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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

or

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

For the transition period from _____to _____

Commission file number: 001-36199

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

Delaware	**46-1821392**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
99 Hayden Avenue, Suite 390 Lexington, MA	**02421**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**The NASDAQ Stock Market LLC**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

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	[X]	Smaller reporting company	[X]
		Emerging Growth Company	[ ]

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes [ ] No [X]

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, as of June 30, 2020, the last business day of registrants most recently completed second fiscal quarter, was $43,642,977.

As of March 19,2021, the registrant had 56,249,062 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of Pulmatrix, Inc.'s Definitive Proxy Statement on Schedule 14A relating to the 2021 Annual Meeting of Stockholders are incorporated by reference into PART III.

PULMATRIX, INC.

TABLE OF CONTENTS

PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical fact contained herein, including statements regarding our business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings, or other aspects of our operating results, are forward-looking statements. Words such as "anticipates," "assumes," "believes," "can," "could," "estimates," "expects," "forecasts," "guides," "intends," "is confident that," "may," "plans," "seeks," "projects," "targets," and "would," and their opposites and similar expressions, as well as statements in future tense, are intended to identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- the impact of the novel coronavirus ("COVID-19") pandemic on the Company's ongoing and planned clinical trials;
- the geographic, social and economic impact of the COVID-19 pandemic on the Company's ongoing and planned clinical trials;
- 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 collaborators' inability to successfully carry out their contractual duties;
- termination of certain license agreements;
- our ability to adequately protect and enforce rights to intellectual property, or defend against claims of infringement by others;
- 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, personnel and 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 risks that may affect our business and that could cause our actual results to differentiate equally from those projected in these forward-looking statements, see the risk factors and uncertainties described under the heading "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events, except as required by law.

Unless otherwise stated, references in this Annual Report on Form 10-K to "us," "we," "our," or "Company" refer to Pulmatrix, Inc., a Delaware corporation.

"iSPERSE" is one of our trademarks used in this Annual Report on Form 10-K. Other trademarks appearing in this report are the property of their respective holders. Solely for convenience, these and other trademarks, trade names and service marks referred to in this report appear without the ®, TM and SM symbols, but those references are not intended to indicate, in any way, we or the owners of such trademarks will not assert, to the fullest extent under applicable law, their rights to these trademarks and trade names.

ITEM 1. BUSINESS.

Overview

We are a clinical stage biotechnology company focused on the discovery and development of novel inhaled therapeutic products intended to prevent and treat respiratory and other diseases 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 diseases, including allergic bronchopulmonary aspergillosis ("ABPA") in patients with asthma, and in patients with cystic fibrosis ("CF"), lung cancer, and in patients suffering from neurological diseases such as acute migraine.

Corporate History

We were incorporated in 2013 as a Delaware corporation. Our resources are focused on the development of novel inhaled therapeutic products intended to prevent and treat respiratory diseases and other diseases where inhaled drug delivery offers a potential therapeutic advantage.

Business Strategy

Our goal is to develop breakthrough therapeutic products that are safe, convenient, and more efficient than the existing therapeutic products for respiratory and other diseases where iSPERSE properties are advantageous.

The iSPERSE technology may potentially improve upon the known efficacy and safety profile of currently available therapies. Our current pipeline is aligned to this goal with the Pulmazole program for inhaled antifungal therapy to treat ABPA in patients with asthma, the PUR3100 program for treatment of acute migraine, and the PUR1800 program, which has potential application in both lung cancer and chronic obstructive pulmonary disease ("COPD"). All of these programs leverage improvements provided by iSPERSE. We intend to capitalize on our iSPERSE technology platform and our expertise in inhaled therapeutics to identify new product candidates for the prevention and treatment of diseases with significant unmet medical needs and to build our product pipeline beyond our existing candidates. In order to advance clinical trials for our therapeutic candidates and leverage the iSPERSE platform to enable delivery of partnered compounds, we intend to form strategic alliances with third parties, including pharmaceutical and biotechnology companies or academic or private research institutes.

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

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

  We will continue to direct resources to advance the research and development of Pulmazole for ABPA in patients with asthma and CF. In 2018, we successfully conducted clinical testing of Pulmazole in normal healthy volunteers and asthma patients. In 2019, we began a Phase 2 study of Pulmazole with patients who have asthma and are suffering from ABPA but stopped the Phase 2 study due to the COVID-19 pandemic and its impact on enrollment. In January 2021, we conducted a Type-C meeting with the U.S Food and Drug Administration ("FDA") to discuss our plans for a Phase 2b study. Utilizing the FDA feedback, we now intend to advance Pulmazole into a Phase 2b efficacy study that will include a sixteen-week dosing regimen, rather than the four weeks dosing regimen in the terminated Phase 2 study.

- *Focus on the development of an inhaled kinase inhibitor for lung cancer prevention treatment.*

  We completed preclinical safety studies for our lead iSPERSE formulation in 2018 and advanced our formulation and process development efforts to support clinical testing in stable moderate-severe COPD patients. In 2019, Pulmatrix entered into a License, Development and Commercialization Agreement for PUR1800, an inhaled kinase inhibitor with Johnson & Johnson Enterprise Innovation, Inc. ("JJEI"). In February 2021, we successfully dosed the first patient with PUR1800, in a Phase 1b study in patients with stable COPD. The Phase 1b study data is anticipated in the fourth quarter 2021. JJEI retains an option for a worldwide license to develop and commercialize PUR1800 and other kinase inhibitors as part of its Lung Cancer Initiative.

- *Focus on the development of an inhaled dihydroergotamine ("DHE") for treatment of acute migraine.*

  We developed PUR3100, an iSPERSE formulation of DHE in 2020 and completed a pharmacokinetic study in dogs in January 2021. We will continue to direct resources to advance the research and development of PUR3100 in treatment of acute migraine including completion of preclinical safety studies in 2021 to enable a Phase 1/Phase 2 study start in Q1 2022.

- *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 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. These potential product candidates are potentially safer and more effective than the current standard of care for prevention and treatment of diseases with significant unmet medical needs.

