warrant and one Series B Warrant. The public offering price was \$6.50 per Common Unit and \$6.40 per Pre-Funded Unit, and the gross proceeds received by the Company on April 3, 2018 pursuant to such sales were \$15,197, prior to deducting underwriting discounts and commissions and other estimated offering expenses.

In addition, on April 4, 2018, the Company closed on the sale of 115,000 additional Common Units pursuant to the Underwriters' option to purchase up to an additional 115,000 Units, which were exercised in full. After giving effect to the exercise of the Underwriters' overallotment option, the gross aggregate proceeds from the offering on April 3 and 4 were \$15,944, prior to deducting underwriting discounts and commissions and other estimated offering expenses.

All of the pre-funded warrants issued in the offering were exercised in April 2018 and, as 15,000 were exercised on a cashless basis, resulted in the issuance of an additional 783,707 shares of common stock with gross proceeds of \$77.

The Series A Warrants included in the Common Units and the Pre-Funded Units were immediately exercisable at a price of \$6.50 per share of common stock, subject to adjustment in certain circumstances, and expired according to their terms on October 3, 2018 and October 4, 2018, respectively. The Series B Warrants included in the Common Units and the Pre-Funded Units were immediately exercisable at a price of \$7.50 per share of common stock, subject to adjustment in certain circumstances, and will expire five years from the date of issuance. The shares of common stock, or Pre-Funded Warrants in the case of the Pre-Funded Units, and the Series A Warrants and Series B Warrants were offered together, but the securities contained in the Common Units and the Pre-Funded Units were issued separately.

The Company agreed to pay Oppenheimer a commission of (a) 7% of the gross proceeds raised up to \$5,000 and (b) 6.5% of the gross proceeds raised in excess of \$5,000. The Company also agreed to pay or reimburse certain expenses on behalf of Oppenheimer. A total of \$1,501 of commissions and other issuance costs were associated with the public offering.

The net proceeds to the Company from the Offering were approximately \$14,520, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the Offering for research and development of its therapeutic candidates, particularly the development of Pulmazole, as well as for working capital and general corporate purposes.

#### *At-the-Market Offering*

On March 17, 2017, the Company entered into an At-The-Market Sales Agreement (the "Sales Agreement") with BTIG, LLC ("BTIG") to act as the Company's sales agent with respect to the issuance and sale of up to \$11,000,000 of the Company's shares of common stock, from 0time to time in an at-the-market public offering (the "Offering"). Sales of common stock under the Sales Agreement are made pursuant to an effective shelf registration statement on Form S-3, which was filed with the Securities and Exchange Commission on July 15, 2016, and subsequently declared effective on August 3, 2016 (File No. 333-212546), and a related prospectus. BTIG acts as the Company's sales agent on a commercially reasonable efforts basis, consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The NASDAQ Capital Market. If expressly authorized by the Company, BTIG may also sell the Company's common stock in privately negotiated transactions. There is no specific date on which the Offering will end, there are no minimum sale requirements and there are no arrangements to place any of the proceeds of this offering in an escrow, trust or similar account.

BTIG is entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of the Company's common stock pursuant to the Sales Agreement.

During 2017, the Company sold 310,336 shares of its common stock under the Sales Agreement at an average selling price of approximately \$29.30 per share which resulted in gross proceeds of approximately \$9,096 and net proceeds of approximately \$8,712 after payment of 3% commission to BTIG and other issuance costs.

During 2018, the Company sold 123,266 shares of its common stock under the Sales Agreement at an average selling price of approximately \$15.40 per share which resulted in gross proceeds of approximately \$1,904 and net proceeds of approximately \$1,847 after payment of 3% commission to BTIG and other issuance costs.

#### 2017 Registered Direct Offerings

On January 27, 2017, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain investors for the sale by the Company of 200,000 shares (the “Shares”) of the Company’s common stock, par value \$0.0001 per share, at a purchase price of \$25.00 per share in a registered direct offering. The closing of the sale of the Shares under the Purchase Agreement occurred on February 2, 2017.

