

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2016

or

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

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

Commission file number: 001-36199

**PULMATRIX, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
99 Hayden Avenue, Suite 390  
Lexington, MA  
(Address of principal executive offices)

46-1821392  
(I.R.S. Employer  
Identification No.)

02421  
(Zip Code)

Registrant's telephone number, including area code (781) 357-2333

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	The NASDAQ Stock Market LLC

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> [Do not check if a smaller reporting company]	Smaller reporting company	<input checked="" type="checkbox"/>

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, 2016, the last business day of registrant's most recently completed second fiscal quarter, was \$29,060,912.

As of February 28, 2017, the registrant had 17,830,679 shares of common stock outstanding excluding 99,308 shares of common stock deliverable on a delayed basis pursuant to restricted stock units that have vested.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for the 2016 Annual Meeting of Stockholders, which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates, are incorporated by reference in Part III of this Annual Report on Form 10-K.

PULMATRIX, INC.

TABLE OF CONTENTS

	<u>Page No.</u>
<a href="#">Forward-Looking Statements</a>	1
<b><a href="#">PART I</a></b>	
Item 1. <a href="#">Business.</a>	2
Item 1A. <a href="#">Risk Factors.</a>	17
Item 1B. <a href="#">Unresolved Staff Comments.</a>	34
Item 2. <a href="#">Properties.</a>	35
Item 3. <a href="#">Legal Proceedings.</a>	35
Item 4. <a href="#">Mine Safety Disclosures.</a>	35
<b><a href="#">PART II</a></b>	
Item 5. <a href="#">Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</a>	36
Item 6. <a href="#">Selected Financial Data.</a>	37
Item 7. <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations.</a>	37
Item 7A. <a href="#">Quantitative and Qualitative Disclosures About Market Risk.</a>	50
Item 8. <a href="#">Financial Statements and Supplementary Data.</a>	50
Item 9. <a href="#">Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</a>	50
Item 9A. <a href="#">Controls and Procedures.</a>	50
Item 9B. <a href="#">Other Information.</a>	51
<b><a href="#">PART III</a></b>	
Item 10. <a href="#">Directors, Executive Officers and Corporate Governance.</a>	52
Item 11. <a href="#">Executive Compensation.</a>	52
Item 12. <a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</a>	52
Item 13. <a href="#">Certain Relationships and Related Transactions, and Director Independence.</a>	52
Item 14. <a href="#">Principal Accounting Fees and Services.</a>	52
<b><a href="#">PART IV</a></b>	
Item 15. <a href="#">Exhibits, Financial Statement Schedules.</a>	53
Item 16. <a href="#">Form 10-K Summary.</a>	53
<a href="#">Signatures</a>	54

## EXPLANATORY NOTE

This report is the Annual Report on Form 10-K for the fiscal year ended December 31, 2016 of Pulmatrix, Inc., which was formerly known as Ruthigen, Inc., prior to the consummation on June 15, 2015 of the merger described below.

On June 15, 2015, pursuant to the previously announced Agreement and Plan of Merger, dated March 13, 2015 (the “Merger Agreement”), by and among Pulmatrix, Inc., a Delaware corporation previously known as Ruthigen, Inc. (the “Company”), Ruthigen Merger Corp., a Delaware corporation and a wholly owned subsidiary of the Company (“Merger Sub”), and Pulmatrix Operating Company, a Delaware corporation previously known as Pulmatrix Inc. (“Pulmatrix Operating”), Merger Sub was merged with and into Pulmatrix Operating, with Pulmatrix Operating continuing as the surviving entity and a wholly owned subsidiary of the Company (the “Merger”). At the effective time of the Merger (the “Effective Time”), without any action on the part of any stockholder, each issued and outstanding share of Pulmatrix Operating’s common stock, par value \$0.01 per share (the “Pulmatrix Operating Common Stock”), was converted into the right to receive 0.148187124066461 shares (the “Exchange Ratio”) of the Company’s common stock, par value \$0.0001 per share (the “Company Common Stock”). Immediately following the Effective Time, the Company effected a 1-for-2.5 reverse stock split of the issued and outstanding Company Common Stock (the “Reverse Stock Split”). Following the Merger, former Pulmatrix Inc. equity holders owned approximately 81.7% of the outstanding shares of Company Common Stock, and former Ruthigen, Inc. equity holders, including those who purchased shares of the Company in a private placement that the Company closed prior to the Merger, owned approximately 18.3% of the outstanding shares of Company Common Stock, in each case excluding shares of Company Common Stock held in escrow to secure indemnification obligations under the Merger Agreement.

The Merger has been accounted for as a “reverse merger” under the acquisition method of accounting for business combinations with Pulmatrix Operating being treated as the accounting acquirer of Pulmatrix. As such, the historical financial statements of Pulmatrix Operating will be treated as the historical financial statements of the combined company. Accordingly, the financial results for the fiscal year ended December 31, 2015 presented in this Form 10-K reflect the operations of Pulmatrix Operating for the period of January 1, 2015 through June 15, 2015, and the operations of the post-combination Company for the period of June 16, 2015 through December 31, 2015. The results of the Company for the fiscal year ended December 31, 2016 reflect the operating results of the combined entity.

See Notes 1 and 3 of the notes to the financial statements for additional information.

## 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,” “expects,” “forecasts,” “guides,” “intends,” “is confident that,” “may,” “plans,” “seeks,” “projects,” “targets,” and “would,” and their opposites and similar expressions, as well as statements in future tense, are intended to identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management’s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

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

For a more detailed discussion of these and other that may affect our business and that could cause our actual results to differentiate equally from those projected in these forward-looking statements, see the risk factors and uncertainties described under the heading “Risk Factors” in Part I, Item 1A of this Annual Report 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. References to “Ruthigen” refer to our Company prior to the Merger.

## [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.**

#### *Completion of Merger*

On June 15, 2015, pursuant to the Merger Agreement, by and among our Company (previously known as Ruthigen, Inc.), Merger Sub, and Pulmatrix Operating, Merger Sub was merged with and into Pulmatrix Operating, with Pulmatrix Operating continuing as the surviving entity and our wholly owned subsidiary. At the Effective Time of the Merger, without any action on the part of any stockholder, each issued and outstanding share of Pulmatrix Operating Common Stock was converted into the right to receive 0.148187124066461 pre-reverse stock split shares of Company Common Stock. Following the Merger, former Pulmatrix Inc. equity holders owned approximately 81.7% of the outstanding shares of Company Common Stock, and former Ruthigen, Inc. equity holders, including those who purchased shares of Company Common Stock in a private placement that closed prior to the Merger, owned approximately 18.3% of the outstanding shares of Company Common Stock, in each case excluding shares of Company Common Stock held in escrow to secure indemnification obligations under the Merger Agreement.

#### *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 cystic fibrosis (“CF”), idiopathic pulmonary fibrosis (“IPF”) and chronic obstructive pulmonary disease (“COPD”).

#### *Corporate History*

Ruthigen was incorporated in 2013 as a Nevada corporation and converted to a Delaware corporation in September 2013. Ruthigen operated as a wholly owned subsidiary of Oculus Innovative Sciences, Inc. (“Oculus”) until the completion of Ruthigen’s initial public offering in March 2014. Prior to the Merger, Ruthigen was primarily engaged in the development of pharmaceutical-grade hypochlorous acid based therapeutics designed to prevent and treat infection in invasive applications.

We completed the Merger with Pulmatrix Operating on June 15, 2015, and in connection with the Merger, changed our name to “Pulmatrix, Inc.” and relocated our corporate headquarters to Lexington, Massachusetts. Following the Merger, we focused our resources on the development of products within the scope of Pulmatrix

## [Table of Contents](#)

Operating's former business plan, which was principally based on the development of novel inhaled therapeutic products intended to prevent and treat respiratory diseases and infections. Pulmatrix was founded by David A. Edwards, Ph.D., professor of Biomedical Engineering at Harvard University, Mark Gabrielson, owner and general partner of p-Value Capital, Alexander Klibanov, Ph.D., professor of Chemistry and Bioengineering at Massachusetts Institute of Technology, and Robert Langer, Ph.D., professor of Chemical and Biomedical Engineering at Massachusetts Institute of Technology.

### *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 treat and prevent pulmonary infections in CF and severe asthma patients and other rare/orphan indications.* We intend to direct our resources to, and focus on, advancing the research and development of PUR1900, an inhaled anti-fungal therapy for respiratory infections in CF and severe asthma patients and compromised patient populations. We expect to begin clinical testing of PUR1900 in health normal volunteers and asthma patients in the second half of 2017.
- *Form strategic alliances to advance clinical trials for our therapeutic candidates for COPD.* We had a strategic collaboration with Mylan N.V. ("Mylan") to advance the clinical development of PUR0200, our lead COPD bronchodilator candidate, in Europe for pharmacokinetics equivalence regulatory pathway. Under the strategic collaboration, we completed a pilot bioequivalence study of PUR0200 with Mylan in Europe in May 2016. As part of the collaboration, Mylan had an option to negotiate the exclusive right to develop, manufacture, commercialize and market any resulting products of PUR0200 outside the United States. Mylan's option has expired and Pulmatrix owns the exclusive right to develop, manufacture, commercialize and market any resulting products of PUR0200. We intend to form strategic collaborations with third parties with respect to the clinical development of PUR0200 in the United States and outside the United States.
- *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 its 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, 2016, Pulmatrix had 115 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 10 issued or allowed U.S. patents, with expiration dates ranging from 2025 to 2031, as well as 44 issued or allowed foreign patents, with expiration dates of 2025 to 2031. We had approximately 61 additional pending patent applications (including provisionals) in the United States, Europe, Asia and other jurisdictions as of such date. We intend to aggressively continue patenting 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, which showed in preclinical and early clinical studies that specific ratios of cations driven mainly by calcium salts reduced eosinophilic and neutrophilic inflammatory responses to stimuli by downregulating the pro-inflammatory chemokine/cytokine pathways of respiratory tract epithelium. In 2009, we developed dry powder iCALM formulations for handheld dry powder inhalers with what we believe have several commercial advantages over nebulized liquid formulations, including ease of use, speed of dosing, improved portability and enhanced intellectual property protection. The high degree of aerosol efficiency and the density profile of our dry powder iCALM formulations provided the foundation for our development of iSPERSE in 2012, using other monovalent and divalent salts.

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

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

#### ***Cystic Fibrosis and Severe Asthma***

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

## [Table of Contents](#)

CF is among the most common genetic diseases in Caucasian populations. The disease is characterized by thick, sticky mucus that accumulates most critically in the lungs. According to the Cystic Fibrosis Foundation, CF affects approximately 30,000 children and adults in the United States and approximately 70,000 children and adults worldwide. The accumulation of mucus with abnormally high viscosity obstructs airways and leads to infection and then inflammation, which further exacerbates obstruction of the airways and can result in progressive lung damage and diminished pulmonary function. According to the Cystic Fibrosis Foundation, today the median life expectancy for those with CF in the United States is close to 40 years. The most common causes of death in CF patients are related to CF lung deterioration, which can be caused by chronic infection.

Pulmonary infections are a significant source of morbidity and mortality across multiple respiratory diseases, including CF. While pulmonary infections can be caused by a number of pathogens, to the best of our knowledge, both approved and developmental inhaled therapeutics target only a limited number of pathogens and infections, and the majority of these inhaled therapeutics are intended to target a single pathogen, *Pseudomonas aeruginosa*, which is the major pathogen found in the lungs of individuals with CF. Approved inhaled therapies do not exist for a number of other clinically significant pathogens that exacerbate infections in CF patients.

Pulmonary fungal infections in patients with CF are common; up to 50% of CF patients harbor infections from *Aspergillus* spp. *Aspergillus* infections are likely underdiagnosed and occur frequently in patients of all ages. 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 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 CF patients with *Aspergillus* infection has allergic bronchopulmonary aspergillosis (“ABPA”), which is a complex hypersensitivity reaction to fungal antigens. ABPA is a severe disease resulting in mucus production, wheezing, pulmonary infiltrates, worsening bronchiectasis and fibrosis of the lung. In addition to patients with CF, ABPA also afflicts severe asthmatics with a similar pathophysiology and clinical presentation. Worldwide, approximately 5 million of asthmatics suffer from ABPA.

In both CF and asthma 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.

PUR1900 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 PUR1900 is focused on treatment of *Aspergillus* spp. infection in patients with CF and severe asthma. Through the direct delivery of itraconazole to the lungs, PUR1900 achieves high local drug concentrations and overcomes several limitations of traditional oral anti-fungal therapies including poor oral bioavailability and lung penetration, drug-drug interactions and gastrointestinal side effects. We expect to begin clinical testing of PUR1900 in healthy normal volunteers and asthma patients in the second half of 2017.

### *Competition and Market Opportunities*

There are a number of pathogens that chronically infect CF patients and are associated with reduced lung function or exacerbations other than *Pseudomonas aeruginosa*, for which, to the best of our knowledge, few or



## [Table of Contents](#)

no drugs in the form of inhalation dry powder have been approved for marketing. The currently available primary anti-infective therapies against pathogens other than *Pseudomonas aeruginosa* are mostly in injectable or oral forms. Inhalation delivery of drugs directly to the respiratory tract typically results in much higher concentrations in the infected organ, even with relatively small doses, as compared to the concentrations of the drug that could be achieved through safe, approved doses delivered via injection or by oral administration. 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.

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 CF and severe asthma. 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 is contraindicated for a large number of drugs 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.

There is precedent for dry powder inhalation therapy addressing specific pulmonary infections in CF patients which demonstrates both the 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, to the best of our knowledge, has completed Phase II clinical trials. Bayer AG has dry powder ciprofloxacin and amikacin in Phase III development for pulmonary infections.

There are additional nebulized liquid anti-infective products marketed or in development that further supports the market opportunity. Cayston, marketed by Gilead Sciences, Inc., is a nebulized formulation of aztreonam for treatment of *Pseudomonas aeruginosa* infections in patients with CF. Inmed Incorporated is developing a nebulized amikacin antibiotic treatment for *Pseudomonas aeruginosa* and non-tuberculous mycobacterial infections, and CURx Pharmaceuticals is developing an inhaled antibiotic consisting of fosfomycin and tobramycin for treatment of *Pseudomonas aeruginosa* lung infection in CF patients entering Phase III clinical trials.

CF patients are affected by both chronic *Aspergillus* spp. infections and ABPA, which together affect nearly 50% of CF patients. New methods to detect *Aspergillus* spp. infection in sputum have improved the sensitivity of diagnosis and clinical appreciation for these infections. In addition to CF patients, 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 PUR1900 has the potential to address up to 5 million patients when all indications are considered. In addition, we believe that PUR1900 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*

PUR1900 is our lead iSPERSE anti-infective development program and we expect to begin Phase I/Ib clinical studies of PUR1900 in the second half of 2017.

## **COPD**

We are developing an iSPERSE-based inhaled bronchodilator, PUR0200, intended to treat COPD. COPD is a group of progressive respiratory illnesses 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. Pulmonary exacerbations caused by COPD (worsening of respiratory symptoms) are a major contributor to health care costs and can lead to serious consequences such as hospitalization and death. According to the Centers for Disease Control and Prevention, chronic lower respiratory disease, primarily COPD, was the third leading cause of death in the United States in 2014 and, according to the World Health Organization, the fourth leading cause of death worldwide in 2015.

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 and is delivered by inhalation using the iSPERSE dry powder delivery platform.