- *Invest in protecting and expanding our intellectual property portfolio and file for additional patents to strengthen our intellectual property rights.*

  The status of our patent portfolio changes frequently in the ordinary course of patent prosecution. As of December 31, 2020, our patent portfolio related to iSPERSE included approximately 112 granted patents, 16 of which are granted US patents, with expiration dates from 2024 to 2034, and approximately 61 additional pending patent applications in the US and other jurisdictions. Our in-licensed portfolio related to kinase inhibitors included approximately 241 granted patents, 31 of which are granted US patents, with expiration dates from 2029 to 2035, and approximately 42 additional pending patent applications in the US and other jurisdictions. On March 3, 2021 we filed a provisional patent application in the United States Patent and Trademark Office ("USPTO") that discloses and claims certain formulations and methods of use relevant to our PUR3100 program. We plan to file an international patent application under the patent cooperation treaty, or PCT, based on the provisional patent application by the applicable deadline.

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, which uses other monovalent and divalent salts.

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

- *Flexible drug loading for delivery of a single microgram to tens of milligrams per dose*.

  iSPERSE particles can be engineered to include significantly less than one percent (1%) to greater than eighty percent (80%) active pharmaceutical ingredients ("APIs"), which allows flexibility for dosing both high potency and high-drug load therapeutics.

- *Superior flow rate independent lung delivery without carriers*.

  The iSPERSE technology enables pulmonary delivery independent of lactose or other carriers, which results in significantly greater lung dose at a matched nominal dose of conventional lactose-based formulations. iSPERSE formulations are dispersible across a range of flow rates with consistent emitted dose and particle size. Performance across flow rates provides reliable dose delivery across patient populations and reduces patient-to-patient variability.

- *Delivery of macromolecules and biologics*.

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

- *Homogenous combinations of multiple drugs*.

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

- *Strong safety profile*.

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

Therapeutic Candidates

Pulmazole

We are developing iSPERSE-based inhaled formulations of anti-fungal drugs for the prevention and treatment of fungal infections and allergic/hypersensitivity reactions to fungus in patients with severe lung disease, including those with asthma and CF. On January 28, 2020, Pulmazole received Fast Track designation from the FDA for the treatment of ABPA. *Aspergillus* colonization and infections are likely underdiagnosed and occur frequently in patients of all ages. Colonization and infection with *Aspergillus* spp. can lead to clinical disease with differing severities and complications depending on the immune status of the host. Invasive aspergillosis is a frequently fatal disease that occurs in patients that are typically immune suppressed as a result of treatment for hematologic cancers or immunosuppression prior to solid organ transplantation. In patients with asthma and CF, *Aspergillus* can cause chronic infections that may be associated with worsening disease and larger declines in lung function than patients without infection. A subset of patients with asthma and CF with *Aspergillus* colonization and/or infection develop ABPA, which is a complex hypersensitivity reaction to fungal antigens. ABPA is a disease resulting in mucus production, wheezing, pulmonary infiltrates, worsening bronchiectasis, and fibrosis of the lung.

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

Pulmazole is our inhaled formulation of itraconazole, an anti-fungal drug commercially available as an oral drug that we are developing to treat and prevent pulmonary fungal infections. Development of Pulmazole is focused on treatment of *Aspergillus* spp. colonization and infection in patients with asthma and CF. In a Phase 1/1b clinical trial, Pulmazole appeared to be safe and well tolerated in healthy normal volunteers (Parts 1 and 2) and in patients with asthma (Part 3). In Part 3 of the Phase 1/1b study, following a single dose of Pulmazole, the pharmacokinetics ("PK") analysis of sputum samples demonstrated ~70-fold higher maximum lung concentration of itraconazole following inhalation of Pulmazole compared to oral Sporanox® (Janssen Pharmaceuticals) despite inhaling only one tenth the dose of itraconazole (20 mg) relative to the dose of oral Sporanox (200 mg). Lung exposure, as measured by sputum induction and analysis, was approximately 50-fold higher and plasma exposure was approximately 85-fold lower following inhalation of 20 mg of Pulmazole compared to 200 mg of oral Sporanox**.** All endpoints from the Phase 1/1b study were successfully met.

On April 15, 2019, we entered into a Development and Commercialization Agreement (the "Cipla Agreement") with Cipla Technologies LLC ("Cipla") for the co-development and commercialization, on a worldwide exclusive basis, of Pulmazole, our inhaled iSPERSE drug delivery system enabled formulation of the antifungal drug, itraconazole, which is only available as an oral drug, for the treatment of all pulmonary indications, including ABPA in patients with asthma. In July of 2019, we initiated a Phase 2 clinical study for Pulmazole. Due to delays in patient enrollment in the Phase 2 clinical study, exacerbated by the ongoing COVID-19 pandemic, Cipla informed us that it desired to amend the Cipla Agreement. In connection with our renegotiation of the Cipla Agreement, on July 10, 2020, the Pulmatrix/Cipla steering committee recommended the termination of the Phase 2 study due the COVID-19 pandemic.

We conducted a Type C meeting with the FDA on January 27, 2021 and leveraging the insights gained from this meeting, now plan to commence the Phase 2b study when the risks of study conduct presented by the ongoing COVID-19 pandemic are reduced to an acceptable level. The Phase 2b study design includes a 16-week dosing regimen as well as an exploration of potential efficacy endpoints, whereas the terminated Phase 2 study comprised only a 4-week dosing regimen with safety and tolerability as its primary endpoint. The longer dosing regimen of the planned new Phase 2b study is supported by the 6-month inhalation toxicology study in dogs completed in April 2020.

In addition to the planned new Phase 2b study, as part of the contemplated amendments to the Cipla Agreement, we may assign to Cipla the exclusive rights to develop and commercialize Pulmazole in India, South Africa and other regional markets where Cipla has strong clinical development and business capabilities. We have not agreed to any amendments to the Cipla Agreement as of the date of the filing this Annual Report. However, we expect that discussions regarding amendments to the Cipla Agreement will continue. No assurance can be given that we will be able to reach a mutually acceptable arrangement with Cipla for the conduct of the Phase 2b clinical study in the future. Accordingly, if we are unable to agree with Cipla on such matters such as cost sharing for the new study, we may be forced to suspend further development of Pulmazole.

Competition and Market Opportunities

Current treatments of pulmonary fungal infections highlight the limitations of oral or intravenous anti-infective treatments for lung infections. Itraconazole is one of the most commonly prescribed therapies for treating *Aspergillus* spp. infections in patients with asthma and CF. Itraconazole is available commercially as Sporanox in both a capsule and oral solution form. Itraconazole is metabolized in the liver by CYP3A4 and coadministration with a large number of drugs is contraindicated due to the potential for severe drug-drug interactions.

