

Pulmatrix, Inc.  
Form S-1/A  
April 01, 2019  
**Table of Contents**

As filed with the Securities and Exchange Commission on April 1, 2019

Registration No. 333-230395

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, DC 20549**

**Amendment No. 1**  
**to**  
**FORM S-1**  
**REGISTRATION STATEMENT**  
***UNDER***  
***THE SECURITIES ACT OF 1933***

**PULMATRIX, INC.**  
**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**2834**  
**(Primary Standard Industrial**  
**Classification Code Number)**  
**99 Hayden Avenue, Suite 390**

**46-1821392**  
**(I.R.S. Employer**  
**Identification Number)**

**Lexington, MA 02421**

**(781) 357-2333**

**(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)**

**Robert W. Clarke, Ph.D.**

**Chief Executive Officer and President**

**Pulmatrix, Inc.**

**99 Hayden Avenue, Suite 390**

**Lexington, MA 02421**

**(781) 357-2333**

**(Name, address, including zip code, and telephone number, including area code, of agent for service)**

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this registration statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

**Table of Contents**

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act.

**CALCULATION OF REGISTRATION FEE**

<b>Title of Each Class of Securities to be Registered</b>	<b>Proposed Maximum</b>	
	<b>Aggregate Offering Price(1)(3)</b>	<b>Amount of Registration Fee</b>
Units, each Unit consisting of one share of Common Stock, par value \$0.0001 per share and one common warrant to purchase share of Common Stock(2)(4)	\$13,800,000	\$1,672.56
(i) Common Stock included in the Units(5)		
(ii) Common warrants included in the Units(5)		
Pre-funded Units, each Pre-funded Unit consisting of one Pre-funded Warrant to purchase one share of Common Stock and one common warrant to purchase one share of Common Stock(2)(4)	\$12,000,000	\$1,659.49
(i) Pre-funded Warrants included in the Pre-funded Units(5)		
(ii) Common warrants included in the Pre-funded Units(5)		
Shares of Common Stock issuable upon exercise of the Pre-funded Warrants included in the Pre-funded Units(4)		
Shares of Common Stock issuable upon exercise of the common warrants included in the Units and the Pre-funded Units(4)	\$13,800,000	\$1,672.56
Underwriter's warrants to purchase common stock and common stock underlying the underwriter warrants(6)	\$1,121,250	\$135.90
Common Stock issuable upon exercise of Underwriter warrants(6)(7)	\$	\$
<b>Total</b>	<b>\$40,721,250</b>	<b>\$4,935.42(8)</b>

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
- (2) Includes the aggregate offering price of additional shares of common stock and/or common warrants to purchase common stock that the underwriter has the option to purchase, if any. See Underwriting beginning on page 43 for additional information.
- (3) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.
- (4) The proposed maximum aggregate offering price of the units proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded units offered and sold in the offering (plus the aggregate exercise price of the shares of common stock issuable upon exercise of the pre-funded warrants included in the pre-funded units). Accordingly, the proposed maximum aggregate offering price of the units and pre-funded units (including the common stock issuable upon exercise of the pre-funded warrants included in the pre-funded units), if any, is \$12,000,000, or \$13,800,000 if the underwriter's option to purchase additional shares of common stock and/or common warrants to purchase shares of common stock is exercised in full.
- (5) No additional registration fee is payable pursuant to Rule 457(i) under the Securities Act of 1933, as amended.
- (6) Represents warrants issuable to H.C. Wainwright & Co., LLC or its designees (the underwriter warrants) to purchase a number of shares of common stock equal to 6.5% of the number of shares of common stock (including the number of shares of common stock issuable upon exercise of the pre-funded warrants included in the pre-funded units) being offered at an exercise price equal to 125% of the public offering price per unit. Resales of the underwriter warrants on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, are registered hereby. See Underwriting.
- (7) No additional registration fee is payable pursuant to Rule 457(g) under the Securities Act of 1933, as amended.
- (8) A filing fee of \$3,274.68 was previously paid.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**Table of Contents**

**The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**Subject to Completion, dated April 1, 2019**

**Preliminary Prospectus**

**Up to 9,375,000 Units (each Unit contains One Share of Common Stock and One Warrant to purchase One Share of Common Stock)**

**Up to 9,375,000 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Common Warrant to purchase One Share of Common Stock)**

**Shares of Common Stock Underlying the Pre-funded Warrants and**

**Shares of Common Stock Underlying the Common Warrants**

We are offering up to 9,375,000 units (each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock) pursuant to this prospectus. Each common warrant contained in a unit has an exercise price of \$ \_\_\_\_\_ per share of common stock. The common warrants contained in the units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the units.

We are also offering to certain purchasers whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock), in lieu of shares of common stock that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Because we will issue a common warrant as part of each unit or pre-funded unit, the number of common warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold. Each pre-funded warrant contained in a pre-funded unit will be exercisable for one share of our common stock. The purchase price of each pre-funded unit will equal the price per unit being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit will be \$0.01 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any

pre-funded warrants contained in the pre-funded units sold in this offering. Each common warrant contained in a pre-funded unit has an exercise price of \$ per share of common stock. The common warrants contained in the pre-funded units will be exercisable immediately and will expire five years from the date of issuance. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the pre-funded units.

For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the common warrants included in the units or the pre-funded units, can only be purchased together in this offering, but the securities contained in the units or pre-funded units will be issued separately and will be immediately separable upon issuance.

Our common stock is listed on the Nasdaq Capital Market under the symbol PULM. On March 29, 2019, the last reported sale price of our common stock was \$1.27 per share. We have assumed a public offering price of \$1.28 per unit, the last reported sale price for our common stock as reported on the Nasdaq Capital Market on March 28, 2019, and \$1.27 per pre-funded unit. The actual public offering price per unit or pre-funded unit, as

**Table of Contents**

the case may be, will be determined among us, the underwriter and investors based on market conditions at the time of pricing, and may be at a discount to the current market price to our common stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final offering price. There is no established public trading market for the pre-funded warrants or common warrants, and we do not expect a market to develop. We do not intend to apply for listing of the pre-funded warrants or common warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants and the common warrants will be limited.

We are an emerging growth company as the term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See Prospectus Summary Implications of Being an Emerging Growth Company.

Effective as of 5:00 pm Eastern Time on February 5, 2019, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of our common stock, at a ratio of one share for ten shares. All share and per share prices in this prospectus have been adjusted to reflect the reverse stock split.

**Investing in our securities involves a high degree of risk. See Risk Factors beginning on page 12 of this prospectus and elsewhere in this prospectus for a discussion of information that should be considered in connection with an investment in our securities.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

	<b>Per Unit</b>	<b>Per pre- funded Unit</b>	<b>Total</b>
Price to the public	\$	\$	\$
Underwriting discounts and commissions(1)	\$	\$	\$
Proceeds to us (before expenses)	\$	\$	\$

- (1) In addition, we have agreed to reimburse the underwriter certain offering-related expenses, including a management fee of 1% of the gross proceeds raised in this offering, and to issue the underwriter or its designees warrants to purchase a number of shares of common stock equal to 6.5% of the shares of common stock and pre-funded warrants sold in this offering. See Underwriting for addition information and a description of the compensation payable to the underwriter.

The offering is being underwritten on a firm commitment basis. We have granted the underwriter an option for a period of 30 days from the date of this prospectus to purchase up to an additional 1,406,250 shares of our common stock, at the public offering price of \$1.28, and/or common warrants to purchase up to an additional 1,406,250 shares of our common stock, at a public offering price of \$ , less the underwriting discounts and commissions. If the



underwriter exercises this option in full, the total underwriting discounts and commissions payable by us will be \$ , and the total proceeds to us, before expenses, will be \$ , excluding potential proceeds from the exercise of the common warrants included in such option.

Delivery of the securities offered hereby is expected to be made on or about , 2019.

**H.C. Wainwright & Co.**

**Prospectus dated , 2019**

Table of Contents

## TABLE OF CONTENTS

<b><u>PROSPECTUS SUMMARY</u></b>	<b>1</b>
<b><u>RISK FACTORS</u></b>	<b>12</b>
<b><u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u></b>	<b>33</b>
<b><u>USE OF PROCEEDS</u></b>	<b>34</b>
<b><u>CAPITALIZATION</u></b>	<b>35</b>
<b><u>DILUTION</u></b>	<b>37</b>
<b><u>DESCRIPTION OF SECURITIES WE ARE OFFERING</u></b>	<b>39</b>
<b><u>UNDERWRITING</u></b>	<b>43</b>
<b><u>LEGAL MATTERS</u></b>	<b>47</b>
<b><u>EXPERTS</u></b>	<b>47</b>
<b><u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u></b>	<b>47</b>
<b><u>INCORPORATION OF DOCUMENTS BY REFERENCE</u></b>	<b>48</b>

The registration statement we filed with the Securities and Exchange Commission (the "SEC") includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein or any amendment thereto. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading "Where You Can Find Additional Information." Information contained in later-dated documents incorporated by reference will automatically supplement, modify or supersede, as applicable, the information contained in this prospectus or in earlier-dated documents incorporated by reference.

We have not, and the underwriter has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus, the documents incorporated by reference herein or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus, the documents incorporated by reference herein or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

**This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the underwriter is not, making an offer to sell these securities in any state or jurisdiction where the offer or sale is not permitted.**

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**Table of Contents****PROSPECTUS SUMMARY**

*This summary provides an overview of selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read the prospectus, the information incorporated by reference and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under Risk Factors in this prospectus and the documents incorporated by reference and our financial statements and notes thereto that are incorporated by reference in this prospectus. Some of the statements in this prospectus and the documents incorporated by reference herein constitute forward-looking statements that involve risks and uncertainties. See information set forth under the section Special Note Regarding Forward-Looking Statements. As used in this prospectus, unless the context otherwise indicates, the terms we, our, us, or the Company refer to Pulmatrix, Inc., a Delaware corporation, and its subsidiaries taken as a whole.*

**Overview**

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

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

**iSPERSE Technology**

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

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

*Flexible drug loading for delivery of a single microgram to tens of milligrams per dose. iSPERSE particles can be engineered to include significantly less than one percent (1%) to greater than eighty*

## **Table of Contents**

percent (80%) active pharmaceutical ingredients ( APIs ), which allows flexibility for dosing low potency and high drug load therapeutics.

