

Pulmatrix, Inc.  
Form 10-K  
March 13, 2018  
Table of Contents

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

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2017**

**or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number: 001-36199**

**PULMATRIX, INC.**

**(Exact name of registrant as specified in its charter)**

<b>Delaware</b> <b>(State or other jurisdiction of</b>	<b>46-1821392</b> <b>(I.R.S. Employer</b>
<b>incorporation or organization)</b>	<b>Identification No.)</b>
<b>99 Hayden Avenue, Suite 390</b> <b>Lexington, MA</b>	<b>02421</b>
<b>(Address of principal executive offices)</b>	<b>(Zip Code)</b>
<b>Registrant's telephone number, including area code (781) 357-2333</b>	

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

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
<b>Common Stock, par value \$0.0001 per share</b>	<b>The NASDAQ Stock Market LLC</b>
<b>Securities registered pursuant to Section 12(g) of the Exchange Act: None</b>	

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Edgar Filing: Pulmatrix, Inc. - Form 10-K

Non-accelerated filer       [Do not check if a smaller reporting company]       Smaller reporting company  
 Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes       No

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, as of June 30, 2017, the last business day of registrant's most recently completed second fiscal quarter, was \$47,823,941.

As of March 8, 2018, the registrant had 22,280,160 shares of common stock outstanding.

**Table of Contents****PULMATRIX, INC.****TABLE OF CONTENTS**

	<b>Page No.</b>
<u>Forward-Looking Statements</u>	1
<b><u>PART I</u></b>	
Item 1. <u>Business.</u>	2
Item 1A. <u>Risk Factors.</u>	16
Item 1B. <u>Unresolved Staff Comments.</u>	35
Item 2. <u>Properties.</u>	35
Item 3. <u>Legal Proceedings.</u>	35
Item 4. <u>Mine Safety Disclosures.</u>	36
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u>	37
Item 6. <u>Selected Financial Data.</u>	38
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	38
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	48
Item 8. <u>Financial Statements and Supplementary Data.</u>	48
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</u>	48
Item 9A. <u>Controls and Procedures.</u>	49
Item 9B. <u>Other Information.</u>	49
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance.</u>	50
Item 11. <u>Executive Compensation.</u>	56
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</u>	63
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence.</u>	70
Item 14. <u>Principal Accounting Fees and Services.</u>	71
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits, Financial Statement Schedules.</u>	72

Item 16.	<u>Form 10-K Summary</u>	72
	<u>Signatures</u>	75

**Table of Contents**

**PART I**

**Forward-Looking Statements**

This Annual Report on Form 10-K 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, forecasts, guides, intends, is confident that, may, plans, seeks, projects, targets, and would, and the 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 on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K 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 on Form 10-K to us, we, our, or Company refer to Pulmatrix, Inc., a Delaware corporation.

## **Table of Contents**

iSPERSE is one of our trademarks used in this Annual Report on Form 10-K. 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. We began clinical testing of Pulmazole in normal healthy volunteers and asthma patients in the first quarter of 2018.*



*Focus on development of an inhaled kinase inhibitor to treat acute exacerbations in 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. We expect to advance our lead iSPERSE formulation to preclinical safety studies in 2018 and continue to advance our formulation and process development efforts to support clinical testing in stable moderate-severe COPD patients.*

---

**Table of Contents**

*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.* As of December 31, 2017, we had 138 patents and pending patent applications (including provisional applications) related to the iSPERSE technology in our patent portfolio, of which we were the sole owner of 12 issued or allowed U.S. patents, with expiration dates ranging from 2025 to 2034, as well as 53 issued or allowed foreign patents e.g. Europe and Asia, with expiration dates of 2025 to 2034. In addition to the patents and pending patent applications directed related to the iSPERSE technology, we have in-licensed kinase inhibitors patents and patent applications that encompass the new chemical entities being developed in the PUR1800 and PUR5700 programs. As of December 31, 2017, our in-licensed portfolio contains 299 active patents related to PUR1800, PUR5700, or other similar compounds, with expiration dates ranging from 2029 to 2035. We intend to continue to aggressively pursue patents claims covering aspects of iSPERSE technology, expand our patent portfolio, and actively pursue any infringement covered by any of Pulmatrix's patents. We believe that our patents and patent applications, once allowed, are important for maintaining the competitive differentiation of our products and maximizing our return on research and development investments, as well as providing for the expansion of intellectual property protection for partner molecules in development partnerships.

***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

## **Table of Contents**

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 (formerly PUR1900)***

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 allergic bronchopulmonary aspergillosis ( 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 preclinical models, through the direct delivery of itraconazole to the lungs, Pulmazole achieves high local drug concentrations and has the potential to overcome several limitations of traditional oral anti-fungal therapies including poor oral bioavailability and lung penetration, drug-drug interactions and gastrointestinal and cardiac side effects. We began clinical testing of Pulmazole in normal healthy volunteers and asthma patients in the first quarter of 2018.

---

**Table of Contents***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 delivery of itraconazole to lungs will achieve high local lung concentrations while achieving systemic exposure that is significantly lower than that of oral dosing. Furthermore, administration by inhalation may also significantly reduce the exposure of the drugs in the rest of the body, which is beneficial in reducing systemic side effects and the risk of potentially damaging drug-drug interactions. We believe that inhaled therapies could offer improved efficacy and reduced side effects and could lead to improved patient efficacy and use profile. There is precedent for inhaled anti-infective therapy, dry powder and nebulized, addressing specific pulmonary infections in patients which demonstrates the inhaled drug delivery utility and market opportunity. Novartis 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 is completing Phase III trials for Amikacin Liposome Inhalation Suspension nebulization in adult patients with treatment refractory nontuberculous mycobacterial lung disease caused by mycobacterium avium complex. Pulmocide Ltd has initiated a Phase I clinical trial to investigate PC945, a novel triazole antifungal, as a nebulized treatment for pulmonary aspergillosis. There are currently no products 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 will generate value based on treating and preventing pulmonary fungal infections in multiple patient populations.

*Clinical Development*

Pulmazole is our lead iSPERSE anti-infective development program and we began Phase I/Ib clinical studies in the first half of 2018.

***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

## **Table of Contents**

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 intend to conduct preclinical safety studies in 2018 and then 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 Ib 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.

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 Ib 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 Ib 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.



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

---

**Table of Contents**

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 ( $C_{max}$ ) 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 ( $C_{max}$ ) 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 March 24, 2015, we entered into a letter agreement with Mylan related to the development, manufacture and commercialization of PUR0200. Pursuant to the letter agreement, we agreed to work with Mylan to develop a pharmacokinetic study plan of PUR0200 that was subject to their written approval. Following an amendment to the letter agreement, Mylan agreed to reimburse us up to \$1,878,074 of expenses incurred in connection with the agreed-upon study plan. As consideration for Mylan funding the studies, we granted Mylan an option to negotiate for the exclusive right to develop, manufacture, commercialize and market any resulting products outside the United States for one hundred eighty (180) days following the date that we deliver a report detailing the outcome of the pharmacokinetic studies of PUR0200 to Mylan, in exchange for our receipt of gross profit share of up to twenty percent (20%) of the gross profit of such pharmaceutical company's sales of PUR0200 outside the United States. In 2016, Mylan's option for PUR0200 expired.

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 ). Vectura and/or its partners are responsible for all future development costs to advance the product for the U.S. We are required to provide the data package for PUR0200 and assist with the transfer of development and manufacturing activities to Vectura. As part of the agreement, a technology access fee of \$1 million is payable to us upon successful achievement of pre-agreed pharmaceutical development criteria. Following the payment of the technology access fee, Vectura is required to commence development and pay us a mid-teen percentage share of any future revenues that Vectura receives relating to future development and sale of PUR0200 and PUR0200-related products including future combinations.

### *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 251 million people worldwide suffering from the disease. 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. We have out-licensed the US market rights of PUR0200, iSPERSE reformulated tiotropium, to Vectura and Vectura is developing PUR0200 for use in their multi-dose dry powder inhalation device. The resulting product candidate is

expected to differentiate itself from the currently marketed LAMA products, including but not limited to Boehringer Ingelheim's Spiriva, that use a single-dose delivery device.

## **Table of Contents**

### ***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.

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 and Biogen Idec are developing oral and injectable therapies for IPF that are in Phase II 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:

iSPERSE powder compositions of matter and properties;

in-licensed kinase inhibitors compositions of matter; and

formulation compositions of matter and methods of use for the Pulmazole, PUR0200, PUR1800 and PUR5700 programs; and

methods of use for local or systemic delivery of drugs for many indications; and

process, manufacturing, device and packaging of a therapeutic candidate and including combination therapeutic uses.

The iSPERSE composition of matter patents encompass the salt formulations, and variants and derivatives thereof, including claims to products under development. The status of individual filings varies, and, as of December 31, 2017, we have been granted or allowed nationally 65 active patents related to iSPERSE, 12 of which are granted or allowed U.S. patents. The expiration dates of the U.S. and foreign patents range from 2025 to 2034. Also as of December 31, 2017, we had approximately 73 additional pending patent applications (including provisional applications) in the United States, Europe, Asia and other jurisdictions totaling 138 active patents and pending patent applications (including provisional applications) related to the iSPERSE technology.

The in-licensed kinase inhibitors composition of matter patents encompass the new chemical entities being developing in the PUR1800 and PUR5700 programs. The status of individual filings varies, and, as of December 31, 2017, the in-licensed portfolio contains 299 active patents related to PUR1800, PUR5700, or other similar compounds, with expiration dates ranging from 2029 to 2035.

## **Table of Contents**

As of December 31, 2017, we had 369 patents and pending patent applications related to the in-licensed kinase inhibitor technology in our patent portfolio, of which 21 are issued or allowed U.S. patents, with expiration dates ranging from 2029 to 2035, as well as 278 issued or allowed foreign patents, with expiration dates of 2029 to 2035. There were approximately 70 additional pending patent applications in the United States, Europe, Asia and other jurisdictions as of such date.

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. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of its issued patents in any jurisdiction where these 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

## **Table of Contents**

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 both fiscal years ended December 31, 2017 and 2016, we spent approximately \$10.2 million 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.

## **Table of Contents**

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 I.* In Phase I 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 I studies is generally in the range of 20 to 80.

*Phase II.* In Phase II 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 II studies typically are larger than Phase I but smaller than Phase III studies and may involve

several hundred participants.