### *Competition and Market Opportunities*

The global market for COPD therapeutics was \$11.3 billion in 2013 according to GBI Research ([Chronic Obstructive Pulmonary Disease \(COPD\) Market to 2019](#)). With a high number of new, more efficient and convenient drugs crowding the market, it is expected that this market will grow at a cumulative annual growth rate, or CAGR, of four percent (4%) to reach close to \$15.4 billion by 2020, according to a 2015 report by EvaluatePharma, a leading market intelligence and information resource. According to the same report, the global market for LAMAs in 2013 was estimated to be \$5.0 billion, of which Spiriva (tiotropium bromide) by Boehringer Ingelheim was the largest seller generating \$4.7 billion worldwide with no generic competition. Despite the arrival of new combination therapeutics, EvaluatePharma predicts that LAMAs are expected to remain the first line therapy among COPD patients, with 2016 annual sales projected to exceed \$5.2 billion worldwide. Tiotropium bromide is expected to retain the majority of share of the LAMA market.

PUR0200 is manufactured without lactose blending using the iSPERSE dry powder delivery platform. Pulmatrix expects 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.

As described below, in 2016 we completed a clinical trial in Europe to study the pharmacokinetic profile of PUR0200 compared to the reference product. This study identified two formulations of PUR0200 with a similar pharmacokinetic profile to the reference product. Using these data, we expect to take advantage of the bioequivalence regulatory pathway in Europe and plan to engage with European regulators in 1H 2017. Additionally, the data support a product understanding to support a 505(b)(2) regulatory pathway in the United States. We believe that each of these regulatory pathways would result in significant cost and time savings compared to traditional regulatory pathways. For additional information about the 505(b)(2) regulatory pathway, see “— Government Regulation — *Section 505(b)(2) New Drug Applications*” below.

### *Clinical Development*

In December 2013, we completed a two-part Phase 1b placebo control, 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.

## [Table of Contents](#)

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.

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

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

On 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.

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.

### **IPF**

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 recently approved drugs, Ofev (nintedanib) and Esbriet (pirfenidone) offer the first

## [Table of Contents](#)

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.

### *Clinical Development*

The PUR1500 program is evaluating possible inhaled therapies for IPF in formulation feasibility and preclinical studies. In October 2015, we entered into an alliance with Celdara Medical, LLC to develop an inhaled biologic to treat IPF and were awarded a \$1.7 million grant by the National Institutes of Health to fund our development activities. The research and development associated with these feasibility programs may result in additional grants and their successful completion of feasibility programs may result in licensing agreements of the iSPERSE platform should the partner wish to continue development.

## **Intellectual Property**

### *Patents and Patent Applications*

We protect our intellectual property by filing patents on:

- iSPERSE powder composition of matter and properties;
- method 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 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, 2016, we have been granted or allowed nationally 54 active patents related to iSPERSE, with expiration dates ranging from 2025 to 2031.

As of December 31, 2016, we had 115 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 10 issued or allowed U.S. patents, with expiration dates ranging from 2025 to 2031, as well as 44 issued or allowed foreign patents, with expiration dates of 2025 to 2031. We had approximately 61 additional pending patent applications (including provisionals) in the United States, Europe, Asia and other jurisdictions as of such date. There can be no assurance that these 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.

## [Table of Contents](#)

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

### *Trade Secrets*

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

### **Manufacturing**

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We have small-scale production capabilities and generally perform early process development for our product candidates to produce the quantities necessary to conduct preclinical studies of our investigational product candidates. We do not have, and do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical studies. We rely on contract manufacturing organizations ("CMOs") and third party contractors to generate drug-loaded formulations and produce larger 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 current good manufacturing practices ("cGMP") required for our 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 cGMP for use in clinical trials. The cGMP compliance includes strict adherence to regulations for quality control, quality assurance, and the maintenance of records and documentation. The manufacturing facilities for our approved products, if any, must meet cGMP 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 rely on third-party vendors to supply the APIs that are used to formulate our therapeutic candidates. We place purchase orders with a single supplier for the APIs required for PUR0200 and PUR1900, but there are many other potential API suppliers in the market.

## Research and Development

During the fiscal years ended December 31, 2016 and 2015, we spent approximately \$10.0 million and \$7.2 million on research and development activities, respectively.

## Government Regulation

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

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

### *FDA Approval Process*

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

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

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

## [Table of Contents](#)

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 drug 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 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

## [Table of Contents](#)

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 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



## [Table of Contents](#)

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

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

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

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

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

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

## [Table of Contents](#)

### *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.

### *Foreign Regulation*

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

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

### **Reimbursement**

In the United States and other countries, sales of any products for which Pulmatrix receives regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers, including government health administrative authorities, 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 and Modernization Act of 2003 (the “MMA”), sets forth the 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.

## [Table of Contents](#)

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, 2016 and 2015 and subsequently has not had a material effect upon our capital expenditures, earnings or competitive position.

### **Employees**

As of December 31, 2016, we had 24 full-time employees, 18 of whom were engaged in full-time research and development activities, and 1 part-time employee. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

### **Properties**

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

### **Available Information**

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

**ITEM 1A. RISK FACTORS.**

*The following risk factors, together with all of the other information included or incorporated in this Annual Report 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**

***There is substantial doubt about our ability to continue as a going concern.***

We have incurred net losses each year since our inception, including net losses of \$27.8 million and \$26.2 million for years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had an accumulated deficit of \$156.0 million. These conditions coupled with our current liquidity position raise substantial doubt about our ability to continue as a going concern. Furthermore, we may incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our product candidates. We expect that our ability to continue as a going concern depends, in large part, 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. If we are unable to raise additional capital, we may be forced to cease operations.

***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 being marketed or commercialized. Our product candidates will require significant additional development, clinical studies, regulatory clearances and additional investment 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, including net losses of \$27.8 million and \$26.2 million for years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had an accumulated deficit of \$156.0 million. Our losses are principally as 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.***

In general, our research and development programs are in developmental stages. One or more of our product candidates may fail to meet safety and efficacy standards in human testing, even if those product candidates are found to be effective in animal studies. To develop and commercialize inhaled therapeutic treatment for chronic obstructive pulmonary disease and cystic fibrosis and other iSPERSE-based product candidates, we must provide the FDA and foreign regulatory authorities with human clinical and non-clinical animal data that demonstrate adequate safety and effectiveness. To generate these data, we will have to subject our product candidates to

## [Table of Contents](#)

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, PUR1900, and a bronchodilator therapy for COPD, PUR0200. Even if PUR1900 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. The drug may:

- be shown to be ineffective or to cause harmful side effects during preclinical testing or clinical trials;
- fail to receive regulatory approval on a timely basis or at all;
- be difficult to manufacture on a large scale;
- be uneconomical;
- not be prescribed by doctors or accepted by patients;
- fail to receive a sufficient level of reimbursement from government or third-party payors; or
- infringe on intellectual property rights of another 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. 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 comparator 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 increases for our drug candidates that are based on new technologies, such as the application of our dry powder delivery platform, iSPERSE, including PUR1900, PUR0200, PUR1500 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

## [Table of Contents](#)

may not be sufficient to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if, or when, we may have an approved product for commercialization or whether we will ever achieve sales of or profits on our product candidates or those we may pursue in the future.

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

Our future success and ability to compete in the biotechnology industry is substantially dependent on our ability to identify, attract, and retain highly qualified key managerial, scientific, medical, and operations personnel. The market for key employees in the pharmaceutical and biotechnology industries can be 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 Savara Pharmaceuticals, Cardeas Pharma Corp., SkyePharma PLC

## [Table of Contents](#)

and Respira Therapeutics Inc., which we consider our potential competitors in this regard. If we are unable to compete successfully with these and other potential future competitors, we may be unable to grow or generate revenue.

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

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

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

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

## [Table of Contents](#)

one manufacturing batch to the next. For PUR0200 and PUR1900, 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 PUR0200 and PUR1900 and incur additional costs if we changed from this supplier for any reason. Similarly, replacing our manufacturers could cause us to incur added costs and experience delays in identifying, engaging, qualifying and training any such replacements.

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

***We may 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.***

There can be no assurance that the diligence we conducted in connection with the Merger revealed all material issues that may be present or that factors outside of our control will not later arise. During 2016, a full write-off was made of in-process research and development, \$4.5 million net of tax provision, acquired from this merger. We 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 receive an appropriate price in a future sale or assignment of our rights related to our current drug candidates.***

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

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

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

Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All



## [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.

***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 former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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

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

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

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

## 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 Phase I clinical trials for PUR0200. The clinical trials of our product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical trials may not be sufficient to support regulatory approval of our various product candidates. Even if we believe the data collected from our clinical trials are sufficient, the FDA has substantial discretion in the approval process and may disagree with our interpretation of the data.

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

The requirements governing the conduct of clinical trials and manufacturing and marketing of our product candidates outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes include essentially all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries, or vice versa. In addition, changes in regulatory policy in the United States or in foreign countries for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections.

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

## [Table of Contents](#)

***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 FDA pre-or post-approval cGMP requirements, then the FDA or other foreign regulatory authorities could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies.

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

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

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

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

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

We and our contract manufacturers are, and will be, required to adhere to laws, regulations and guidelines of the FDA or other foreign regulatory authorities setting forth current good manufacturing practices. These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping

## [Table of Contents](#)

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

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

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

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

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

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

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

***If we are found in violation of federal or state “fraud and abuse” laws, we may be required to pay a penalty and/or be suspended from participation in federal or state health care programs, which 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 in federal and state health care programs, which could affect it, 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 that is intended to induce the referral of business, 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. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental health care programs. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines 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 health care services reimbursed by any source, not just governmental payers. Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and if we are found in violation of one of these laws, we could be required to pay a 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 there will be continued doubt about our ability 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 expect that our expenses will increase substantially as we advance PUR1900 into Phase I/Ib trials and PUR0200 into further clinical trials in Europe and initiate U.S. clinical trials and pursue development of 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 through the end of the third quarter of 2017. 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 \$156.0 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;
- 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

## [Table of Contents](#)

reduce expenses through the delay, reduction or curtailment of our projects, including PUR1900 and PUR0200 development activities, or reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be continued doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. If we are or become insolvent, investors in our stock may lose the entire value of their investment.

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

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

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

### **Risks Related to Our Intellectual Property**

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

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

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

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

## [Table of Contents](#)

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

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

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

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

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

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

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our products, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable and a court may determine that the right belongs to a third party.

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

The development, manufacture, use, offer for sale, sale or importation of our product candidates may infringe on the claims of third-party patents or other intellectual property rights. The nature of claims contained in



## [Table of Contents](#)

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 PCT or other mechanisms. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our therapeutic candidates in the event of an infringement action.

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

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

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

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

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

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

- the announcement of new products, new developments, services or technological innovations by us or our competitors;
- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;
- announcements relating to strategic relationships, mergers, acquisitions, partnerships, collaborations, joint ventures, capital commitments, or other events by us or our competitors;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the economic performance or market valuations of other biotechnology and pharmaceutical companies;

## Table of Contents

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

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

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

As a publicly traded company, we incur significant additional legal, accounting and other expenses that we did not incur as a privately held company and are not fully reflected in our results of operations. 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 listing requirements of the stock exchange on which our securities are listed. 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 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.

## [Table of Contents](#)

***In the foreseeable future, we do not intend to pay cash dividends on shares of Company Common Stock so any returns 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 return to stockholders will therefore be limited to the increase, if any, of our share price.

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

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

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

## [Table of Contents](#)

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

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

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

In addition, as of February 28, 2017, 1,497,354 shares remained available to be awarded under our 2013 Employee, Director and Consultant Equity Incentive Plan (the “Incentive Plan”). Further, an aggregate of 2,667,600 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 February 28, 2017, approximately 43% 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.

**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 February 28, 2017, was \$5,739,557.

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, 2016 was approximately \$610,680. 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>
2017	632
2018	654
2019	676
2020	698
<b>Total</b>	<b><u>\$2,660</u></b>

We believe that our facility is well maintained and is 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 any of our subsidiaries is a party or to which any of our property is subject, nor are we aware of any such threatened or pending litigation or proceedings known to be contemplated by governmental authorities.

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

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.****Market Information**

Our common stock began trading on the NASDAQ Capital Market on March 21, 2014 under the symbol "RTGN." As a result of the Merger, the common stock ceased to trade under the symbol "RTGN" at the close of market on June 15, 2015. On June 16, 2015, our common stock began trading on a combined company basis 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 Capital Market or the NASDAQ Global Market, as applicable, for the periods shown, as adjusted for the 1-for-2.5 reverse stock split effected on June 15, 2015.

	High	Low
<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
	High	Low
<b>Year ended December 31, 2015</b>		
First Quarter	\$11.60	\$8.13
Second Quarter	\$14.55	\$7.25
Third Quarter	\$ 9.83	\$4.30
Fourth Quarter	\$ 5.56	\$3.30

On February 28, 2017, the last reported sale price of our common stock on the NASDAQ Global Market was \$4.10 per share.

**Stockholders**

As of February 28, 2017, there were approximately 189 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, 2016.

## 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. References to "Ruthigen" refer to our Company prior to the merger (the "Merger") on June 15, 2015, of Ruthigen Merger Corp, a Delaware corporation and our wholly owned subsidiary ("Merger Sub"), with and into Pulmatrix Operating Company, a Delaware corporation previously known as Pulmatrix Inc. ("Pulmatrix Operating"), pursuant to which Pulmatrix Operating became our wholly subsidiary, our Company was renamed "Pulmatrix, Inc." and we issued approximately 81.7% of the shares of our common stock to the former holders of Pulmatrix Operating, as measured by the number of shares of our common stock outstanding following the Merger.*

### Overview

Prior to the Merger, Ruthigen was a biopharmaceutical company focused on pioneering new hypochlorous acid, or HOCl, based therapies designed to improve patient outcomes and reduce healthcare costs associated with infections related to post-operative invasive procedures. Following the Merger, 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. The Company's proprietary product pipeline is focused on advancing treatments for rare diseases, including PUR1900, an inhaled anti-fungal for patients with cystic fibrosis, or CF, as well as PUR1500, an inhaled product for the treatment of idiopathic pulmonary fibrosis. In addition, we intend to pursue opportunities in major pulmonary diseases through collaborations, which include PUR0200, a branded generic in clinical development for chronic obstructive pulmonary disease, or COPD in partnership with Mylan N.V., or Mylan. 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 treat and prevent pulmonary infections in 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 three existing candidates. In order to advance our clinical trials for our therapeutic candidates for COPD 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.



## [Table of Contents](#)

Since our inception in 2003, we have devoted substantially all of our efforts to product research and development, market research, and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations to date through proceeds from issuances of common and convertible preferred stock, issuances of convertible debt, collaborations with third parties and non-dilutive grants received from government agencies.

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 PUR1900 for CF and in immunocompromised at risk patients;
- seek regulatory approval for our product candidates;
- hire personnel to support our product development, commercialization and administrative efforts; and
- advance the research and development related activities for inhaled therapeutic products in our pipeline.

We will not generate product sales unless and until we successfully complete clinical developments and obtain regulatory approvals for our product candidates. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities, and 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, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

### **Completion of Merger**

On June 15, 2015, pursuant to the Agreement and Plan of Merger, dated March 13, 2015 (the “Merger Agreement”), by and among us (previously known as Ruthigen, Inc.), Merger Sub, and Pulmatrix Operating Company, we completed the Merger whereby Merger Sub was merged with and into Pulmatrix Operating, with Pulmatrix Operating continuing after the Merger as the surviving entity and our wholly owned subsidiary. At the effective time of the Merger (the “Effective Time”), without any action on the part of any stockholder, each issued and outstanding share of Pulmatrix Operating’s common stock, par value \$0.01 per share (the “Pulmatrix Operating Common Stock”), was converted into the right to receive 0.148187124066461 pre-reverse stock split shares (the “Exchange Ratio”) of our common stock, par value \$0.0001 per share (the “Company Common Stock”). Following the Merger, former Pulmatrix Inc. equity holders owned approximately 81.7% of our outstanding shares of common stock, par value \$0.0001 per share (“Company Common Stock”), and former Ruthigen, Inc. equity holders, including those who purchased shares of Company Common Stock in a private placement that we closed prior to the Merger, owned approximately 18.3% of the outstanding shares of Company Common Stock, in each case excluding shares of Company Common Stock held in escrow to secure indemnification obligations under the Merger Agreement.