*Reproducible and one-step manufacturing.* iSPERSE powders are manufactured by a simple and reproducible one-step spray drying process with high and consistent yields. Formulations can be created independent of API physical chemistry in either crystalline or amorphous excipient matrices, as opposed to conventional dry power technologies that require the API to be in crystalline form and suitable for micronization.

*Superior flow rate independent lung delivery without carriers.* The iSPERSE technology enables pulmonary delivery independent of lactose or other carriers, which results in significantly greater lung dose at a matched nominal dose of conventional lactose-based formulations. iSPERSE formulations are dispersible across a range of flow rates with consistent emitted dose and particle size. Performance across flow rates provides reliable dose delivery across patient populations and reduces patient-to-patient variability.

*Delivery of macromolecules and biologics.* iSPERSE powders can be used with an array of dry powder inhaler technologies and can be formulated with a broad range of therapeutic compounds ranging from small molecules to proteins for both local and systemic drug delivery applications.

*Homogenous combinations of multiple drugs.* iSPERSE creates homogenous particles including excipients and API, which allow for the consistent delivery of multiple APIs in a product. We have successfully formulated iSPERSE-based products with dual and triple API combinations.

*Strong safety profile.* Current iSPERSE products and planned clinical stage products to be formulated in iSPERSE are supported by robust preclinical safety profiles. iSPERSE excipients include those with inhalation precedent and those that are generally regarded as safe ( GRAS ) by other routes of administration.

## **Our Therapeutic Candidates**

### *Pulmazole*

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

Pulmazole is our inhaled formulation of itraconazole, an anti-fungal drug commercially available as an oral drug that we are developing to treat and prevent pulmonary fungal infections. Development of Pulmazole is focused on treatment of *Aspergillus* spp. colonization and infection in patients with asthma and CF. In preclinical models, through the direct delivery of itraconazole to the lungs, Pulmazole achieves high local drug concentrations and has the potential to overcome several limitations of traditional oral anti-fungal therapies including poor oral bioavailability and lung penetration, drug-drug interactions and gastrointestinal and cardiac side effects. Pulmazole is our lead iSPERSE anti-infective development program.

On April 1, 2019, we entered into a binding term sheet (the Term Sheet ) with Cipla Technologies LLC ( Cipla ) for the co-development and commercialization of Pulmazole on a worldwide exclusive basis. The Term Sheet sets forth the anticipated commercial and strategic terms of a definitive agreement into which we expect to enter with Cipla during the second quarter of 2019. Pursuant to the Term Sheet, we will be primarily responsible for implementing the clinical development of Pulmazole and Cipla will be responsible for commercializing Pulmazole. See Recent Developments Co-Development and Commercialization of Pulmazole.

On November 21, 2018, we announced the results of the completed Phase 1/1b first-in-human study of Pulmazole for the treatment of ABPA in patients with asthma. Pulmazole appeared to be safe and well tolerated

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**Table of Contents**

in normal healthy subjects in Parts 1 and 2 of the study at doses up to 35 mg, the maximal dose tested, over 14 days of administration. Single doses of Pulmazole 20 mg and oral Sporanox 200 mg appeared to be safe and well tolerated in asthmatic subjects. The most common adverse event (AE) reported was mild cough during dosing, which resolved spontaneously in seconds to minutes. No subject experienced an AE leading to withdrawal. Sustained low-level systemic exposure after single and multiple doses over 24 hours post-dose is indicative of high and sustained lung exposure and supports once daily dosing. Very low systemic exposure for itraconazole was observed across all doses, with 106- to 400-fold lower itraconazole exposure after 14 days of 10 to 35 mg

Pulmazole compared to expected values following administration of oral Sporanox®200 mg twice daily. In asthmatics, adjusted geometric mean AUC<sub>0-t</sub> was 66-fold lower after a single 20 mg inhaled Pulmazole dose compared to a single 200 mg oral Sporanox® dose. Geometric mean sputum itraconazole C<sub>max</sub> was ~70-fold higher following 20 mg inhaled Pulmazole versus 200 mg oral Sporanox® (4530 ng/mL compared to 65.4 ng/mL). We intend to initiate a Phase 2 trial in asthmatic patients with ABPA in the first-half of 2019, utilizing, in part, the proceeds from this offering. If we and Cipla enter into a definitive agreement pursuant to the Term Sheet, during the time such agreement is effective, the development and commercialization of Pulmazole will be conducted pursuant to the terms of that definitive agreement.

*PUR1800*

On June 9, 2017, we entered into an exclusive, worldwide license agreement (the License Agreement) with RespiVert Ltd. ( RespiVert ), a wholly owned subsidiary of Janssen Biotech, Inc. ( Janssen ), for access to a portfolio of novel drug candidates in a class called kinase inhibitors. The first of which, PUR1800 (previously RV1162), we intend to develop for the treatment of acute exacerbations in patients with COPD (AECOPD). COPD is a progressive respiratory illness marked by inflammation and destruction of airways and lungs, typically brought about by longstanding smoking. COPD exacerbations (worsening of respiratory symptoms) are a major contributor to health care costs as well disease progression that can lead to serious consequences such as hospitalization and death. There are currently no therapies approved in the U.S. or the European Union ( EU ) to specifically treat AECOPD. COPD patients are commonly treated with corticosteroids to control inflammation; however, AECOPDs still occur frequently.

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

We completed non-clinical safety studies in 2018 and plan to complete additional pre-clinical studies in 2019 related to the PUR1800 iSPERSE formulation, as well as the chemistry, manufacturing and controls work required to initiate a Phase 2a study in early 2020.

*PUR0200*

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

PUR0200 is manufactured without lactose blending using the iSPERSE dry powder delivery platform. We expect that PUR0200 will deliver comparable pharmacokinetic and pharmacodynamic profiles to the reference product at significantly lower exposure doses to patients. Other potential advantages of PUR0200 include improved patient use

profile and reduced cost of goods due to reduced nominal dose of the API and the availability of the abbreviated regulatory pathway ( bioequivalence ) in Europe and the 505(b)(2) regulatory pathway in the United States.



## **Table of Contents**

In December 2013, we completed a two-part Phase 1b placebo-controlled, randomized clinical trial in the United Kingdom involving moderate to severe COPD patients to assess the safety and tolerability of PUR0200 along with the pharmacodynamics and pharmacokinetics in a single dose, dose escalation trial. 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. A second clinical trial was completed in Europe in 2016 to further study the pharmacokinetic profile of PUR0200 compared to the reference product. Based on the PK profile, two PUR0200 formulations have been identified as bioequivalent drug product candidates.

### *PUR5700*

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

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

## **Our 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. The core components of our strategy are as follows:

*Focus on development of inhaled anti-fungal therapies to prevent and treat pulmonary infections and allergic/hypersensitivity responses to fungus in asthma and CF patients and other rare/orphan indications.*

We intend to direct resources to advance the research and development of Pulmazole for ABPA in asthmatics and CF patients. In 2018, we conducted clinical testing of Pulmazole in normal healthy volunteers and asthma patients, and we plan to initiate a Phase 2 trial in asthmatic patients with ABPA in the first-half of 2019.

*Focus on development of an inhaled kinase inhibitor to treat acute exacerbations in COPD patients. We completed preclinical safety studies for our lead iSPERSE formulation in 2018 and have the ability to advance our formulation and process development efforts to support clinical testing in stable moderate-severe COPD patients. We intend to direct resources to advance the research and development of PUR1800, an inhaled kinase inhibitor for the treatment of acute exacerbations in COPD patients.*

*Capitalize on our proprietary iSPERSE technology and our expertise in inhaled therapeutics and particle engineering to identify new product candidates for prevention and treatment of respiratory diseases with significant unmet medical needs. To add additional inhaled therapeutics to our discovery pipeline and facilitate additional discovery collaborations, we are leveraging our iSPERSE technology and our management's expertise in inhaled therapeutics and particle engineering to identify potential product*

candidates that are potentially safer and more effective than the current standard of care for prevention and treatment of respiratory diseases with significant unmet medical needs.

*Invest in protecting and expanding our intellectual property portfolio and file for additional patents to strengthen our intellectual property rights.* As of December 31, 2018, our patent portfolio related to iSPERSE included approximately 92 granted and allowed patents, 12 of which are granted or allowed

## **Table of Contents**

US patents, with expiration dates from 2024 to 2034, and approximately 75 additional pending patent applications in the US and other jurisdictions. Our in-licensed portfolio related to kinase inhibitors included approximately 225 granted and allowed patents, 26 of which are granted or allowed US patents, with expiration dates from 2029 to 2035, and approximately 52 additional pending patent applications in the US and other jurisdictions.

## **Risks Associated with Our Business and this Offering**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled **Risk Factors** immediately following this prospectus summary. These risks include, but are not limited to, the following:

We have had a history of recurring losses and negative cash flows from operating activities, and currently have significant future commitments, and we face many uncertainties regarding the adequacy of our liquidity to pursue or complete our business objectives;

We may be unable to successfully carry out our research, development and commercialization plans;

We may be unable to manufacture our product candidates on a commercial scale on our own or in collaborations with third parties;

We may be unable to complete preclinical testing and clinical trials as anticipated;

We may be unable to adequately protect and enforce rights to our intellectual property;

We may have difficulties in obtaining financing on commercially reasonable terms, or at all;

We face 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;

We may face new competitors and products and potential technological obsolescence of our products;

We may face adverse market and economic conditions;

We may lose of one or more of our key executives or scientists; and

We may be unable to secure regulatory approval to market our product candidates.

## **Implications of Being an Emerging Growth Company and a Smaller Reporting Company**

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act (the JOBS Act) enacted in April 2012. An emerging growth company may take advantage of exemptions from some of the reporting requirements that are otherwise applicable to public companies. These exceptions include:

being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;

not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act);

reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration 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.

## **Table of Contents**

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering in March 2014. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenue exceeds \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to avail ourselves of this exemption.

Finally, we are a smaller reporting company (and may continue to qualify as such even after we no longer qualify as an emerging growth company) and accordingly may provide less public disclosure than larger public companies. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

## **Recent Developments**

### *Co-Development and Commercialization of Pulmazole*

On April 1, 2019, we entered into the Term Sheet with Cipla for the co-development and commercialization of Pulmazole on a worldwide exclusive basis. The Term Sheet sets forth the anticipated commercial and strategic terms of a definitive agreement into which we expect to enter with Cipla during the second quarter of 2019. Pursuant to the Term Sheet, we will be primarily responsible for implementing the clinical development of Pulmazole and Cipla will be responsible for commercializing Pulmazole.