*Phase III.* Phase III 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 III studies usually involve several hundred to several thousand participants.

*Phase IV.* Phase IV 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

---

**Table of Contents**

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 IV clinical trial requirement. These clinical trials are often referred to as Phase IV post-approval or post marketing commitments. Failure to promptly conduct Phase IV 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 increase 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 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

---

**Table of Contents**

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 IV 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.

---

**Table of Contents**

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.

## **Table of Contents**

### **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, 2017 and 2016 and subsequently has not had a material effect upon our capital expenditures, earnings or competitive position.

### **Employees**

As of December 31, 2017, we had 24 full-time employees, 17 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.

**Table of Contents**

**ITEM 1A. RISK FACTORS.**

*The following risk factors, together with all of the other information included or incorporated in this Annual Report on Form 10-K, 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 \$18.0 million for the fiscal year ended December 31, 2017 and had a net loss of approximately \$27.8 million during the fiscal year ended December 31, 2016. As of December 31, 2017, we had an accumulated deficit of \$174 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 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, 2017, includes an explanatory paragraph as to our potential inability to continue as a going concern. 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 two months from the date of filing of this 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.

## **Table of Contents**

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 Food and Drug Administration (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;

**Table of Contents**

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

## **Table of Contents**

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, 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.

---

**Table of Contents**

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 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.

---

**Table of Contents**

***We may be required to take write-downs or write-offs, restructuring and impairment or other charges that could have a significant negative effect on our financial condition, results of operations and stock price, which could cause our investors to lose some or all of their investment.***

During 2016, a full write-off was made of in-process research and development, \$4.5 million net of tax provision, acquired from the merger with Pulmatrix Operating Company. During 2016, we also concluded that the carrying amount of the goodwill exceeded its fair value and recorded a resulting impairment charge of \$5.0 million. We may be forced to take a further write down of the remaining goodwill which would result in losses. Even if due diligence successfully identified certain risks, unexpected risks may arise and previously known risks may materialize in a manner not consistent with our preliminary risk analysis. Even though these charges may be non-cash items and not have an immediate impact on liquidity, the fact that we report charges of this nature could contribute to negative market perceptions about our securities. In addition, charges of this nature may make future financing difficult to obtain on favorable terms or at all.

***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.

***We may not receive royalty or milestone revenue under our collaboration and license agreements for several years, or at all.***

Certain of our collaboration and license agreements provide for payments on achievement of development or commercialization milestones and for royalties on product sales. However, because none of our drug candidates has been approved for commercial sale, many of our drug candidates are at early stages of development and drug development entails a high risk of failure, we may never realize much of the milestone revenue provided for in our collaboration and license agreements and we do not expect to receive any royalty revenue for several years, if at all. Similarly, drugs we select to commercialize ourselves or partner for later stage co-development and commercialization may not generate revenue for several years, or at all.

***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

## **Table of Contents**

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

## **Table of Contents**

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.

## **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.

## **Table of Contents**

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.

---

**Table of Contents**

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;

**Table of Contents**

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

## **Table of Contents**

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 Phase I/Ib trials 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 2018. 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 \$174.0 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;

**Table of Contents**

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.

---

**Table of Contents**

**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.

---

**Table of Contents**

***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

## **Table of Contents**

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;

---

**Table of Contents**

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 that we did not incur as a privately held company. 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 Global 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

---

**Table of Contents**

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 Global 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 Global Market. For continued listing on The NASDAQ Global 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 Global 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

---

**Table of Contents**

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 March 8, 2018, 1,359,051 shares remained available to be awarded under our 2013 Employee, Director and Consultant Equity Incentive Plan (the 2013 Plan). Further, an aggregate of 3,693,348 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.

***The concentration of the capital stock ownership with our insiders will likely limit the ability of other stockholders to influence corporate matters.***

As of March 8, 2018, approximately 28% of our outstanding shares of Company Common Stock was controlled by our officers, directors, beneficial owners of 10% or more of our securities and their respective affiliates. As a result, these stockholders, if they acted together, may be able to determine or influence matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other stockholders may view as beneficial.

***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.





**Table of Contents****Risks Related to our Indebtedness**

*Our obligations under our outstanding term loan are secured by all of our assets other than intellectual property, so if we default on those obligations, the lender could foreclose on our assets. As a result of these security interests, such assets would only be available to satisfy claims of our general creditors or to holders of our equity securities if we were to become insolvent at a time when the value of such assets exceeded the amount of our indebtedness and other obligations. In addition, the existence of these security interests may adversely affect our financial flexibility.*

Hercules Technology Growth Capital, Inc., the lender under our term loan has a security interest in all of our assets and those of Pulmatrix Operating Company, our wholly-owned subsidiary. As a result, if we default under our obligations to the lender, the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations. The current principal amount of the term loan as of March 8, 2018, was \$2,540,161.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, the lender would have a prior right to substantially all of our assets to the exclusion of our general creditors. In that event, our assets would first be used to repay in full all indebtedness and other obligations secured by the lender, resulting in all or a portion of our assets being unavailable to satisfy the claims of any unsecured indebtedness. Only after satisfying the claims of any unsecured creditors would any amount be available for our equity holders. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, a material adverse effect occurring, the occurrence of certain defaults under certain other indebtedness or certain final judgments against us.

The pledge of these assets and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the term loan, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

**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, 2017 was approximately \$632,490. 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):

<b>Year</b>	<b>Amount</b>
2018	654
2019	676

2020	698
Total	\$ 2,028

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

**Table of Contents**

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.

**Table of Contents****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 Global Market under the symbol PULM. Our common stock began trading on the NASDAQ Global Market on December 18, 2015.

The following table sets forth the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market, for the periods shown.

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2017</b>		
First Quarter	\$ 6.98	\$ 0.55
Second Quarter	\$ 3.57	\$ 2.25
Third Quarter	\$ 2.67	\$ 1.40
Fourth Quarter	\$ 2.38	\$ 1.35
<b>Year Ended December 31, 2016</b>		
First Quarter	\$ 4.94	\$ 1.92
Second Quarter	\$ 3.59	\$ 1.84
Third Quarter	\$ 2.63	\$ 1.37
Fourth Quarter	\$ 1.81	\$ 0.50

On March 8, 2018, the last reported sale price of our common stock on the NASDAQ Global Market was \$1.45 per share.

**Stockholders**

As of March 8, 2018, 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. Pursuant to the Loan and Security Agreement, dated June 11, 2015, governing our term loan from Hercules Technology Growth Capital, Inc., we are prohibited from declaring or paying cash dividends or making any distributions on any class of our stock or equity interests. 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, 2017.

---

**Table of Contents**

**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 on Form 10-K. 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 on Form 10-K, entitled Business, under Forward-Looking Statements and Item 1A of this Annual Report on Form 10-K, 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.



## **Table of Contents**

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**

To date, we have not generated any product sales. Our 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 allergic bronchopulmonary aspergillosis ( ABPA ) in patients with asthma and cystic fibrosis.

Our 2016 revenue resulted from the long-acting muscarinic agent collaboration agreement that we entered into with Mylan in 2015. Under the agreement, we were eligible to receive reimbursement for third-party out of pocket expenses directly related to clinical trials. The collaboration agreement concluded in 2016.

## ***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 69%, of our staff are research

## **Table of Contents**

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 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.

### ***Interest Expense***

Interest expense primarily reflects the amortization of debt discounts and interest expense accrued in connection a term loan that was outstanding during the period. We have been incurring and expect to continue to incur 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.

### ***Other Expenses, Net***

Other expenses, net is comprised primarily of gains and/or losses resulting from fair value adjustments on compound derivative instruments embedded within certain of our convertible notes.

### **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,

## **Table of Contents**

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 on Form 10-K, 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 fees for services and 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.

### ***Service revenues***

We 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, we review and adjust, 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***

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.

---

**Table of Contents**

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, 2017 and 2016, 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 the first step of the goodwill impairment test. As of December 31, 2016, we

determined that goodwill was impaired by \$5,029 and adjusted the goodwill to reflect its fair value of \$10,914. As of December 31, 2017, we determined that goodwill was not impaired, and no further adjustment was deemed necessary.



**Table of Contents*****In-process Research & Development***

In-process research & development, or IPR&D, represents the fair value assigned to research and development assets that were not fully developed at the date of acquisition. IPR&D acquired in a business combination or recognized from the application of push-down accounting is capitalized on our consolidated balance sheet at its acquisition-date fair value. Until the project is completed, the assets are accounted for as indefinite-lived intangible assets and subject to impairment testing. Upon completion of a project, the carrying value of the related IPR&D is reclassified to intangible assets and is amortized over the estimated useful life of the asset.

When performing the impairment assessment, the Company first assesses qualitative factors to determine whether it is necessary to recalculate the fair value of its acquired IPR&D. If the Company believes, as a result of the qualitative assessment, that it is more likely than not that the fair value of acquired IPR&D is less than its carrying amount, it calculates the asset's fair value. If the carrying value of the Company's acquired IPR&D exceeds its fair value, then the intangible asset is written down to its fair value. During the fiscal year ended December 31, 2016, a full write-off of the IPR&D and its related deferred tax liability, \$7,534 and \$2,959 respectively, were recorded. During the fiscal year ended December 31, 2017, no such write-offs were recorded.

**Results of Operations*****Year Ended December 31, 2017 Compared with Year ended December 31, 2016***

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>2017</b>	<b>2016</b>	<b>Change</b>
Revenues	\$ 335	\$ 835	\$ (500)
<b>Operating expenses</b>			
Research and development	10,243	10,152	91
General and administrative	7,567	8,015	(448)
Write-off of intangibles		7,534	(7,534)
Total operating expenses	17,810	25,701	(7,891)
Loss from operations	(17,475)	(24,866)	7,391
Interest expense	(643)	(881)	238
Impairment of goodwill		(5,029)	5,029
Fair value adjustment of derivative liability	34	(24)	58
Other income (expenses), net	28	(2)	30
Loss before income taxes	(18,056)	(30,802)	12,746
Benefit from income taxes		2,959	(2,959)
Net loss	\$ (18,056)	\$ (27,843)	\$ 9,787

**Revenue** Revenue was \$0.3 million for the year ended December 31, 2017, compared to \$0.8 million for the year ended December 31, 2016, a decrease of \$0.5 million. The decrease was the result of the conclusion of the clinical study funded under our collaboration agreement with Mylan in 2016, partially offset by the revenue from the CFFT award in 2017.