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

There is precedent for both dry powder and nebulized inhaled anti-infective therapy to address specific pulmonary infections in patients which demonstrates potential utility of inhaled drug delivery and market opportunity. Mylan currently markets TOBI Podhaler for treatment of *Pseudomonas aeruginosa* infection in the United States and Forest Laboratories U.K. Limited (a subsidiary of Actavis PLC) markets inhaled colistin, Colobreathe, for the same infection in Europe. Insmed currently markets Amikacin Liposome Inhalation Suspension (Arikayce) in the United States for the treatment of lung disease caused by a group of bacteria, *Mycobacterium avium complex* in a limited population of patients with the disease who do not respond to conventional treatment (refractory disease). Arikayce is the first drug to be approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs, or LPAD pathway, established by Congress under the 21st Century Cures Act to advance development and approval of antibacterial and antifungal drugs to treat serious or life-threatening infections in a limited population of patients with unmet need. As required for drugs approved under the LPAD pathway, labeling for Arikayce includes certain statements to convey that the drug has been shown to be safe and effective only for use in a limited population. Arikayce was also approved under the Accelerated Approval pathway. Under this approach, the FDA may approve drugs for serious or life-threatening diseases or conditions where the drug is shown to have an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. The approval of Arikayce was based on achieving three consecutive negative monthly sputum cultures by month six of treatment. Insmed was required by the FDA to conduct an additional, post-market study to describe the clinical benefits of Arikayce. There are currently no products specifically approved for treatment of ABPA, however, there are several inhaled anti-fungal agents currently in early stages of development for invasive aspergillosis that could also have efficacy for ABPA.

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

Clinical Development

Pulmazole is our lead iSPERSE development program. We successfully completed a Phase 1/1b clinical study in 2018 which enabled us to initiate a Phase 2 study in 2019, entitled: “A Randomized, Double-Blind, Multicenter, Placebo-Controlled, Phase 2 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Itraconazole Administered as a Dry Powder for Inhalation (PUR1900) in Adult Asthmatic Patients with ABPA. This study was terminated in July 2020 due to the ongoing impact of the COVID-19 pandemic on patient enrollment and study conduct. The completion of a 6-month inhalation toxicology study in dogs in 2020 enables the conduct of a Phase 2b study that will allow for a 16-week dosing regimen and exploration of potential endpoints. This study can be initiated when conditions related to the COVID-19 pandemic are favorable with respect to study conduct and patient enrollment. For more discussion of risks related to the COVID-19 pandemic, please see “Item 1A. RISK FACTORS.—Risks Related to Our Business—Business interruptions could limit our ability to operate our business.

PUR1800

On June 9, 2017, we entered into an exclusive, worldwide license agreement (the “RespiVert License Agreement”) with RespiVert Ltd. (“RespiVert”), a wholly owned subsidiary of Janssen Biotech, Inc. (“Janssen”), and an affiliate of JJEI, for access to a portfolio of novel drug candidates in a class called kinase inhibitors. The RespiVert License Agreement terminates upon the expiration of the Company’s obligation to pay royalties for all licensed products, unless earlier terminated. In addition, the RespiVert License Agreement may be terminated (i) by the Company for any reason upon 120 days’ advance notice to RespiVert; (ii) by RespiVert upon receipt of notice from the Company of either voluntary or involuntary insolvency proceedings of the Company; and (iii) by either party for a material breach which remains uncured following the applicable cure period.

We successfully reformulated RV1162 into PUR1800. PUR1800 demonstrated the efficiency of the iSPERSE platform in non-clinical toxicology results which showed a significant increased lung dose compared to earlier formulations of RV1162 and improved physical /chemical stability of the product.

On December 26, 2019, Pulmatrix entered into a License, Development and Commercialization Agreement with JJEI (the “JJEI License Agreement”). Under the JJEI License Agreement, the Company has granted JJEI an option to acquire (1) the Company’s rights to an intellectual property portfolio of materials and technology related to narrow spectrum kinase inhibitor compounds and (2) an exclusive, worldwide, royalty bearing license to PUR1800.

In February 2021, the first patient was dosed in a Phase 1b safety, tolerability and biomarker study that will enroll 15 patients with stable moderate-severe COPD. The Phase 1b study will be randomized and double-blind and will include 14 days of daily dosing with a 28 day follow up period. The COVID-19 pandemic could delay enrollment to the extent patients remain or become subject to government “stay at home” mandates, patients feel like they cannot safely visit trial sites or patients drop out due issues related to COVID-19.

Clinical Development

Studies conducted by RespiVert/Janssen for the small molecule formulated in PUR1800 (previously RV1162) demonstrated that the molecule has been well tolerated for up to 14 days of dosing in patients with COPD. Analysis of sputum collected from patients with COPD 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. These findings suggest that inhalation of RV1162 may confer anti-inflammatory benefits after a short dosing regimen.

The ongoing Phase1b study of an iSPERSE formulation, PUR1800, in patients with stable moderate-severe COPD, is intended to show similar results as the Phase 1/1b clinical study of RV1162 conducted by Janssen (Janssen Study EST001, ClinicalTrials.gov NCT01970618), while demonstrating safety and tolerability of PUR1800 in patients with stable COPD. As we conduct the Phase 1b study of PUR1800, we continue to assess the impact of the COVID-19 pandemic on our studies and current timeline. An increase of COVID-19 cases where we are conducting the Phase 1b study may delay enrollment of patients and divert healthcare resources from our study. We cannot predict the extent to which the COVID-19 pandemic may impact our clinical trials. However, it could result in a delay or indefinite suspension of the trials. For more discussion of risks related to coronavirus, please see "Item 1A. RISK FACTORS.—Risks Related to Our Business—Business interruptions could limit our ability to operate our business.

PUR5700

We received access to PUR5700 (previously RV7031), a second novel drug candidate through the RespiVert License Agreement. On December 26, 2019, Pulmatrix entered into the JJEI License Agreement, pursuant to which the Company provided an assignment option to JJEI of all the Company's rights under the RespiVert License Agreement, to develop and commercialize PUR1800, PUR5700 and other kinase inhibitors.