The Merger has been accounted for as a “reverse merger” under the acquisition method of accounting for business combinations with Pulmatrix Operating treated as the accounting acquirer of Pulmatrix. As such, the

## [Table of Contents](#)

historical financial statements of Pulmatrix Operating have become the historical financial statements of Pulmatrix, or the combined company, and are included in this filing labeled “Pulmatrix, Inc.” As a result of the Merger, historical common stock, stock options and additional paid-in capital, including share and per share amounts, have been retroactively adjusted to reflect the equity structure of the combined company, including the effect of the Exchange Ratio and the Company Common Stock.

### **Presentation for Reverse Stock Split**

On June 15, 2015, immediately following the Effective Time, we effected a 1-for-2.5 reverse stock split of our issued and outstanding Company Common Stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, the per share exercise price of, and the number of shares of Company Common Stock underlying, our stock options and warrants outstanding immediately prior to the Reverse Stock Split were automatically proportionally adjusted based on the 1-for-2.5 split ratio in accordance with the terms of such options and warrants, as the case may be. Share and per-share amounts of Company Common Stock, options and warrants included herein have been adjusted to give effect to the Reverse Stock Split. The Reverse Stock Split did not alter the par value of Company Common Stock, \$0.0001 per share, or modify any voting rights or other terms of the common stock. Unless otherwise noted, the accompanying financial statements and notes thereto, including the Exchange Ratio applied to historical Pulmatrix Operating common stock and stock options, give retroactive effect to the Reverse Stock Split for all periods presented.

### **Financial Overview**

#### ***Revenues***

To date, we have not generated any product sales. Our limited revenues have been derived from feasibility work as part of agreements with other pharmaceutical companies and grants from government agencies. On March 24, 2015, we entered into the long-acting muscarinic agent collaboration agreement with Mylan under which we are eligible to receive reimbursement of up to \$1.5 million for third-party out of pocket expenses directly related to clinical trials. On September 14, 2015, we amended this agreement to provide for reimbursements up to a new cost cap of \$1.9 million. As consideration for the funding received, we agreed to grant to Mylan an option 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 company’s sales on the resulting products.

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.

#### ***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, contract manufacturing organizations, 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.

## [Table of Contents](#)

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 including PUR1900, our lead anti-fungal, PUR0200, our lead COPD bronchodilator, and PUR1500, our preclinical stage therapeutic for treatment of idiopathic pulmonary fibrosis, or IPF. In order to move these programs forward along our development timelines, a large portion, approximately 75%, of our staff are research and development employees. In addition, we maintain a 12,000 square foot research and development facility which includes capital equipment for the manufacture, characterization, and in vitro/in vivo evaluation 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 with convertible notes and a term loan that were outstanding during the period. In connection with the Merger, all of our outstanding convertible notes, including the convertible notes issued in February 2015, and accrued and unpaid interest, were converted into, or exchanged for, equity. Following the Merger, we have been incurring and expect to continue to incur interest expense associated with the \$7 million term loan from Hercules Technology Growth Capital, Inc., or Hercules, in June 2015, or the Term Loan.

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

Other expenses, net is comprised primarily of gains and/or losses resulting from fair value adjustments on warrants for the purchase of our preferred stock and 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, 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.

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, 2016 and 2015, we did not have any significant uncertain tax positions. We recognize interest and penalties related to uncertain tax positions in income tax expense.

### **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

## [Table of Contents](#)

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.

### ***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.

**Results of Operations****Year Ended December 31, 2016 Compared with Year ended December 31, 2015**

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

	Year ended December 31,		Change
	2016	2015	
Revenue	\$ 835	\$ 1,201	\$ (366)
<b>Operating expenses</b>			
Research and development	10,152	7,187	2,965
General and administrative	8,015	17,032	(9,017)
Write-off of intangibles	7,534	—	7,534
Total operating expenses	25,701	24,219	1,482
Loss from operations	(24,866)	(23,018)	(1,848)
Interest expense	(881)	(953)	72
Impairment of goodwill	(5,029)	—	(5,029)
Loss on the conversion of convertible notes	—	(1,170)	1,170
Fair value adjustment of preferred stock warrant liability	—	1,309	(1,309)
Fair value adjustment of derivative liability	(24)	(2,291)	2,267
Other expenses, net	(2)	(44)	42
Loss before income taxes	\$(30,802)	\$(26,167)	\$(4,635)
Benefit from income taxes	2,959	—	2,959
Net loss	<u>\$(27,843)</u>	<u>\$(26,167)</u>	<u>\$(1,676)</u>

**Revenue** — Revenue was \$0.8 million for the year ended December 31, 2016, compared to \$1.2 million for the year ended December 31, 2015, a decrease of \$0.4 million. The decrease was the result of the decreased revenue associated with the conclusion of the clinical study funded under our collaboration agreement with Mylan.

**Research and development expenses** — Research and development expense was \$10.2 million for the year ended December 31, 2016, compared to \$7.2 million for the year ended December 31, 2015, an increase of \$3.0 million. The increase was primarily due to increases of \$2.4 million on the PUR1900 project, \$0.9 million in employment related costs, and \$0.2 million in other development costs, net of decreases of \$0.5 million on the PUR0200 project.

**General and administrative expenses** — General and administrative expense was \$8.0 million for the year ended December 31, 2016, compared to \$17.0 million for the year ended December 31, 2015, a decrease of \$9.0 million. The decrease was primarily due to costs incurred during the year ended December 31, 2015 that did not reoccur. The expense reductions were primarily comprised of \$1.6 million in employee stock-based compensation expense and non-recurring Merger related expenses of \$3.4 million in advisory costs and \$4.0 million in legal costs.

**Write-off of intangibles** — For the year ended December 31, 2016, the write-off of intangibles, was \$7.5 million compared to \$0 for the year ended December 31, 2015. During 2016, as a result of the in-license agreement with Oculus Innovative Sciences, Inc. lapse, a full write-off was made of the IPR&D acquired from the Merger.

**Interest expense** — Interest expense was \$0.9 million for the year ended December 31, 2016, compared to \$1.0 million for the year ended December 31, 2015, a decrease of \$0.1 million. During the year ended December 31, 2016, interest expense incurred related to the term loan agreement that we entered into in June 2015. Interest expense incurred during the year ended December 31, 2015 was comprised primarily of interest

## [Table of Contents](#)

accrued on, and amortization of discount and deferred finance costs related to, the 2015 Bridge Notes and the term loan agreement that we entered into in June 2015.

**Loss on conversion of convertible notes** — For the year ended December 31, 2016, the loss on the conversion of convertible notes was \$0 compared to \$1.2 million for the year ended December 31, 2015. In 2015, the loss on the conversion of convertible notes was due to the difference between the fair value of the common shares issued upon exchange and the combined carrying amounts of \$4.5 million aggregate principal amount of notes that were issued in February 2015 (the “2015 Bridge Notes”), related accrued interest, embedded compound derivatives and unamortized issuance costs in connection with the Merger.

**Fair value adjustment of preferred stock warrant liability** — The fair value adjustment of preferred stock warrant liability was \$0 for the year ended December 31, 2016, compared to \$1.3 million for the year ended December 31, 2015. The \$1.3 million fair value adjustment of the preferred stock warrant liability in the year ended December 31, 2015 was due to the imminent cancellation of the warrants immediately prior to the Effective Time, per the terms of the Note Conversion and Warrant Termination Agreement entered into in March 2015 with the holders of our then outstanding notes and warrants.

**Fair value adjustment of derivative liability** — For the year ended December 31, 2016, the fair value adjustment of derivative liability was \$0.0 million compared to \$2.3 million for the year ended December 31, 2015. The fair value adjustment of the derivative liability, recorded during the year ended December 31, 2015, was recognized in connection with six embedded derivatives associated with the 2015 Bridge Notes that were exchanged for shares of common stock upon completion of the Merger on June 15, 2015, at which time the embedded derivatives were extinguished.

**Write-off of deferred tax liability** — For the year ended December 31, 2016, the write-off of deferred tax liability was \$3.0 million compared to \$0 for the year ended December 31, 2015. 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, 2016, the goodwill impairment charge was \$5.0 million compared to \$0 for the year ended December 31, 2015. 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, 2016, we have incurred an accumulated deficit of \$156.0 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 and our recent Merger. We have financed our operations since inception primarily through the sale of preferred and common stock and the issuance of convertible promissory notes and term loans. Our total cash and cash equivalents balance as of December 31, 2016 was \$4.2 million. In February 2017, we closed on two registered direct offerings that brought in net proceeds of approximately \$7.5 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.

In February 2015, Pulmatrix Operating issued the 2015 Bridge Notes with an aggregate principal amount of \$4.5 million to new investors. On June 15, 2015, in connection with and immediately prior to the Effective Time,



## [Table of Contents](#)

all of Pulmatrix Operating's outstanding convertible notes other than the 2015 Bridge Notes, plus accrued and unpaid interest, and all of Pulmatrix Operating's outstanding convertible preferred stock was converted into shares of Pulmatrix Operating common stock pursuant to the Note Conversion and Warrant Termination Agreement. Also on June 15, 2015, immediately prior to the Effective Time, Pulmatrix Operating issued shares of its common stock and warrants to purchase its common stock to existing investors in Pulmatrix Operating for proceeds of \$10 million (the "Pulmatrix Operating Private Placement"). At the Effective Time, these shares of Pulmatrix Operating common stock were exchanged for shares of Company Common Stock at the Exchange Ratio, and these warrants converted into the right to purchase Company Common Stock after adjusting for the Exchange Ratio. In addition, at the Effective Time, we assumed the 2015 Bridge Notes and thereafter issued shares of Company Common Stock upon the automatic exchange of the 2015 Bridge Notes at the rate of \$6.875 per share for the unpaid principal and accrued interest on the 2015 Bridge Notes.

In addition, we sold 379,387 shares of Company Common Stock at a price of \$6.875 per share in a private placement for aggregate gross proceeds of approximately \$2.6 million that closed on June 15, 2015 following the Effective Time (the "Ruthigen Private Placement"). On June 11, 2015, Pulmatrix Operating entered into the Term Loan agreement to borrow \$7.0 million, contingent upon the closing of the Merger. On June 16, 2015, we executed a joinder to make our Company a co-borrower on the term loan, and the Term Loan was funded. We believe that our existing resources, including proceeds from the issuance of these convertible promissory notes, the issuance of Pulmatrix Common Stock and Company Common Stock and the Term Loan, will be sufficient to fund our planned operations into the second quarter of 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our preclinical studies and clinical trials. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials or obtain approval of any product candidates from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities.

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

	Year ended December 31,	
	2016	2015
Net cash used in operating activities	<u>\$(13,243)</u>	<u>\$(12,472)</u>
Net cash (used in) provided by investing activities	(431)	9,405
Net cash (used in) provided by financing activities	<u>(1,046)</u>	<u>21,518</u>
Net increase (decrease) in cash and cash equivalents	<u>\$ (14,720)</u>	<u>\$ 18,451</u>

### **Cash Flows from Operating Activities**

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.

Net cash used in operating activities for the year ended December 31, 2015 was \$12.5 million, which was primarily the result of a net loss of \$26.2 million, partially offset by \$12.8 million of net non-cash adjustments

## [Table of Contents](#)

and \$0.9 million in cash inflows associated with changes in operating assets and liabilities. Partially offset by a \$1.3 million gain resulting from the decrease in the fair value of the preferred stock warrant liability, our non-cash adjustments include \$4.2 million in consulting expenses settled in stock, \$2.3 million in expense associated with the increase in the fair value of the derivative liability, \$5.5 million of stock-based compensation expense, \$1.2 million related to the loss on the conversion of convertible notes, and \$0.6 million of non-cash interest expense. The net cash inflows associated with changes in operating assets and liabilities was primarily due to an increase in accounts payable of \$0.8 million

### ***Cash Flows from Investing Activities***

Net cash used in investing activities for the year ended December 31, 2016 was \$0.4 million, compared to net cash provided by investing activities of \$9.4 million for the year ended December 31, 2015. Net cash used in 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. Net cash provided by investing activities for the year ended December 31, 2015 represents Ruthigen's cash balance immediately prior to the Effective Time, net of purchases of property and equipment.

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

Net cash used in financing activities for the year ended December 31, 2016 was \$1.0 million, as compared to net cash provided of \$21.5 million for the year ended December 31, 2015. Net cash used in financing activities for the year ended December 31, 2016 resulted from principle payments as required by the loan and security agreement with Hercules, the holder of the term loan. Net cash provided by financing activities for the year ended December 31, 2015 resulted primarily from the issuance of Pulmatrix Operating common stock and warrants for proceeds of \$10.0 million in the Pulmatrix Operating Private Placement, \$6.9 million from the issuance of Term Loan, \$4.5 million from the issuance of the 2015 Bridge Notes and \$0.1 million in proceeds from the exercise of common stock.

### ***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 PUR1900 and PUR0200, and pre-clinical evaluation of PUR1500 for IPF. 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;

## [Table of Contents](#)

- 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.

### *Convertible Promissory Notes*

From August 2011 through December 2014, Pulmatrix Operating issued \$36.2 million of convertible promissory notes that bore interest at a rate of 6% per annum. Included in these convertible promissory notes are the notes issued during 2013 and 2014 with a principal balance totaling \$2.7 million for which, upon settlement of the notes, the note holders would receive five times the stated principal value of the notes, five times the shares into which the rest of the notes would be convertible or five times the value in new equity shares upon an automatic conversion in a qualified financing, or the 5X Notes. The outstanding principal balance of all of the notes, including the 5X Notes, and accrued interest were payable on demand by at least a majority of the holders of the notes at any time following January 15, 2015. In October 2014, \$7.1 million of Pulmatrix Operating's convertible notes and \$0.9 million of accrued interest were converted into 15,886,994 shares of Pulmatrix Operating's Series B preferred stock. On June 15, 2015, in connection with the Merger and immediately prior to the Effective Time, all of the remaining outstanding convertible notes and accrued and unpaid interest totaling \$43.1 million were converted into 86,118,402 shares of Pulmatrix Operating's common stock in full settlement of the Notes and interest payable. At the Effective Time, we exchanged these shares for an aggregate of 5,104,661 shares of Company Common Stock pursuant to the Exchange Ratio in the Merger.

### *Promissory Note*

On January 21, 2015, Barry Honig provided Pulmatrix Operating with a bridge loan of \$350,000 evidenced by a promissory note. On February 19, 2015, Pulmatrix Operating repaid Mr. Honig in full for the promissory note.

### *2015 Bridge Notes*

In February 2015 Pulmatrix Operating issued the 2015 Bridge Notes with an aggregate principal amount of \$4.5 million to new investors. The 2015 Bridge Notes bore interest at a rate of 5% per annum, and the outstanding principal and accrued interest were payable in February 2016 unless exchanged in connection with the Merger. On June 15, 2015, at the Effective Time, we assumed Pulmatrix Operating's obligations under the 2015 Bridge Notes, and immediately following the Effective Time, the 2015 Bridge Notes, including accrued and unpaid interest thereon, totaling \$4.6 million were exchanged for 664,559 shares of Company Common Stock in full settlement of the notes and interest payable.

### *Term Loan and Warrant*

On June 11, 2015 Pulmatrix Operating 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, 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,

## [Table of Contents](#)

2016, we will be 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 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, 2015 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 Company 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.