On February 3, 2017, the Company entered into a Securities Purchase Agreement (the “Second Purchase Agreement”) with certain investors for the sale by the Company of 95,000 shares of the Company’s common stock, par value \$0.0001 per share, at a purchase price of \$35.00 per share in a registered direct offering. The closing of the sale of the Shares under the Second Purchase Agreement occurred on February 8, 2017.

Net of commissions, fees and other issuance costs totaling \$727, aggregate net proceeds of the two noted registered direct offerings were \$7,598 during 2017.

### 9. Warrants

A rollforward of the common stock warrants outstanding at December 31, 2018 is as follows.

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2018	328,444	\$77.90		\$—
Series A warrants issued	2,465,000	\$ 6.50		
Series A warrants expired	(2,465,000)	\$ (6.50)		
Series B warrants issued	2,465,000	\$ 7.50		
Pre-funded warrants issued	784,000	\$ 6.50		
Pre-funded warrants exercised	(784,000)	\$ (6.50)		
Warrants issued	937,500	\$ 3.90		
Pre-funded warrants issued	697,500	\$ 0.01		
Outstanding December 31, 2018	<u>4,428,444</u>	\$10.78	4.30	\$—

The following represents a summary of the warrants outstanding at each of the dates identified:

Issue Date	Classification	Exercise Price	Expiration Date	Number of Shares Underlying Warrants	
				For the Year Ended December 31, 2018	2017
December 3, 2018	Equity	\$ 3.90	June 3, 2024	937,500	—
December 3, 2018	Equity	\$ 3.20	Prefunded	697,500	—
April 3, 2018	Equity	\$ 7.50	April 3, 2023	2,407,500	—
April 4, 2018	Equity	\$ 7.50	April 4, 2023	57,500	—
June 15, 2015	Equity	\$ 75.50	June 15, 2020	319,003	319,003
June 15, 2015	Equity	\$ 83.50	June 16, 2020	2,515	2,515
August 31, 2015	Equity	\$118.00	August 31, 2020	3,000	3,000
March 21, 2014	Equity	\$226.60	March 21, 2019	3,710	3,710
March 21, 2014	Equity	\$226.60	March 21, 2019	216	216

All warrants are exercisable for common stock.

**10. Stock-Based Compensation**

The Company sponsors the Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan (the “2013 Plan”). As of December 31, 2018, the 2013 Plan provides for the grant of up to 1,250,000 shares of the Company’s common stock, of which 272,219 shares remained available for future grant.

In addition, the Company sponsors two legacy plans under which no additional awards may be granted. As of December 31, 2018, the two legacy plans have a total of 49,110 options outstanding all of which are fully vested and for which common stock will be delivered upon exercise.

*Options*

During the year ended December 31, 2018, the Company granted options to purchase 596,604 shares of the Company’s common stock to employees and options to purchase 77,500 shares of the Company’s common stock to directors. No options were granted to advisors during the period. The stock options granted vest over time (the “Time Based Options”). Time Based Options vest over either 36 or 48 months. Subject to the grantee’s continuous service with the Company, Time Based Options vest in one of the following ways: (i) 25% at the one year anniversary of the Vesting Start Date and the remainder in 36 equal monthly installments beginning in the thirteenth month after the Vesting Start Date or (ii) 25% at the time of grant and the remainder in 36 equal monthly installments beginning in the first month after the Vesting Start Date. Stock options generally expire ten years after the date of grant.

The following table summarizes stock option activity for the year ended December 31, 2018:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding — January 1, 2018 . . . . .	369,619	\$56.92		\$—
Granted . . . . .	674,104	\$ 4.68		
Exercised . . . . .	—	—		
Forfeited or expired . . . . .	(71,150)	\$13.92		
Outstanding — December 31, 2018 . . . . .	<u>972,573</u>	\$23.85	8.46	\$—
Exercisable — December 31, 2018 . . . . .	<u>516,087</u>	\$36.31	7.84	\$—
Vested and expected to vest — December 31, 2018 . . . . .	<u>959,929</u>	\$24.04	8.45	\$—