Pursuant to the Term Sheet, within 30 days following entry into the definitive agreement, Cipla will make an initial upfront payment of \$22 million to the Company (the Upfront Payment) in exchange for an irrevocable assignment of our intellectual property rights and other associated rights and assets with respect to Pulmazole, which Cipla will then irrevocably license back to us only for non-pulmonary application. In addition, Cipla will be granted a non-exclusive, perpetual, royalty-free and sub-licensable license with respect to our iSPERSE technology. As a condition precedent to signing the definitive agreement, we must demonstrate to Cipla that we have at least \$15 million of unencumbered cash available for the development of Pulmazole, and within 30 days following the signing of the definitive agreement, we must make available at least \$24 million of cash dedicated to the development of Pulmazole. After such \$24 million is exhausted, each of us and Cipla will bear 50% of any costs incurred with respect to the development, regulatory and commercialization costs of Pulmazole. The parties will share equally the total free cash flow in relation to the commercialization of Pulmazole.

Upon signing the definitive agreement, we and Cipla will each grant the other party a right of first offer with respect to the rights and assets related to Pulmazole under the definitive agreement. If either party proposes to sell or in any way alienate such rights or assets, such other party will have a period of 60 days following its receipt of written notice to purchase the rights and/or assets, as applicable, on the same terms. In addition, if the Company develops Pulmazole in respect of indications other than those related to pulmonary applications or develops any other inhaled anti-fungal product, then Cipla shall have a right of first refusal with respect to such other indications and/or products.

Pursuant to the Term Sheet, we agreed to use commercially reasonable efforts to enter into a definitive agreement with Cipla within 45 days of signing the Term Sheet. In addition, we granted Cipla a 45-day exclusivity period during which we, its affiliates and representatives will not initiate, engage in, solicit or accept any offer or proposal regarding the in-licensing or acquisition of Pulmazole by a person or entity other than Cipla.



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**Table of Contents***Reverse Stock Split*

Effective as of 5:00 pm Eastern Time on February 5, 2019, we filed an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of the issued and outstanding shares of our common stock, at a ratio of one share for ten shares (the Reverse Stock Split). We made proportionate adjustments to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock units (if any) and warrants outstanding as of the effective time of the Reverse Stock Split in accordance with the terms of each security based on the reverse stock split ratio (i.e., the number of shares issuable under such securities has been divided by ten, and, in the case of stock options and warrants, the exercise or conversion price per share has been multiplied by ten). Also, we reduced the number of shares reserved for issuance under our equity compensation plans proportionately based on the Reverse Stock Split ratio. Except for adjustments that resulted from the rounding up of fractional shares to the next whole share, the Reverse Stock Split affected all stockholders uniformly and did not change any stockholder's percentage ownership interest in the Company. All share and related option and warrant information presented in this prospectus have been retroactively adjusted to reflect the reduced number of shares outstanding and the increase in share price which resulted from this action.

*Recent Offerings*

On December 3, 2018, we closed a (i) registered direct offering of an aggregate of 240,000 shares of our common stock at an offering price of \$3.20 per share and pre-funded warrants to purchase 697,500 shares of common stock at an offering price of \$3.10 per pre-funded warrant, pursuant to a Securities Purchase Agreement, dated November 29, 2018, with an institutional investor, and (ii) a concurrent private placement of common warrants to purchase an aggregate of 937,500 shares of common stock at an exercise price of \$3.90 per share issued to the same institutional investor (the December 2018 Financing). We received gross proceeds of approximately \$2.93 million from the December 2018 Financing before deduction of offering expenses. The common warrants are initially exercisable six months following issuance and terminate five and one-half years following issuance. We are required to file a registration statement on Form S-1 within 120 calendar days of the issuance of the common warrants to provide for the resale of the shares of common stock issuable upon the exercise of the common warrants sold in the private placement.

On January 31, 2019, we closed an underwritten public offering of 156,118 shares of our common stock at a public offering price of \$1.70 per share (the January Offering). We received aggregate gross proceeds of approximately \$265,400 from the January Offering before deducting underwriting discounts and commissions and offering expenses. Upon closing of the January Offering, we issued to designees of the underwriter in the January Offering warrants to purchase an aggregate of 10,150 shares of common stock. These underwriter warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and until January 26, 2024, at a price per share equal to \$2.125.

On February 4, 2019, we closed an underwritten public offering of 532,353 shares of our common stock at a public offering price of \$1.70 per share (the February 4th Offering). We received aggregate gross proceeds of approximately \$841,650 from the February 4th Offering before deducting underwriting discounts and commissions and offering expenses. Upon closing of the February 4th Offering, we issued to designees of the underwriter in the February 4th Offering warrants to purchase an aggregate of 34,605 shares of common stock. These underwriter warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and until January 30, 2024, at a price per share equal to \$2.125.

On February 12, 2019, we closed a (i) registered direct offering of an aggregate of 1,706,484 shares of our common stock at an offering price of \$1.465 per share, pursuant to a Securities Purchase Agreement, dated February 7, 2019,

with certain institutional investors, and (ii) a concurrent private placement of common



**Table of Contents**

warrants to purchase an aggregate of 1,706,484 shares of common stock at an exercise price of \$1.34 per share issued to the same institutional investors (the February 12th Offering ). We received gross proceeds of approximately \$2.5 million from the February 12th Offering before the deduction of placement agent fees and offering expenses. The common warrants are immediately exercisable upon issuance and terminate five and one-half years following issuance.

**Corporate Information**

We were incorporated in 2013 as a Nevada corporation and converted to a Delaware corporation in September 2013. On June 15, 2015, we completed a merger with Pulmatrix Operating Company, changed our name to Pulmatrix, Inc. and relocated our corporate headquarters to Lexington, Massachusetts. Our principal executive offices are located at 99 Hayden Avenue, Suite 390, Lexington, MA 02421 and our telephone number is (781) 357-2333. Our website is [www.pulmatrix.com](http://www.pulmatrix.com). Information contained on our website or that can be accessed through our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus.

Table of Contents

**THE OFFERING**

Units offered by us in this offering	9,375,000 units, each consisting of one share of our common stock and one common warrant to purchase one share of our common stock
Pre-funded units offered by us in this offering	We are also offering to certain purchasers whose purchase of shares of units in this offering would otherwise result in the purchaser, together with its affiliates, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if such purchasers so choose, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of common stock and one common warrant to purchase one share of common stock), in lieu of units that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. The purchase price of each pre-funded unit will equal the public offering price at which the units are being sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant included in each pre-funded unit will be \$0.01 per share. The pre-funded warrants included in the pre-funded units will be exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. Because we will issue a common warrant as part of each unit or pre-funded unit, the number of common warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold.
Common warrants offered by us in the offering	Common warrants to purchase an aggregate of 9,375,000 shares of common stock. Each unit and each pre-funded unit includes one common warrant entitles the holder to purchase one share of common stock at an exercise price of \$        per share, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.
Option to purchase additional securities	The underwriter has a 30-day option to purchase up to an additional 1,406,250 shares of our common stock and/or common warrants to purchase up to an additional 1,406,250 shares of our common stock from us at the public offering price, less underwriting discounts and commissions.

Common stock outstanding after this offering	17,402,895 shares (or 18,809,145 shares of common stock if the underwriter exercises in full its option to purchase additional shares
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**Table of Contents**

of common stock) in each case assuming no sale of pre-funded warrants and assuming no exercise of any common warrants issued in this offering.

Use of proceeds

We intend to use the net proceeds from this offering for research and development of our therapeutic candidates, particularly the development of Pulmazole, as well as for working capital and general corporate purposes. See **Use of Proceeds** on page 34 of this prospectus.

Dividend policy

We have never paid cash dividends on our common stock. 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.

Risk factors

See **Risk Factors** beginning on page 12 and the other information included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our equity securities.

Nasdaq Capital Market symbol

Our common stock is listed on the Nasdaq Capital Market under the symbol **PULM**. There is no established trading market for the pre-funded warrants or the common warrants, and we do not expect a trading market to develop. We do not intend to list the pre-funded warrants or the common warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the pre-funded warrants and the common warrants will be extremely limited.

The number of shares of common stock to be outstanding immediately after this offering is based on 8,027,895 shares of our common stock outstanding as of March 29, 2019, and excludes, as of such date:

5,589,187 shares of common issuable upon the exercise of warrants outstanding with an exercise price ranging from \$1.34 to \$77.40 per share and a weighted average exercise price of \$8.92 per share;

901,235 shares of common stock issuable upon the exercise of options outstanding at a weighted average exercise price of \$25.07 per share pursuant to the Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan (the **Incentive Plan**), 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**);

590,193 shares of common stock available for future issuance under the **Incentive Plan**;

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9,375,000 shares of shares of common stock issuable upon exercise of the pre-funded warrants offered hereby by us at an exercise price of \$0.01 per share;

9,375,000 shares of common stock issuable upon the exercise of the common warrants issued in this offering; and

700,781 shares of common stock issuable upon the exercise of underwriter's warrants (assuming full exercise of the underwriter's option to purchase additional shares of our common stock and/or common warrants), with an exercise price of \$ exercise price of to be issued to the underwriter in connection with this offering.

**Table of Contents**

Unless otherwise indicated, all information contained in this prospectus assumes (i) that the underwriter has not exercised its option to purchase additional shares of common stock and/or common warrants from us, (ii) no sale of pre-funded units in this offering, which, if sold, would reduce the number of units that we are offering on a one-for-one basis, and (iii) no exercise of options issued under our equity incentive plans or of warrants, including the common warrants offered hereby and the underwriter's warrants to be issued to the underwriter in connection with this offering.

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**Table of Contents**

**RISK FACTORS**

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

**Risks Related to Our Business**

*We have a history of net losses and expect to experience losses for the indefinite future.*

We have yet to establish any history of profitable operations, and do not have any revenue-producing products. We reported a net loss of \$20.6 million for the fiscal year ended December 31, 2018 and had a net loss of approximately \$18.1 million during the fiscal year ended December 31, 2017. As of December 31, 2018, we had an accumulated deficit of \$194.6 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will develop any marketable products or be able to achieve sufficient revenues to be profitable in the future.

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

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

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

Our current capital will only be sufficient to enable us to continue operations for a short period of time. In order to fully realize all of our business objectives, absent any non-dilutive funding from a strategic partner or some other strategic transactions, we need to promptly raise additional capital following the completion of this offering, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

advancing the research and development of Pulmazole and PUR1800;

investing in protecting and expanding our intellectual property portfolio, including filing for additional patents to strengthen our intellectual property rights;

hiring and retaining qualified management and key employees;

responding to competitive pressures; and

maintaining compliance with applicable laws.