### *Pulmatrix Operating Private Placement*

On June 15, 2015, immediately prior to the Effective Time, pursuant to a securities purchase agreement between Pulmatrix Operating and certain existing investors of Pulmatrix Operating dated March 13, 2015, Pulmatrix Operating sold such investors 24,538,999 units, with each unit consisting of (i) one share of Pulmatrix Operating's common stock and (ii) a warrant representing the right to purchase 2.193140519 shares of Pulmatrix Operating common stock at an exercise price of \$0.448266 per share (each pre-Reverse Stock Split and before giving effect to the Exchange Ratio), for aggregate gross proceeds of \$10 million in the Pulmatrix Operating Private Placement. Upon the Effective Time, the Pulmatrix Operating common stock underlying the units was exchanged for an aggregate of 1,454,549 shares of Company Common Stock, and the warrants underlying the units were converted into warrants to purchase an aggregate of 3,190,030 shares of Company Common Stock at an exercise price of \$7.563 per share.

## [Table of Contents](#)

### *Ruthigen Private Placement*

Immediately after the Effective Time, we closed a private placement of 379,387 shares of Company Common Stock at a price of \$6.875 per share in a private placement for aggregate gross proceeds of approximately \$2.6 million.

### *Commitments*

We have contracted with contract research organizations and contract manufacturing organizations in order to further the development of our most advanced assets. As of December 31, 2016, we had aggregate commitments to pay \$992 on these contracts.

### **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.

### **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

## [Table of Contents](#)

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, 2016.

### *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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

None.

**PART III**

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

Information required by this item will be set forth in our definitive proxy statement for the 2016 annual meeting of stockholders, which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this report (our "Proxy Statement"), and is incorporated herein by reference.

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.**

Information required by this item will be set forth in our Proxy Statement and is incorporated herein by reference.

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

Information required by this item will be set forth in our Proxy Statement and is incorporated herein by reference.

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

Information required by this item will be set forth in our Proxy Statement and is incorporated herein by reference.

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

Information required by this item will be set forth in our Proxy Statement and is incorporated herein by reference.

**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:

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit)/Equity	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	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.



**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 10, 2017

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Robert W. Clarke, Ph.D.</u> Robert W. Clarke, Ph.D.	Chief Executive Officer, President and Director (Principal Executive Officer)	March 10, 2017
<u>/s/ William Duke, Jr.</u> William Duke, Jr.	Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 10, 2017
<u>/s/ Mark Iwicki</u> Mark Iwicki	Chairman of the Board of Directors	March 10, 2017
<u>/s/ Steven Gillis, Ph.D.</u> Steven Gillis, Ph.D.	Director	March 10, 2017
<u>/s/ Michael J. Higgins</u> Michael J. Higgins	Director	March 10, 2017
<u>/s/ Terrance G. McGuire</u> Terrance G. McGuire	Director	March 10, 2017
<u>/s/ Scott M. Rocklage, Ph.D.</u> Scott M. Rocklage, Ph.D.	Director	March 10, 2017
<u>/s/ Matthew Sherman, M.D.</u> Matthew L. Sherman	Director	March 10, 2017

**INDEX TO EXHIBITS**

<b><u>Exhibit Number</u></b>	<b><u>Exhibit Description</u></b>	<b><u>Filed with this Report</u></b>	<b><u>Incorporated by Reference herein from Form or Schedule</u></b>	<b><u>Filing Date</u></b>	<b><u>SEC File/Reg Number</u></b>
2.1#	Agreement and Plan of Merger, dated March 13, 2015, by and among Pulmatrix, Inc., Pulmatrix Operating Company and Ruthigen Merger Corp.		Form 8-K (Exhibit 2.1)	03/13/15	001-36199
3.1	Amended and Restated Certificate of Incorporation of Pulmatrix, Inc., as amended through June 15, 2015.		Form 10-Q (Exhibit 3.1)	08/14/15	001-36199
3.2	Restated Bylaws of Pulmatrix, Inc., as amended through June 15, 2015.		Form 10-Q (Exhibit 3.2)	08/14/15	001-36199
4.1	Form of Specimen Stock Certificate.		Form 8-K (Exhibit 4.1)	06/16/15	001-36199
4.2	Securities Escrow Agreement, dated June 12, 2015, by and among Pulmatrix, Inc., Pulmatrix Operating Company, Inc. and VStock Transfer, LLC, as Escrow Agent.		Form 10-Q (Exhibit 4.1)	08/14/15	001-36199
4.3	Form of Representative's Warrant Agreement.		Form S-1 (Exhibit 4.2)	02/24/14	333-190476
4.4	Warrant Agreement, dated June 16, 2015, by and between Pulmatrix, Inc. and Hercules Technology Growth Capital, Inc.		Form 8-K (Exhibit 10.3)	06/16/15	001-36199
4.5	Form of Warrant issued in Pulmatrix Operating Private Placement, dated June 15, 2015.		Form 10-Q (Exhibit 10.8)	08/14/15	001-36199
10.1	Form of Subscription Agreement		Form 8-K (Exhibit 10.1)	06/12/15	001-36199
10.2*	Executive Employment Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and Robert W. Clarke, Ph.D.		Form 8-K (Exhibit 10.4)	06/16/15	001-36199
10.3*	Executive Employment Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and David L. Hava, Ph.D.		Form 8-K (Exhibit 10.5)	06/16/15	001-36199
10.4*	Executive Employment Agreement, dated June 24, 2015, by and between Pulmatrix, Inc. and William Duke, Jr.		Form 10-Q (Exhibit 10.4)	08/14/15	001-36199
10.5*	Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan.		Form S-8 (Exhibit 99.2)	07/20/15	333-205752
10.6*	Pulmatrix Inc. 2003 Employee, Director and Consultant Stock Plan.		Form S-8 (Exhibit 99.3)	07/20/15	333-205752

## Table of Contents

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed with this Report</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg Number</u>
10.7*	Employment Agreement by and between Ruthigen, Inc. and Sameer Harish, dated March 13, 2015.		Form S-4 (Exhibit 10.3.1)	04/15/15	333-203417
10.8*	Cancellation Agreement, by and between Ruthigen, Inc. and Sameer Harish, dated March 13, 2015.		Form S-4 (Exhibit 10.3.2)	04/15/15	333-203417
10.9*	Lock-Up Agreement, by and between Ruthigen, Inc. and Sameer Harish, dated March 13, 2015.		Form S-4 (Exhibit 10.3.3)	04/15/15	333-203417
10.10*	Employment Agreement by and between Ruthigen, Inc. and Hojabr Alimi, dated March 13, 2015.		Form S-4 (Exhibit 10.4.1)	04/15/15	333-203417
10.11*	Cancellation Agreement, by and between Ruthigen, Inc. and Hojabr Alimi, dated March 13, 2015.		Form S-4 (Exhibit 10.4.2)	04/15/15	333-203417
10.12*	Lock-Up Agreement, by and between Ruthigen, Inc. and Hojabr Alimi, dated March 13, 2015.		Form S-4 (Exhibit 10.4.3)	04/15/15	333-203417
10.13	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		Form 8-K (Exhibit 10.1)	06/16/15	001-36199
10.14	Joinder Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and Hercules Technology Growth Capital, Inc.		Form 8-K (Exhibit 10.2)	06/16/15	001-36199
10.15	Loan and Security Agreement, by and among Pulmatrix Operating Company, Inc. and the lenders identified on Schedule A thereto, dated February 26, 2015.		Form 8-K (Exhibit 10.1)	06/16/15	001-36199
10.16	Securities Purchase Agreement, by and among Pulmatrix Operating Company, Inc. and the purchasers identified on Schedule A thereto, dated March 13, 2015.		Form 8-K (Exhibit 10.2)	06/16/15	001-36199
10.17	Securities Purchase Agreement, dated January 8, 2015, by and among Oculus Innovative Sciences, Inc., the Buyer, and, solely with respect to Section 4 and Section 9 thereof, Ruthigen, Inc., and Dawson James Securities, Inc.		Form 8-K (Exhibit 10.1)	01/13/15	001-36199

## Table of Contents

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed with this Report</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Reg Number</u>
10.18	Securities Purchase Follow Up Agreement, dated March 12, 2015, by and among Oculus Innovative Sciences, Inc., the Buyer, Ruthigen, Inc. and Dawson James Securities, Inc.		Form 8-K (Exhibit 10.1)	03/13/15	001-36199
10.19	Securities Purchase Agreement, dated March 12, 2015, by and among Oculus Innovative Sciences, Inc., the investors identified therein, and, solely with respect to Section 4 and Section 10 thereof, Ruthigen, Inc., and Dawson James Securities, Inc.		Form 8-K (Exhibit 10.2)	03/13/15	001-36199
21.1	List of Subsidiaries.	X			
23.1	Consent of Marcum LLP, independent registered public accounting firm, to the Form 10-K.	X			
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	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.	X			
32.2	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.	X			
101	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.	X			

# 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.

PULMATRIX, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Balance Sheets</a>	F-3
<a href="#">Consolidated Statements of Operations</a>	F-4
<a href="#">Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' (Deficit)/Equity</a>	F-5
<a href="#">Consolidated Statements of Cash Flows</a>	F-6
<a href="#">Notes to Consolidated Financial Statements</a>	F-7

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying consolidated balance sheets of Pulmatrix, Inc. (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders’ (deficit)/equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

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

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As more fully described in Note 1, the Company 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 with regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

/s/ Marcum LLP

Marcum LLP  
New York, NY  
March 10, 2017

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

	December 31,	
	2016	2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,182	\$ 18,902
Prepaid expenses and other current assets	577	1,560
Total current assets	4,759	20,462
Property and equipment, net	786	685
Long-term restricted cash	204	250
Intangible assets	—	7,534
Goodwill	10,914	15,942
Total assets	<u>\$ 16,663</u>	<u>\$ 44,873</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Loan Payable, net of debt discount and issuance costs	2,586	1,029
Accounts payable	747	1,090
Accrued expenses	1,317	1,486
Total current liabilities	4,650	3,605
Loan payable, net of current portion, debt discount and issuance costs	3,217	5,692
Derivative liability	35	11
Deferred tax liability	—	2,959
Total liabilities	<u>7,902</u>	<u>12,267</u>
Stockholders' Equity:		
Common stock, \$0.0001 par value — 100,000,000 shares and 233,500,000 shares authorized at December 31, 2016 and December 31, 2015; 14,850,526 shares and 14,745,754 shares issued and outstanding, including vested restricted stock units of 99,308 and 229,744, at December 31, 2016 and December 31, 2015, respectively	1	1
Additional paid-in capital	164,706	160,708
Accumulated deficit	(155,946)	(128,103)
Total stockholders' equity	8,761	32,606
Total liabilities and stockholders' equity	<u>\$ 16,663</u>	<u>\$ 44,873</u>

*See accompanying notes to consolidated financial statements.*

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

	Years ended December 31,	
	2016	2015
Revenues	\$ 835	\$ 1,201
Operating expenses		
Research and development	10,152	7,187
General and administrative	8,015	17,032
Write off of intangibles	7,534	—
Total operating expenses	<u>25,701</u>	<u>24,219</u>
Loss from operations	<u>(24,866)</u>	<u>(23,018)</u>
Other income (expense)		
Interest expense	(881)	(953)
Impairment of goodwill	(5,029)	—
Loss on the conversion of convertible notes	—	(1,170)
Fair value adjustment of preferred stock warrant liability	—	1,309
Fair value adjustment of derivative liability	(24)	(2,291)
Other expense, net	(2)	(44)
Loss before income taxes	<u>(30,802)</u>	<u>(26,167)</u>
Benefit from income taxes	2,959	—
Net loss	<u>\$ (27,843)</u>	<u>\$ (26,167)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.88)</u>	<u>\$ (3.23)</u>
Weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders	<u>14,815,230</u>	<u>8,089,925</u>

*See accompanying notes to consolidated financial statements.*



**PULMATRIX, INC.**  
**Consolidated Statements of Redeemable Convertible Preferred Stock**  
**and Stockholders' (Deficit)/Equity**  
(in thousands, except share data and per share data)

	Series B Redeemable Convertible Preferred Stock		Seed Redeemable Convertible Preferred Stock		Series A-4 Redeemable Convertible Preferred Stock		Series B-1 Redeemable Convertible Preferred Stock		Junior Seed Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Share	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance — January 1, 2015	41,788,790	\$ 20,894	1,219,508	\$ 1,331	1,307,190	\$ 4,000	18,687,554	\$ 9,344	410,000	\$ 4	188,625	\$ —	\$ 23,142	\$ (101,936)	\$(78,794)
Conversion of preferred stock into common stock	(41,788,790)	(20,894)	(1,219,508)	(1,331)	(1,307,190)	(4,000)	(18,687,554)	(9,344)	(410,000)	(4)	4,155,539	—	35,573	—	35,573
Conversion of convertible notes into common stock	—	—	—	—	—	—	—	—	—	—	5,104,661	1	43,059	—	43,060
Conversion of 2015 Bridge notes into common stock	—	—	—	—	—	—	—	—	—	—	664,559	—	8,407	—	8,407
Issuance of common stock and warrants	—	—	—	—	—	—	—	—	—	—	1,454,549	—	10,000	—	10,000
Issuance of warrant with term loan	—	—	—	—	—	—	—	—	—	—	—	—	198	—	198
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	71,323	—	151	—	151
Stock issued for consulting services in connection with the Merger	—	—	—	—	—	—	—	—	—	—	335,844	—	4,248	—	4,248
Exchange of common stock in connection with the Merger	—	—	—	—	—	—	—	—	—	—	2,540,910	—	30,422	—	30,422
Vesting of restricted stock units	—	—	—	—	—	—	—	—	—	—	229,744	—	3,028	—	3,028
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	2,480	—	2,480
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(26,167)	(26,167)
Balance — December 31, 2015	—	—	—	—	—	—	—	—	—	—	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

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2016	2015
<b>Cash flows from operating activities:</b>		
Net loss	\$(27,843)	\$(26,167)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	250	232
Write-off of intangibles, net of tax provision	4,575	—
Impairment of goodwill	5,029	—
Stock-based compensation	3,998	5,508
Stock issued for consulting services in connection with the Merger	—	4,248
Non-cash rent expense	43	(21)
Non-cash interest expense	212	613
Non-cash debt issuance expense	16	66
Fair value adjustment on preferred stock warrant liability	—	(1,309)
Fair value adjustment on derivative liability	24	2,291
Loss on conversion of convertible notes	—	1,170
Loss on disposal of property and equipment	82	13
Changes in operating assets and liabilities:		
Restricted Cash	46	—
Prepaid expenses and other current assets	983	(1,107)
Accounts payable	(346)	806
Accrued expenses	(312)	1,185
Net cash used in operating activities	<u>(13,243)</u>	<u>(12,472)</u>
<b>Cash flows from investing activities:</b>		
Cash acquired from the merger transaction	—	9,671
Proceeds on sale of equipment	24	—
Purchases of property and equipment	(455)	(266)
Net cash (used in) provided by investing activities	<u>(431)</u>	<u>9,405</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock and warrants	—	10,000
Proceeds from exercise of stock options	—	151
Proceeds from issuance of convertible promissory notes	—	4,457
Principle payments term loan	(1,046)	6,910
Net cash (used in) provided by financing activities	<u>(1,046)</u>	<u>21,518</u>
<b>Net (decrease) increase in cash and cash equivalents</b>	<u>(14,720)</u>	<u>18,451</u>
<b>Cash and cash equivalents — beginning of period</b>	<u>18,902</u>	<u>451</u>
<b>Cash and cash equivalents — end of period</b>	<u>\$ 4,182</u>	<u>\$ 18,902</u>
<b>Supplemental disclosures of noncash financing and investing activities:</b>		
Conversion of convertible notes and accrued interest into common stock	\$ —	\$ 43,060
Conversion of 2015 Bridge notes into common stock	\$ —	\$ 8,407
Fair value of assets and liabilities acquired in the Merger:		
Fair value of assets acquired in Merger	\$ —	\$ 23,772
Fair value of liabilities assumed in Merger	\$ —	\$ (3,022)
Fair value of net assets acquired in the Merger	\$ —	\$ 20,750
Fixed asset trade in value	\$ 60	\$ —
Fixed asset purchases in accounts payable at year-end	\$ 2	\$ 37

See accompanying notes to consolidated financial statements

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

**1. Organization**

Ruthigen was incorporated in 2013 as a Nevada corporation and converted to a Delaware corporation in September 2013. Ruthigen operated as a wholly owned subsidiary of Oculus Innovative Sciences, Inc. (“Oculus”) until the completion of Ruthigen’s initial public offering in March 2014. Prior to the Merger, Ruthigen was a biopharmaceutical company focused on pioneering new hypochlorous acid (HOCl) based therapies designed to improve patient outcomes and reduce healthcare costs associated with infections related to post-operative invasive procedures.