PUR3100

In 2020, Pulmatrix developed PUR3100, the iSPERSE formulation of DHE, for the treatment of acute migraine. Over 38 million people suffer from migraine in the United States. Currently DHE is only available for intravenous infusion and therefore is not widely used. If approved for commercialization, PUR3100 should be the first orally inhaled DHE treatment for acute migraine and be an alternative to other acute therapies, such as oral and intravenous triptans that currently represent over 90% of the annual migraine prescriptions in the United States. Given the oral inhaled route of delivery, PUR3100 is anticipated to provide a rapid onset of migraine symptom relief with a favorable tolerability profile.

Competition and Market Opportunities

Current treatments for migraine include oral, intranasal, intravenous ("IV") or intramuscular ("IM") formulations of triptans, dihydroergotamine, and CGRP antagonists. Studies show that migraineurs are underdiagnosed, undertreated, and experience substantial decreases in functioning and productivity, which in turn translates into diminished quality of life for individuals, and financial burdens to both health-care systems and employers. All current treatments suffer from limited efficacy and/or tolerability and there exists a significant unmet need for safe and effective alternatives to current treatments.

DHE has been shown to be effective in the treatment of migraine and, in particular, hard to treat migraines, such as menstrual migraine, migraine upon awakening, and severe migraine. Utilization of DHE has been limited due to its poor oral bioavailability, requiring IV or intranasal dosing. IV dosing generally requires administration in a healthcare setting and the high exposure levels results in significant nausea and emesis and as such has been limited to use only in patients with severe intractable migraine. Intranasal dosing with Migranal (Bausch Health US LLC) has been poorly adopted due to poor exposure resulting in inconsistent efficacy.

There is precedent for an inhaled DHE therapy. MAP Pharmaceuticals, Inc. developed MAP0004, also known as Levadex or Semprana, a liquid suspension formulation of DHE, designed to be dosed via a pMDI inhalation device. Their published data indicate a safe and well tolerated formulation with rapid onset and long-lasting efficacy that compared very favorably to existing treatments. Development of MAP0004 led to a new drug application ("NDA") but was halted after several complete response letters from the FDA citing Chemistry, Manufacturing and Controls ("CMC") issues related to dose uniformity and stability issues. Regardless of the failure of MAP0004, the efficacy and tolerability of the formulation reported by MAP Pharmaceuticals provides proof of concept for an inhaled DHE formulation. PUR3100, the iSPERSE formulation planned by Pulmatrix is anticipated to deliver DHE to the lung with efficacy and tolerability that compares favorably with MAP0004..

There are no other inhaled DHE formulations currently in development. There are two intranasal formulations of DHE currently in development. Satsuma Pharmaceuticals have developed a dry powder formulation of DHE for intranasal dosing and recently completed a Phase 3 study (ClinicalTrials.gov NCT03901482). Despite failure of this study to achieve its primary endpoint, Satsuma have announced that development of this formulation will continue, though no timeline for additional clinical studies has been announced. Impel Neuropharma is developing a formulation of DHE based on the Migranal formulation with an improved POD delivery technology using a propellant to deliver the formulation deep into the sinus cavity. Impel recently announced acceptance of their NDA by the FDA with a target Prescription Drug User Fee Act ("PDUFA") date of September 2021.

Clinical Development

Pulmatrix plans to conduct a 14-day GLP toxicology study in 2021 that will enable an Investigational New Drug ("IND") filing with FDA in Q1 2022. Following the filing of the IND, Pulmatrix plans to initiate a 2-part Phase 1/Phase 2 study in patients with episodic migraine using the iSPERSE formulation PUR3100. This study will evaluate single dose PK, safety and tolerability, and the effect of dose on a range of relevant clinical endpoints.

Business Development

On April 15, 2019, Pulmatrix entered into a Development and Commercialization Agreement (the "Cipla Agreement") with Cipla Technologies LLC ("Cipla") for the co-development and commercialization, on a worldwide exclusive basis, of Pulmazole, our inhaled iSPERSE drug delivery system enabled formulation of the antifungal drug, itraconazole. According to the agreement, Pulmatrix and Cipla share equally product development and commercialization costs and free cash flow from worldwide commercialization from future sales of Pulmazole.

On December 26, 2019, Pulmatrix entered into a License, Development and Commercialization Agreement with JJEI (the "JJEI License Agreement"). Under the JJEI License Agreement, the Company has granted JJEI an option to acquire (1) the Company's rights to an intellectual property portfolio of materials and technology related to narrow spectrum kinase inhibitor compounds and (2) an exclusive, worldwide, royalty bearing license to PUR1800 and PUR5700.

On April 9, 2020, we entered into a Collaboration and License Agreement (the "Sensory Cloud Agreement") with Sensory Cloud, Inc. ("Sensory Cloud"). Under the terms of the Sensory Cloud Agreement, we have granted Sensory Cloud an exclusive, worldwide, royalty bearing license to PUR003 and PUR006 (the "Sensory Licensed Product"), our proprietary aerosol salt solution for delivery or administration to or through the nasal passages also known as NasoCalm, as well as related patents and know-how, for use in the field. PUR003 and PUR006, were originally developed by the Company as potential anti-infective biodefense medical countermeasure products. However, the Company decided to no longer develop these products and instead prioritized the development of other programs. For purposes of the Sensory Cloud Agreement, the field means the formulation and commercialization of over-the-counter

products for the prophylaxis, prevention and treatment of upper and lower respiratory disease that are delivered or administered to or through the nasal passages. The license granted to Sensory Cloud does not cover the development or commercialization of any prescription products.

Intellectual Property

Patents and Patent Applications

We protect our intellectual property by filing and advancing patent applications and maintaining granted patents on our iSPERSE platform technology and in-licensed kinase inhibitors, which includes claims to compositions of matter and methods of use for our Pulmazole, PUR1800 and PUR3100 programs, and PUR003 and PUR006, as well as, manufacturing processes, devices and packaging relevant to our iSPERSE platform and product candidates.

The status of our patent portfolio changes frequently in the ordinary course of patent prosecution. As of December 31, 2020, our patent portfolio related to iSPERSE included approximately 112 granted patents, 16 of which are granted US patents, with expiration dates from 2024 to 2034, and approximately 61 additional pending patent applications in the US and other jurisdictions. Our in-licensed portfolio related to kinase inhibitors included approximately 241 granted patents, 31 of which are granted US patents, with expiration dates from 2029 to 2035, and approximately 42 additional pending patent applications in the US and other jurisdictions. On March 3, 2021 we filed a provisional patent application in the USPTO that discloses and claims certain formulations and methods of use relevant to our PUR3100 program. We plan to file an international patent application under the patent cooperation treaty based on the provisional patent application by the applicable deadline.