## **Table of Contents**

Pursuant to the Term Sheet we entered into with Cipla, as a condition precedent to signing the definitive agreement, we must demonstrate to Cipla that we have at least \$15 million of unencumbered cash available for the development of Pulmazole, and within 30 days following the signing of the definitive agreement, we must make available at least \$24 million of cash dedicated to the development of Pulmazole. To meet such condition precedent, considering our current unrestricted cash, we will need to raise additional capital.

Any additional capital raised through the sale of equity or equity backed securities will dilute our stockholders ownership percentages and could also result in a decrease in the market value of our equity securities. The terms of any securities issued by us in future financing transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

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

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

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

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

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

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

All of our research and development programs are in developmental stages. One or more of our product candidates may fail to meet safety and efficacy standards in human testing, even if those product candidates are found to be effective in animal studies. To develop and commercialize inhaled therapeutic treatment for COPD and CF and other iSPERSE-based product candidates, we must provide the U.S. Food and Drug Administration ( FDA ) and foreign regulatory authorities with human clinical and non-clinical animal data that demonstrate

**Table of Contents**

adequate safety and effectiveness. To generate these data, we will have to subject our product candidates to significant additional research and development efforts, including extensive non-clinical studies and clinical testing. Our approach to drug discovery may not be effective or may not result in the development of any drug. Currently our development efforts are primarily focused on our lead anti-fungal product candidate, Pulmazole, and PUR1800, our lead anti-inflammatory candidate for COPD. Even if Pulmazole, PUR1800 or our other product candidates are successful when tested in animals, such success would not be a guarantee of the safety or effectiveness of such product candidates in humans. It can take several years for a product to be approved and we may not be successful in bringing any therapeutic candidates to the market. A new drug may appear promising at an early stage of development or after clinical trials and never reach the market, or it may reach the market and not sell, for a variety of reasons. For example, the drug may:

be shown to be ineffective or to cause harmful side effects during preclinical testing or clinical trials;

fail to receive regulatory approval on a timely basis or at all;

be difficult to manufacture on a large scale;

not be economically viable;

not be prescribed by doctors or accepted by patients;

fail to receive a sufficient level of reimbursement from government, insurers or other third-party payors; or

infringe on intellectual property rights of any other party.

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

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

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

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

In addition, the results of preclinical studies and clinical trials of previously published iSPERSE-based products may not necessarily be indicative of the results of our future clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of inhaled drugs used historically in the industry and if those assumptions are incorrect, the trials may not produce statistically significant results. Preliminary results

## **Table of Contents**

may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical trials. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if, or when, we may have an approved product for commercialization or whether we will ever achieve sales of or profits on our product candidates or those we may pursue in the future.

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

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

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

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

Despite our efforts to retain valuable employees, members of our management and scientific and development teams may terminate their employment with us at any time. Although we have written employment offer letter agreements with our executive officers, 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

## **Table of Contents**

parts of the world that have or are developing technologies for inhaled drug delivery for the prevention and treatment of respiratory diseases, including GlaxoSmithKline, Mereo BioPharma, Mylan, Forest Laboratories U.K. Limited, Savara, Insmed, Bristol-Meyers and Pulmocide, which we consider our potential competitors in this regard. If we are unable to compete successfully with these and other potential future competitors, we may be unable to grow or generate revenue.

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

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

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

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

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

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

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

terms, if at all, we may be unable to locate alternative suppliers or manufacturers on acceptable terms, if at all, or produce necessary materials or components on our own.

While there may be several alternative suppliers of API in the market, changing API suppliers or finding and qualifying new API suppliers can be costly and can take a significant amount of time. Many APIs require



## **Table of Contents**

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

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

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

We may seek to sell or assign our rights related to our current drug candidates. Pursuant to the Term Sheet, within 30 days following entry into the definitive agreement, Cipla will make an initial Upfront Payment of \$22 million to the us in exchange for an irrevocable assignment of our intellectual property rights and other associated rights and assets with respect to Pulmazole. The definitive agreement we may enter into with Cipla or any other sale or assignment, if completed, 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, subject to the availability of adequate financing. However, our internal research capabilities are limited, and we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

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

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

*these agreements.*

Our current business strategy may include the entry into additional collaborative or license agreements for the development and commercialization of our product candidates and technologies, including a definitive agreement

## **Table of Contents**

with Cipla pursuant to the Term Sheet. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators or licensees and require significant time and resources. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators or licensees, we compete with numerous other third parties with product opportunities as well as the collaborators' or licensees' own internal product opportunities. We may not be able to consummate collaborative or license agreements, or we may not be able to negotiate commercially acceptable terms for these agreements.

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

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

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

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

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

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

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

*investors views of us.*

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be

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## **Table of Contents**

evaluated frequently. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock.

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

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an ownership change is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards or other tax attributes, or NOLs, to offset future taxable income or reduce taxes. Our past issuances of stock and other changes in our stock ownership may have resulted in ownership changes within the meaning of Section 382 of the Code; accordingly, our pre-change NOLs may be subject to limitation under Section 382. If we determine that we have not undergone an ownership change, the Internal Revenue Service could challenge our analysis, and our ability to use our NOLs to offset taxable income could be limited by Section 382 of the Code. Future changes in our stock ownership, including in connection with our initial public offering, some of which are outside of our control, could result in ownership changes under Section 382 of the Code further limiting our ability to utilize our NOLs. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability.

## **Risks Related to Regulatory Matters**

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

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

product design, development, manufacture and testing;

product labeling;

product storage and shipping;

pre-market clearance or approval;

advertising and promotion; and

product sales and distribution.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We cannot predict whether our current or future trials and studies will adequately demonstrate the safety and efficacy of any of our product candidates or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date, including the clinical trials for

## **Table of Contents**

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

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

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

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

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

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

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

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

We will be subject to extensive regulation by U.S. federal and state and foreign governments in each of the markets where we intend to sell our product candidates if and after we are approved. If we fail to comply with applicable regulations, including the FDA's pre- or post-approval current Good Manufacturing Practices ( 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;

20



**Table of Contents**

suspend regulatory approval;

suspend any of our ongoing clinical trials;

refuse to approve pending applications or supplements to approved applications submitted by us;

impose restrictions on our operations, including closing our contract manufacturers' facilities; or

seize or detain products or require a product recall.

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

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

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

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

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

Even if our therapeutic candidates receive regulatory approval, we or our commercialization partners, as applicable, will be subject to ongoing reporting obligations, including pharmacovigilance, and the therapeutic candidates and the manufacturing operations will be subject to continuing regulatory review, including inspections by the FDA or other foreign regulatory authorities. The results of this ongoing review may result in the withdrawal of a therapeutic candidate from the market, the interruption of the manufacturing operations and/or the imposition of labeling and/or marketing limitations. Since many more patients are exposed to drugs following their marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the therapeutic candidate. In addition, the

**Table of Contents**

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;

finest;

refusal to permit the import or export of our therapeutic candidates;

product seizure or detentions;

injunctions or the imposition of civil or criminal penalties; or

adverse publicity.

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

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

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

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

In the United States, we will be subject to various federal and state health care fraud and abuse laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse the healthcare industry, which could affect us, particularly upon successful commercialization of our products in the United States. The

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**Table of Contents**

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

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

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

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

Pharmaceutical product development, which includes research and development, pre-clinical and clinical studies and human clinical trials, is a time-consuming and expensive process that takes years to complete. We anticipate that our expenses will increase substantially as we advance Pulmazole into the Phase 2 trial and pursue development of PUR1800 or other iSPERSE-based product candidates and/or pursue development of iSPERSE-based pharmaceuticals in additional indications. Based upon our current expectations, we believe that our existing capital resources will enable us to continue planned operations through mid-May of 2019. We cannot assure you, however, that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. We will need to raise additional funds, whether through the sale of equity or debt securities, the entry into strategic business collaborations, the establishment of other funding facilities, licensing arrangements, or asset sales or other means, in order to continue our research and development and clinical trial programs for our iSPERSE-based product candidates and to support our other ongoing activities. However, it may be

difficult for us to raise additional funds on reasonable terms or at all. Since inception, we have incurred losses each year and have an accumulated deficit of \$194.6 million, which may raise concerns about our solvency and affect our ability to raise additional capital.

**Table of Contents**

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

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

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

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

the number of product candidates in development;

the regulatory clarity and path of each of our product candidates;

the progress, success and cost of our clinical trials and research and development programs, including manufacturing;

the costs, timing and outcome of regulatory review and obtaining regulatory clarity and approval of our product candidates and addressing regulatory and other issues that may arise post-approval;

the costs of enforcing our issued patents and defending intellectual property-related claims;



## **Table of Contents**

the costs of manufacturing, developing sales, marketing and distribution channels;

our ability to successfully commercialize our product candidates, including securing commercialization agreements with third parties and favorable pricing and market share; and

our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

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

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

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

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

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

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

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

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

## **Table of Contents**

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

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

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

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

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

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

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a

product candidate or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly.

## **Table of Contents**

*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 This Offering and Our Common Stock and Warrants**

*The price of our 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 our common stock may fluctuate as a result of, among other factors:

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

actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;

announcements relating to strategic relationships, mergers, acquisitions, partnerships, collaborations, joint ventures, capital commitments, or other events by us or our competitors;

conditions or trends in the biotechnology and pharmaceutical industries;

changes in the economic performance or market valuations of other biotechnology and pharmaceutical companies;

general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance or financial condition;

purchase or sale of our common stock by stockholders, including executives and directors;

volatility and limitations in trading volumes of our 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 our common stock by stockholders;

our cash position;

announcements and events surrounding financing efforts, including debt and equity securities;

**Table of Contents**

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 our 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.

***You will experience immediate and substantial dilution.***

As of December 31, 2018, our net tangible book value was approximately \$1.0 million, or \$0.20 per share. Since the effective price per share of common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units being offered in this offering is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock included in the units or issuable upon exercise of the pre-funded warrants included in the pre-funded units you purchase in this offering. Based on the assumed public offering price of \$1.28 per unit being sold in this offering (the last reported sale price of our common stock on the Nasdaq Capital Market on March 28, 2019) and our net tangible book value per share as of December 31, 2018, assuming no sale of pre-funded units, if you purchase securities in this offering, you will suffer immediate and substantial dilution of \$0.42 per share with respect to the net tangible book value of the common stock. See the section entitled "Dilution" for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

***Our management team may invest or spend the proceeds raised in this offering in ways with which you may not agree or which may not yield a significant return.***

Our management will have broad discretion over the use of proceeds from this offering. We intend to use the net proceeds from this offering for research and development of our therapeutic candidates, particularly the development of Pulmazole, as well as for working capital and general corporate purposes. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply

these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline, and delay the development of our product candidates.