**Research and development expenses** Research and development expense was \$10.2 million for the year ended December 31, 2017, compared to \$10.2 million for the year ended December 31, 2016. The minimal increase in 2017 was primarily due to increases in employment related costs.

**General and administrative expenses** General and administrative expense was \$7.6 million for the year ended December 31, 2017, compared to \$8.0 million for the year ended December 31, 2016, a decrease of \$0.4 million.

---

## **Table of Contents**

The decrease was primarily due to a decrease of \$1.1 million in stock-based compensation expense, net of increases of \$0.4 million in salary related expense and \$0.3 million in patent and legal expense.

***Write-off of intangibles*** Write-off of intangibles was \$0 for the year ended December 31, 2017 and \$7,534 for the year ended December 31, 2016, a decrease of \$7,534. A full write-off was made of the IPR&D acquired from our 2015 merger with Pulmatrix Operating Company, Inc. during the year ended December 31, 2016.

***Interest expense*** Interest expense was \$0.6 million for the year ended December 31, 2017, compared to \$0.9 million for the year ended December 31, 2016, a decrease of \$0.2 million. The decrease in interest expense resulted from the decrease in outstanding principal of the term loan during that period. For both years, interest expense incurred related to the term loan agreement that we entered into in June 2015.

***Write-off of deferred tax liability*** For the year ended December 31, 2017, the write-off of deferred tax liability was \$0.0 million compared to \$3.0 for the year ended December 31, 2016. During 2016, as a result of the Oculus Innovative Sciences, Inc. agreement lapse, a full write-off was made of the deferred tax liability associated with the IPR&D acquired from the merger.

***Impairment of goodwill*** For the year ended December 31, 2017, the goodwill impairment charge was \$0.0 million compared to \$5.0 for the year ended December 31, 2016. In 2016, the Company performed an impairment assessment. The Company concluded that the carrying amount of the goodwill exceeded its fair value and recorded a resulting impairment charge of \$5.0 million.

## **Liquidity and Capital Resources**

Through December 31, 2017, we have incurred an accumulated deficit of \$174.0 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and general and administrative expenses supporting those activities, as well as a net loss of \$18.0 million and negative operating cash flows. Our total cash and cash equivalents balance as of December 31, 2017 was \$3.6 million. We expect to continue incurring losses and negative cash flows from operations until our products reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we only have sufficient resources to fund operations into the second quarter of 2018. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include the continued commercialization of our products and raising capital through the sale of additional equity securities or capital inflows from strategic partnerships. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our products and raising capital, we may need to reduce activities, curtail or cease operations.

During 2017, we closed two registered direct offerings and periodically sold shares of common stock pursuant to at-the-market offering described below that resulted in net proceeds of approximately \$16.3 million. We anticipate that we will continue to incur losses, and that such losses will increase over the next several years due to development costs associated with our iSPERSE pipeline programs. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding and other collaborations and strategic alliances. There will be continued doubt about the Company's ability to continue as a going concern if we are unable to do so.

Edgar Filing: Pulmatrix, Inc. - Form 10-K

On June 11, 2015, we entered into a Term Loan agreement to borrow \$7.0 million. The term loan funded on June 16, 2015 and will mature on July 1, 2018.

We believe that our existing resources will be sufficient to fund our planned operations into the second quarter of 2018. We have based this estimate on assumptions that may prove to be wrong, and we could use our available

**Table of Contents**

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>2017</b>	<b>2016</b>
Net cash used in operating activities	\$ (14,477)	\$ (13,243)
Net cash used in investing activities	(74)	(431)
Net cash provided by (used in) financing activities	13,919	(1,046)
Net decrease in cash and cash equivalents	\$ (632)	\$ (14,720)

***Cash Flows from Operating Activities***

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.

Net cash used in operating activities for the year ended December 31, 2016 was \$13.2 million, which was primarily the result of a net loss of \$27.8 million, partially offset by \$14.2 million of net non-cash adjustments and \$0.4 million in cash inflows associated with changes in operating assets and liabilities. Our non-cash adjustments were primarily comprised of \$5.0 million goodwill impairment, \$4.6 million of the write-off of IPR&D, net of tax provision, \$4.0 million of stock-based compensation expense, \$0.3 million of depreciation and amortization, and \$0.3 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 \$1.0 million decrease in prepaid expenses and other current assets, partially offset by a \$0.3 million decrease in accounts payable and a \$0.3 million decrease in accrued expenses.

***Cash Flows from Investing Activities***

Net cash used in investing activities for the year ended December 31, 2017 was \$0.1 million, compared to net cash used in investing activities of \$0.4 million for the year ended December 31, 2016. Net cash used in investing activities for the year ended December 31, 2017 was primarily due to purchases of property and equipment. Net cash provided by investing activities for the year ended December 31, 2016 was primarily due to purchases of property and equipment, partially offset by proceeds from sale of equipment.

***Cash Flows from Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2017 was \$13.9 million, as compared to net cash used in financing activities of \$1.0 million for the year ended December 31, 2016. Net cash provided by financing activities for the year ended December 31, 2017 was due to the issuance of common stock that

**Table of Contents**

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.

Net cash used in financing activities for the year ended December 31, 2016 was \$1.0 million which resulted from 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 be sufficient to enable us to support chemistry manufacturing and control activities in support of Pulmazole and pre-clinical evaluation of PUR1800 for COPD. The funding will not be sufficient 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 all of 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.

*Registered Direct Offering*

On January 27, 2017, we entered into a Securities Purchase Agreement (the *Purchase Agreement* ) with certain investors for the sale of 2,000,000 shares (the *Shares* ) of our common stock, par value \$0.0001 per share, at a purchase price of \$2.50 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, we entered into a Securities Purchase Agreement (the *Second Purchase Agreement* ) with certain investors for the sale of 950,000 shares of our common stock, par value \$0.0001 per share, at a purchase price of \$3.50 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. The shares issued in the offerings were offered and sold by us pursuant to



---

**Table of Contents**

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.

*At-the-Market Offering*

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 Global 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 3,103,360 shares of its common stock under the Sales Agreement at an average selling price of approximately \$2.93 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.

*Term Loan and Warrant*

On June 11, 2015 Pulmatrix Operating Company Inc. entered into a Loan and Security Agreement ( *LSA* ) with Hercules, for the Term Loan in a principal amount of \$7.0 million. On June 15, 2015, following the effective time of the merger with Pulmatrix Operating Company Inc., we signed a joinder agreement with Hercules to make our Company a co-borrower under the LSA. The Term Loan is secured by substantially all of our and our subsidiary's assets, excluding our and our subsidiary's intellectual property.

The Term Loan bears 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%. We are required to make interest payments in cash on the first business day of each month, beginning on July 1, 2015. Beginning on August 1, 2016, we are required to make monthly payments on the first business day of each month consisting of principal and interest based upon a 30-month amortization schedule, and any remaining unpaid principal and interest will be due on the maturity date of July 1, 2018. Upon repayment of the Term Loan, we are also required to pay an end of term fee to the lenders of approximately \$0.2 million.

We may elect to prepay all, but not less than all, of the outstanding principal balance of the Term Loan, subject to a prepayment fee of 1% - 3%, depending on the date of repayment. Contingent on the occurrence of several events, including that our closing stock price exceed \$11.73 per share for the seven days preceding a payment date, we may elect to pay, in whole or in part, any regularly scheduled installment of principal up to an aggregate maximum amount of \$1.0 million by converting a portion of the principal into shares of our common stock at a price of \$11.73 per share. Hercules may elect to receive payments of any regularly scheduled amounts of principal in shares of our common stock based on a price of \$11.73 per share, subject to an aggregate maximum principal amount of \$1.0 million.

The credit facility includes affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring us to maintain legal existence and governmental approvals and to deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on

## **Table of Contents**

transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets, and suffering a change in control, in each case subject to certain exceptions. In general, the term loan prohibits us from (i) repurchasing or redeeming any class of capital stock, including common stock or (ii) declaring or paying any cash dividend or making cash distribution on any class of capital stock, including common stock. As of December 31, 2017, and 2016, we were in compliance with all covenants.

The credit facility also includes events of default, the occurrence and continuation of which provide Hercules, as agent, with the right to exercise remedies against us and the collateral securing the Term Loan under the credit facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the credit facility, our insolvency, a material adverse effect occurring, the occurrence of certain defaults under certain other indebtedness or certain final judgments against us.

In June 2015, in connection with the LSA, we granted to Hercules a warrant to purchase 25,150 shares of our common stock at an exercise price of \$8.35 per share. The warrants are exercisable in whole or in part any time prior to the expiration date of June 16, 2020. In the event the warrants are not fully exercised, upon the expiration date any outstanding warrants will be automatically exercised for shares of our common stock on a net basis. If the fair market value of one share of our common stock is greater than the exercise price of the warrant, in lieu of exercising the warrant for cash, Hercules may elect to convert all or a portion of the warrant into common stock on a net basis.

### *Commitments*

We contract with various other organizations to conduct research and development activities. As of December 31, 2017, we had aggregate commitments to pay approximately \$2.8 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 on Form 10-K beginning on page F-1.

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

Not applicable.

## **Table of Contents**

### **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 on Form 10-K, 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, 2017.

##### *Changes in Internal Controls*

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

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

None.

**Table of Contents****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.

<b>Name</b>	<b>Age</b>	<b>Position with the Company</b>
Robert W. Clarke, Ph.D	49	Chief Executive Officer and Director
William E. Duke, Jr.	45	Chief Financial Officer
David L. Hava, Ph.D	43	Chief Scientific Officer
Teofilo Raad	48	Chief Business Officer
James Roach, M.D.	58	Chief Medical Officer
Steven Gillis, Ph.D	64	Director
Michael J. Higgins	55	Director
Mark Iwicki	52	Director
Terrance McGuire	61	Director
Amit D. Munshi	49	Director
Matthew L. Sherman, M.D.	62	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 this year, 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 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 twenty (20) 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's 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



---

**Table of Contents**

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.