On June 15, 2015 (the “Effective Time”), Pulmatrix Operating Company, Inc., a Delaware corporation previously known as Pulmatrix Inc. (“Pulmatrix Operating”), completed its merger with Ruthigen Merger Corp. (“Merger Sub”), a wholly owned subsidiary of Pulmatrix, Inc., a Delaware corporation previously known as Ruthigen, Inc. (“Ruthigen”), pursuant to the terms of the Agreement and Plan of Merger (the “Merger Agreement”), dated March 13, 2015, by and among Pulmatrix Operating, Merger Sub and Pulmatrix, Inc. (the “Merger”).

In connection with the Merger, we changed our name to “Pulmatrix, Inc.” and relocated our corporate headquarters to Lexington, Massachusetts. Following the Merger, we began focusing our resources on the development of products within the scope of Pulmatrix Operating’s former business plan, which was principally based on the development of novel inhaled therapeutic products intended to prevent and treat respiratory diseases and infections. Pulmatrix, Inc. is a clinical stage biotechnology company focused on the discovery and development of a novel class of inhaled therapeutic products intended to prevent and treat respiratory diseases and infections that have significant unmet medical needs. Pulmatrix Operating’s proprietary dry powder delivery platform, iSPERSE (inhaled Small Particles Easily Respirable and Emitted), is engineered to deliver small, dense particles with highly efficient dispersibility and delivery to the airways, which can be used with an array of dry powder inhaler technologies and can be formulated with a variety of drug substances. Pulmatrix, Inc. is developing a pipeline of iSPERSE-based therapeutic candidates targeted at prevention and treatment of a range of rare or orphan respiratory diseases and infections, including chronic obstructive pulmonary disease, cystic fibrosis and idiopathic pulmonary fibrosis.

The term “Company” as used in these notes to the consolidated financial statements refers to Pulmatrix Operating prior to the completion of the Merger and Pulmatrix, Inc. subsequent to the completion of the Merger.

*Liquidity*

At December 31, 2016, the Company had unrestricted cash and cash equivalents of \$4,182 and an accumulated deficit of \$155,946. 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. As per Note 17, in February 2017, we closed on two registered direct offerings that brought in net proceeds of approximately \$7,500.

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.

## [Table of Contents](#)

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 we are unable to do so. The Company's consolidated financial statements as of December 31, 2016 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.

#### *Merger and Exchange Ratio*

The Merger has been accounted for as a "reverse merger" under the acquisition method of accounting for business combinations with Pulmatrix Operating treated as the accounting acquirer of Ruthigen. The historical financial statements of Pulmatrix Operating have become the historical financial statements of the Company, or the combined company, and are included in this filing labeled "Pulmatrix, Inc." As a result of the Merger, historical common stock, stock options and additional paid-in capital, including share and per share amounts, have been retroactively adjusted to reflect the equity structure of the combined company, including the effect of the Merger exchange ratio and the common stock par value of \$0.0001 per share. See Note 3, "Merger," for additional discussion of the Merger and the exchange ratio.

#### *Reverse Stock Split*

On June 15, 2015, following the Effective Time, the Company effected a 1-for-2.5 reverse stock split (the "Reverse Stock Split") of its outstanding common stock, par value \$0.0001 per share ("Company Common Stock"). The accompanying consolidated financial statements and notes to the consolidated financial statements, including the Merger exchange ratio (Note 3) applied to historical Pulmatrix Operating common stock and stock options unless otherwise noted, give retroactive effect to the Reverse Stock Split for all periods presented. The shares of Company Common Stock retained a par value of \$0.0001 per share.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which requires an entity to recognize revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective in the annual period ending December 31, 2017, including interim periods within that annual period. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial position and results of operations.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements — Going Concern* ("ASU 2014-15"), which requires management to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The standard defines substantial doubt as when it is probable (i.e., likely) that the entity will be unable to meet its obligations as they become due within one year of the date the financial statements are issued. The ASU is effective for the annual period ending December 31, 2016 and

## [Table of Contents](#)

interim periods thereafter. Early application is permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company has adopted this standard and its impact on its consolidated financial statements and related disclosures was immaterial.

In November 2014, the FASB issued ASU No. 2014-16, (Topic 815) *Derivatives and Hedging* (“ASU 2014-16”), which provides clarification on how current guidance should be interpreted in evaluating the economic characteristics and risks of a host contract in a hybrid financial instrument that is issued in the form of a share. Specifically, the amendments clarify that an entity should consider all relevant terms and features in evaluating the host contract and that no single term or feature would necessarily determine the economic characteristics and risks of the host contract. ASU 2014-16 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The amendment should be applied on a modified retrospective basis to existing hybrid financial instruments issued in the form of a share as of the beginning of the year for which the amendments are effective. The Company has adopted this standard and its impact on its consolidated financial statements and related disclosures was immaterial.

In December 2014, the FASB has issued ASU No. 2014-12, *Compensation — Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period*. This ASU requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. The Company has adopted this standard and its impact on its consolidated financial statements and related disclosures was immaterial.

In May 2015, the FASB issued ASU 2015-07, *Fair Value Measurement*, to remove the requirement to categorize within the fair value hierarchy all investments for which fair value is measured using the net asset value per share practical expedient. The amendments also remove the requirement to make certain disclosures for all investments that are eligible to be measured at fair value using the net asset value per share practical expedient. The ASU is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. The Company has adopted this standard and its impact on its consolidated financial statements and related disclosures was immaterial.

In September 2015, the FASB issued ASU No. 2015-16, “*Business Combinations (Topic 805), Simplifying the Accounting for Measurement-Period Adjustments*”. The update requires that the acquirer in a business combination recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined (not retrospectively as with prior guidance). Additionally, the acquirer must record in the same period’s financial statements the effect on earnings of changes in depreciation, amortization or other income effects as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the time of acquisition. The acquiring entity is required to disclose, on the face of the financial statements or in the footnotes to the financial statements, the portion of the amount recorded in current period earnings, by financial statement line item, that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The guidance in ASU No. 2015-16 is effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The Company has adopted this standard and its impact on its consolidated financial statements and related disclosures was immaterial.

In March 2016 the FASB issued ASU No. 2016-06, “*Derivatives and Hedging (Topic 815): Contingent Put and Call Options in Debt Instruments*” (“ASU 2016-06”). This new standard simplifies the embedded derivative analysis for debt instruments containing contingent call or put options by removing the requirement to assess

## [Table of Contents](#)

whether a contingent event is related to interest rates or credit risks. This new standard will be effective for us on January 1, 2017. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

In March 2016, the FASB issued ASU No. 2016-09 (“ASU 2016-09”), “Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.” ASU 2016-09 will affect all entities that issue share-based payment awards to their employees and is effective for annual periods beginning after December 15, 2016 for public entities. The areas for simplification in ASU 2016-09 involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company is currently evaluating the effect that ASU 2016-09 will have on the Company’s financial position and results of operations.

In August 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-15, “*Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments*” (“ASU 2016-15”). ASU 2016-15 is intended to address how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This update addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the ASU 2016-15 and does not believe this ASU will have a material impact on its consolidated financial statements.

In October 2016, the FASB issued ASU 2016-17, “*Consolidation (Topic 810): Interests held through Related Parties that are under Common Control*,” (“ASU 2016-17”) which alters how a decision maker considers indirect interests in a variable interest entity (VIE) held through an entity under common control and simplifies that analysis to require consideration of only an entity’s proportionate indirect interest in a VIE held through a common control party. The Company is currently evaluating the effect that ASU 2016-17 will have on the Company’s financial position or results of operations.

In December 2016, the FASB issued ASU 2016-18 “*Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force)*,” which clarifies the presentation requirements of restricted cash within the statement of cash flows. The changes in restricted cash and restricted cash equivalents during the period should be included in the beginning and ending cash and cash equivalents balance reconciliation on the statement of cash flows. When cash, cash equivalents, restricted cash or restricted cash equivalents are presented in more than one line item within the statement of financial position, an entity shall calculate a total cash amount in a narrative or tabular format that agrees to the amount shown on the statement of cash flows. Details on the nature and amounts of restricted cash should also be disclosed. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. The Company does not expect this new guidance to have a material impact on its financial position or results of operations.

In January 2017, the FASB issued ASU 2017-01 “*Business Combinations (Topic 805): Clarifying the Definition of a Business*”, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. The Company does not expect this new guidance to have a material impact on its financial position, results of operations or financial statement disclosures.

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

## [Table of Contents](#)

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 does not expect this new guidance to have a material impact on its financial positions or results of operations.

There have been four new ASUs issued amending certain aspects of ASU 2014-09, ASU 2016-08, “*Principal versus Agent Considerations (Reporting Revenue Gross Versus Net)*,” was issued in March, 2016 to clarify certain aspects of the principal versus agent guidance in ASU 2014-09. In addition, ASU 2016-10, “*Identifying Performance Obligations and Licensing*,” issued in April 2016, amends other sections of ASU 2014-09 including clarifying guidance related to identifying performance obligations and licensing implementation. ASU 2016-12, “*Revenue from Contracts with Customers — Narrow Scope Improvements and Practical Expedients*” provides amendments and practical expedients to the guidance in ASU 2014-09 in the areas of assessing collectability, presentation of sales taxes received from customers, noncash consideration, contract modification and clarification of using the full retrospective approach to adopt ASU 2014-09. Finally, ASU 2016-20, “*Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*,” was issued in December 2016, and provides elections regarding the disclosures required for remaining performance obligations in certain cases and also makes other technical corrections and improvements to the standard. With its evaluation of the impact of ASU 2014-09, the Company will also consider the impact on its financial statements related to the updated guidance provided by these four new ASUs.

### **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 fair value of net assets acquired in business combinations, 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*

## [Table of Contents](#)

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

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

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

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

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

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

### **Redeemable Convertible Preferred Stock**

The Company classifies its redeemable convertible preferred stock as temporary equity on the balance sheets because redemption is not solely within the control of the Company. On issuance, the Company records the preferred stock at fair value which is normally the issue price. The carrying value of redeemable convertible preferred stock is increased by periodic accretions so that the carrying amount will equal the redemption amount at the date when a majority of holders of such stock may elect to redeem it. These increases are effected through charges against additional paid-in capital, to the extent it is available, or to accumulated deficit. As of December 31, 2015, all redeemable convertible preferred stock had converted to shares of common stock (see Note 8).

### **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



## [Table of Contents](#)

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.

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 instruments 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.

## [Table of Contents](#)

At December 31, 2016 the Company had a \$153 letter of credit as a security deposit on its leased office and laboratory facility that expires in March 2017 and that 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. At December 31, 2015, the Company had a \$200 letter of credit as a security deposit on its leased office and laboratory facility that expired in December, 2016 and that was secured by a deposit in a money market account, as well as \$50 deposited in a money market account as security for a credit card.

### **Property and Equipment, net**

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

Depreciation is provided over the following estimated useful lives:

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

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

### **Deferred Rent**

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

### **Impairment of Long-Lived Assets**

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

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

Other than impairment of IPR&D, to date no such impairment have been recognized on long-lived assets other than goodwill.

## **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 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, restricted stock units ("RSUs") and performance stock units ("PSU"), 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

## [Table of Contents](#)

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 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.

### **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.

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 the fair value of the company to its carrying value and then the Company performed a second step by comparing the enterprise value to the carrying value of goodwill. The Company determined that goodwill was impaired and recorded an impairment charge of \$5,029 that revalued goodwill to \$10,914 as of December 31, 2016.

### **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. During the year ended December 31, 2016, the Company determined that there was a full impairment of its IPR&D and \$7,534 was revalued to \$0.

### **3. Merger**

As described in Note 1, on June 15, 2015, the Company completed the Merger with Pulmatrix Operating. Pursuant to the Merger Agreement, each outstanding share of capital stock of Pulmatrix Operating was exchanged for 0.148187124066461 pre-Reverse Stock Split shares of Company Common Stock (the “Exchange Ratio”). All Pulmatrix Operating stock options granted under the Pulmatrix Operating stock option plans (whether or not then exercisable) that were outstanding prior to the Effective Time converted into options to purchase Company Common Stock at the same ratio as described below. Immediately prior to the Effective Time, the outstanding shares of convertible preferred stock of Pulmatrix Operating converted into an aggregate of 70,105,854 shares (pre-Reverse Stock Split and before giving effect to the Exchange Ratio) of Pulmatrix Operating common stock, which shares were exchanged in the Merger for an aggregate of 4,155,539 shares of Company Common Stock, and convertible debt of Pulmatrix Operating converted into an aggregate of 86,118,402 shares of Pulmatrix Operating common stock (pre-Reverse Stock Split and before giving effect to the Exchange Ratio), which shares were exchanged in the Merger for an aggregate of 5,104,661 shares of Company Common Stock. All outstanding Pulmatrix Operating preferred stock warrants were cancelled immediately prior to the Effective Time. In addition, immediately following the Effective Time the Company issued 664,559 shares of Company Common Stock in exchange for \$4,500 aggregate principal amount of bridge notes and \$69 in related accrued interest assumed by the Company in the Merger.

All Pulmatrix Operating stock options granted under the Pulmatrix Operating stock option plans (whether or not then exercisable) that were outstanding at the Effective Time converted into options to purchase Company Common Stock. After the Effective Time, all outstanding and unexercised Pulmatrix Operating stock options assumed by the Company may be exercised solely for shares of Company Common Stock. The number of shares of Company Common Stock subject to each Pulmatrix Operating stock option assumed by the Company was determined by multiplying (a) the number of shares of Pulmatrix Operating common stock that were subject to such Pulmatrix Operating stock option, as in effect immediately prior to the Effective Time, by (b) the Exchange Ratio, and rounding the resulting number down to the nearest whole number of shares of Company Common Stock. The per share exercise price for the Company Common Stock issuable upon exercise of each Pulmatrix Operating stock option assumed by the Company was determined by dividing (a) the per share exercise price of Pulmatrix Operating common stock subject to such Pulmatrix Operating stock option, as in effect immediately prior to the Effective Time, by (b) the Exchange Ratio and rounding the resulting exercise price up to the nearest whole cent.

## [Table of Contents](#)

As a result of the Merger, the vesting of 67,732 restricted stock units and 24,400 options granted prior to the Merger by Ruthigen under the Ruthigen 2013 Employee, Director and Consultant Equity Incentive Plan was accelerated. The acceleration clause was included as part of the original terms of the equity awards.

The Merger has been accounted for as a reverse acquisition under the acquisition method of accounting with Pulmatrix Operating treated as the accounting acquirer and Ruthigen treated as the acquired company for financial reporting purposes. Pulmatrix Operating was determined to be the accounting acquirer based upon the terms of the Merger and other factors, such as relative voting rights and the composition of the combined company's board of directors and senior management. Accordingly, the Ruthigen tangible and identifiable intangible assets acquired and liabilities assumed were recorded at fair value as of the date of acquisition, with the excess consideration transferred recorded as goodwill.

See Note 12, "Stock-Based Compensation," for additional details regarding the accounting treatment for the equity awards of Pulmatrix Operating and Ruthigen.