The estimated fair values of employee stock options granted during the year ended December 31, 2018 and 2017, were determined on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	For the year ended December 31,	
	2018	2017
Expected option life (years) . . . . .	5.00 – 6.50	5.50–9.41
Risk-free interest rate . . . . .	2.74% – 2.84%	1.89% – 2.25%
Expected volatility . . . . .	78.5% – 82.9%	74.0% – 86.3%
Expected dividend yield . . . . .	0%	0%

The risk-free interest rate was obtained from U.S. Treasury rates for the applicable periods. The Company's expected volatility was based upon the historical volatility for industry peers and used an average of those volatilities. The expected life of the Company's options was determined using the simplified method as a result of limited historical data regarding the Company's activity. The forfeiture rate is calculated for non-performance grants based on actual forfeiture historical values. The dividend yield considers that the Company has not historically paid dividends and does not expect to pay dividends in the foreseeable future.

As of December 31, 2018, there was \$3,014 of unrecognized stock-based compensation expense related to unvested stock options granted under the Company's stock award plans. This expense is expected to be recognized over a weighted-average period of approximately 1.97 years.

#### *Restricted Stock Units*

In August 2015, the Company granted 1,038 RSUs to other employees that vest over a two-year period. The Company recorded stock-based compensation expense of \$0 and \$13 for the RSUs vested during the years ended December 31, 2018 and 2017, respectively. There were no RSUs granted during 2018 nor were any outstanding as of December 31, 2018 and 2017, respectively.

The following table presents total stock-based compensation expense for the years ended December 31, 2018 and 2017, respectively:

	<b>For the years ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Research and development .....	\$ 970	\$ 710
General and administrative .....	2,003	2,095
Total stock-based compensation expense .....	<u>\$2,973</u>	<u>\$2,805</u>

## **11. Fair Value Measurements**

### *Embedded Compound Derivatives — LSA with Hercules*

As described in Note 6. The LSA contained an interest rate reset upon an event of default and a put option upon an event of default or qualified change of control. Final payments were made in June 2018 and as of June 30, 2018, the Term Loan was paid in full and the embedded compound derivative liability became \$0.

A roll-forward of the derivative liability categorized with Level 3 inputs is as follows:

	<b>Derivative Instruments</b>
Balance — January 1, 2017 .....	\$ 35
Change in fair value .....	<u>(34)</u>
Balance — December 31, 2017 .....	<u>1</u>
Change in fair value .....	<u>(1)</u>
Balance — December 31, 2018 .....	<u>\$ —</u>

Gains and/or losses arising from changes in the estimated fair value of the warrants and embedded compound derivatives were recorded within other income, net, on the consolidated statement of operations.

## 12. Income Taxes

The Company had no income tax expense due to operating losses incurred for the year ended December 31, 2018 and 2017.

A reconciliation of the provision for income taxes computed at the statutory federal income tax rate to the provision for income taxes as reflected in the financial statements is as follows:

	<u>2018</u>	<u>2017</u>
Income tax computed at federal statutory tax rate .....	21.0%	34.0%
State taxes, net of federal benefit .....	6.2%	5.0%
Research and development credits .....	1.9%	0.9%
Nondeductible interest .....	0.0%	(0.1)%
Permanent differences .....	(0.6)%	(0.3)%
Deferred rate change .....	0.0%	(97.7)%
Other .....	(0.3)%	(3.1)%
Change in valuation allowance .....	<u>(28.2)%</u>	<u>61.3%</u>
Total .....	<u>0.0%</u>	<u>0.0%</u>

The significant components of the Company's deferred tax assets as of December 31, 2018 and 2017 were as follows:

	<u>2018</u>	<u>2017</u>
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 37,640	\$ 32,820
Research and development credit carryforwards .....	3,170	2,789
Capitalized start-up expenses .....	851	983
Stock Compensation .....	2,589	1,905
Other .....	<u>520</u>	<u>472</u>
Total deferred tax assets .....	44,770	38,969
Valuation allowance .....	<u>(44,770)</u>	<u>(38,969)</u>
Net deferred tax liabilities .....	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2018, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately \$149,374 and \$99,230 respectively, which were available to reduce future taxable income. Federal and state net operating loss carryforwards of \$131,487 and \$99,230 respectively, will expire at various dates from 2023 through 2038. \$17,887 of the federal net operating losses can be carried forward indefinitely. The Company has research and development credits for federal and state income tax purposes of approximately \$2,218 and \$1,204, respectively, which expire at various dates from 2022 through 2038.