***There is no public market for the pre-funded warrants or the common warrants being offered by us in this offering.***

There is no established public trading market for the pre-funded warrants or the common warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or the common warrants on any national securities exchange or other nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the pre-funded warrants and the common warrants will be limited.



**Table of Contents**

***Holders of pre-funded warrants or common warrants purchased in this offering will have no rights as common stockholders until such holders exercise their pre-funded warrants or common warrants and acquire our common stock.***

Until holders of pre-funded warrants or common warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying the pre-funded warrants or common warrants. Upon exercise of the pre-funded warrants or common warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

***Common warrants are speculative in nature.***

The common warrants do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the common warrants may exercise their right to acquire the common stock and pay an exercise price of \$        per share of common stock, subject to certain adjustments, prior to five years from the date of issuance, after which date any unexercised common warrants will expire and have no further value. Moreover, following this offering, the market value of the common warrants, if any, is uncertain and there can be no assurance that the market value of the common warrants will equal or exceed their imputed offering price. The common warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the common warrants, and consequently, it may not ever be profitable for holders of the common warrants to exercise the common warrants.

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

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

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

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



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**Table of Contents**

***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 our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We could remain an emerging growth company until the earliest to occur of earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) December 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 our common stock.

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

Our common stock is listed on The NASDAQ Capital Market. For continued listing on The NASDAQ Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the minimum stockholders' equity requirement, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. In the event that we fail to satisfy any of the listing requirements of The NASDAQ Capital Market, our 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 Markets or on the

pink sheets. As a result, we could face significant adverse consequences including:

a limited availability of market quotations for our securities;

**Table of Contents**

a determination that our common stock is a penny stock, which would require brokers trading in our 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 are likely to issue additional equity securities in the future, which are likely to result in dilution to existing investors and investors purchasing securities in this offering.***

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 our 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. We cannot assure you that we will be able to sell shares of our common stock or other equity securities, including any pre-funded warrants, in any other offering at a price per share or unit that is equal to or greater than the price per share paid by investors in this offering. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering. If we sell additional equity securities, existing stockholders may be materially diluted. In addition, new investors could gain rights superior to existing stockholders, such as liquidation and other preferences. In addition, the exercise or conversion of outstanding options or warrants to purchase shares of capital stock may result in dilution to our stockholders upon any such exercise or conversion.

In addition, as of March 29, 2019, (i) 590,193 shares remained available to be awarded under our Incentive Plan. Further, an aggregate of 901,235 shares of our 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, and (ii) warrants to purchase an aggregate of 5,589,187 shares of common stock were outstanding. We may also issue additional options, warrants and other types of equity in the future as part of stock-based compensation, capital raising transactions, technology licenses, financings, strategic licenses or other strategic transactions. To the extent these options are exercised, existing stockholders would experience additional ownership dilution. In addition, the number of shares available for future grant under our equity compensation plans may be increased in the future, as our equity compensation plan contains an evergreen provision, pursuant to which additional shares may be authorized for issuance under the plan each year.

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

We are subject to the anti-takeover provisions of Delaware law, including Section 203 of the General Corporation Law of Delaware (the "DGCL"). Under these provisions, if anyone becomes an interested stockholder, we may not enter into a business combination with that person for three (3) years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 203 of the DGCL, interested stockholder means, generally, someone owning fifteen percent (15%) or more of our outstanding voting stock or an affiliate that owned fifteen percent (15%) or more of our outstanding voting stock

during the past three (3) years, subject to certain exceptions as described in Section 203 of the DGCL.

**Table of Contents**

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

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

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the documents incorporated by reference herein contain 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, 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 this prospectus and in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC on February 19, 2019 and any updates subsequently provided in our Quarterly Reports on Form 10-Q. The forward-looking statements contained in this prospectus and in any of the documents incorporated by reference are expressly qualified in their entirety by this cautionary statement. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. 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.

**Table of Contents**

**USE OF PROCEEDS**

We estimate the net proceeds from this offering will be approximately \$10.7 million from the sale of our securities in this offering, based on an assumed public offering price of \$1.28 per unit (the last reported sale price of our common stock on the Nasdaq Capital Market on March 28, 2019) and assuming the sale of 9,375,000 units and no sale of any pre-funded units in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriter exercises its option to purchase additional shares of common stock and/or common warrants to purchase additional shares of common stock in full, we estimate the net proceeds from this offering will be approximately \$12.3 million from the sale of our securities, based on an assumed public offering price of \$1.28 per unit and assuming the sale of 10,781,250 units and no sale of any pre-funded units in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. These estimates exclude the proceeds, if any, from the exercise of common warrants sold in this offering. The actual public offering price per unit or pre-funded unit will be negotiated between us and the underwriter based on the trading of our shares of common stock prior to the offering, among other things, and may be at a discount to the current market price.

A \$0.10 increase (decrease) in the assumed public offering price of \$1.28 per unit would increase (decrease) the expected net proceeds to us from this offering by approximately \$0.9 million, assuming that the number of units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the common warrants issued in this offering.

Similarly, a 100,000 share increase or decrease in the number of units offered by us, as set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us by approximately \$0.1 million, assuming the assumed public offering price of \$1.28 per unit remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the common warrants issued in this offering.

We currently expect to use the net proceeds from this offering for research and development of our therapeutic candidates, particularly the development of Pulmazole, as well as for working capital and general corporate purposes. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, our management will have broad discretion and flexibility in applying the net proceeds from the sale of securities sold pursuant to this prospectus. In addition, our existing resources, together with the proceeds from this offering, may not be adequate to permit us to complete such clinical development or fund our operations over the longer term. We may need to secure additional resources to complete such development and to support our continued operations. Pending application of the net proceeds as described above, we intend to invest the net proceeds to us from this offering in a variety of capital preservation investments, including short-term, investment-grade and interest-bearing instruments.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash and cash equivalents, as well as our capitalization, as of December 31, 2018 as follows:

on an actual basis;

on a pro forma basis, giving effect to the following issuances of common stock after December 31, 2018: (i) an aggregate of 2,394,955 shares of common stock in the January Offering, the February 4th Offering and the February 12th Offering, (ii) an aggregate of 697,500 shares of common stock upon the exercise of pre-funded warrants sold in December 2018 at an exercise price of \$0.01 per share; and (iii) 2,717 shares of common stock to round up any fractional shares of common stock resulted from the Reverse Stock Split to the nearest whole share; and

on a pro forma as adjusted to give effect to the sale by us of 9,375,000 units in this offering at an assumed public offering price of \$1.28 per unit, which is the last reported sale price of our common stock on the Nasdaq Capital Market on March 28, 2019, after deducting the estimated underwriting discounts and commissions and estimated offering expenses, and assuming no sale of any pre-funded units in this offering and excluding the proceeds, if any, from the exercise of common warrants issued in this offering.

The pro forma and pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information together with our consolidated financial statements and related notes incorporated by reference in this prospectus.

	<b>As of December 31, 2018</b>		
	<b>Actual</b>	<b>Pro Forma</b>	<b>Pro Forma As Adjusted(1)</b>
	<b>(in thousands, except share amounts)</b>		
Cash and cash equivalents	\$ 2,563	\$ 5,832	\$ 16,522
Stockholders' equity			
Common stock, \$0.0001 par value 200,000,000 shares authorized; 4,932,723 shares issued and outstanding actual, 8,027,895 shares issued and outstanding pro forma, and 17,402,895 shares issued and outstanding pro forma as adjusted		1	2
Additional paid-in capital	206,409	209,677	220,366
Accumulated deficit	(194,565)	(194,565)	(194,565)
Total stockholders' equity	11,844	15,113	25,803
Total capitalization	\$ 11,844	\$ 15,113	\$ 25,803

- (1) A \$0.10 increase or decrease in the assumed public offering price of \$1.28 per unit, which is the last reported sale price of our common stock on the Nasdaq Capital Market on March 28, 2019, would increase or decrease, as appropriate, our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders equity and total capitalization by approximately \$0.9 million, assuming the number of units offered by us as set forth on the cover page of this prospectus remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no sale of any pre-funded units in this offering. Similarly, a 100,000 share increase or decrease in the number of units offered by us, based on the assumed public offering price of \$1.28 per unit, would increase or decrease our pro forma as adjusted cash and cash equivalents, total assets and total stockholders equity by approximately \$0.1 million, after deducting the estimated underwriting discounts and

**Table of Contents**

commissions and estimated offering expenses payable by us, and assuming no sale of any pre-funded units in this offering and excluding the proceeds, if any, from the exercise of common warrants issued in this offering. The number of shares of common stock to be outstanding immediately after this offering is based on 4,923,723 shares of our common stock outstanding as of December 31, 2018, and excludes as of that date:

5,589,187 shares of common issuable upon the exercise of warrants outstanding with an exercise price ranging from \$1.34 to \$77.40 per share and a weighted average exercise price of \$8.92 per share;

901,235 shares of common stock issuable upon the exercise of options outstanding at a weighted average exercise price of \$25.07 per share pursuant to the Incentive Plan, the Original 2013 Plan and the 2003 Plan;

590,193 shares of common stock available for future issuance under the Incentive Plan;

9,375,000 shares of shares of common stock issuable upon exercise of the pre-funded warrants offered hereby by us at an exercise price of \$0.01 per share;

9,375,000 shares of common stock issuable upon the exercise of the common warrants issued in this offering; and

700,781 shares of common stock issuable upon the exercise of underwriter's warrants (assuming full exercise of the underwriter's option to purchase additional shares of our common stock and/or common warrants), with an exercise price of \$ exercise price of to be issued to the underwriter in connection with this offering.

**Table of Contents****DILUTION**

Our net tangible book value as of December 31, 2018 was approximately \$1.0 million, or \$0.20 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of December 31, 2018. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

Our pro forma net tangible book value as of December 31, 2018, was approximately \$4.3 million, or \$0.53 per share, after giving effect to the following issuances of common stock after December 31, 2018: (i) an aggregate of 2,394,955 shares of common stock in the January Offering, the February 4th Offering and the February 12th Offering, (ii) an aggregate of 697,500 shares of common stock upon the exercise of pre-funded warrants sold in December 2018 at an exercise price of \$0.01 per share; and (iii) 2,717 shares of common stock to round up any fractional shares of common stock resulted from the Reverse Stock Split to the nearest whole share.