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

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

Trade Secrets

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

Manufacturing

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

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

Suppliers

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

Research and Development

For fiscal years ended December 31, 2020 and 2019, we spent approximately $15.6 million and $12.8 million, respectively on research and development activities.

Government Regulation

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

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

FDA Approval Process

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

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

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

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

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

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

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

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

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

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

As a product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA would generally increase as clinical studies progress. We and the third-party manufacturers on which we rely for the manufacture of our product candidates and their respective components (including the API) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements.

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

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

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

If the FDA approves one of our therapeutic candidates, we will be required to comply with a number of post-approval regulatory requirements. We will also be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or its API, the FDA may require stability or other data from the new manufacturer, which will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in its ability to meet commercial demand, if any. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

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

Section 505(b)(2) New Drug Applications

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

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

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

Orphan Drug Designation

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

Foreign Regulation

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

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

Reimbursement

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

The passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") sets forth requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, which may affect the marketing of our products. The MMA also introduced a new reimbursement methodology. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

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

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

Compliance with Environmental Laws

Compliance with applicable environmental requirements during the years ended December 31, 2020 and 2019 has not had a material effect upon our capital expenditures, earnings or competitive position.

Employees

As of December 31, 2020, we had 2 part-time and 20 full-time employees, 17 of whom were engaged in full-time research and development activities. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

Properties

Our corporate headquarters is located in Lexington, Massachusetts. We currently lease approximately 22,119 square feet of office and lab space in Lexington, Massachusetts under a lease that originally expired on December 31, 2020. On April 23, 2020, an extension to our lease for office and lab space was signed between us and 99 Hayden LLC. The extension to the original lease executed on May 31, 2007 will now expire on June 30, 2022. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms for our future growth.

Available Information

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

ITEM 1A. RISK FACTORS.

The following risk factors, together with all of the other information included or incorporated in this Annual Report on Form 10-K, should be carefully considered. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risk Factor Summary

We are providing the following summary of the risk factors contained in this Annual Report on Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Annual Report on Form 10-K in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following:

- We have a history of net losses and may experience future losses;
- We will need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute our stockholders' ownership interests;
- We are a clinical development stage biotechnology company and have never been profitable;
- All of our product candidates are still under development, and there can be no assurance of successful commercialization of any of our products;
- 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;
- If our collaborators are not successful, we may not effectively develop and market some of our therapeutic candidates;
- 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;
- If the third parties on which we rely to conduct our clinical trials and to assist us with preclinical 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;
- Our failure to successfully acquire, develop and market additional drug candidates or approved drug products could impair our ability to grow;
- We may be subject to claims that our employees, independent consultants or agencies have wrongfully used or inadvertently disclosed confidential information of third parties;
- The COVID-19 pandemic has caused interruptions or delays of our clinical studies and may have a significant adverse effect on our business;
- Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations;
- 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;
- 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 U.S. Food and Drug Administration ("FDA") or foreign regulatory agencies, if at all;
- We and our third-party manufacturers are, and will be, subject to regulations of the FDA and other foreign regulatory authorities;
- 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;
- 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 price of Company Common Stock is subject to fluctuation and has been, and may, continue to be volatile;
- 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;
- 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; and
- Protective provisions in our charter and bylaws could prevent a takeover which could harm our stockholders.

Risks Related to Our Business

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

We have yet to establish any history of profitable operations. We reported a net loss of $19.3 million and $20.6 million for the fiscal years ended December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $234.5 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

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

Our current capital will be sufficient to enable us to continue operations for at least 12 months following the filing date of this Annual Report. In order to continue our operations and to fully realize all of our business objectives, absent any non-dilutive funding from a strategic partner or some other strategic transactions, we will need to raise additional capital, which 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 our therapeutic candidates;
- investing in protecting and expanding our intellectual property portfolio, including filing for additional patents to strengthen our intellectual property rights;
- hiring and retaining qualified management and key employees;
- responding to competitive pressures; and
- maintaining compliance with applicable laws.

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

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

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

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

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

We are a clinical development stage biotechnology company. We have not commercialized any product candidates or recognized any revenues from our 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 and 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 ABPA, acute migraine, and other iSPERSE-based product candidates, we must provide the FDA and foreign regulatory authorities with human clinical and non-clinical animal data that demonstrate adequate safety and effectiveness. To generate these data, we will have to subject our product candidates to significant additional research and development efforts, including extensive non-clinical studies and clinical testing. Our approach to drug discovery may not be effective or may not result in the development of any drug. Currently our development efforts are primarily focused on Pulmazole, PUR1800, and PUR3100. Even if Pulmazole, PUR1800, PUR3100 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.

On December 26, 2019, we entered into the Johnson & Johnson Enterprise Innovation, Inc. (“JJEI”) License Agreement. Under the terms of the JJEI License Agreement, we have granted JJEI an option to acquire (1) JJEI’s rights to an intellectual property portfolio of materials and technology related to narrow spectrum kinase inhibitor compounds and (2) an exclusive, worldwide, royalty bearing license to PUR1800. JJEI will have three months from the later of the completion of a Phase 1b clinical study for PUR1800 and JJEI’s receipt of audited draft reports for a toxicology study of PUR1800 to exercise the option. We will be conducting the Phase 1b clinical study and the chronic toxicology program. If our Phase 1b clinical study or the chronic toxicology program is not successful, we may jeopardize the fulfillment of the option to JJEI under the JJEI License Agreement, thereby hurting our product development efforts and potential to earn royalty payments, which will in turn negatively influence our financial condition. Furthermore, JJEI may terminate the JJEI License Agreement for any reason upon 90 days advance written notice. We cannot predict JJEI’s decision to terminate the JJEI License Agreement. The termination of the JJEI License Agreement may negatively influence our financial condition.

Due to delays in patient enrollment in the Pulmazole Phase 2 clinical study, exacerbated by the ongoing COVID-19 pandemic, Cipla Technologies, LLC (“Cipla”), with whom we entered into a development and commercialization agreement (the “Cipla Agreement”) on April 15, 2019 for the development and commercialization of Pulmazole, informed us that it desired to amend the Cipla Agreement. In connection with our renegotiation of the Cipla Agreement, on July 10, 2020, the joint steering committee established by us and Cipla terminated the Phase 2 study in order to facilitate the commencement of a newly designed Phase 2b study that would supersede the prior Phase 2 study. We have not agreed to any amendments to the Cipla Agreement as of the date of the filing of this Annual Report. However, we expect that discussions regarding amendments to the Cipla Agreement will continue. No assurance can be given that we will be able to reach a mutually acceptable arrangement with Cipla for the conduct of any proposed Phase 2b clinical study in the future. Accordingly, if we are unable to agree with Cipla on such matters such as cost sharing for the new study, we may be forced to suspend further development of Pulmazole.