The acquisition-date fair value of the consideration transferred is as follows:

Number of shares of Company Common Stock owned by Ruthigen stockholders (1)	2,404,835
Multiplied by the price per share of Company Common Stock (2)	\$ 12.65
Total consideration transferred	<u>\$ 30,422</u>

- (1) The stock transferred in the table above is calculated as the sum of a) 1,921,716 shares of Company Common Stock outstanding at the time of the Merger, b) 379,387 shares of Company Common Stock issued immediately following the closing of the Merger in a private placement, c) 36,000 shares of Company Common Stock issued to certain employees, pursuant to the terms of the Merger Agreement and d) 67,732 shares of Company Common Stock issued pursuant to restricted stock units that became fully vested upon completion of the Merger.
- (2) The shares outstanding are multiplied by the closing trading price of Company Common Stock as of the Merger date.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the date of acquisition:

	<u>June 15, 2015</u>
Cash and cash equivalents	\$ 9,671
In-process research and development	7,534
Goodwill	15,942
Property and equipment	156
Prepaid and other current assets	141
Total assets acquired	<u>33,444</u>
Accrued expenses and other current liabilities	(63)
Deferred tax liability	(2,959)
Total liabilities assumed	<u>(3,022)</u>
Total net assets acquired	<u>\$ 30,422</u>

The purchase price allocation is subject to change as additional information becomes available concerning the fair value and tax basis of the assets acquired and the liabilities assumed. Any adjustments to the purchase price allocation will be made as soon as practicable but no later than one year from June 15, 2015, the acquisition date. As of December 31, 2016, no adjustments have been made.

## [Table of Contents](#)

For acquired working capital accounts such as prepaid expenses and other current assets, property and equipment, accounts payable and certain accrued expenses, the Company determined that no fair value adjustments were required due to the short timeframe until settlement for these assets and liabilities.

The acquired IPR&D consisted of RUT58-60, a proprietary formulation of HOCl and Ruthigen's lead drug candidate, which was designed to prevent and treat infection in invasive applications. RUT58-60 was developed in collaboration with Ruthigen's former parent, Oculus Innovative Sciences, Inc. ("Oculus"), under a license agreement. Concurrent with entering into the Merger Agreement, Pulmatrix, Ruthigen and Oculus entered into a side letter agreement that clarified certain rights and obligations of each party following the closing date of the Merger with respect to certain agreements previously executed between Ruthigen and Oculus, including the license agreement. Under the terms of the side letter agreement, the Company's obligation to develop and commercialize RUT58-60 was waived for one year following the Merger closing date. Also under the terms of the agreement, the Company may sell its rights to develop RUT58-60 if it receives at least \$1,000 therefor, and Oculus has a right of first refusal with respect to any offers to purchase RUT58-60, such that Oculus could elect to purchase RUT58-60 for identical terms negotiated with a prospective buyer. In the event that the Company sells its rights to develop RUT58-60 for an amount in excess of \$10,000, the Company must pay 10% of the gross consideration received to Oculus.

The fair value of the IPR&D was determined using a discounted cash flow analysis of the expected cash flows to be generated by the IPR&D over its remaining life, net of returns on contributory assets including working capital and real and personal property assets. A discount rate of 26.6% was used in the analysis. The resulting present value of the cash flows was combined with the estimated present value of the amortization tax benefit that a purchaser of the asset could be expected to receive to arrive at the estimated fair value of the IPR&D. The Company believes the assumptions used are consistent and representative of those a market participant would use in estimating the fair value of the IPR&D. If, at the end of the one year waiver period, the Company has not been successful in finding a buyer for RUT58-60, Oculus will have the right to cancel the license agreement and reclaim all rights to RUT58-60. During the year ended December 31, 2016, as a sale of RUT58-60 did not take place within the waiver period, the Company revalued its IPR&D of \$7,534 to \$0 in a complete write-off .

The deferred tax liability of \$2,959 relates to the temporary difference associated with the \$7,534 value of the IPR&D asset, which is not deductible for tax purposes. The deferred tax liability was recorded based on a 39.28% effective tax rate. A full write-off of the deferred tax liability was recorded on June 15, 2016, as the term for the license agreement has terminated.

Goodwill is calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill is not expected to be deductible for income tax purposes. Goodwill is recorded as an indefinite-lived asset and is not amortized but tested for impairment on an annual basis or when indications of impairment exist. The Company determined that goodwill was impaired and recorded an impairment charge of \$5,029 that revalued goodwill to \$10,914 as of December 31, 2016.

The operating results of Ruthigen for the period from June 16, 2015 to December 31, 2015, including operating losses of \$1,388 have been included in the Company's consolidated financial statements as of and for the year ended December 31, 2015.

The Company incurred a total of \$6,863 in transaction costs in connection with the Merger, excluding Ruthigen transaction costs, which were included in general and administrative expense within the consolidated statements of operations for the year ended December 31, 2015. The following supplemental audited pro forma information presents the Company's financial results as if the acquisition of Ruthigen had occurred on January 1, 2015:

## [Table of Contents](#)

	<b>For the Year ended December 31, 2015</b>
Total revenues, net	\$ 1,201
Net loss	\$ (19,093)

The above pro forma information was determined based on the historical GAAP results of the Company and Ruthigen. The audited pro forma consolidated results are not necessarily indicative of what the Company's consolidated results of operations actually would have been if the acquisition was completed on January 1, 2015. The audited pro forma consolidated net loss includes pro forma adjustments primarily relating to the following non-recurring items directly attributable to the business combination:

- (1) Elimination of \$9,956 of transaction costs for both the Company and Ruthigen from the year ended December 31, 2015.
- (2) Elimination of \$901 of stock-based compensation expense related to the acceleration of vesting of previously unvested Ruthigen awards in connection with the Merger from the year ended December 31, 2015;
- (3) Elimination of \$995 of expense related to stay bonuses from the year ended December 31, 2015;
- (4) Elimination of \$1,309 of other income and \$2,291 of other expense related to the change in the fair values of liability-classified warrants and derivative instruments from the year ended December 31, 2015, respectively, as the Company's outstanding preferred stock warrants and certain derivative instruments were extinguished in connection with the completion of the Merger;
- (5) Elimination of \$1,170 loss on conversion of convertible notes from the year ended December 31, 2015, as the Company's 2015 Bridge Notes (defined below) were automatically converted to equity upon completion of the Merger; and
- (6) Elimination of \$477 and \$6,868 of interest expense related to our convertible notes, including the 2015 Bridge Notes, from the year ended December 31, 2015, as all of the Company's outstanding convertible notes were automatically converted to equity in connection with the closing of the Merger.

#### **4. Goodwill and IPR&D**

The Company recognized \$15,942 of goodwill in connection with the Merger as discussed in Note 3. As of December 31, 2016, there was an impairment loss of \$5,029. Goodwill has been assigned to the Company's single reporting unit.

The Company recognized \$7,534 of IPR&D in connection with the Merger as discussed in Note 3. The acquired IPR&D consisted of RUT58-60, a proprietary formulation of HOCl and Ruthigen's lead drug candidate, which was designed to prevent and treat infection in invasive applications. The IPR&D will be classified as an intangible asset on the consolidated balance sheet and until the project is completed, the assets will be accounted for as indefinite-lived intangible assets.

The deferred tax liability of \$2,959 relates to the temporary difference associated with the \$7,534 value of the IPR&D asset, which is not deductible for tax purposes. The deferred tax liability was recorded based on a 39.28% effective tax rate. A full write-off of the deferred tax liability was recorded on June 15, 2016, as the term for the license agreement has terminated.

As of December 31, 2016, there was an impairment loss of \$9,604, net of tax provision, associated with goodwill and other intangible assets.



## 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	For the year ended December 31,	
	2016	2015
Prepaid Insurance	\$ 197	\$ 220
Prepaid Clinical Trials	9	169
Prepaid Other	58	92
Accounts receivable	206	481
Deferred Clinical Costs	107	598
	<u>\$ 577</u>	<u>\$ 1,560</u>

## 6. Property and Equipment, Net

Property and equipment consisted of the following:

	For the Year Ended December 31,	
	2016	2015
Laboratory equipment	\$ 2,414	\$ 2,239
Computer equipment	254	159
Office furniture and equipment	214	211
Leasehold improvements	575	503
Capital Improvements in progress	—	178
Total property and equipment	3,457	3,290
Less accumulated depreciation and amortization	(2,671)	(2,605)
Property and equipment — net	<u>\$ 786</u>	<u>\$ 685</u>

Depreciation and amortization expense for the years ended December 31, 2016 and 2015 was \$250 and \$232, respectively. During the year ended 2016, the Company recorded gross fixed asset disposals of \$350 and related accumulated depreciation of \$184.

## 7. Significant Agreements

### *Palladium Advisory Agreement*

On February 8, 2015, the Company entered into an agreement with Palladium Capital Advisors, LLC (“Palladium”), whereby Palladium agreed to (i) act as the non-exclusive placement agent for the Bridge Loan financing that occurred on February 26, 2015 (Note 8) and (ii) serve as the Company’s non-exclusive advisor in connection with a merger. As consideration for Palladium’s services under the engagement agreement, the Company paid Palladium a commission on the proceeds received from the issuance of the 2015 Bridge Notes (Note 8) of approximately \$315, and issued to Palladium 235,844 shares of the Company’s common stock. On June 16, 2015, the Company paid Palladium \$1,080 in commissions, based on a percentage of the unencumbered cash acquired in the Merger (Note 3), a percentage of the amount borrowed under the Term Loan (Note 8) and a percentage of the cash proceeds raised by the Company in connection with the Merger. The Company recognized expense of \$4,378 equal to the sum of the cash payments totaling \$1,395 and the fair value of the common stock issued to Palladium of \$2,983 within general and administrative expenses in the consolidated statements of operations for the year ended December 31, 2015.

## [Table of Contents](#)

### *Consulting Agreements*

On June 15, 2015, Ruthigen entered into consulting agreements with three individuals for services relating to business development, strategic relationships and strategic planning. The agreements were contingent upon the completion of the Merger. The term of the agreements commenced upon the closing of the Merger and expire on August 31, 2016. On June 15, 2015, in connection with the closing of the Merger, the Company issued a total of 100,000 shares of unregistered restricted common stock to the three parties as consideration for services to be provided under the agreements as well as services previously provided. The shares are restricted and cannot be sold or transferred until the contract term has ended. Although the stock was issued as compensation for future services, under the terms of the agreements, the issuance of the stock was issued as non-refundable and without recourse. The Company recognized expense equal to the fair value of the common stock issued of \$1,265 within general and administrative expenses in the consolidated statements of operations for the year ended December 31, 2015.

### *Material Transfer Agreement*

On November 5, 2013, the Company entered into the Material Transfer Agreement (the "MTA") with Mylan N.V. ("Mylan"). The focus of the MTA is to further the development of PUR0200, the Company's clinical stage bronchodilator therapy candidate. Under the MTA, the Company has agreed to share materials for the research and development of PUR0200 and Mylan has agreed to share the results of such research activities. The agreement will remain in effect for seven years from the effective date of the agreement or until the completion of Mylan research activities. The agreement is cancelable by either party upon 30 days' written notice.

On June 9, 2015, the Company amended the MTA with Mylan. Additionally under the amended agreement the Company was eligible to receive up to \$77 in expense reimbursement to cover the costs to manufacture materials that are transferred under the MTA. As per the amended terms of the MTA, the MTA terminated on June 30, 2016. The Company recognized \$0 and \$77 of revenue during 2016 and 2015, respectively, in connection with this agreement.

### *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 agreed to conduct certain clinical trials related to the Product and is eligible to receive reimbursement of up to \$1,500 for third-party out-of-pocket expenses directly related to trial expenses. On September 14, 2015, the Company entered into an amendment to the Mylan Agreement to provide for reimbursements up to a new cost cap of \$1,878. 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 and 1,019 of revenue under the Mylan Agreement during the years ended December 31, 2016 and 2015, respectively. 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.

## 8. Debt

### *Convertible Notes, Including 5X Notes*

As of December 31, 2014, the Company had outstanding unsecured convertible promissory notes payable to certain existing stockholders with aggregate principal values totaling \$29,088 (the “Notes”), including promissory notes with aggregate principal values totaling \$2,658 for which, upon settlement of the notes, the note holders would receive five times the stated principal value of the notes, five times the shares into which the rest of the notes would be convertible, or five times the value in new equity shares upon an automatic conversion in a qualified financing (the “5X Notes”). The Notes had a stated annual interest rate of 6%, and the outstanding principal balance of all of the Notes, including the effective principal value of the 5X Notes, and accrued interest were payable on demand by at least a majority of the holders of the Notes, at any time following January 15, 2015, the maturity date, as amended in October 2014, or upon an event of default, as defined within the agreement, at the request of Note holders representing at least a majority of the aggregate principal amount then outstanding under all the Notes. The Notes were unsecured and were issued on various dates during the years ended December 31, 2011, 2012, 2013, and 2014.

The Notes had an optional conversion feature where in the event that a qualified financing or a liquidation event, as defined in the Notes, did not occur prior to January 15, 2015, a majority of the Note holders could elect to put the Notes back to the Company for their effective principal amounts, including the five times stated principal amount for the 5X Notes, plus accrued but unpaid interest or to convert all, but not less than all, of the unpaid principal amount of the Notes, plus accrued but unpaid interest through the date of such conversion, into shares of the Company’s Series B Preferred Stock at \$0.50 per share. No such qualified financing occurred prior to January 15, 2015 and as such, the Note holders were entitled to put the Notes back to the Company or convert all of the unpaid principal plus interest at any time.

In connection with entering into the Merger Agreement (Note 3), the Company and the investors agreed that the Notes would cease to accrue interest as of December 31, 2014. The Company determined that the amendment to cease accrual of interest represented a modification to the Notes. The modification did not give rise to any adjustments to the classification or carrying amounts related to the Notes.

On March 13, 2015, pursuant to the Merger Agreement, and as a condition to closing the Merger, the Company entered into a Note Conversion and Warrant Termination Agreement with the holders of the outstanding Notes, including the 5X Notes. Under the terms of the Note Conversion and Warrant termination Agreement, on June 15, 2015, immediately prior to the Effective Time, the outstanding Notes, including the 5X Notes, plus accrued and unpaid interest were automatically converted into 86,118,402 shares (pre-Reverse Stock Split and before giving effect to the Exchange Ratio) of Pulmatrix Operating common stock and all of Pulmatrix Operating’s outstanding warrants to purchase shares of preferred stock were cancelled. No gain or loss was recognized on the conversion of the Notes. These 86,118,402 shares (pre-Reverse Stock Split and before giving effect to the Exchange Ratio) of Pulmatrix Operating common stock were exchanged for 5,104,661 shares of Company Common Stock pursuant to the Exchange Ratio in the Merger.

For the year ended December 31, 2016 and 2015, non-cash interest expense aggregating to \$0 and \$18 were recorded respectively, which includes accretion of debt discount \$0 and \$18, respectively.

### *Promissory Note*

On January 21, 2015, Barry Honig provided the Company with a bridge loan of \$350 evidenced by a promissory note. On February 19, 2015, the Company repaid Mr. Honig in full for the promissory note.

*2015 Bridge Notes*

In February 2015, the Company issued and sold convertible promissory notes (the “2015 Bridge Notes”), in the aggregate principal amount of \$4,500, of which none was issued to existing investors. The 2015 Bridge Notes had a stated interest rate of 5% per annum, which would reset to 15% upon an event of default, as defined in the agreement, and were due and payable on February 26, 2016. Upon the completion of the Merger, subject to certain limitations, the unpaid principal amount of the 2015 Bridge Notes, plus accrued but unpaid interest through the date of such transaction, automatically converted into shares of common stock of the Company equal to the principal and unpaid accrued interest dollar value divided by \$6.875. Upon an event of default, including a change of control other than as defined in the Merger Agreement, at any time or if the Merger had not occurred by February 26, 2016, a majority of the holders of the 2015 Bridge Notes could elect to put the notes back to the Company for the unpaid principal amount of the 2015 Bridge Notes, plus unpaid accrued interest, plus an amount equal to 25% of the outstanding principal balance would become due and payable immediately.