After giving effect to the sale of 9,375,000 units at the assumed public offering price of \$1.28 per unit (the last reported sale price of our common stock on the Nasdaq Capital Market on March 28, 2019), assuming no sale of any pre-funded units in this offering and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2018 would have been approximately \$15.0 million, or \$0.86 per share of common stock, based on 17,402,895 shares of common stock outstanding on a pro forma as adjusted basis at that time. This represents an immediate increase in pro forma as adjusted net tangible book value of \$0.33 per share to our existing stockholders, and an immediate dilution of \$0.42 per share to new investors purchasing securities in this offering at the assumed public offering price. The following table illustrates this dilution on a per share basis:

Assumed public offering price per unit (based upon the last reported sales price of our common stock as reported on the Nasdaq Capital Market on March 28, 2019)	\$ 1.28
Historical Net tangible book value per share as of December 31, 2018	\$ 0.20
Pro forma increase in net tangible book value per share	\$ 0.33

Pro forma net tangible book value per share as of December 31, 2018	\$ 0.53
Increase in pro forma as adjusted net tangible book value per share attributable to this offering	\$ 0.33

Pro forma as adjusted net tangible book value per share as of December 31, 2018, after giving effect to this offering	\$ 0.86
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Dilution per share to new investors in this offering	\$ 0.42
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A \$0.10 increase in the assumed public offering price of \$1.28 per unit would increase our pro forma as adjusted net tangible book value after this offering by \$0.9 million, or \$0.05 per share, and the dilution per share to investors purchasing securities in this offering would be approximately \$0.37 per share, assuming that the number of units, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from exercise of the common warrants issued in this offering. Similarly, a \$0.10 decrease in the assumed public offering price of \$1.28 per unit would decrease our pro forma as adjusted net tangible book value after this offering by \$0.9 million, or \$0.05 per share, and the dilution per share to investors purchasing securities in this offering would be \$0.47 per share, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this

prospectus remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from exercise of the common warrants issued in this offering.

We may also increase or decrease the number of units we are offering from the assumed number of units set forth above. An increase of 100,000 units from the assumed number of units set forth on the cover page of this

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**Table of Contents**

prospectus would increase our pro forma as adjusted net tangible book value after this offering by \$0.1 million, or \$0.00 per share, and the dilution per share to investors purchasing securities in this offering would be approximately \$0.42 per share, assuming that the public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from exercise of the common warrants issued in this offering. Similarly, a decrease of 100,000 units from the assumed number of units set forth on the cover page of this prospectus would decrease our pro forma as adjusted net tangible book value after this offering by \$0.1 million, or \$0.00 per share, and the dilution per share to investors purchasing securities in this offering would be approximately \$0.42, assuming that the public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and excluding the proceeds, if any, from exercise of the common warrants issued in this offering.

The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of units and pre-funded units that we offer in this offering, and other terms of this offering determined at pricing. The discussion and table above assume (i) no sale of pre-funded units, which, if sold, would reduce the number of units that we are offering on a one-for-one basis and (ii) no exercise of the underwriter's option to purchase up to an additional 1,406,250 shares of common stock and/or common warrants to purchase 1,406,250 shares of common stock.

If the underwriter exercises its option to purchase additional shares of common stock and/or common warrants to purchase common stock in full at the public offering price of \$1.28 per unit, less underwriting discounts and commissions, our pro forma as adjusted net tangible book value after this offering would be approximately \$16.6 million, or \$0.88 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$0.35 per share to our existing stockholders, and an immediate dilution of \$0.40 per share to new investors purchasing securities in this offering at the assumed public offering price.

The foregoing discussion and table does not take into account further dilution to investors in this offering that could occur upon the exercise of outstanding options and warrants, including the pre-funded warrants and the common warrants offered pursuant to this offering, having a per share exercise price less than the public offering price per unit in this offering.

The number of shares of common stock to be outstanding immediately after this offering is based on 4,923,723 shares of our common stock outstanding as of December 31, 2018, and excludes as of that date:

5,589,187 shares of common issuable upon the exercise of warrants outstanding with an exercise price ranging from \$1.34 to \$77.40 per share and a weighted average exercise price of \$8.92 per share;

901,235 shares of common stock issuable upon the exercise of options outstanding at a weighted average exercise price of \$25.07 per share pursuant to the Incentive Plan, the Original 2013 Plan and 2003 Plan;

590,193 shares of common stock available for future issuance under the Incentive Plan;

9,375,000 shares of shares of common stock issuable upon exercise of the pre-funded warrants offered hereby by us at an exercise price of \$0.01 per share;



9,375,000 shares of common stock issuable upon the exercise of the common warrants issued in this offering; and

700,781\ shares of common stock issuable upon the exercise of underwriter s warrants (assuming full exercise of the underwriter s option to purchase additional shares of our common stock and/or common warrants), with an exercise price of \$ exercise price of to be issued to the underwriter in connection with this offering.

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**Table of Contents**

**DESCRIPTION OF SECURITIES WE ARE OFFERING**

We are offering (i) up to 9,375,000 units, each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock and (ii) up to 9,375,000 pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock (excluding the underwriter's option to purchase up to an additional 1,406,250 shares of common stock and/or common warrants to purchase 1,406,250 additional shares of common stock for up to 30 days following the date of this prospectus). For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis.

The share of common stock and accompanying common warrant included in each unit will be issued separately and will be immediately separable upon issuance, and the pre-funded warrant to purchase one share of common stock and the accompanying common warrant included in each pre-funded unit will be issued separately and will be immediately separable upon issuance. The units and pre-funded units will not be issued or certificated. We are also registering the shares of common stock included in the units and the shares of common stock issuable from time to time upon exercise of the pre-funded warrants included in pre-funded units and common warrants included in the units and the pre-funded units offered hereby.

**Common Stock**

We have authorized 200,500,000 shares of capital stock, par value \$0.0001 per share, of which 200,000,000 are shares of common stock and 500,000 are shares of blank check preferred stock. As of March 29, 2019, there were 8,027,895 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding. The authorized and unissued shares of common stock and the authorized and undesignated shares of preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors does not intend to seek stockholder approval for the issuance and sale of our common stock or preferred stock.

The holders of our common stock are entitled to one vote per share. Our certificate of incorporation does not provide for cumulative voting. Our directors are divided into three classes. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire are elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of our board of directors and issued in the future.

The foregoing description summarizes important terms of our capital stock, but is not complete. For the complete terms of our common stock, please refer to our amended and restated certificate of incorporation, as amended, any certificates of designation for our preferred stock, and our restated bylaws, as amended, as may be amended from time to time.

The transfer agent and registrar for our common stock is Vstock Transfer, LLC. The transfer agent's address is 18 Lafayette Place, Woodmere, NY 11598. Our common stock is listed on the Nasdaq Capital Market under the symbol

PULM.

**Pre-Funded Warrants**

The following summary of certain terms and provisions of pre-funded warrants included in the pre-funded units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of

## **Table of Contents**

the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

### ***Duration and Exercise Price***

Each pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.01. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

### ***Exercisability***

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or at the election of a holder prior to the date of issuance, 9.99%) of the outstanding common stock immediately after exercise (the Beneficial Ownership Limitation); provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

### ***Cashless Exercise***

If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

### ***Transferability***

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

### ***Fractional Shares***

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

### ***Trading Market***

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the pre-funded warrants is currently listed on the Nasdaq Capital Market.

## **Table of Contents**

### ***Right as a Stockholder***

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

### ***Fundamental Transaction***

In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

### ***Common Warrants***

The following summary of certain terms and provisions of common warrants included in the units and the pre-funded units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of common warrant for a complete description of the terms and conditions of the common warrants.

### ***Duration and Exercise Price***

Each common warrant included in the units and the pre-funded units offered hereby will have an initial exercise price equal to \$ \_\_\_\_\_ per share of common stock. The common warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants will be issued separately from the common stock included in the units, or the pre-funded warrants included in the pre-funded units, as the case may be. A common warrant to purchase one share of our common stock will be included in each unit or pre-funded unit purchased in this offering.

### ***Cashless Exercise***

If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

### ***Exercisability***

The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the common warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days

## **Table of Contents**

prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants. Purchasers of common warrants in this offering may also elect prior to the issuance of the common warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

### ***Fractional Shares***

No fractional shares of common stock will be issued upon the exercise of the common warrants. Rather, at our election, we will either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up the number of shares of common stock to be issued to the nearest whole number.

### ***Transferability***

Subject to applicable laws, the common warrants may be offered for sale, sold, transferred or assigned without our consent. There is currently no trading market for the common warrants.

### ***Exchange Listing***

There is no trading market available for the common warrants on any securities exchange or nationally recognized trading system. We do not intend to list the common warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the common warrants is currently listed on the Nasdaq Capital Market under the symbol PULM.

### ***Right as a Stockholder***

Except as otherwise provided in the common warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

### ***Fundamental Transaction***

In the event of a fundamental transaction, as described in the common warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction.



**Table of Contents****UNDERWRITING**

We have entered into an underwriting agreement with H.C. Wainwright & Co., LLC, as underwriter, dated \_\_\_\_\_, 2019, with respect to the securities being offered hereby. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase from us the number of units and pre-funded units set forth opposite its name below.

<b>Underwriter</b>	<b>Number of Units</b>	<b>Number of Pre-Funded Units</b>
H.C. Wainwright & Co., LLC		

The underwriting agreement provides that the obligations of the underwriter are subject to certain conditions precedent and that the underwriter has agreed to purchase all of the units and pre-funded units sold under the underwriting agreement if any of these units and pre-funded units are purchased.

The underwriter is offering the units and pre-funded units, subject to prior sale, when, as and if issued to and accepted by it, subject to approval of legal matters by its counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

*Underwriting Discounts and Commissions.* The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses to us.

We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$470,000 and is payable by us. Subject to compliance with FINRA Rule 5110(f), we have agreed to pay the underwriter \$40,000 for its non-accountable expenses, reimburse the expenses of the underwriter, including its legal fees, up to \$100,000 in connection with this offering, and \$10,000 for the clearing expenses of the underwriter in connection with this offering. We have also agreed to pay the underwriter a management fee equal to 1% of the aggregate gross proceeds in this offering.