Management of the Company evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and determined that it is more likely than not that the Company will not recognize the benefits of the deferred tax assets. As a result, a full valuation allowance was recorded as of December 31, 2018 and 2017. The valuation allowance increased by \$5,801 during the year ended December 31, 2018, primarily due to the current period losses incurred by the Company.

The Company applies FASB Topic 740 Income Taxes for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. Unrecognized tax benefits represent tax positions for which reserves have been established. A full valuation allowance has been provided against the Company's deferred tax assets, so that the effect of the unrecognized tax benefits is to reduce the gross amount of the deferred tax asset and the corresponding valuation allowance.



The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company files income tax returns in the United States for federal and state income taxes. In the normal course of business, the Company is subject to examination by tax authorities in the United States. Since the Company is in a loss carry-forward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carry-forward is utilized. The Company's returns remain subject to federal and state audits for the years 2015 through 2018. However, carryforward attributes from prior years may still be adjusted upon examination by tax authorities if they are used in an open period.

The Company may from time to time be assessed interest or penalties by major tax jurisdictions. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. The Company has not recorded interest or penalties on any unrecognized tax benefits since its inception.

The Company anticipates that the amount of unrecognized tax benefits will not materially change in the next twelve months.

The roll-forward of the Company's gross uncertain tax positions is as follows:

	<b>Gross Uncertain Tax Position</b>
Balance — January 1, 2017 . . . . .	\$1,172
Additions for current year tax positions . . . . .	59
Reductions for prior year tax positions . . . . .	<u>(122)</u>
Balance — December 31, 2017 . . . . .	1,109
Additions for current year tax positions . . . . .	115
Additions for prior year tax positions . . . . .	<u>20</u>
Balance — December 31, 2018 . . . . .	<u><u>\$1,244</u></u>

In general, if we experience a greater than 50 percent aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, utilization of our pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, and similar state laws. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization and may be substantial. We have not, as of yet, completed a study to determine if any such changes have occurred that could limit our ability to use the net operating losses and tax credit carryforwards.

### 13. Net Loss Per Share

The following potentially dilutive securities outstanding prior to the use of the treasury stock method have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive.

	<b>As of December 31,</b>	
	<b>2018</b>	<b>2017</b>
Options to purchase common stock . . . . .	972,573	369,619
Warrants to purchase common stock . . . . .	3,730,944	328,444
Settlement of Term Loan . . . . .	<u>—</u>	<u>8,526</u>
Total . . . . .	<u><u>4,703,517</u></u>	<u><u>706,589</u></u>

**14. Commitments**

On October 27, 2015, the Company amended its operating lease for office and lab space to extend the termination date of the lease from December 2016 to December 2020, among other things. The amended lease provides for base rent, and the Company is responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises. The amended lease agreement provides for an increasing monthly payment over the lease term.

Future minimum lease payments under non-cancelable operating lease for office and lab space is as follows:

	<u>Amount</u>
2019 .....	676
2020 .....	<u>698</u>
Total .....	<u>\$1,374</u>

The Company has contracted with contract research organizations and contract manufacturing organizations to further the development of its most advanced assets. As of December 31, 2018, the outstanding obligation on these contracts totaled \$2.9 million.

**15. Subsequent Events**

Pursuant to the evergreen provision under the Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan, on January 1, 2019, 246,636 shares were added to the total number of authorized shares under the plan.

On January 14, 2019, 172,500 pre-funded warrants were exercised, and the Company collected proceeds of \$17

On January 29, 2019, 272,500 pre-funded warrants were exercised, and the Company collected proceeds of \$27.