The provisions requiring the embedded interest rate reset upon an event of default, automatic conversion of the convertible promissory notes upon the Merger and the put option upon an event of default or failure to close the Merger each represent an embedded derivative instrument requiring bifurcation from the notes. The embedded derivatives were bundled and valued as one compound derivative in accordance with the applicable accounting guidance for derivatives and hedging. The derivative liability was remeasured at fair value at each reporting date, with changes in fair value being recorded as other income (expense) in the statements of operations (Note 14). The net debt discounts resulting from the embedded compound derivative and lender fees were being amortized as interest expense from the date of issuance through the maturity date using the effective interest method. At issuance, the Company recorded a derivative liability and a discount on the 2015 Bridge Notes of \$1,547. Amortization of the discount totaled \$386 for the year ended December 31, 2015. Amortization of the issuance costs totaled \$4 for the year ended December 31, 2015.

On June 15, 2015, at the Effective Time, Pulmatrix Operating’s obligations under the 2015 Bridge Notes were assumed by Company, and immediately after the Effective Time, the 2015 Bridge Notes of \$4,500 and accrued and unpaid interest of \$69, were exchanged for an aggregate of 664,559 shares of Company Common Stock. The exchange of the 2015 Bridge Notes for shares of Company Common Stock resulted in the extinguishment of the embedded compound derivative. Following the exchange, the Company’s obligation to repay the 2015 Bridge Notes was satisfied. Immediately prior to the exchange, the Company recorded a loss of \$2,692 for the increase in the estimated fair value of the derivatives. The Company recorded a loss upon the conversion of the 2015 Bridge Notes, including the extinguishment of the embedded compound derivative, of \$1,170, equal to the difference between the fair value of the shares issued and the sum of the carrying amount of the 2015 Bridge Notes, including accrued and unpaid interest, and the carrying amount of the compound derivatives at the time of the conversion.

For the year ended December 31, 2015, non-cash interest expense aggregating to \$459 includes accretion of debt discount and debt issuance costs of \$386 and \$4, respectively.

*Loan and Security Agreement and Warrant Agreement*

On June 11, 2015, Pulmatrix Operating entered into a Loan and Security Agreement (“LSA”) with Hercules Technology Growth Capital, Inc. (“Hercules”), for a term loan in a principal amount of \$7,000 (the “Term Loan”). 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.

## [Table of Contents](#)

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 10.00% and 9.75% at December 31, 2016 and 2015, 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. The end of term charge 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 effect 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, 2016 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, 2016 and 2015.

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 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

[Table of Contents](#)

recorded as other income (expense) in the consolidated statements of operations (Note 13). At December 31, 2016, the fair value of the derivative liability was remeasured and valued at \$35. 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 \$881 during the year ended December 31, 2016, which includes accretion of debt discount of \$112 and \$669 which was payable in cash. 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 Company incurred interest expense of \$476 during the year ended December 31, 2015, which includes accretion of debt discount of \$52 and \$368 which was payable in cash. For the year ended December 31, 2015, the Company also accreted debt issuance costs of \$9 recorded to general and administrative expenses in accompanying consolidated statement of operations.

The carrying amounts of the Company's Notes, including the 5X conversion liability, and the Term Loan as of December 31, 2016 and December 31, 2015 were as follows:

	<u>Principal Amount of Notes</u>	<u>5X Conversion Liability</u>	<u>Debt Discount</u>	<u>Issuance Costs</u>	<u>2015 Bridge Notes</u>	<u>Hercules Term Loan</u>	<u>Total</u>
Balance — January 1, 2015	\$ 29,088	\$ 10,633	\$ (18)	\$ —	\$ —	\$ —	\$ 39,703
Conversion of debt	(29,088)	(10,633)	—	—	—	—	(39,721)
Term loan, debt discount and issuance costs	—	—	(1,847)	(43)	4,500	7,000	9,610
Accretion of debt discount and issuance costs	—	—	1,617	12	—	—	1,629
Conversion of Debt	—	—	—	—	(4,500)	—	(4,500)
Balance — December 31, 2015	—	—	(248)	(31)	—	7,000	6,721
Term loan, debt discount and issuance costs	—	—	—	—	—	(1,046)	(1,046)
Accretion of debt discount and issuance costs	—	—	112	16	—	—	128
Balance — December 31, 2016	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (136)</u>	<u>\$ (15)</u>	<u>\$ —</u>	<u>\$ 5,954</u>	<u>\$ 5,803</u>

Future principal payments in connection with the Term Loan are as follows:

2017	\$2,698
2018	3,256
	<u>\$5,954</u>

## 9. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following:

	December 31,	
	2016	2015
Accrued vacation	\$ 54	\$ 45
Accrued wages and incentive	796	673
Accrued clinical & consulting	202	622
Accrued legal & patent	51	62
End of term fee	155	55
Deferred rent	46	4
Accrued other expenses	13	25
Total accrued expenses	<u>\$1,317</u>	<u>\$1,486</u>

## 10. Common Stock

### *Pulmatrix Operating Private Placement*

On June 15, 2015, immediately prior to the Effective Time, pursuant to a securities purchase agreement between the Company and certain existing investors of the Company dated March 13, 2015, the Company sold to such investors 24,538,999 units, with each unit consisting of (i) one share of Pulmatrix Operating's common stock and (ii) a warrant representing the right to purchase 2.193140519 shares of Pulmatrix Operating common stock at an exercise price of \$0.448266 per share (each pre-Reverse Stock Split and before giving effect to the Exchange Ratio), for aggregate gross proceeds of \$10,000 (the "Pulmatrix Operating Private Placement"). Upon the Effective Time, the Pulmatrix Operating common stock underlying the units was exchanged for an aggregate of 1,454,549 shares of Company Common Stock, and the warrants underlying the units were converted into warrants to purchase an aggregate of 3,190,030 shares of Company Common Stock at an exercise price of \$7.563 per share. The proceeds from the issuance of the units were allocated between the Company Common Stock and the warrants based on their relative fair values.

### *Ruthigen Private Placement*

Immediately after the Effective Time, the Company closed a private placement of 379,387 shares of Company Common Stock at a price of \$6.875 per share in a private placement for aggregate gross proceeds of approximately \$2.6 million (the "Ruthigen Private Placement").

## 11. Warrants

### *Preferred Stock Warrants Issued with Notes Payable to Stockholders*

Pulmatrix Operating issued warrants to purchase preferred stock in connection with the issuance of Notes to stockholders (Note 8) on various dates in 2011 through 2014 (the "Preferred Stock Warrants"). The number and type of shares issuable upon exercise of the warrants was variable based on the following: (a) upon the completion of a qualified financing, the warrants would be exercisable into a number of qualified financing shares determined by multiplying 0.25 by the quotient obtained by dividing the original principal amount of the Notes by the issuance price in the qualified financing or, (b) upon the completion of an optional conversion of the Notes into shares of Series B preferred stock by the Note holders, the warrants would be exercisable into a number of shares of Series B preferred stock determined by multiplying 0.25 by the quotient obtained by dividing the original principal amount of the Notes by \$0.50 (subject to any adjustments for any stock splits, combinations, reclassifications, and the like). If the Preferred Stock Warrants had become exercisable into a number of qualified financing shares, the exercise price per share would have been the per share issuance price of the qualified financing shares. If the Preferred Stock Warrants had become exercisable into shares of Series B preferred stock, the exercise price would have been \$0.50 per share.

## [Table of Contents](#)

The Preferred Stock Warrants were exercisable at any time on or after the earlier of a qualified financing or an optional conversion of the Notes and expire 10 years from the date of issuance.

As described more fully in Note 8, the Company entered into a Note Conversion and Warrant Termination Agreement with the holders of the outstanding Notes, under the terms of which all of the Company's outstanding Preferred Stock Warrants were terminated on June 15, 2015, immediately prior to the Effective Time. As of December 31, 2015, there were no outstanding Preferred Stock Warrants.

A roll-forward of the Preferred Stock Warrants is as follows:

	<u>Preferred Stock Warrants</u>	<u>Estimated Fair Value</u>
Balance — January 1, 2015	14,544,247	\$ 1,309
Decrease in estimated fair value of warrants	—	(1,309)
Cancellation and gain (loss) on extinguishment	<u>(14,544,247)</u>	<u>—</u>
Balance — December 31, 2015	<u>—</u>	<u>\$ —</u>

For the years ended December 31, 2016 and December 31, 2015, the Company recorded other income of \$0 and \$1,309 which related to the change in the fair value of the warrants classified as liabilities.

### *Common Stock Warrants Issued in Pulmatrix Operating Private Placement*

At December 31, 2015, the Company had outstanding warrants to purchase 3,190,030 shares of Company Common Stock at an exercise price of \$7.563 per share. The warrants were issued on June 15, 2015 immediately prior to the Effective Time in connection with the Pulmatrix Operating Private Placement.

Each warrant issued in the Pulmatrix Operating Private Placement has a five-year term and becomes exercisable at the earliest to occur of the date that (i) the Company enters into a strategic license agreement with a third party related to any of the Company's products whereby the Company is guaranteed to receive consideration having a value of at least \$20,000, (ii) the Company consummates a public or private offering of common stock or securities convertible into common stock that results in aggregate gross proceeds of at least \$20,000 and the per share value of such consideration is equal to at least \$10.00 per share, subject to certain adjustments, (iii) for a period of sixty consecutive trading days, the volume weighted average price per share of common stock exceeds \$12.50, subject to certain adjustments, and the average daily trading volume on such trading market exceeds 40,000 shares per trading day, subject to certain adjustments, or (iv) a change of control transaction occurs. The number of shares of common stock underlying each warrant and the exercise price per share are subject to adjustment in the case of standard dilutive events.

Each warrant provides that, following it initially becoming exercisable, if (i) the volume weighted average price of common stock exceeds one hundred fifty percent (150%) of the exercise price of the warrant for thirty (30) consecutive trading days, (ii) the daily trading volume for common stock exceeds 80,000 shares per trading day, subject to certain adjustments, for thirty (30) consecutive trading days and (iii) there is an effective registration statement under the Securities Act of 1933, as amended, covering the resale of the shares of common stock issuable upon the exercise of the warrant, then the Company shall cancel the unexercised portion of the warrant for consideration equal to \$0.001 per share of common stock underlying the warrant.

The proceeds from the issuance of the units were allocated between the Company Common Stock and the warrants based on their relative fair values. The value allocated to the warrants was classified within equity on Company's consolidated balance sheet.



## [Table of Contents](#)

### *Warrants Assumed in Merger*

Between March 2014 and May 2014, in connection with its initial public offering (“IPO”), Ruthigen issued warrants to purchase an aggregate of 1,219,000 units (the “Series A Warrants”). The Series A Warrants were originally each exercisable at a price of \$18.125 per warrant for (x) 0.4 shares of common stock and (y) a warrant (the “Series B Warrant”) to purchase 0.4 shares of common stock at an exercise price of \$22.65625 per share. The Series A Warrants are exercisable from the date of issuance and terminate on the second anniversary of the date of issuance. The exercise price and the number of shares for which each Series A Warrant may be exercised is subject to adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the Company’s common stock. In addition, subject to certain exceptions, the exercise price of each of the Series A Warrants and the Series B Warrants is subject to a weighted average reduction if the Company issues shares of common stock (or securities convertible into common stock) in the future at a price below both (a) the current exercise price of the Series A Warrant; and (b) the current market price of the Company’s common stock. The Series A Warrants may be called by the Company, for consideration equal to \$0.00025 per Series A Warrant, on not less than 10 business days’ notice if the closing price of the common stock is above 150% of the \$18.125 IPO price per unit for any period of 20 consecutive business days ending not more than three business days prior to the call notice date. The Series B Warrants will be exercisable upon issuance and will terminate on the fifth anniversary of the date of issuance. The Company agrees that, during the period the Series A Warrants are outstanding, it will maintain the effectiveness of the registration statement such that the holder may exercise the Series A Warrants to receive registered shares of common stock and registered Series B Warrants (and the shares of common stock underlying the Series B Warrants). The Company determined that the Series A Warrants and Series B Warrants are equity instruments because the warrants are (a) freestanding financial instruments; (b) indexed to the Company’s own stock; (c) not permitted to be settled for cash; and (d) exercisable into common stock for which the Company has sufficient authorized and unissued shares.

Immediately following the Merger, the Company issued 136,000 shares of its common stock to Ruthigen’s financial advisor and an aggregate of 379,387 shares in the Ruthigen Private Placement at a price of \$6.875 per share. Pursuant to the weighted average exercise price reduction provisions of the Series A Warrants and the Series B Warrants, these issuances caused the exercise price per unit of the Series A Warrants and the exercise price per share of the Series B Warrants to drop to \$17.83 and \$22.28, respectively.

1,219,000 Series A Warrants were outstanding at December 31, 2015. There were no exercises of any Series A Warrants prior to March 26, 2016 and they expired according to their terms on March 26, 2016. As no Series A Warrants were exercised, no Series B Warrants were issued. There are no Series A nor Series B Warrants outstanding at December 31, 2016.

Ruthigen issued to the representative of the underwriters in the IPO warrants to purchase 37,100 shares of the Company’s common stock at an exercise price of \$22.65625 per share (the “Representative’s Warrants”). The Representative’s Warrants are exercisable commencing on March 21, 2015 and expire on March 21, 2019.

Following the closing of the IPO and in connection with the IPO, the underwriters exercised a portion of the over-allotment option. In connection with the underwriters’ partial exercise of the over-allotment option, Ruthigen issued to the representative of the underwriters a five-year warrant to purchase an additional 2,160 shares of the Company’s common stock at an exercise price of \$22.65625 per share (“Underwriter’s Warrant”). The Underwriter’s Warrant is exercisable commencing one year from the date of issuance.

### *Common Stock Warrants Issued with Term Loan*

As described in Note 8, on June 11, 2015, Pulmatrix Operating entered into a LSA with Hercules for a Term Loan in the principal amount of \$7,000. On June 16, 2015, in connection with the LSA, the Company granted to Hercules a warrant to purchase 25,150 shares of Company Common Stock (the “Hercules Warrants”) at an exercise price of \$8.35 per share. The warrants are exercisable in whole or in part any time prior to the expiration

## [Table of Contents](#)

date of June 16, 2020. 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. A portion of the proceeds from the Term Loan were allocated to the warrants based on their grant date fair value. The value allocated to the warrants of \$198 was classified within equity on Company's consolidated balance sheet, with a corresponding amount recorded as a discount to the debt. The fair value of the warrants was determined using the Black-Scholes option pricing model, using the following assumptions:

Exercise price	\$ 8.35
Fair value of underlying stock	\$ 11.80
Expected volatility	72.52%
Contractual term	5 years
Risk-free interest rate	1.68%
Expected dividend yield	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 dividend yield considers that the Company has not historically paid dividends, and does not expect to pay dividends in the foreseeable future.

### *Common Stock Warrant Issued for Consulting Services*

On August 31, 2015, the Company issued a fully vested non-forfeitable warrant to purchase 30,000 shares of Company Common Stock (the "MTS Warrants") at an exercise price of \$11.80 per share to MTS Health Partners, L.P. in exchange for consulting services. The warrant is exercisable in whole or in part any time prior to the expiration date of August 31, 2020. The Company recognized \$211 of stock-based compensation expense at the time of issuance. The fair value of the warrant was determined using the Black-Scholes option pricing model, using the following assumptions:

Exercise price	\$ 11.80
Fair value of underlying stock	\$ 11.80
Expected volatility	72.0%
Contractual term	5 years
Risk-free interest rate	1.54%
Expected dividend yield	0%

## [Table of Contents](#)

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

Prior to 2015, the Company had no common stock warrant activity. The following represents the common stock issued or assumed during the years ended December 31, 2015. All warrants are exercisable for Common Stock.