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, PUR3100 and other iSPERSE-based drug candidates currently in discovery research or preclinical development. The failure of one or more of our iSPERSE-based drug candidates could have a material adverse effect on our business, financial condition, and results of operations.

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

If our collaborators are not successful, we may not effectively develop and market some of our therapeutic candidates.

We have entered into co-development agreements regarding two of our therapeutic candidates and, as a result, we no longer have complete control over the development of these candidates. If our collaborators do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed or may not obtain regulatory approval for, or commercialize, our product candidates. If our relationships with these collaborators terminate, we believe that we would be able to enter into arrangements with alternative third parties. However, replacing any of these collaborators could delay our clinical trials and could jeopardize our ability to obtain regulatory approvals and commercialize our product candidates on a timely basis, if at all.

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

While there may be several alternative suppliers of API in the market, changing API suppliers or finding and qualifying new API suppliers can be costly and can take a significant amount of time. Many APIs require significant lead time to manufacture. There can also be challenges in maintaining similar quality or technical standards from one manufacturing batch to the next. We place purchase orders with a single supplier to supply the API, and we could experience a delay in conducting clinical trials of or obtaining regulatory approval for Pulmazole, PUR1800, PUR3100 or our other drug candidates and incur additional costs if we changed from this supplier for any reason. Similarly, replacing our manufacturers could cause us to incur added costs and experience delays in identifying, engaging, qualifying and training any such replacements.

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

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

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

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

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market additional product candidates and technologies, 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. We cannot guarantee that we will be able to successfully conduct the preclinical studies of the identified potential product candidates as anticipated.

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

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

If we do enter into such arrangements, we could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to researching our product candidates pursuant to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. If we do not consummate collaborative or license agreements, we may use our financial resources more rapidly on our product development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business prospects. Further, we may not be successful in overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative or license relationships, our business prospects could suffer.

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

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

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

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

The COVID-19 pandemic has caused interruptions or delays of our clinical studies and may have a significant adverse effect on our business

The global outbreak of COVID-19 has resulted in, and is likely to result in, substantial disruptions to markets and economies around the world, including government-imposed quarantines, travel restrictions and other public health safety measures. We terminated our Phase 2 clinical study for Pulmazole as a result of the disruptions and safety concerns caused by the COVID-19 pandemic.

We plan to initiate a Phase 2b clinical study for Pulmazole when the conditions related to the COVID-19 pandemic are favorable with respect to study conduct and patient enrollment, and have commenced a Phase 1b study of PUR1800 in stable moderate-severe COPD patients in February 2021. The COVID-19 pandemic could delay these studies or impact enrollment generally to the extent we cannot secure sites to enroll patients, patients remain or become subject to government “stay at home” mandates, patients feel like they cannot safely visit trial sites or patients drop out due to COVID-19 related issues. The extent to which the COVID-19 pandemic may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, but the enrollment of patients in our study may be delayed or suspended should there be an outbreak of COVID-19 in areas where we are conducting trials, as hospitals and clinics in those regions may shift resources to patients affected by the disease. Additionally, if our trial participants are unable to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from COVID-19, we may experience higher drop-out rates or delays in our clinical trials. Government-imposed quarantines and restrictions may also require us to temporarily terminate our clinical sites. Furthermore, if we determine that our trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical trials, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected development timeline for Pulmazole and PUR1800 may be negatively impacted. Moreover, the Covid-19 pandemic has begun to have indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that this Covid-19 pandemic or any other pandemic harms the global economy generally. We cannot predict the ultimate impact of the COVID-19 outbreak as consequences of such health pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impact on our business, our clinical trials or the global economy as a whole. However, any one or a combination of these events could have an adverse effect on the operation of and results from our clinical trials and on our other business operations. We will continue to monitor the effects of COVID-19 on an ongoing basis.

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

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Section 404 of the Sarbanes-Oxley Act of 2002 (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 (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 (“NOLs”), to offset future taxable income or reduce taxes. Our past issuances of stock and other changes in our stock ownership may have resulted in ownership changes within the meaning of Section 382 of the Code; accordingly, our pre-change NOLs may be subject to limitation under Section 382. If we determine that we have not undergone an ownership change, the Internal Revenue Service could challenge our analysis, and our ability to use our NOLs to offset taxable income could be limited by Section 382 of the Code. Future changes in our stock ownership, including in connection with our initial public offering, some of which are outside of our control, could result in ownership changes under Section 382 of the Code further limiting our ability to utilize our NOLs. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability.

Risks Related to Regulatory Matters

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

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

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

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

We are not permitted to market our product candidates in the United States until we receive approval of a 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;
- 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, refusal of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates, and materially and adversely affect our business, financial condition and results of operations.

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

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

- restrictions on such therapeutic candidate, manufacturer or manufacturing process;

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

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

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

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

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

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

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for, or purchase, order or recommendation of, goods or services reimbursed by any source, not just governmental payers. The scope and enforcement of these laws are uncertain and subject to change in the current environment of healthcare reform. We cannot predict the impact on our business, financial condition nor results of operations of any changes in these laws. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Law enforcement authorities are increasingly focused on enforcing these laws, and if we are challenged under of 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, preclinical 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 to the extent that we advance Pulmazole to a planned new Phase 2b trial and pursue development of PUR1800 and PUR3100 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 for at least 12 months following the filing date of this Annual Report. 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 as of December 31, 2020 of $234.5 million, which may raise concerns about our solvency and affect our ability to raise additional capital.

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

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

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

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, including Pulmazole, PUR1800 or PUR3100 development activities, or reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be continued doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. If we are or become insolvent, investors in our stock may lose the entire value of their investment.

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Company Common Stock

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

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

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

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

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

As a publicly traded company, we incur significant additional legal, accounting and other expenses. The obligations of being a public reporting company require significant expenditures, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and corporate governance practices, among many other complex rules that are often difficult and time consuming to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly as we are no longer an "emerging growth company."

In addition, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. Compliance with such requirements also places demands on management's time and attention.