**David L. Hava, Ph.D.** Dr. Hava has served as our chief scientific officer since June 15, 2015 and served as the chief scientific officer of Pulmatrix Operating from July 2012 until June 15, 2015. Dr. Hava leads the research and development of the iSPERSE dry powder delivery platform and directs and manages the Company's therapeutic strategy to identify and prioritize iSPERSE-based therapeutic candidates. Dr. Hava joined our company in 2006 as one of our first senior scientists and has been involved in the early stage research and development programs that identified and characterized several of the key aspects of our technology. Dr. Hava received his Ph.D. in Molecular Biology and Microbiology at Tufts University and completed post-doctoral training in immunology and host-pathogen interactions at Harvard Medical School. Dr. Hava has co-authored over twenty (20) papers and abstracts focused on pulmonary infectious disease, immunology and chronic lung diseases.

**Ted Raad.** Mr. Raad has served as our chief business officer since May 2017 and leads our commercial and business development efforts. He has 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 PUR1900 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 US 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. 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 Shire plc, Accelerator Corporation, Homology Medicines, Inc. and serves as director and chairman of VentiRX Pharmaceuticals, Inc.,

---

**Table of Contents**

Theraclone Sciences, Inc., Lycera Corp., Faraday Pharmaceuticals, Inc., Oncofactor Corp., VBI Vaccines and PhaseRx, 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 Company, Inc., previously known as Pulmatrix Inc. (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 Genocea Biosciences, Voyager Therapeutics, Kindex Pharmaceuticals, Madauder 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. 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 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, Taris Biomedical and Oxeia Biopharmaceuticals. He previously served on the boards of Civitas, Sunovion and Blend, 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 twenty-five (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 seven (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 two other public companies: Acceleron Pharma Inc. and Ironwood Pharmaceuticals Inc. Mr. McGuire also serves on the boards of several private companies, including Adimab, Alector, Quantum Designs, Inc., Arsenal Medical/480 Biomedical, Iora Health and MicroCHIPS. Mr. McGuire has formerly served on the board of directors of Editas, Life Line Screening, NextCode, Trevena 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



---

## **Table of Contents**

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 currently serves on the board of Cytrellis Biosystems, Inc.

**Matthew L. Sherman, M.D.** Dr. Sherman became a director of our Company in September 2016. Dr. Sherman has served as the Chief Medical Officer of Acceleron Pharma Inc. since May 2006 and as the Executive Vice President Acceleron Pharma Inc. since March 2015. 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<sup>®</sup> 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.

---

## **Table of Contents**

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, 2017.

### **Independent Directors**

We are currently listed on the NASDAQ Global 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, as well as our former director, Dr. Rocklage prior to his resignation had, 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 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, 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 March 8, 2018, Polaris beneficially owned 18.1% of our common stock and ARCH Venture Partners beneficially owned 10.3% of our common stock.

Our former director, Dr. Rocklage has served as a Managing Partner of 5AM Ventures LLC and 5AM Co-Investors LLC (collectively, "5AM Ventures") since 2004. Together with Polaris and ARCH Venture Fund, 5AM Ventures beneficially owned 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. During 2017 and through the time of Dr. Rocklage's resignation which became effective on March 13, 2017, 5AM Ventures beneficially owned in excess of 4.9% of our common stock, but not more than 9.9% of our outstanding common stock. As of March 8, 2018, 5AM Ventures does not beneficially own any 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.

**Table of Contents**

As of March 8, 2018, the following table sets forth the membership of each of the Board committees listed above.

<b>Name</b>	<b>Audit Committee</b>	<b>Compensation Committee</b>	<b>Nominating and Corporate Governance Committee</b>
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

## **Table of Contents**

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](http://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, 2017, with compensation of \$100,000 or more (our Named Executive Officers ) for the year ended December 31,2017:

<b>Name</b>	<b>Position</b>
Robert W. Clarke, Ph.D.	President, Chief Executive Officer, Director
Teofilo Raad	Chief Business Officer
James Roach, M.D.	Chief Medical Officer

**Table of Contents****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, 2017 and the fiscal year ended December 31, 2016.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Non-qualified incentive compensation			All Other compensation (\$)	Total (\$)
				Stock Awards (\$)	Option Awards (\$)	Other (\$)		
Robert W. Clarke, Ph.D. (Chief Executive Officer)	2017	407,862	164,969	305,011			5,776 (2)	883,618
	2016	396,920	159,390	566,517			5,684 (3)	1,128,511
Teofilo Raad (4) (Chief Business Officer)	2017	215,769	79,333	594,572			4,663 (5)	894,337
	2016							
James Roach, M.D. (6) (Chief Medical Officer)	2017	51,269	172,000	377,754			1,069 (7)	602,092
	2016							

- (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 11 to our consolidated financial statements for the fiscal year ended December 31, 2017 in our Annual Report on Form 10-K for the year ended December 31, 2017.
- (2) 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.
- (3) 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 \$384.
- (4) Began to serve on May 1, 2017.
- (5) 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.
- (6) Began to serve on November 1, 2017.
- (7) Represents Company 401(k) plan contributions of \$1,025 and payment made by the Company for life, AD&D and LTD premiums in the amount of \$44.

**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

## **Table of Contents**

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, Mr. Raad and Dr. Roach 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.



---

**Table of Contents*****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.

***Dr. Roach***

In November 2017, we entered into an employment agreement with Dr. Roach to serve as our chief scientific officer. Dr. Roach's employment with us is at-will, and the agreement does not include a specified term. Both Dr. Roach'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. Roach's employment is terminated (i) by the Company without cause or (ii) by Dr. Roach for good reason, then the Company must pay Dr. Roach, 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 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 Dr. Roach that would have vested during the nine



(9) months following the termination date will immediately vest and become exercisable. If Dr. Roach's employment is terminated (i) by the Company without cause or (ii) by Dr. Roach for

**Table of Contents**

good reason, within twelve (12) months following a change in control, then Dr. Roach 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. Roach'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. Roach's employment agreement, "good reason" is defined as (i) relocation of Dr. Roach's principal business location to a location more than fifty (50) miles from his then-current business location; (ii) a material diminution in Dr. Roach's duties, authority or responsibilities; or (iii) a material reduction in Dr. Roach's base salary; provided that (A) Dr. Roach 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. Roach terminates his employment within ninety (90) 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, 2017:

**Outstanding Equity Awards at Fiscal Year End Table****2017****Option Awards**

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards:		Option exercise price (\$)	Option expiration date
			Number of securities underlying unexercised options (#)	Number of securities underlying unearned		
Robert W. Clarke, Ph.D.	2,665 (1)				2.21	02/10/2020
	2,413 (1)				2.21	05/24/2020
	11,855 (1)				2.21	06/15/2021
	23,710 (1)				2.03	06/08/2022
	171,009 (1)				2.03	09/18/2022
	65,625 (1)				1.88	10/11/2023
	356,918 (2)	50,989			11.80	06/16/2025
	38,798 (2)	5,543			11.00	06/24/2025
	145,748 (3)	172,252			2.80	02/03/2026
	(3)	159,000			2.78	03/20/2027
Teofilo Raad	(3)	330,500			2.70	05/01/2027

James Roach, M.D.	(3)	360,000	1.57	10/27/2027
-------------------	-----	---------	------	------------

- (1) Fully vested.
- (2) 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.
- (3) 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.

**Table of Contents****Director Compensation**

The following table presents the total compensation for each person who served as a member of our Board during 2017. 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****2017**

<b>Name</b>	<b>Fees earned or paid in cash (\$)(1)</b>	<b>Stock awards (\$)</b>	<b>Option awards (\$)</b>	<b>All other compensation (\$)</b>	<b>Total (\$)</b>
Steven Gillis, Ph.D	45,773		7,881 (2)		53,654
Michael J. Higgins	50,000		7,881 (3)		57,881
Mark Iwicki	68,000		7,881 (4)		75,881
Terrance G. McGuire	47,000		7,881 (5)		54,881
Amit D. Munshi (6)	20,330		14,028 (7)		34,358
Scott M. Rocklage, Ph.D. (8)	6,989				6,989
Matthew L. Sherman, M.D.	33,000		7,881 (9)		40,881

- (1) Amounts of the fees for directors who were elected (or who resigned) in 2017 reflect their partial year of service.
- (2) As of December 31, 2017, Dr. Gillis had outstanding options representing the right to purchase 32,018 shares of our common stock.
- (3) As of December 31, 2017, Mr. Higgins had outstanding options representing the right to purchase 50,836 shares of our common stock.
- (4) As of December 31, 2017, Mr. Iwicki had outstanding options representing the right to purchase 77,881 shares of our common stock.
- (5) As of December 31, 2017, Mr. McGuire had outstanding options representing the right to purchase 32,018 shares of our common stock.
- (6) Mr. Munshi was elected to the Board effective June 13, 2017.
- (7) As of December 31, 2017, Mr. Munshi had outstanding options representing the right to purchase 8,800 shares of our common stock.
- (8) Dr. Rocklage resigned from the Board, effective March 13, 2017. As of December 31, 2017, Dr. Rocklage had no outstanding options.
- (9) As of December 31, 2017, Dr. Sherman had outstanding options representing the right to purchase 13,200 shares of our common stock.

**Table of Contents**

We have entered into a director's agreement with each of our non-employee directors. In 2017, under these agreements, non-employee directors were paid cash compensation payable in four quarterly payments as set forth in the table below.

	<b>Annual Retainer</b>
<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 2017, 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. Each of Messrs. Higgins, Iwicki, McGuire and Drs. Gillis and Sherman received an option to purchase 4,400 shares of the Company's common stock at an exercise price of \$2.78 per share, which was the closing price on March 20, 2017, the grant date. Mr. Munshi received an option to purchase 8,800 shares of the Company's common stock at an exercise price of \$2.39 per share, which was the closing price on the June 13, 2017, the grant date.

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

**Table of Contents****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, 2017:

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (3)</b>
Equity compensation plans approved by security holders (1)	3,725,634	\$ 5.69	453,554
Equity compensation plans not approved by security holders (2)			
<b>Total</b>	<b>3,725,634</b>	<b>\$ 5.69</b>	<b>453,554</b>

(1) Represents shares available for issuance under the 2013 Plan.