	<b>Per Unit</b>	<b>Per Pre-Funded Unit</b>	<b>Total Without Option</b>	<b>Total With Option</b>
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions	\$	\$	\$	\$
Proceeds, before expenses	\$	\$	\$	\$

The underwriter proposes to offer the units and pre-funded units to the public at the public offering prices set forth on the cover of this prospectus. The underwriter may offer the units or pre-funded units to securities dealers at the public offering price less a concession not in excess of \$ \_\_\_\_\_ per unit or pre-funded unit. If all of the units and pre-funded units are not sold at the public offering prices, the underwriter may change the offering price and other selling terms.

In addition, we have agreed to issue to the underwriter warrants to purchase up to \_\_\_\_\_ shares of common stock, representing 6.5% of the aggregate number of shares of common stock sold in this offering (including the number of shares of common stock issuable upon exercise of the pre-funded warrants and assuming full exercise of the underwriter's option to purchase additional shares of common stock and/or common warrants), at an exercise price of

\$        per share (representing 125% of the public offering price per unit to be sold in this offering). The underwriter warrants will be exercisable immediately and for five years from the effective date of the registration statement of which this prospectus forms a part. Pursuant to FINRA Rule 5110(g), the underwriter warrants and any shares issued upon exercise of the underwriter warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period

## Table of Contents

of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the underwriter or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

In addition, pursuant to that certain termination agreement, dated January 24, 2019, between us and Oppenheimer & Co. Inc. ( OpCo ), we may pay OpCo an advisory fee of \$150,000, if the gross proceeds from this offering are at least \$5 million, or \$300,000, if the gross proceeds from this offering are at least \$15 million, provided that the closing of this offering occurs on or prior to May 24, 2019.

*Option to Purchase Additional Shares.* We have granted the underwriter the option to purchase up to additional 1,406,250 shares of common stock and/or up to 1,406,250 additional shares of common warrants to purchase 1,406,250 shares of common stock, at the public offering price per share of common stock, less the underwriting discounts and commissions set forth on the cover page of this prospectus. The underwriter may exercise its option at any time, and from time to time, within 30 days from the date of this prospectus. If any additional shares of common stock or common warrants are purchased pursuant to such option, the underwriter will offer these securities on the same terms as those on which the securities are being offered hereby.

*Right of First Refusal.* We have also granted the underwriter a twelve-month right of first refusal to act as sole book-running manager, sole underwriter or sole placement agent for each and every future public or private equity offering by us or any of our successors or subsidiaries, under certain circumstances.

*Discretionary Accounts.* The underwriter does not intend to confirm sales of the shares or pre-funded warrants to any accounts over which it has discretionary authority.

*Over-Allotment, Stabilization, Short Positions and Penalty Bids.* In connection with this offering, the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in connection with our common stock.

Overallotment transactions involve sales by the underwriter of shares of common stock in excess of the number of shares the underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that it may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriter may close out any short position by exercising its overallotment option and/or purchasing shares in the open market.

Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum.

Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

**Table of Contents**

*Passive Market Making.* In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

*Lock-Up Agreements.* We and each of our directors and executive officers have entered into lock-up agreements that prevent us and them from selling any shares of our common stock or any securities convertible into or exercisable or exchangeable into share of common stock, subject to certain exceptions, for a period of 90 days, respectively, after the date of this prospectus. The underwriter, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release the common stock and other securities from lock-up agreements, the underwriter will consider, among other factors, the holder's reasons for requesting the release and the number of shares of common stock or other securities for which the release is being requested.

In addition, we have agreed not to issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or any securities convertible into or exercisable or exchangeable for our common stock for a period of 90 days following the closing of this offering, and not effect or enter into an agreement to effect any variable rate transaction for a period of one year after the closing of this offering, without the prior written consent of H.C. Wainwright & Co., LLC. This consent may be given at any time without public notice.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriter and its respective affiliates, with a view to the final placement of the securities as contemplated in this prospectus. Accordingly, no purchaser of the units or pre-funded units, other than the underwriter, is authorized to make any further offer of units or pre-funded units on our behalf or on behalf of the underwriter.

*Electronic Offer, Sale and Distribution of Securities.* A prospectus in electronic format may be made available on the websites maintained by the underwriter or selling group members, if any, participating in this offering and the underwriter participating in this offering may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

*Other Relationships.* The underwriter and its respective affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. The underwriter has received, or may in the future receive, customary fees and commissions for these transactions.

*Indemnification.* We have agreed to indemnify the underwriter against specified liabilities, including liabilities under the Securities Act of 1933, as amended (the Securities Act), and to contribute to payments the underwriter may be required to make in respect thereof.

*NASDAQ Capital Market Listing.* Our common stock is listed on the Nasdaq Capital Market under the symbol PULM.

*Offers outside the United States.* Other than in the United States, no action has been taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus in any jurisdiction

**Table of Contents**

where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

**Table of Contents**

**LEGAL MATTERS**

The validity of the securities offered hereby will be passed upon for us by Haynes and Boone, LLP, New York, New York. Ellenoff Grossman & Schole LLP, New York, New York, has acted as counsel for the underwriter in connection with certain legal matters related to this offering.

**EXPERTS**

The consolidated financial statements of Pulmatrix, Inc. as of December 31, 2018 and 2017, and for each of the two years in the period ended December 31, 2018, incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2018, have been so incorporated in reliance on the report of Marcum LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We are subject to the informational requirements of the Exchange Act and in accordance therewith file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC's website is [www.sec.gov](http://www.sec.gov).

We make available free of charge on or through our website at [www.pulmatrix.com](http://www.pulmatrix.com), our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the SEC.

We have filed with the SEC a registration statement under the Securities Act relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the SEC at the address listed above, or for free at [www.sec.gov](http://www.sec.gov). The registration statement and the documents referred to below under "Incorporation of Certain Information By Reference" are also available on our website, [www.pulmatrix.com](http://www.pulmatrix.com).

We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.



**Table of Contents**

**INCORPORATION OF DOCUMENTS BY REFERENCE**

The SEC allows us to incorporate by reference the information we have filed with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We specifically are incorporating by reference the following documents filed with the SEC (excluding those portions of any Current Report on Form 8-K that are furnished and not deemed filed pursuant to the General Instructions of Form 8-K):

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 19, 2019; and

Our Current Reports on Form 8-K filed with the SEC January 30, 2019, February 1, 2019, February 6, 2019, February 11, 2019, February 22, 2019, and April 1, 2019; and

The description of our common stock contained in our Registration Statement on Form S-4 (File No. 333-203417) filed with the SEC on April 15, 2015, as amended by Pre-Effective Amendment No. 1 to Registration Statement on Form S-4 filed on May 1, 2015 and Post-Effective Amendment No. 1 on Form S-3 to Registration Statement on Form S-4 filed on September 18, 2015, including any amendments or reports filed for the purpose of updating such description.

All reports and definitive proxy or information statements subsequently filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, but excluding information furnished to, rather than filed with, the SEC, shall be deemed to be incorporated by reference herein and to be a part hereof from the date such documents are filed.

Any statement contained herein or in any document incorporated or deemed to be incorporated by reference shall be deemed to be modified or superseded for purposes of the registration statement of which this prospectus forms a part to the extent that a statement contained in any other subsequently filed document which also is or is deemed to be incorporated by reference modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed to constitute a part of the registration statement of which this prospectus forms a part, except as so modified or superseded.

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus or the date of the documents incorporated by reference in this prospectus.

We will provide without charge to each person to whom a copy of this prospectus is delivered, upon written or oral request, a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with this prospectus (other than an exhibit to these filings, unless we have specifically incorporated that exhibit by reference in this prospectus). Any such request should be addressed to us at:

Pulmatrix, Inc.

Edgar Filing: Pulmatrix, Inc. - Form S-1/A

Attn: Secretary

99 Hayden Avenue, Suite 390

Lexington, MA 02421

(781) 357-2333

You may also access the documents incorporated by reference in this prospectus through our website at [www.pulmatrix.com](http://www.pulmatrix.com). Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

**Table of Contents**

**Up to 9,375,000 Units (each Unit contains One Share of Common Stock and One Warrant to purchase One Share of Common Stock)**

**Up to 9,375,000 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Common Warrant to purchase One Share of Common Stock)**

**Shares of Common Stock Underlying the Pre-funded Warrants and**

**Shares of Common Stock Underlying the Common Warrants**

**Prospectus**

**, 2019**

**H.C. Wainwright & Co.**

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. *Other Expenses of Issuance and Distribution***

The following table sets forth the estimated costs and expenses payable by the registrant expected to be incurred in connection with the issuance and distribution of the common stock being registered hereby (other than underwriting discounts and commissions). All of such expenses are estimates, except for the Securities and Exchange Commission ( SEC ) registration fee, the Financial Industry Regulatory Authority ( FINRA ) filing fee and the listing fee.

	<b>Amount to be Paid</b>
SEC registration fee	\$ 4,935.42
FINRA filing fee	6,900.00
Printing fees and expenses	15,000.00
Legal fees and expenses	420,000.00
Transfer agent and registrar fees	2,000.00
Accounting fees and expenses	20,000.00
Miscellaneous	5,000.00
 Total	 \$ 473,835.42

Each of the amounts set forth above, other than the registration fee and the FINRA filing fee, is an estimate.

**Item 14. *Indemnification of Directors and Officers***

Section 145 of the General Corporation Law of the State of Delaware provides, in general, that a corporation incorporated under the laws of the State of Delaware, as we are, may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than a derivative action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. In the case of a derivative action, a Delaware corporation may indemnify any such person against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made in respect of any claim, issue or matter as to which such person will have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or any other court in which such action was brought determines such person is fairly and reasonably entitled to indemnity for such expenses.

Our certificate of incorporation and bylaws provide that we will indemnify our directors, officers, employees and agents to the extent and in the manner permitted by the provisions of the General Corporation Law of the State of Delaware, as amended from time to time, subject to any permissible expansion or limitation of such indemnification, as may be set forth in any stockholders' or directors' resolution or by contract. Any repeal or modification of these provisions approved by our stockholders will be prospective only and will not adversely affect any limitation on the liability of any of our directors or officers existing as of the time of such repeal or modification.

II-1

**Table of Contents**

We are also permitted to apply for insurance on behalf of any director, officer, employee or other agent for liability arising out of his actions, whether or not the General Corporation Law of the State of Delaware would permit indemnification.