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

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

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant due to our dependence on positive clinical trial outcomes and regulatory approvals. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and result in a decline in the market price of Company Common Stock.

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

The Company Common Stock is listed on The NASDAQ Capital Market. For continued listing on The NASDAQ Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the 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, the Company Common Stock may be delisted. If our securities are delisted from trading on The NASDAQ Stock Market, and we are not able to list our securities on another exchange or to have them quoted on The NASDAQ Stock Market, our securities could be quoted on the OTC 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;
- a determination that Company Common Stock is a "penny stock," which would require brokers trading in Company Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

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

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

In addition, as of March 19, 2021,1,902,017 shares remained available to be awarded under our 2013 Employee, Director and Consultant Equity Incentive Plan (the "2013 Plan). Further, an aggregate of 3,893,304 shares of Company Common Stock could be delivered upon the exercise or conversion of outstanding stock options or restricted stock units under the Incentive Plan and other equity incentive plans we previously assumed. We may also issue additional options, warrants and other types of equity in the future as part of stock-based compensation, capital raising transactions, technology licenses, financings, strategic licenses or other strategic transactions. To the extent these options are exercised, existing stockholders would experience additional ownership dilution. In addition, the number of shares available for future grant under our equity compensation plans may be increased in the future, as our equity compensation plan contains an "evergreen" provision, pursuant to which additional shares may be authorized for issuance under the plan each year.

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters are located at 99 Hayden Avenue, Suite 390, Lexington, Massachusetts. We currently lease approximately 22,119 square feet of office space in Lexington, Massachusetts under an original lease that expired on December 31, 2020. We have extended the lease and it currently expires on June 30, 2022. Base rent expense for the year ended December 31, 2020 was approximately $698. The extended lease agreement, as amended on April 23, 2020, provides for a base monthly rent, and we are also responsible for real estate taxes, maintenance and other operating expenses applicable to the leased premises. Our future minimum lease payments under the lease are as follows (dollars in thousands):

Year	Amount
2021	$ 1,194
2022 (six months)	615
Total	$ 1,809

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

ITEM 3. LEGAL PROCEEDINGS.

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

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

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

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

On March 19, 2021, the last reported sale price of our common stock on the NASDAQ Capital Market was $1.44 per share.

Stockholders

As of March 19, 2021, there were approximately 192 stockholders of record of our common stock.

Dividends

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

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2020.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

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

The information set forth below should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion and analysis contain forward-looking statements based on our current expectations, assumptions, estimates and projections. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those indicated in these forward-looking statements as a result of certain factors, including those discussed in Item 1 of this Annual Report on Form 10-K, entitled "Business," under "Forward-Looking Statements" and Item 1A of this Annual Report on Form 10-K, entitled "Risk Factors." References in this discussion and analysis to "us," "we," "our," or our "Company" refer to Pulmatrix, Inc., a Delaware corporation.

Overview

We are a clinical stage 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 diseases, including allergic bronchopulmonary aspergillosis ("ABPA") in patients with asthma, and in patients with cystic fibrosis ("CF"), lung cancer, and in patients suffering from neurological diseases such as acute migraine.

Our goal is to develop breakthrough therapeutic products that are safe, convenient, and more efficient than the existing therapeutic products for respiratory and other diseases where iSPERSE properties are advantageous. The iSPERSE technology may potentially improve upon the known efficacy and safety profile of currently available therapies. Our current pipeline is aligned to this goal with the Pulmazole program for inhaled antifungal therapy to treat ABPA in patients with asthma, the PUR3100 program for treatment of acute migraine, and the PUR1800 program, which has potential application in both lung cancer and chronic obstructive pulmonary disease ("COPD"). All of these programs leverage improvements provided by iSPERSE. We intend to capitalize on our iSPERSE technology platform and our expertise in inhaled therapeutics to identify new product candidates for the prevention and treatment of diseases with significant unmet medical needs and to build our product pipeline beyond our existing candidates. In order to advance our clinical trials for our therapeutic candidates for respiratory and neurological diseases and leverage the iSPERSE platform to enable delivery of partnered compounds, we intend to form strategic alliances with third parties, including pharmaceutical and biotechnology companies or academic or private research institutes.

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

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

- initiate and expand clinical trials for Pulmazole for ABPA, and other indications for immunocompromised at-risk patients;
- expand clinical trials for PUR1800 focused on COPD and lung cancer prevention;
- continue preclinical studies of PUR3100 for treatment of acute migraine to enable a Phase 2 study start in early 2022
- seek regulatory approval for our product candidates;
- hire personnel to support our product development, commercialization and administrative efforts; and
- advance the research and development related activities for inhaled therapeutic products in our pipeline.

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

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

Recent Developments

License, Development and Commercialization Agreement with JJEI

On December 26, 2019, we entered into a License, Development and Commercialization Agreement (the "JJEI License Agreement") with Johnson & Johnson Enterprise Innovation, Inc. ("JJEI"). Under the terms of the JJEI License Agreement, we have granted JJEI an option to acquire (1) the Company's rights to an intellectual property portfolio of materials and technology related to narrow spectrum kinase inhibitor compounds (the "Licensed Product") and (2) an exclusive, worldwide, royalty bearing license to PUR1800, our inhaled iSPERSE drug delivery system as formulated with one of the kinase inhibitor compounds. We will conduct a clinical and chronic toxicology program in 2021 focused on COPD and lung cancer interception.

As consideration for our entry into the JJEI License Agreement, JJEI paid an upfront fee of $7.2 million to conduct the research on the Phase 1b clinical study and will also fund $3.4 million for the toxicology study costs. We are also eligible to earn a $2.0 million milestone payment for the completion of the Phase 1b study of the Licensed Product. If JJEI exercises the license option under the JJEI License Agreement, Pulmatrix is also eligible to receive a $14.0 million option exercise payment, up to an additional $32.0 million in development milestone payments, $45.0 million in commercial milestones, as well as royalty payments ranging from 1% to 2% of sales.

Under the terms of the JJEI License Agreement, JJEI will have three months from the later of (1) the completion of a Phase 1b clinical study for the Licensed Product and JJEI's receipt of audited final reports and (2) JJEI's receipt of audited draft reports for a toxicology study of the Licensed Product to exercise the option. If the option is not exercised, we may terminate the JJEI License Agreement by providing a 30-day written notice, and all licenses will revert back to Pulmatrix. The agreement may otherwise be terminated by JJEI for any reason upon 90 days advance notice, or upon notice of our entering into insolvency or bankruptcy proceedings. Either party may terminate the agreement for material breach of contract that is not cured within 60 days.