(2) Excludes 499,271 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, 2017, there were 95,591 options with a weighted average exercise price of \$1.88 per share outstanding pursuant to the Original 2013 Plan. As of December 31, 2017, there were 403,680 options with a weighted average exercise price of \$2.10 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 the lowest of: (i) 903,600 shares of our common stock; (ii) five percent (5%) of the number of shares of our common stock outstanding as of such date; and (iii) an amount determined by our Board. Effective January 1, 2018, under the 2013 Plan's evergreen provision, the number of shares of our common stock available for issuance was increased by 903,600 shares to a total of 5,096,675 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. As of December 31, 2017, the 2013 Plan provided for the grant of up to 4,196,075 shares of our common stock, of which 453,554 shares remained available for future grant. Effective January 1, 2018, under the 2013 Plan's evergreen provision, the number of shares of our common

stock available for issuance was increased by 903,600. As of March 8, 2018, the total authorized shares under the 2013 Plan were 5,096,675 shares of which 1,359,051 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

## **Table of Contents**

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 95,591 and 403,680 shares of our common stock may be delivered under options outstanding as of December 31, 2017 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.

In connection with the merger with Pulmatrix Operating, all outstanding stock options of Pulmatrix Operating converted into stock options to purchase our common stock, subject to the Exchange Ratio. The conversion of the Pulmatrix Operating stock options for stock options to purchase our common stock was treated as a modification of the awards. The modification of the stock options did not result in any incremental compensation expense as the modification did not increase the fair value of the stock options.

### ***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 March 8, 2018, the total authorized shares under the 2013 Plan were 5,096,675 shares of which 1,359,051 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 the lowest of: (i) 903,600 shares of our common stock; (ii) five percent (5%) of the number of shares of our common stock outstanding as of such date; and (iii) 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. The 2013 Plan provides that no participant may receive awards for more than 800,000 shares of common stock in any fiscal year.

*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

---

**Table of Contents**

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.



**Table of Contents**

*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.

---

**Table of Contents**

*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 March 8, 2018, 403,680 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 March 8, 2018, 95,591 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

**Table of Contents**

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 March 8, 2018 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,

**Table of Contents**

Lexington, MA 02421, unless otherwise noted. Percentage of ownership is based on 22,280,160 shares of common stock issued and outstanding as of March 8, 2018.

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 March 8, 2018 by that stockholder are deemed outstanding.

Name	Number of Shares Beneficially Owned (1)(2)	Percentage of Shares Outstanding (1)
<b><u>Directors and Officers</u></b>		
Robert W. Clarke, Ph.D.	955,807	4.12%
William E. Duke, Jr.	271,440	1.20%
Steven Gillis, Ph.D.	2,305,925 (3)	10.34%
David L. Hava, Ph.D.	369,061	1.63%
Michael J. Higgins	32,799	*
Mark Iwicki	44,055	*
Terrance G. McGuire	4,049,703 (4)	18.16%
Amit D. Munshi		*
Teofilo Raad	82,625	*
James Roach, M.D.		*
Matthew L. Sherman, M.D.	4,675	*
<b>All directors and executive officers as a group of eleven persons</b>	<b>8,116,090 (3)(4)</b>	<b>33.75%</b>
<b><u>Five Percent (5%) Stockholders</u></b>		
Polaris	4,030,234 (5)	18.09%
ARCH Venture Fund	2,286,456 (6)	10.26%

\* 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 March 8, 2018.
- (2) Includes the number of shares of common stock underlying stock options set forth opposite the person's name in the following table, which shares are deemed to be beneficially owned for purposes hereof as a result of the ownership of stock options.

	<b>Stock Options</b>
Robert W. Clarke, Ph.D.	932,615
William E. Duke, Jr.	271,440
Steven Gillis, Ph.D.	19,469
David L. Hava, Ph.D.	361,935
Michael J. Higgins	32,799

Edgar Filing: Pulmatrix, Inc. - Form 10-K

Mark Iwicki	44,055
Terrance G. McGuire	19,469
Amit D. Munshi	
Teofilo Raad	82,625
James Roach, M.D.	
Matthew L. Sherman, M.D.	4,675
All directors and officers as a group	1,769,082

- (3) Based solely on the information contained in the Schedule 13D filed by ARCH Venture Fund with the SEC on January 5, 2018. Includes the following shares which are also reported on this table as being

**Table of Contents**

beneficially owned by ARCH Venture Fund: 2,286,456 shares of Pulmatrix common stock. 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.

- (4) Based solely on the information contained in the Schedule 13D filed by Polaris with the SEC on June 25, 2015. Includes the following shares which are also reported on this table as being beneficially owned by Polaris: 4,030,234 shares of Pulmatrix common stock. Mr. McGuire is a General Partner of Polaris and may be deemed to directly or indirectly control Polaris. Accordingly, Mr. McGuire may be deemed to beneficially own the securities held by Polaris. Mr. McGuire disclaims beneficial ownership of these securities and this disclosure shall not be deemed an admission that Mr. McGuire is the beneficial owner of such securities for purposes of Section 13(d) of the Exchange Act or any other purpose.
- (5) The business address of Polaris is 1 Marina Park Dr., Boston, Massachusetts, 02210.
- (6) The business address of ARCH Venture Fund is 8725 W. Higgins Rd., Suite 290, Chicago, Illinois 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 March 8, 2018, Polaris beneficially owns approximately 18.1% 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 March 8, 2018, ARCH Venture Fund beneficially owns approximately 10.3% of our Company's outstanding common stock.

**Table of Contents****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, 2017 and 2016:

	<b>2017</b>	<b>2016</b>
Audit Fees	\$ 155,778	\$ 168,969
Audit-Related Fees	61,850	9,958
Tax Fees		
All Other Fees		2,500
<b>Total Fees</b>	<b>\$ 217,628</b>	<b>\$ 181,427</b>

*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 of the services rendered by Marcum LLP in 2017 were pre-approved by the Audit Committee.



**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

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

(2) Financial Statement Schedules:

None. Financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

(3) Exhibits:

See Index to Exhibits for a description of our exhibits.

**Item 16. FORM 10-K SUMMARY**

Not applicable.



**Table of Contents****INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed with this Report</b>	<b>Incorporated by Reference</b>		
			<b>herein from Form or Schedule</b>	<b>Filing Date</b>	<b>SEC File/Reg Number</b>
3.1	<u>Amended and Restated Certificate of Incorporation of Pulmatrix, Inc., as amended through June 15, 2015.</u>		Form 10-Q (Exhibit 3.1)	08/14/15	001-36199
3.2	<u>Restated Bylaws of Pulmatrix, Inc., as amended through June 15, 2015.</u>		Form 10-Q (Exhibit 3.2)	08/14/15	001-36199
4.1	<u>Form of Specimen Stock Certificate.</u>		Form 8-K (Exhibit 4.1)	06/16/15	001-36199
4.2	<u>Securities Escrow Agreement, dated June 12, 2015, by and among Pulmatrix, Inc., Pulmatrix Operating Company, Inc. and VStock Transfer, LLC, as Escrow Agent.</u>		Form 10-Q (Exhibit 4.1)	08/14/15	001-36199
4.3	<u>Form of Representative s Warrant Agreement.</u>		Form S-1 (Exhibit 4.2)	02/24/14	333-190476
4.4	<u>Warrant Agreement, dated June 16, 2015, by and between Pulmatrix, Inc. and Hercules Technology Growth Capital, Inc.</u>		Form 8-K (Exhibit 10.3)	06/16/15	001-36199
4.5	<u>Form of Warrant issued in Pulmatrix Operating Private Placement, dated June 15, 2015.</u>		Form 10-Q (Exhibit 10.8)	08/14/15	001-36199
10.1	<u>Form of Subscription Agreement</u>		Form 8-K (Exhibit 10.1)	06/12/15	001-36199
10.2*	<u>Executive Employment Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and Robert W. Clarke, Ph.D.</u>		Form 8-K (Exhibit 10.4)	06/16/15	001-36199
10.3*			Form 8-K	06/16/15	001-36199

Edgar Filing: Pulmatrix, Inc. - Form 10-K

	<u>Executive Employment Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and David L. Hava, Ph.D.</u>	(Exhibit 10.5)		
10.4*	<u>Executive Employment Agreement, dated June 24, 2015, by and between Pulmatrix, Inc. and William Duke, Jr.</u>	Form 10-Q (Exhibit 10.4)	08/14/15	001-36199
10.5*	<u>Pulmatrix, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan.</u>	Form 8-K (Exhibit 10-6)	06/16/15	001-36199
10.6*	<u>Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan.</u>	Form S-8 (Exhibit 99.2)	07/20/15	333-205752
10.7*	<u>Pulmatrix Inc. 2003 Employee, Director and Consultant Stock Plan.</u>	Form S-8 (Exhibit 99.3)	07/20/15	333-205752
10.8	<u>Loan and Security Agreement, dated June 11, 2015, by and among Pulmatrix Operating Company, Inc., Hercules Technology Growth Capital, Inc. and the lenders party thereto from time to time</u>	Form 8-K (Exhibit 10.1)	06/16/15	001-36199

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed with this Report</b>	<b>Incorporated by Reference</b>		<b>SEC File/Reg Number</b>
			<b>herein from Form or Schedule</b>	<b>Filing Date</b>	
10.9	<u>Joinder Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and Hercules Technology Growth Capital, Inc.</u>		Form 8-K (Exhibit 10.2)	06/16/15	001-36199
10.10	<u>License, Development and Commercialization Agreement, dated June 9, 2017, by and between Pulmatrix, Inc. and Respivert Ltd.</u>		Form 10-Q (Exhibit 10.1)	08/04/17	001-36199
10.11	<u>Feasibility and Development Agreement, dated September 5, 2017, by and between Pulmatrix, Inc. and Vectura Limited</u>		Form 10-Q (Exhibit 10.1)	11/09/17	001-36199
10.12*	<u>Executive Employment Agreement, dated October 30, 2017, by and between Pulmatrix, Inc. and James Roach</u>		Form 8-K (Exhibit 10.1)	11/03/17	001-36199
21.1	<u>List of Subsidiaries.</u>	X			
23.1	<u>Consent of Marcum LLP, independent registered public accounting firm, to the Form 10-K.</u>	X			
31.1	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	X			
31.2	<u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	X			
32.1	<u>Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	X			
32.2	<u>Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	X			
101		X			

The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statement of Changes in Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements.

# Certain schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Pulmatrix, Inc. hereby undertakes to furnish supplementally copies of any of the omitted schedules upon request by the Securities and Exchange Commission.

\* These exhibits are management contracts

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**PULMATRIX, INC.**

Date: March 13, 2018

By: /s/ Robert W. Clarke, Ph.D.

Robert W. Clarke Ph.D.

Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Robert W. Clarke, Ph.D.	Chief Executive Officer, President and Director	March 13, 2018
Robert W. Clarke, Ph.D.	(Principal Executive Officer)	
/s/ William Duke, Jr.	Chief Financial Officer, Treasurer and Secretary	March 13, 2018
William Duke, Jr.	(Principal Financial Officer and Principal Accounting Officer)	
/s/ Mark Iwicki	Chairman of the Board of Directors	March 13, 2018
Mark Iwicki		
/s/ Steven Gillis, Ph.D.	Director	March 13, 2018
Steven Gillis, Ph.D.		
/s/ Michael J. Higgins	Director	March 13, 2018
Michael J. Higgins		
/s/ Terrance G. McGuire	Director	March 13, 2018
Terrance G. McGuire		
/s/ Amit D. Munshi	Director	March 13, 2018
Amit D. Munshi		

/s/ Matthew L. Sherman, M.D.

Director

March 13, 2018

Matthew L. Sherman, M.D.

Table of Contents

**PULMATRIX, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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

F-1

---

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Audit Committee of 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, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

**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 has a significant working capital deficiency, 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 provides a reasonable basis for our opinion.

Marcum LLP



/s/ Marcum LLP

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

New York, NY

March 13, 2018

F-2

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

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,550	\$ 4,182
Prepaid expenses and other current assets	696	577
<b>Total current assets</b>	<b>4,246</b>	<b>4,759</b>
Property and equipment, net	614	786
Long-term restricted cash	204	204
Goodwill	10,914	10,914
<b>Total assets</b>	<b>\$ 15,978</b>	<b>\$ 16,663</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Loan Payable, net of debt discount and issuance costs	3,221	2,586
Accounts payable	457	747
Accrued expenses	2,162	1,317
<b>Total current liabilities</b>	<b>5,840</b>	<b>4,650</b>
Loan payable, net of current portion, debt discount and issuance costs		3,217
Derivative liability	1	35
<b>Total liabilities</b>	<b>5,841</b>	<b>7,902</b>
Stockholders Equity:		
Common stock, \$0.0001 par value 100,000,000 shares authorized at December 31, 2017 and December 31, 2016; 21,047,498 and 14,850,526 shares issued and outstanding including vested and restricted stock of 0 and 99,308, at December 31, 2017 and December 31, 2016, respectively	2	1
Additional paid-in capital	184,137	164,706
Accumulated deficit	(174,002)	(155,946)
<b>Total stockholders equity</b>	<b>10,137</b>	<b>8,761</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 15,978</b>	<b>\$ 16,663</b>

*See accompanying notes to consolidated financial statements.*



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

	<b>Years ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Revenues	\$ 335	\$ 835
Operating expenses		
Research and development	10,243	10,152
General and administrative	7,567	8,015
Write off of intangibles		7,534
Total operating expenses	17,810	25,701
Loss from operations	(17,475)	(24,866)
Other income (expense)		
Interest expense	(643)	(881)
Impairment of goodwill		(5,029)
Fair value adjustment of derivative liability	34	(24)
Other income (expense), net	28	(2)
Loss before income taxes	(18,056)	(30,802)
Benefit from income taxes		2,959
Net loss	\$ (18,056)	\$ (27,843)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.93)	\$ (1.88)
Weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders	19,371,564	14,815,230

*See accompanying notes to consolidated financial statements.*

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

		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
		Shares	Amount			
Balance	January 1, 2016	14,745,754	\$ 1	\$ 160,708	\$ (128,103)	\$ 32,606
	Exercise of common stock options	277				
	Vesting of restricted stock units	104,495		1,171		1,171
	Stock-based compensation			2,827		2,827
	Net loss				(27,843)	(27,843)
Balance	December 31, 2016	14,850,526	1	164,706	(155,946)	8,761
	Issuance of common stock, net of issuance costs	6,053,360		16,310		16,310
	Exercise of common stock options	138,425	1	303		304
	Vesting of restricted stock units	5,187				
	Stock-based compensation			2,818		2,818
	Net loss				(18,056)	(18,056)
Balance	December 31, 2017	21,047,498	\$ 2	\$ 184,137	\$ (174,002)	\$ 10,137

*See accompanying notes to consolidated financial statements.*

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

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (18,056)	\$ (27,843)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	246	250
Write-off of intangibles, net of tax provision		4,575
Impairment of goodwill		5,029
Stock-based compensation	2,818	3,998
Non-cash rent expense	21	43
Non-cash interest expense	171	212
Non-cash debt issuance expense	12	16
Fair value adjustment on derivative liability	(34)	24
Loss on disposal of property and equipment		82
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(119)	983
Accounts payable	(290)	(346)
Accrued expenses	754	(312)
Net cash used in operating activities	(14,477)	(13,243)
<b>Cash flows from investing activities:</b>		
Proceeds on sale of equipment		24
Purchases of property and equipment	(74)	(455)
Net cash used in investing activities	(74)	(431)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock and warrants, net	16,310	
Proceeds from exercise of stock options	304	
Principal payments term loan	(2,695)	(1,046)
Net cash provided by (used in) financing activities	13,919	(1,046)
<b>Net decrease in cash and cash equivalents</b>	<b>(632)</b>	<b>(14,720)</b>
<b>Cash and cash equivalents beginning of period</b>	<b>4,182</b>	<b>18,902</b>
<b>Cash and cash equivalents end of period</b>	<b>\$ 3,550</b>	<b>\$ 4,182</b>

**Supplemental disclosures of noncash financing and investing activities:**

Fixed asset trade in value	\$	\$	60
Fixed asset purchases in accounts payable at year-end	\$	\$	2

*See accompanying notes to consolidated financial statements*

F-6

---

**Table of Contents**

**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.

*Liquidity*

At December 31, 2017, the Company had unrestricted cash of \$3.6 million and working capital deficit of \$1.6 million. The Company had incurred recurring losses and as of December 31, 2017 had an accumulated deficit of \$174 million. The Company has primarily financed operations to date through the sale of equity securities and 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 and meet its obligations. During the year ended December 31, 2017, the Company raised an aggregate of \$16.3 million in net proceeds through the sale of its common stock (note 9).

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.

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. The Company's consolidated financial statements as of December 31, 2017 do not include any adjustments that might result from the outcome of this uncertainty.

**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 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

F-7

---

**Table of Contents**

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 is currently evaluating the impact of adopting the available methodologies of ASU 2014-09 and 2015-14 upon its consolidated financial statements in future reporting periods. The Company is also in the process of evaluating the new standard against its existing revenue recognition accounting policies to determine the effect the guidance will have on its consolidated financial statements and what changes to systems and controls may be warranted.

In January 2017, the Financial Accounting Standard Board (the FASB) issued Accounting Standards Update (ASU) 2017-04: *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which removes Step 2 from the goodwill impairment test. It is effective for annual and interim periods beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment test performed with a measurement date after January 1, 2017. The Company has adopted this standard and its impact on its consolidated financial statements and related disclosures was immaterial.

In May 2017, the Financial Accounting Standard Board (the FASB) issued Accounting Standards Update (ASU) 2017-09: *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting* which clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The standard is effective beginning after December 15, 2017; early adoption is permitted. The Company has adopted this standard and its impact on its consolidated financial statements and related disclosures was immaterial.

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

F-8

---

**Table of Contents**

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.

**Segment Information**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

**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 fair value of equity instruments recorded as derivative liabilities, 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.

F-9

---

## **Table of Contents**

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.

### **Convertible Instruments**

The Company accounts for hybrid contracts that feature conversion options in accordance with applicable GAAP. Accounting Standards Codification 815 Derivatives and Hedging Activities, (ASC 815) requires companies to bifurcate conversion options from their host instruments and account for them as freestanding derivative financial instruments according to certain criteria. The criteria includes circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

Conversion options that contain variable settlement features such as provisions to adjust the conversion price upon subsequent issuances of equity or equity linked securities at exercise prices more favorable than that featured in the

hybrid contract generally result in their bifurcation from the host instrument.

F-10

**Table of Contents**

The Company accounts for convertible instruments, when the Company has determined that the embedded conversion options should not be bifurcated from their host instruments, in accordance with ASC 470-20 Debt with Conversion and Other Options (ASC 470-20). Under ASC 470-20 the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. The Company accounts for convertible instruments (when the Company has determined that the embedded conversion options should be bifurcated from their host instruments) in accordance with ASC 815. Under ASC 815, a portion of the proceeds received upon the issuance of the hybrid contract are allocated to the fair value of the derivative. The derivative is subsequently marked to market at each reporting date based on current fair value, with the changes in fair value reported in results of operations.

The conversion features of the Notes Payable to Stockholders did not qualify as an embedded derivative instrument and bifurcated from the host convertible debentures was not necessary.

**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, 2017 and 2016 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:

<b>Asset Description</b>	<b>Estimated Useful Lives</b>
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.

F-11

---

**Table of Contents****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.

Other than impairment of in-process research & development (IPR&D), to date no such impairment have been recognized on long-lived assets other than goodwill (Note 3).

**Revenue Recognition**

The Company's principal sources of revenue during the reporting period were income from fees for services and 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

F-12

## **Table of Contents**

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 management fees, and costs associated with monitoring site and data management.

### **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 materially 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

F-13

---

**Table of Contents**

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.

The Tax Cuts and Jobs Act ( the Act ) was enacted on December 22, 2017. The Act reduces the US 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. On December 22, 2017, the Securities and Exchange Commission issued guidance under Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ( SAB 118 ) directing taxpayers to consider the impact of the U.S. legislation as provisional when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law.

At December 31, 2017, the Company has completed its accounting for the tax effects of enactment of the Act, including the effects on its existing deferred tax balances and the one-time transition tax. For the year ended December 31, 2017, the Company recognized no transition tax (Note 13).

**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. The Company initially performs a qualitative assessment of goodwill which considers macro-economic conditions, industry and market trends, and the current and projected financial performance of the reporting unit. No further analysis is required if it is determined that there is a less than 50 percent likelihood that the carrying value is greater than the fair value. The Company completed a qualitative assessment and determined that there was no impairment of goodwill as of December 31, 2017.

**In-process Research & Development**

In-process research & development ( IPR&D ) represents the fair value assigned to research and development assets that were not fully developed at the date of acquisition. IPR&D acquired in a business combination or recognized from the application of push-down accounting is capitalized on the Company's consolidated balance sheet at its acquisition-date fair value. Until the project is completed, the assets are accounted for as indefinite-lived intangible assets and subject to impairment testing. Upon completion of a project, the carrying value of the related IPR&D is reclassified to intangible assets and is amortized over the estimated useful life of the asset.