On January 31, 2019, 156,118 shares of common stock were sold at \$1.70 per share, and the Company collected gross proceeds of \$265. 10,148 warrants were also issued with an exercise price of \$2.125 and a termination date of January 31, 2024. The shares are registered pursuant to a currently effective registration statement on Form S-3 (Registration No. 333-212546) that was originally filed with the Securities and Exchange Commission on July 15, 2016 and declared effective on August 3, 2016.

On February 1, 2019, 250,000 pre-funded warrants were exercised, and the Company collected proceeds of \$25.

On February 4, 2019, 532,353 shares of common stock were sold at \$1.70 per share and the Company collected gross proceeds of \$905. 34,603 warrants were also issued with an exercise price of \$2.125 and a termination date of January 30, 2024. The shares are registered pursuant to a currently effective registration statement on Form S-3 (Registration No. 333-212546) that was originally filed with the Securities and Exchange Commission on July 15, 2016 and declared effective on August 3, 2016.

On February 3, 2019, the Board approved a 1-for-10 reverse stock split of our issued and outstanding shares of common stock (the “Reverse Stock Split”) and the Company’s common stock began trading on a split-adjusted basis when the market opened on February 6, 2019. With the Reverse Stock Split, every 10 shares of the Company’s issued and outstanding common stock (and such shares held in treasury) were automatically converted into one share of common stock, without any change in the par value per share. Any fraction of a share of common stock that would otherwise have resulted from the Reverse Stock Split will be rounded up to the nearest whole share. Accordingly, all common share and per share data are retrospectively restated to give effect of the split for all periods presented herein.

On February 12, 2019, 1,706,484 shares of common stock were sold at \$1.465 and the Company collected gross proceeds of \$2,500. 1,706,484 warrants were issued to investors with an exercise price of \$1.34 and a termination date of August 12, 2024. 110,922 warrants were issued to underwriters with an exercise price of \$1.8313 and a termination date of February 7, 2024. The shares are registered pursuant to a currently effective registration statement on Form S-3 (Registration No. 333-212546) that was originally filed with the Securities and Exchange Commission on July 15, 2016 and declared effective on August 3, 2016.

The Company has evaluated its events subsequent to December 31, 2018 to the date these consolidated financial statements were issued, and has determined that, other than what was disclosed above, it does not have any subsequent events to disclose in these consolidated financial statements.







## ***Executive Officers***

---

### **Teofilo Raad**

Chief Executive Officer, President

### **William E. Duke, Jr.**

Chief Financial Officer

## ***Board of Directors***

---

### **Teofilo Raad**

Chief Executive Officer, President  
Pulmatrix, Inc.

### **Steven Gillis, Ph.D.**

Managing Director  
ARCH Venture Partners

### **Michael J. Higgins**

Entrepreneur-in-Residence  
Polaris Partners

### **Mark Iwicki\***

Chairman and Chief Executive Officer  
Kala Pharmaceuticals

### **Terrance G. McGuire**

Co-Founder and General Partner  
Polaris Partners

### **Matthew L. Sherman, M.D.**

### **Amit D. Munshi**

Chief Executive Officer  
Arena Pharmaceuticals, Inc.

\* Chairman of the Board of Directors – Pulmatrix, Inc.

## ***Stockholder Information***

---

### **Corporate Headquarters**

99 Hayden Avenue, Suite 390  
Lexington, MA 02421  
781.357.2333  
pulmatrix.com

### **Stock Market Information**

Pulmatrix's common stock is traded on the NASDAQ Capital Market under the symbol PULM.

### **Transfer Agent And Registrar**

VStock Transfer, LLC  
18 Lafayette Place  
Woodmere, NY 11598  
855-987-8625  
vstocktransfer.com

### **Independent Registered Public Accounting Firm**

Marcum LLP

### **Annual Meeting**

The Annual Meeting of Stockholders will be held at 11:30 a.m., Eastern Time, on Friday, September 6, 2019 at the Corporate Headquarters of the Company.



99 Hayden Avenue | Suite 390

Lexington, MA 02421

[www.pulmatrix.com](http://www.pulmatrix.com)