Warrants	Issue Date	Classification	Exercise Price	Expiration Date	Number of Shares Underlying Warrants For the Year Ended December 31,	
					2016	2015
Private Placement Warrants	June 15, 2015	Equity	\$ 7.56	June 15, 2020	3,190,030	3,190,030
Hercules Warrants	June 15, 2015	Equity	\$ 8.35	June 16, 2020	25,150	25,150
MTS Warrants	August 31, 2015	Equity	\$ 11.80	August 31, 2020	30,000	30,000
<i>Warrants Assumed in Merger</i>						
Series A Warrants	March-May 2014	Equity	\$ 17.83	March-May 2016	—	1,219,000
Representative's Warrants	March 21, 2014	Equity	\$ 22.66	March 21, 2019	37,100	37,100
Underwriter's Warrants	March 21, 2014	Equity	\$ 22.66	March 21, 2019	2,160	2,160

At December 31, 2016, the intrinsic value of the common stock warrants outstanding was \$0.

## 12. Stock-Based Compensation

The Company sponsors the Ruthigen, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan, and immediately following the Effective Time, renamed the plan the Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan (the "2013 Plan"). The 2013 Plan was amended and restated at the Effective Time to, among other things, (i) increase the number of shares of Company Common Stock authorized under the plan, (ii) comply with the requirements imposed by Section 162(m) of the Internal Revenue Code of 1986, as amended, and (iii) provide an increase in the number of shares of Company Common Stock available for issuance under the 2013 Plan's "evergreen" provision. As of December 31, 2016, the 2013 Plan provides for the grant of up to 3,450,549 shares of Company Common Stock, of which 722,144 shares remained available for future grant.

At the Effective Time, the Company 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"). At the Effective Time, the Company terminated the Original 2013 Plan as to future awards. A total of 644,054 shares of Company Common Stock may be delivered under options outstanding as of December 31, 2016 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.

In connection with the Merger, all outstanding stock options of Pulmatrix Operating converted into stock options to purchase Company Common Stock, subject to the Exchange Ratio. The conversion of the Pulmatrix Operating stock options for stock options to purchase Company 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.

### Options

During the year ended December 31, 2016, the Company granted options to purchase 712,050 shares of Company Common Stock to employees, options to purchase 52,800 shares of Company Common Stock to

## Table of Contents

directors, and options to purchase 0 shares of Company Common Stock to advisors. The stock options granted vest either over time (the “Time Based Options”) or based on achievement of defined milestones. Time Based Options vest over either 36 or 48 months. Subject to the grantee’s continuous service with the Company, Time Based Options vest in one of the following ways: (i) 48 equal monthly installments beginning on the monthly anniversary of the Vesting Start Date (as defined in the grant agreement), (ii) 25% on the option grant date and the remainder in 36 equal monthly installments beginning in the month after the Vesting Start Date, or (iii) 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.

The following table summarizes stock option activity for the year ended December 31, 2016:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding — January 1, 2016	2,316,569	\$ 8.59	8.46	\$ 1,403
Granted	764,850	\$ 2.79		
Exercised	(277)	\$ 1.71		
Forfeited or expired	(251,841)	\$ 10.04		
Outstanding — December 31, 2016	2,829,301	\$ 6.89	7.85	\$ —
Exercisable — December 31, 2016	1,299,157	\$ 6.82	6.73	\$ —
Vested and expected to vest — December 31, 2016	2,770,405	\$ 6.84	7.83	\$ —

The estimated fair values of employee stock options granted during the year ended December 31, 2016 and 2015, were determined on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	For the year ended December 31,	
	2016	2015
Expected option life (years)	6.22	6.22
Risk-free interest rate	1.26% – 2.12%	1.79% – 2.12%
Expected volatility	70.0% – 76.0%	76.0% – 132.0%
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, 2016 there was \$5,571 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 2.3 years.

### Restricted Stock Units

In connection with the Merger, the Company signed one-year employment agreements with the former CEO and CFO of Ruthigen pursuant to which the Company granted such persons 329,052 restricted stock units (the

[Table of Contents](#)

“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 held by the former CEO and CFO of Ruthigen are 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 \$1,171 and \$3,028 for the RSUs vested during the years ended December 31, 2016 and 2015, respectively.

The following table summarizes RSU activity for the year ended December 31, 2016:

	Number of Units	Weighted- Average Grant Date Fair Value	Total Grant Date Fair Value
Outstanding — January 1, 2016	109,682	\$ 11.97	\$ 1,314
Granted	—		
Vested	(104,495)	12.30	(1,285)
Forfeited or expired	—	—	—
Outstanding — December 31, 2016	<u>5,187</u>	<u>\$ 5.50</u>	<u>\$ 29</u>

The following table presents total stock-based compensation expense for the years ended December 31, 2016 and 2015, respectively:

	For the years ended December 31,	
	2016	2015
Research and development	\$ 763	\$ 404
General and administrative	3,235	5,104
Total stock based compensation expense	<u>\$ 3,998</u>	<u>\$ 5,508</u>

### 13. Fair Value Measurements

Information about the liabilities measured at fair value on a recurring basis as December 31, 2016 and December 31, 2015, and the input categories associated with those liabilities, is as follows:

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

  

	December 31, 2015			
	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
<b>Liabilities:</b>				
Embedded compound derivative	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11</u>	<u>\$ 11</u>

## [Table of Contents](#)

### *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 Company performed second step by comparing enterprise value to the carrying value of goodwill. As of December 31, 2016, the Company impaired goodwill for \$5,029. 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.

A roll-forward of Goodwill is as follows:

	<u>Goodwill</u>
Balance — January 1, 2015	\$ —
Goodwill acquired	15,943
Balance — December 31, 2015	15,943
Impairment	(5,029)
Balance — December 31, 2016	<u>\$10,914</u>

### *Preferred Stock Warrants*

The fair values of the preferred stock warrants were determined using the Hybrid Model which consists of the guideline public company (“GPC”) analysis, a market-based approach to estimate the enterprise value of the Company, and the Option Pricing Model (“OPM”) to allocate the enterprise value to each security.

The GPC analysis is based upon the premise that indications of value for a given entity can be estimated based upon the observed valuation multiples of comparable public companies, the equity of which is freely-traded by investors in the public securities markets.

Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class and use inputs such as equity value, time to liquidity, volatility, risk-free rate, dividend yield and strike price. The warrants and underlying convertible redeemable preferred stock were subsequently valued using a back-solve method within the OPM framework to arrive at a concluded fair value of the common stock of the Company. The back-solve method is used when a recent financing has taken place which establishes a reference value for one or more classes of stockholders.

The issuance and sale of the Notes, which took place during 2014, was used as the basis for the valuation during the year ended December 31, 2014. The equity value was allocated to the various share classes based upon their respective claims on a series of call options with strike prices at various value levels depending upon the rights and preferences of each class. The exercise price and number of shares underlying the warrants were determined and the value calculated within the allocation model. The allocation factor was applied to the fair value of the warrants to determine their fair value at December 31, 2014. As described more fully in Note 8, on March 13, 2015, the Company entered into a Note Conversion and Warrant Termination Agreement with the holders of the outstanding warrants, under the terms of which all of the Company’s outstanding warrants to purchase shares of preferred stock were terminated on June, 15, 2015, the Effective Time of the Merger. As of December 31, 2015, there were no outstanding warrants to purchase preferred stock.

## [Table of Contents](#)

The following table provides quantitative information about the fair value measurements, including the range of assumptions for the significant unobservable inputs used in the hybrid method valuations of the warrant liability and “with and without” method used for the embedded compound derivative:

	<u>At December 31, 2014</u>
Time to liquidity event	0.50 years
Risk-free interest rate	0.12%
Volatility	60%
Minority discount	10%
Discount for lack of marketability	23%

### *Embedded Compound Derivatives — 2015 Bridge Notes*

The 2015 Bridge Notes contained an embedded interest rate reset upon an event of default, automatic conversion of the convertible promissory notes upon a Merger or combination with Ruthigen and a put option upon an event of default or the failure to execute a Merger or combination with Ruthigen, each of which represented an embedded derivative instrument requiring bifurcation from the 2015 Bridge Notes. The embedded derivatives were bundled and valued as a single compound derivative. The fair value of the derivative upon issuance of \$1,547 was recognized as a derivative liability and adjusted to fair value at each reporting date.

As described in Note 8, on June 15, 2015, immediately after the Effective Time, the embedded compound derivative was extinguished in connection with the exchange of the 2015 Bridge Notes, including accrued and unpaid interest, into shares of Company Common Stock. Immediately prior to the exchange, the Company remeasured the fair value of the derivatives. Management determined that the derivatives tied to the probability of events of default had no value, as the probability of defaulting on the 2015 Bridge Notes immediately prior to their exchange was zero. At the same time, management determined the probability of exchange of the 2015 Bridge Notes at 100%, thereby resulting in an increase in the fair value of the contingent automatic exchange feature. The Company recorded a loss of \$2,692 for the increase in the estimated fair value of the contingent automatic exchange feature immediately prior to the exchange of the 2015 Bridge Notes. The Company recorded a loss upon the exchange of the 2015 Bridge Notes, including the extinguishment of the embedded compound derivative, of \$1,170 during the year ended December 31, 2015.

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

As described in Note 8, 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.

## [Table of Contents](#)

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

	<u>At Issuance Date</u>	<u>At December 31, 2015</u>
Probability of an event of default	10%	*
Prepayment penalties	1.0% – 3.0%	*
End of term payment	\$245,000	*
Risk-free interest rate	1.01%	*

\* Management determined that there were no changes in the assumptions underlying the value of the derivative instrument between the date of issuance, June 16, 2015, and December 31, 2015.

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

	<u>Preferred Stock Warrants</u>	<u>Derivative Instruments</u>
Balance — January 1, 2015	\$ 1,309	\$ —
Fair value at issuance date	—	1,558
Change in fair value	(1,309)	2,291
Extinguishment on conversion of convertible notes	—	(3,838)
Balance — December 31, 2015	—	11
Change in fair value	—	24
Balance — December 31, 2016	\$ —	\$ 35

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.

## 14. Income Taxes

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. The Company had no income tax expense due to operating losses incurred for the year ended December 31, 2015.

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

	<u>Year Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>
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	<u>\$(2,959)</u>	<u>\$—</u>



## [Table of Contents](#)

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

	<u>2016</u>	<u>2015</u>
Income tax computed at federal statutory tax rate	34.0%	34.0%
State taxes, net of federal benefit	4.3%	3.8%
Research and development credits	0.7%	0.6%
Nondeductible interest	(0.1)%	(3.5)%
Writedown of intangible asset	(5.6)%	0.0%
Permanent differences	(0.5)%	(2.8)%
Transaction Costs	0.0%	(3.4)%
Other	(3.0)%	(0.9)%
Change in valuation allowance	<u>(20.2)%</u>	<u>(27.8)%</u>
Total	<u>9.6%</u>	<u>0.0%</u>

The significant components of the Company's deferred tax assets as of December 31, 2016 and 2015 were as follows:

	<u>2016</u>	<u>2015</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 43,455	\$ 38,179
Research and development credit carryforwards	2,493	2,271
Capitalized start-up expenses	1,221	1,396
In-Process Research and Development	—	(2,959)
Other	2,862	1,937
Total deferred tax assets	<u>50,031</u>	<u>43,783</u>
Valuation allowance	(50,031)	(43,783)
In-process research and development	—	(2,958)
Net deferred tax liabilities	<u>\$ —</u>	<u>\$ (2,958)</u>

At December 31, 2016, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately \$117,151 and \$68,622 respectively, which were available to reduce future taxable income. The net operating loss carryforwards expire at various dates from 2023 through 2036. The Company has research and development credits for federal and state income tax purposes of approximately \$1,814 and \$1,029, respectively, which expire at various dates from 2022 through 2036.

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, 2016 and 2015. The valuation allowance increased by \$6,248 during the year ended December 31, 2016, primarily due to the increase in the Company's net losses.

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.

## [Table of Contents](#)

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 2013 through 2016. 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, 2015	\$ 1,026
Additions for current year tax positions	60
Balance — December 31, 2015	1,086
Additions for current year tax positions	86
Balance — December 31, 2016	<u>\$ 1,172</u>

## 15. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share:

	<b>For the Year Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Numerator:</b>		
Net loss	\$ (27,843)	\$ (26,167)
Net loss attributable to common stockholders	<u>\$ (27,843)</u>	<u>\$ (26,167)</u>
<b>Denominator:</b>		
Weighted average common shares outstanding — basic and diluted	14,815,230	8,089,925
Net loss per share attributable to common stockholders — basic and diluted	<u>\$ (1.88)</u>	<u>\$ (3.23)</u>

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>2016</b>	<b>2015</b>
Options to purchase common stock	2,829,301	2,316,569
Warrants to purchase common stock	3,284,440	4,503,440
Settlement of Term Loan	85,251	85,251
Restricted Stock Units	5,187	109,682
Total	<u>6,204,179</u>	<u>5,795,942</u>

## 16. Commitments

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

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

	<u>Amount</u>
2017	632
2018	654
2019	676
2020	698
<b>Total</b>	<b><u>\$2,660</u></b>

The Company has contracted with contract research organizations and contract manufacturing organizations in order to further the development of its most advanced assets. As of December 31, 2016, the outstanding obligation on these contracts totaled \$992.

## 17. Subsequent Events

On February 2, 2017, the Company closed on the sale of 2,000,000 shares of common stock, at a price of \$2.50 per share, in a registered direct offering. The estimated net proceeds to the Company were approximately \$4.5 million.

On February 8, 2017, the Company closed on the sale of 950,000 shares of common stock, at a price of \$3.50 per share, in a registered direct offering. The estimated net proceeds to the Company were approximately \$3.0 million.

Pursuant to the evergreen provision under the Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan, 742,526 shares were added to the total number of authorized shares under the plan.

**Pulmatrix, Inc.**  
**List of Subsidiaries**

The following is a list of each subsidiary of Pulmatrix, Inc., a Delaware corporation, as of March 10, 2016, and the state in which each such subsidiary is organized.

<u>Name of Subsidiary*</u>	<u>Jurisdiction of Incorporation</u>
Pulmatrix Operating Company, Inc.	Delaware

\* No subsidiary does business under any name other than as listed above.

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Pulmatrix, Inc. on Forms S-3 (File Nos. 333-203417 and 333-212546) and Forms S-8 (File Nos. 333-195737, 333-205752, 333-207002 and 333-212547) of our report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, dated March 10, 2017, with respect to our audits of the consolidated financial statements of Pulmatrix, Inc. as of December 31, 2016 and 2015 and for the years then ended, appearing in the Annual Report on Form 10-K of Pulmatrix, Inc. for the year ended December 31, 2016.

/s/ Marcum LLP

Marcum LLP  
New York, NY  
March 10, 2017

**CERTIFICATION PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13a-14 and 15d-14  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert W. Clarke, President and Chief Executive Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pulmatrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2017

/s/ Robert W. Clarke

---

Robert W. Clarke  
President & Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO  
SECURITIES EXCHANGE ACT RULES 13a-14 and 15d-14  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, William Duke, Jr., Chief Financial Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pulmatrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2017

/s/ William Duke, Jr.

---

William Duke, Jr.  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Pulmatrix, Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Robert W. Clarke, as the President & Chief Executive Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2017

/s/ Robert W. Clarke

\_\_\_\_\_  
Robert W. Clarke  
President & Chief Executive Officer  
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-K or as a separate disclosure document.



**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Pulmatrix, Inc. (the "Company") for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, William Duke, Jr., as the Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2017

/s/ William Duke, Jr.

\_\_\_\_\_  
William Duke, Jr.  
Chief Financial Officer  
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-K or as a separate disclosure document.