**Item 15. *Recent Sales of Unregistered Securities***

The following is a summary of all securities that we have sold during the last three years without registration under the Securities Act of 1933, as amended.

On December 3, 2018, pursuant to a concurrent private placement in connection with a registered direct offering of 240,000 shares of common stock and pre-funded warrants to purchase up to 697,500 shares of common stock for aggregate gross proceeds of \$2,930,250, we issued to an institutional investor a common warrant to purchase up to 937,500 shares of our common stock at an exercise price of \$3.90 per share. The issuance of the common warrant and the shares issuable upon the exercise of such warrant were exempt from the requirements of the Securities Act of 1933, as amended, pursuant to an exemption provided by Section 4(a)(2) thereof and Rule 506(b) of Regulation D thereunder as transactions by an issuer not involving a public offering.

On January 31, 2019, in connection with the closing of our underwritten public offering we issued underwriter's warrants to designees of H.C. Wainwright & Co. LLC to purchase up to 10,148 shares of common stock at an exercise price of \$2.125 per share. The underwriter's warrants and the shares of common stock underlying such warrants were issued in reliance upon the exemption from registration requirements provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

On February 6, 2019, in connection with the closing of our underwritten public offering we issued underwriter's warrants to designees of H.C. Wainwright & Co. LLC to purchase up to 34,603 shares of common stock at an exercise price of \$2.125 per share. The underwriter's warrants and the shares of common stock underlying such warrants were issued in reliance upon the exemption from registration requirements provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

On February 12, 2019, pursuant to a concurrent private placement in connection with a registered direct offering of 1,706,484 shares of common stock for aggregate gross proceeds of approximately \$2.5 million (the February 12th Offering), we issued to certain institutional investors common warrants to purchase up to 1,706,484 shares of our common stock at an exercise price of \$1.34 per share. The issuance of the common warrants and the shares issuable upon the exercise of such warrants were exempt from the requirements of the Securities Act of 1933, as amended, pursuant to an exemption provided by Section 4(a)(2) thereof and Rule 506(b) of Regulation D thereunder as transactions by an issuer not involving a public offering.

On February 12, 2019, we issued to designees of H.C. Wainwright & Co., LLC, the placement agent in connection with the February 12th Offering, placement agent warrants to purchase up to 110,992 shares of our common stock at an exercise price of \$1.8313 per share. The placement agent warrants and the shares of common stock underlying such warrants were issued in reliance upon the exemption from registration requirements provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

**Item 16. *Exhibits and Financial Statement Schedules.***

- (a) The Exhibit Index is hereby incorporated herein by reference.
  
- (b) All schedules have been omitted because they are not required, are not applicable or the information is otherwise set forth in the financial statements and related notes thereto.

II-2

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed Herewith</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date</b>	<b>SEC File/Reg Number</b>
1.1	<u>Form of Underwriting Agreement.</u>	x			
3.1	<u>Amended and Restated Certificate of Incorporation of Pulmatrix, Inc., as amended through June 15, 2015.</u>		Form 10-Q (Exhibit 3.1)	08/14/15	001-36199
3.2	<u>Restated Bylaws of Pulmatrix, Inc., as amended through June 15, 2015.</u>		Form 10-Q (Exhibit 3.2)	08/14/15	001-36199
3.3	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Pulmatrix, Inc., dated June 5, 2018</u>		Form 8-K (Exhibit 3.1)	06/07/18	001-36199
3.4	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Pulmatrix, Inc., dated February 5, 2019</u>		Form 8-K (Exhibit 3.1)	02/06/19	001-36199
4.1	<u>Form of Specimen Stock Certificate.</u>		Form 8-K (Exhibit 4.1)	06/16/15	001-36199
4.2	<u>Securities Escrow Agreement, dated June 12, 2015, by and among Pulmatrix, Inc., Pulmatrix Operating Company, Inc. and VStock Transfer, LLC, as Escrow Agent.</u>		Form 10-Q (Exhibit 4.1)	08/14/15	001-36199
4.3	<u>Form of Representative s Warrant Agreement.</u>		Form S-1 (Exhibit 4.2)	02/24/14	333-190476
4.4	<u>Warrant Agreement, dated June 16, 2015, by and between Pulmatrix, Inc. and Hercules Technology Growth Capital, Inc.</u>		Form 8-K (Exhibit 10.3)	06/16/15	001-36199
4.5	<u>Form of Warrant issued in Pulmatrix Operating Private Placement, dated June 15, 2015.</u>		Form 10-Q (Exhibit 10.8)	08/14/15	001-36199
4.6	<u>Form of Series A Warrant issued in Pulmatrix Public Offering, dated March 28, 2018</u>		Form S-1 (Exhibit 4.6)	03/28/18	333-223630
4.7	<u>Form of Series B Warrant issued in Pulmatrix Public Offering, dated March 28,</u>		Form S-1	03/28/18	333-223630



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	<u>2018</u>	(Exhibit 4.8)		
4.8	<u>Form of Pre-Funded Warrant issued in Pulmatrix Public Offering, dated March 28, 2018</u>	Form S-1	03/28/18	333-223630
		(Exhibit 4.7)		
4.9	<u>Form of Pre-Funded Warrant issued in Pulmatrix Public Offering, dated December 3, 2018</u>	Form 8-K	12/03/18	001-36199
		(Exhibit 4.1)		
4.10	<u>Form of Common Warrant issued in Pulmatrix Public Offering, dated December 3, 2018</u>	Form 8-K	12/03/18	001-36199
		(Exhibit 4.2)		
4.11	<u>Form of Pre-Funded Warrant.</u>	X		
4.12	<u>Form of Underwriter Warrant</u>	X		
4.13	<u>Form of Common Stock Warrant.</u>	X		
5.1	<u>Opinion of Haynes and Boone, LLP.</u>	X		

II-3

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed Herewith</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date</b>	<b>SEC File/Reg Number</b>
10.1	<u>Form of Subscription Agreement.</u>		Form 8-K (Exhibit 10.1)	06/12/15	001-36199
10.2	<u>Executive Employment Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and Robert W. Clarke, Ph.D.</u>		Form 8-K (Exhibit 10.4)	06/16/15	001-36199
10.3	<u>Executive Employment Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and David L. Hava, Ph.D.</u>		Form 8-K (Exhibit 10.5)	06/16/15	001-36199
10.4	<u>Executive Employment Agreement, dated June 24, 2015, by and between Pulmatrix, Inc. and William Duke, Jr.</u>		Form 10-Q (Exhibit 10.4)	08/14/15	001-36199
10.5	<u>Pulmatrix, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan.</u>		Form 8-K (Exhibit 10-6)	06/16/15	001-36199
10.6	<u>Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan.</u>		Form S-8 (Exhibit 99.2)	07/20/15	333-205752
10.7	<u>Pulmatrix Inc. 2003 Employee, Director and Consultant Stock Plan.</u>		Form S-8 (Exhibit 99.3)	07/20/15	333-205752
10.8	<u>Joinder Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and Hercules Technology Growth Capital, Inc.</u>		Form 8-K (Exhibit 10.2)	06/16/15	001-36199
10.9	<u>License, Development and Commercialization Agreement, dated June 9, 2017, by and between Pulmatrix, Inc. and Respivert Ltd.</u>		Form 10-Q (Exhibit 10.1)	08/04/17	001-36199
10.10	<u>Feasibility and Development Agreement, dated September 5, 2017, by and between Pulmatrix, Inc. and Vectura Limited.</u>		Form 10-Q (Exhibit 10.1)	11/09/17	001-36199
10.11	<u>Executive Employment Agreement, dated October 30, 2017, by and between Pulmatrix, Inc. and James Roach.</u>		Form 8-K (Exhibit 10.1)	11/03/17	001-36199
10.12	<u>First Amendment to the Pulmatrix, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive</u>		Form 8-K (Exhibit 10.1)	06/07/18	001-36199

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Plan, dated as of June 5, 2018

10.13	<u>Form of Securities Purchase Agreement</u>	Form 8-K (Exhibit 10.1)	12/03/18	001-36199
10.14	<u>Executive Employment Agreement, dated April 28, 2017, by and between Pulmatrix, Inc. and Teofilo Raad</u>	Form 10-K (Exhibit 10.14)	02/19/19	001-36199
10.15	<u>Term Sheet, between Cipla Technologies LLC and Pulmatrix, Inc., dated as of April 1, 2019</u>	Form 8-K (Exhibit 10.1)	04/01/19	001-36199
21.1	<u>List of Subsidiaries.</u>	Form 10-K (Exhibit 21.1)	03/13/18	001-36199

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed Herewith</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date</b>	<b>SEC File/Reg Number</b>
23.1	<u>Consent of Marcum LLP, independent registered public accounting firm.</u>	X			
23.2	<u>Consent of Haynes and Boone, LLP (included in Exhibit 5.1).</u>	X			
24.1	<u>Power of Attorney (contained in the signature page to this registration statement).</u>				

**Item 17. Undertakings.**

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the Commission) pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement;

provided, however, that paragraphs (i), (ii) and (iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in this Registration Statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the

**Table of Contents**

following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(5) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(6) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(7) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(8) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in

the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

II-6

Table of Contents**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Amendment No. 1 to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Lexington, Commonwealth of Massachusetts on this day of April 1, 2019.

**PULMATRIX, INC.**

By: /s/ Robert W. Clarke, Ph.D.  
 Name: Robert W. Clarke, Ph.D.  
 Title: Chief Executive Officer and  
 President

**Power of Attorney**

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Robert W. Clarke and William Duke, Jr. as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this amendment to the registration statement has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Robert W. Clarke, Ph.D.	Chief Executive Officer, President and Director	April 1, 2019
Robert W. Clarke, Ph.D.	(Principal Executive Officer)	
/s/ William Duke, Jr.	Chief Financial Officer, Treasurer and Secretary	April 1, 2019
William Duke, Jr.	(Principal Financial Officer and Principal Accounting Officer)	
*	Chairman of the Board of Directors	April 1, 2019



Mark Iwicki

\* Director April 1, 2019

Steven Gillis, Ph.D.

\* Director April 1, 2019

Michael J. Higgins

\* Director April 1, 2019

Terrance G. McGuire

**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
* Amit D. Munshi	Director	April 1, 2019
* Matthew L. Sherman, M.D.	Director	April 1, 2019

\* By: /s/ Robert W. Clarke, Ph.D.  
Robert W. Clarke, Ph.D.  
Attorney-in-fact