Annually, or more frequently if events or circumstances indicate that the asset may be impaired, the Company is required to prepare an impairment assessment on IPR&D. When performing the impairment assessment, the Company first assesses qualitative factors to determine whether it is necessary to recalculate the fair value of its acquired IPR&D. If the Company believes, as a result of the qualitative assessment, that it is more likely than not that the fair value of acquired IPR&D is less than its carrying amount, it calculates the asset's fair value. If the carrying value of the Company's acquired IPR&D exceeds its fair value, then the intangible asset is written down to its fair value.

**3. Goodwill and IPR&D**

On June 15, 2015, the Company completed a merger with Pulmatrix Operating Company and recognized \$15,943 of goodwill. The Company also recorded \$7,534 of IPR&D and a related deferred tax liability of \$2,959.

**Table of Contents**

As of December 31, 2017 and 2016, the Company impaired goodwill for \$0 and \$5,029, respectively. Goodwill has been assigned to the Company's single reporting unit.

As of December 31, 2016, the Company recorded a net impairment loss of \$4,575 relating to the write-off of the IPR&D and the related deferred tax liability.

**4. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following:

	<b>For the year ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Prepaid Insurance	\$ 203	\$ 197
Prepaid Clinical Trials	421	9
Prepaid Other	44	58
Accounts receivable	1	206
Deferred Operating Costs	27	107
	<b>\$ 696</b>	<b>\$ 577</b>

**5. Property and Equipment, Net**

Property and equipment consisted of the following:

	<b>For the Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Laboratory equipment	\$ 2,476	\$ 2,414
Computer equipment	216	254
Office furniture and equipment	214	214
Leasehold improvements	578	575
Total property and equipment	3,484	3,457
Less accumulated depreciation and amortization	(2,870)	(2,671)
Property and equipment net	<b>\$ 614</b>	<b>\$ 786</b>

Depreciation and amortization expense for the years ended December 31, 2017 and 2016 was \$246 and \$250, respectively. During the years ended 2017 and 2016, the Company recorded gross fixed asset disposals of \$47 and \$350 and its related accumulated depreciation of \$47 and \$184, respectively.

**6. Significant Agreements**

*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

---

**Table of Contents**

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% to 10% of sales. As of December 31, 2017, 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 IIb Clinical Trial for a licensed product. The payment will be made within 10 days of the first dosing of a patient in a Phase IIb Clinical Trial which is likely to be in 2020.

*Feasibility and Development Agreement*

On September 5, 2017, the Company entered into a Feasibility and Development Agreement to develop Pulmatrix's drug candidate, PUR0200, for chronic obstructive pulmonary disease (COPD) for the U.S. market with Vectura Limited (Vectura). Vectura and/or its partners will be responsible for all future development costs to advance the product for the U.S. Pulmatrix will provide the data package for PUR0200 and assist with the transfer of development and manufacturing activities to Vectura. As part of the agreement, a technology access fee of \$1 million will be payable to Pulmatrix upon successful achievement of pre-agreed pharmaceutical development criteria. Vectura will commence development immediately and will pay Pulmatrix a mid-teen percentage share of any future revenues that Vectura receives relating to future development and sale of PUR0200 and PUR0200-related products including future combinations. As of December 31, 2017, PUR0200 is still in pharmaceutical development.

*Long-Acting Muscarinic Agent Collaboration Agreement*

On March 24, 2015, the Company entered into the long-acting muscarinic agent (LAMA) collaboration agreement (the Mylan Agreement) with Mylan. The focus of the Mylan Agreement is to continue the evaluation of the LAMA project (the Product) for the further development and manufacture as well as the commercialization and marketing of the Product by Mylan in territories outside the United States. Under the terms of the Mylan Agreement, the Company was eligible to receive reimbursement for third-party out of pocket expenses directly related to clinical trials. As consideration for the funding received, the Company agreed to grant to Mylan an option to negotiate for the exclusive right to develop, manufacture, commercialize and market any resulting products outside the United States for 180 days following the delivery of a clinical studies report, in exchange for a tiered share of gross profit of up to 20% of such pharmaceutical sales of the company.

The Company recognized \$835 of revenue under the Mylan Agreement during the year ended December 31, 2016. As of December 31, 2016, Mylan's option expired and Pulmatrix owns the exclusive right to develop, manufacture, commercialize and market any resulting products of PUR0200.

**7. 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

F-16

---

**Table of Contents**

Loan ). On June 15, 2015, following the completion of the Merger, the Company signed a joinder agreement with Hercules making it a co-borrower under the LSA. The entire Term Loan was funded on June 16, 2015. The Term Loan is secured by substantially all of the Company's assets, excluding intellectual property.

The Term Loan bears 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 Company is required to make interest payments in cash on the first business day of each month, beginning on July 1, 2015. The Term Loan interest rate was 10.75% and 10.00% at December 31, 2017 and 2016, respectively. On August 1, 2016, the Company began making monthly payments on the first business day of each month consisting of principal and interest based upon a 30-month amortization schedule, and any unpaid principal and interest is due on the maturity date of July 1, 2018. Upon repayment of the Term Loan, the Company is also required to pay an end of term charge to the lenders equal to \$245. As of December 31, 2017 the Company has accrued \$225 of the total \$245 end of term charge, which is being accrued over the term of the loan to interest expense.

The Company may elect to prepay all, but not less than all, of the outstanding principal balance of the Term Loan, subject to a prepayment fee of 1% to 3%, depending on the date of repayment. Contingent on the occurrence of several events, including that the Company's closing stock price exceed \$11.73 per share for the seven days preceding a payment date, the Company may elect to pay, in whole or in part, any regularly scheduled installment of principal up to an aggregate maximum amount of \$1,000 by converting a portion of the principal into shares of the Company's common stock at a price of \$11.73 per share. Hercules may elect to receive payments in the Company Common Stock by requiring the Company to affect a conversion option whereby Hercules can elect to receive a principal installment payment in shares of the Company Common Stock based on a price of \$11.73 per share, subject to an aggregate maximum principal amount of \$1,000.

The Company determined that the Company's provisions allowing conversion of all or a portion of the LSA contained a beneficial conversion feature ( BCF ). The BCF is contingent upon the occurrence of certain events and as such, the Company will not record the BCF until the contingency is resolved. Through December 31, 2017 the contingency was not resolved.

The credit facility includes affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets, and undergoing a change in control, in each case subject to certain exceptions. In general, the Term Loan prohibits the Company from (i) repurchasing or redeeming any class of capital stock, including common stock or (ii) declaring or paying any cash dividend or making cash distribution on any class of capital stock, including common stock. The Company complied with all covenants during the years ended December 31, 2017 and 2016.

In connection with the making of the term loan the Company agreed that Hercules shall have the right to purchase up to \$1,000 of securities, under terms and conditions equal to those afforded to other investors, in the event that the Company conducts a private placement for \$10,000 or more of securities after the closing date.

On June 16, 2015, in connection with the LSA, the Company granted to Hercules a warrant to purchase 25,150 shares of the Company's common stock at an exercise price of \$8.35 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 LSA includes provisions requiring the embedded interest rate reset upon an event of default and the put option upon an event of default or qualified change of control each represent an embedded derivative instrument

F-17

**Table of Contents**

requiring bifurcation from the loan. The embedded derivatives were bundled and valued as one compound derivative in accordance with the applicable accounting guidance for derivatives and hedging. The fair value of the compound derivative at issuance of \$11 was recorded as a derivative liability and as a discount to the debt. The derivative liability is remeasured at fair value at each reporting date, with changes in fair value being recorded as other income (expense) in the consolidated statements of operations (Note 12). At December 31, 2017, the fair value of the derivative liability was remeasured and valued at \$1. The net debt discounts resulting from the embedded compound derivative and lender fees are being amortized as interest expense from the date of issuance through the maturity date using the effective interest method.

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 Company incurred interest expense of \$881 during the year ended December 31, 2016, which includes accretion of debt discount of \$112. Of the remaining \$769 interest expense, \$669 was payable in cash and \$100 relates to the Hercules end of term fee. For the year ended December 31, 2016, the Company also accreted debt issuance costs of \$16 recorded to general and administrative expenses in accompanying consolidated statement of operations.

The carrying amounts of the Company's Notes as of December 31, 2017 and December 31, 2016 were as follows:

		<b>Hercules Term Loan</b>	<b>Debt Discount</b>	<b>Issuance Costs</b>	<b>Total</b>
Balance	December 31, 2016	\$ 5,954	\$ (136)	\$ (15)	\$ 5,803
	Accretion of debt discount		101		101
	Accretion of issuance costs			12	12
	Principal payments	(2,695)			(2,695)
Balance	December 31, 2017	\$ 3,259	\$ (35)	\$ (3)	\$ 3,221

The remaining principal balance of the term loan of \$3,259 is due for payment on July 1, 2018.

**8. Accrued Expenses and Other Current Liabilities**

Accrued expenses consisted of the following:

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Accrued vacation	\$ 57	\$ 54
Accrued wages and incentive	1,113	796
Accrued clinical & consulting	568	202
Accrued legal & patent	61	51
End of term fee	225	155
Deferred rent	68	46

Accrued other expenses	70	13
Total accrued expenses	\$ 2,162	\$ 1,317

F-18

**Table of Contents**

**9. Common Stock**

*Registered Direct Offering*

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 2,000,000 shares (the *Shares*) of the Company's common stock, par value \$0.0001 per share, at a purchase price of \$2.50 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 950,000 shares of the Company's common stock, par value \$0.0001 per share, at a purchase price of \$3.50 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. 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.

*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 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 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 Global 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 3,103,360 shares of its common stock under the Sales Agreement at an average selling price of approximately \$2.93 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.



**Table of Contents****10. Warrants**

During the years ended December 31, 2017 and 2016, no warrants were issued by the Company. 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, 2017	December 31, 2016
June 15, 2015	Equity	\$ 7.55	June 15, 2020	3,190,030	3,190,030
June 15, 2015	Equity	\$ 8.35	June 16, 2020	25,150	25,150
August 31, 2015	Equity	\$ 11.80	August 31, 2020	30,000	30,000
March 21, 2014	Equity	\$ 22.66	March 21, 2019	37,100	37,100
March 21, 2014	Equity	\$ 22.66	March 21, 2019	2,160	2,160

All warrants are exercisable for common stock. At December 31, 2017, the intrinsic value of the common stock warrants outstanding was \$0.

**11. Stock-Based Compensation**

The Company sponsors the Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan (the 2013 Plan). As of December 31, 2017, the 2013 Plan provides for the grant of up to 4,193,075 shares of the Company's common stock, of which 453,554 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, 2017, the two legacy plans have a total of 499,271 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, 2017, the Company granted options to purchase 1,054,555 shares of the Company's common stock to employees, options to purchase 30,800 shares of the Company's common stock to directors, and options to purchase 10,000 shares of the Company's common stock to advisors. The stock options granted vest over time (the Time Based Options). Time Based Options vest over either 24 or 48 months. Subject to the grantee's continuous service with the Company, Time Based Options vest in one of the following ways: (i) 50% at the one year anniversary of the Vesting Start Date and the remainder in 12 equal monthly installments beginning in the thirteenth month after the Vesting Start Date) or (ii) 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. Stock options generally expire ten years after the date of grant.

**Table of Contents**

The following table summarizes stock option activity for the year ended December 31, 2017:

		<b>Number of Options</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding	January 1, 2017	2,829,301	\$ 6.89	7.85	\$
Granted		1,095,355	\$ 2.34		
Exercised		(138,425)	\$ 2.19		
Forfeited or expired		(90,597)	\$ 8.04		
Outstanding	December 31, 2017	3,695,634	\$ 5.69	7.77	\$
Exercisable	December 31, 2017	1,803,612	\$ 7.21	6.73	\$
Vested and expected to vest	December 31, 2017	3,646,249	\$ 5.69	7.76	\$

The estimated fair values of employee stock options granted during the year ended December 31, 2017 and 2016, were determined on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	<b>For the year ended December 31,</b>			
	<b>2017</b>		<b>2016</b>	
Expected option life (years)	6.12		6.22	
Risk-free interest rate	1.89%	2.25%	1.26%	2.12%
Expected volatility	74.0%	86.3%	70.0%	76.0%
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, 2017, there was \$4,407 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 2.0 years.

**Restricted Stock Units**

In June 2015, the Company granted some former officers 329,052 restricted stock units (the RSUs) of which 130,435 RSUs were immediately vested upon the date of the grant, 99,309 RSUs vested during the six months ended December 31, 2015 and the remaining 99,308 RSUs vested during the first six months in 2016. The shares of common

stock underlying the RSUs were deliverable one year after the applicable vesting date of the respective RSU. In August 2015, the Company granted 10,374 RSUs to other employees that vest over a two-year period. The Company recorded stock-based compensation expense of \$13 and \$1,171 for the RSUs vested during the years ended December 31, 2017 and 2016, respectively.

F-21

**Table of Contents**

The following table summarizes RSU activity for the year ended December 31, 2017:

		Number of Units	Weighted- Average Grant Date Fair Value	Total Grant Date Fair Value
Outstanding	January 1, 2017	5,187	\$ 5.50	\$ 29
Granted				
Vested		(5,187)	5.50	(29)
Forfeited or expired				
Outstanding	December 31, 2017		\$	\$

The following table presents total stock-based compensation expense for the years ended December 31, 2017 and 2016, respectively:

	For the years ended December 31,	
	2017	2016
Research and development	\$ 710	\$ 763
General and administrative	2,095	3,235
Total stock based compensation expense	\$ 2,805	\$ 3,998

**12. Fair Value Measurements**

Information about the liabilities measured at fair value on a recurring basis as December 31, 2017 and December 31, 2016, and the input categories associated with those liabilities, is as follows:

	December 31, 2017 Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
<b>Liabilities:</b>				
Embedded compound derivative	\$	\$	\$ 1	\$ 1

	December 31, 2016 Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
<b>Liabilities:</b>				
Embedded compound derivative	\$	\$	\$ 35	\$ 35

*Goodwill*

As of December 31, 2016, the Company determined that it was more than a 50 percent likelihood that the carrying value of the goodwill was greater than the fair value. As such, the Company performed a two-step quantitative assessment. First, the Company compared fair value of the Company to its carrying value and then performed second step by comparing enterprise value to the carrying value of goodwill. Based on the analysis performed, as of December 31, 2016, the Company impaired goodwill for \$5,029.

At December 31, 2017, based on a qualitative assessment, the Company determined that there was no more than a 50 percent likelihood that the carrying value of the goodwill was greater than the fair value as such impairment of goodwill was not considered necessary. The inputs used are generally unobservable and are therefore considered at level 3 hierarchy. These level 3 inputs were used to measure fair value of carrying value of assets and liabilities of the Company.

**Table of Contents**

A roll-forward of Goodwill is as follows:

	<b>Goodwill</b>
Balance January 1, 2016	\$ 15,943
Impairment	(5,029)
Balance December 31, 2016	10,914
Impairment	
Balance December 31, 2017	\$ 10,914

*Embedded Compound Derivatives LSA with Hercules*

As described in Note 7, the LSA contains an interest rate reset upon an event of default and a put option upon an event of default or qualified change of control. Each of these features represents an embedded derivative instrument requiring bifurcation from the Term Loan. The embedded derivatives were bundled and valued as one compound derivative in accordance with the applicable accounting guidance for derivatives and hedging. The proceeds from the issuance of the Term Loan were allocated first to the warrant and compound derivative at their respective fair values, with the residual going to the carrying amount of the loan resulting in a discount to the face value of the debt. The fair value of the compound derivative upon issuance of \$11 was recognized as a derivative liability and will be adjusted to fair value at each reporting date. The fair value of the derivative instruments is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company used an income approach to estimate the fair value of the derivative liability and estimated the probability of an event of default occurring at various dates and then estimates the present value of the amount the holders would receive upon an event of default.

The significant assumption used in the model is the probability of the following scenarios occurring:

	<b>At Issuance Date</b>	<b>At December 31, 2017</b>
Probability of an event of default	10%	5%
Prepayment penalties	1.0% 3.0%	1.0%
End of term payment	\$245,000	\$245,000
Risk-free interest rate	1.01%	1.53%

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

	<b>Derivative Instruments</b>
Balance January 1, 2016	\$ 11
Change in fair value	24
Balance December 31, 2016	35
Change in fair value	(34)

Balance	December 31, 2017	\$	1
---------	-------------------	----	---

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.

**13. Income Taxes**

The Company had no income tax expense due to operating losses incurred for the year ended December 31, 2017. The Company recorded a deferred income tax benefit for the year ended December 31, 2016 of \$2,959 relating to a book impairment of a deferred tax liability set up in purchase accounting which was not subject to a valuation allowance.

**Table of Contents**

The components of the (benefit) provision for income taxes are as follows:

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Current income tax provision		
Federal	\$	\$
State		
Total current income tax provision		
Deferred income tax (benefit) provision		
Federal		(2,356)
State		(603)
Total deferred income tax (benefit) provision		(2,959)
Total income tax (benefit) provision	\$	\$ (2,959)

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:

	<b>2017</b>	<b>2016</b>
Income tax computed at federal statutory tax rate	34.0%	34.0%
State taxes, net of federal benefit	5.0%	4.3%
Research and development credits	0.9%	0.7%
Nondeductible interest	(0.1)%	(0.1)%
Write-down of intangible asset	0.0%	(5.6)%
Permanent differences	(0.3)%	(0.5)%
Federal deferred rate change	(97.7)%	0.0%
Other	(3.1)%	(3.0)%
Change in valuation allowance	61.3%	(20.2)%
Total	0.0%	9.6%

The significant components of the Company's deferred tax assets as of December 31, 2017 and 2016 were as follows:

	<b>2017</b>	<b>2016</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 32,820	\$ 43,455
Research and development credit carryforwards	2,789	2,493
Capitalized start-up expenses	983	1,221



Edgar Filing: Pulmatrix, Inc. - Form 10-K

Other	2,377	2,862
Total deferred tax assets	38,969	50,031
Valuation allowance	(38,969)	(50,031)
Net deferred tax liabilities	\$	\$

At December 31, 2017, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately \$131,774 and \$81,449 respectively, which were available to reduce future taxable income. The net operating loss carryforwards expire at various dates from 2023 through 2037. The Company has research and development credits for federal and state income tax purposes of approximately \$1,925 and \$1,094, respectively, which expire at various dates from 2022 through 2037.

**Table of Contents**

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, the Company has completed its accounting for the tax effects of enactment of the Act, including the effects on its existing deferred tax balances and the one-time transition tax. For the year ended December 31, 2017, no transition tax is recognized.

As a result of the Act, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they are anticipated to reverse in the future, which is generally 21%. This resulted in a decrease to the Company's gross deferred tax assets and a corresponding decrease in its valuation allowance.

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, 2017 and 2016. The valuation allowance decreased by \$11,062 during the year ended December 31, 2017, primarily due to impact of the decrease in the federal tax rate on the Company's deferred tax assets, offset by current period losses incurred by the Company.

The Company applies FASB Interpretation Number 48, Accounting for Uncertainty in Income Taxes, an interpretation of FAS 109 (codified within ASC 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 2014 through 2017. 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 recorded 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, 2016	\$ 1,086

Edgar Filing: Pulmatrix, Inc. - Form 10-K

Additions for current year tax positions		86
Balance	December 31, 2016	1,172
Additions for current year tax positions		59
Reductions for prior year tax positions		(122)
Balance	December 31, 2017	\$ 1,109

F-25

**Table of Contents****14. 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>2017</b>	<b>2016</b>
Options to purchase common stock	3,695,634	2,829,301
Warrants to purchase common stock	3,284,440	3,284,440
Settlement of Term Loan	85,251	85,251
Restricted Stock Units		5,187
<b>Total</b>	<b>7,065,325</b>	<b>6,204,179</b>

**15. 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:

	<b>Amount</b>
2018	654
2019	676
2020	698
<b>Total</b>	<b>\$ 2,028</b>

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, 2017, the outstanding obligation on these contracts totaled \$2.8 million.

**16. Subsequent Events**

During January and February 2018, the Company closed on the sale of 1,232,662 shares of common stock, at an average price of \$1.54 per share, as part of an at-the-market facility. The estimated net proceeds to the Company were approximately \$1.8 million.

Pursuant to the evergreen provision under the Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan, 903,600 shares were added to the total number of authorized shares under the plan.