In February 2021, the first patient was dosed in the Phase 1b safety, tolerability and biomarker study that will enroll 15 patients with stable moderate-severe COPD. The Phase 1b study will be randomized and double-blind and will include 14 days of daily dosing with a 28 day follow up period. The COVID-19 pandemic could delay enrollment to the extent patients remain or become subject to government "stay at home" mandates, patients feel like they cannot safely visit trial sites or patients drop out due issues related to COVID-19.

Development and Commercialization Agreement with Cipla

On April 15, 2019, we entered into a Development and Commercialization Agreement (the "Cipla Agreement") with Cipla Technologies LLC ("Cipla") for the co-development and commercialization, on a worldwide exclusive basis, of Pulmazole, our inhaled iSPERSE drug delivery system enabled formulation of the antifungal drug, itraconazole, for the treatment of all pulmonary indications, including ABPA in patients with asthma.

Pursuant to the Cipla Agreement, Cipla made an initial upfront payment of $22.0 million to us in exchange for an irrevocable assignment of all existing and future technologies, current and future drug master files, dossiers, third-party contracts, regulatory filings, regulatory materials and regulatory approvals, patents, and intellectual property rights, as well as any other associated rights and assets with respect to Pulmazole, specifically in relation to pulmonary indications (the "Assigned Assets") which Cipla then irrevocably licensed back to us only for non-pulmonary application. As a condition precedent to signing the agreement, we demonstrated to Cipla that we had at least $15.0 million of unencumbered cash available for the development of Pulmazole. Pursuant to the terms of the agreement, we dedicated $24.0 million of cash to the development of Pulmazole. After such $24.0 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 commercialization of Pulmazole. Pulmatrix will remain primarily responsible for the execution of the clinical development of Pulmazole, and Cipla will be responsible for the global commercialization of the product.

We initiated a Phase 2 study in 2019, entitled: "A Randomized, Double-Blind, Multicenter, Placebo-Controlled, Phase 2 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Itraconazole Administered as a Dry Powder for Inhalation (PUR1900) in Adult Asthmatic Patients with ABPA. This study was terminated in July 2020 due to the ongoing impact of the COVID-19 pandemic on patient enrollment and study conduct.

We conducted a Type C meeting with the FDA on January 27, 2021 and leveraging the insights gained from this meeting, now plan to commence the Phase 2b study when the risks to the conduct of the study presented by the ongoing COVID-19 pandemic are reduced to an acceptable level. The Phase 2b study design includes a 16-week dosing regimen as well as an exploration of potential efficacy endpoints, whereas the terminated Phase 2 study comprised only a 4-week dosing regimen with safety and tolerability as its primary endpoint. The longer dosing regimen of the planned new Phase 2b study is supported by the 6-month inhalation toxicology study in dogs completed in April 2020.

In addition to the planned new Phase 2b study, as part of the contemplated amendments to the Cipla Agreement, we may assign to Cipla the exclusive rights to develop and commercialize Pulmazole in India, South Africa and other regional markets where Cipla has strong clinical development and business capabilities. We have not agreed to any amendments to the Cipla Agreement as of filing date of this Annual Report. However, we expect that discussions regarding amendments to the Cipla Agreement will continue. No assurance can be given that we will be able to reach a mutually acceptable arrangement with Cipla for the conduct of the Phase 2b clinical study in the future. Accordingly, if we are unable to agree with Cipla on such matters such as cost sharing for the new study, we may be forced to suspend further development of Pulmazole.

Collaboration and License Agreement with Sensory Cloud

On April 9, 2020, we entered into a Collaboration and License Agreement (the "Sensory Cloud Agreement") with Sensory Cloud, Inc. ("Sensory Cloud"). Under the terms of the Sensory Cloud Agreement, we granted Sensory Cloud an exclusive, worldwide, royalty bearing license to PUR003 and PUR006, the Company's proprietary aerosol salt solution for delivery or administration to or through the nasal passages also known as NasoCalm, as well as related patents and know-how, for use in the field. PUR003 and PUR006, was originally developed by the Company as a potential anti-infective biodefense medical countermeasure product. However, we decided to no longer develop these products and instead prioritized the development of other programs. Sensory Cloud will be using NasoCalm, now integral in their product FEND, a hypertonic calcium chloride salt solution with a nasal mister. For purposes of the Sensory Cloud Agreement, the field means the formulation and commercialization of over-the-counter products for the prophylaxis, prevention and treatment of upper and lower respiratory disease that are delivered or administered to or through the nasal passages. The license granted to Sensory Cloud does not cover the development or commercialization of any prescription products.

Under the Sensory Cloud Agreement, we are entitled to royalties on net sales of licensed products in each country in which there is a valid claim of a patent within the licensed intellectual property covering the licensed product. The royalty rates are as follows: (1) 7% of net sales during calendar year 2020, (2) 14% of net sales during calendar year 2021, and (3) 17% of net sales during calendar year 2022 and each calendar year thereafter during the royalty term. In addition, we are entitled to a milestone payment of $1.0 million following the achievement of aggregate net sales of all Licensed Products of $20.0 million.

Sensory Cloud launched product sales of FEND during the fourth quarter 2020 and minimal royalties have been recorded during the period ending December 31, 2020.

Financial Overview

To date, we have not generated any product sales. Our 2020 revenue was primarily generated through the recognition of revenue from both the Cipla Agreement and the JJEI Agreement and includes minimal royalties generated by sales of FEND by Sensory Cloud. Our 2019 recognized revenue resulted from the Cipla Agreement.

Research and Development Expenses

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

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

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

Research and development activities are central to our business model. We utilize a combination of internal and external efforts to advance product development from early-stage work to clinical trial manufacturing and clinical trial support. External efforts include work with consultants and substantial work at CROs and CMOs. We support an internal research and development team and facility for our pipeline programs. To move these programs forward along our development timelines, a large portion, approximately 85%, of our staff are research and development employees. In addition, we maintain a 22,119 square foot research and development facility which includes laboratory space and capital equipment to promote our iSPERSE powders for our pipeline programs. As we identify opportunities for iSPERSE in additional indications, we anticipate additional head count, capital, and development costs will be incurred to support these programs.

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

General and Administrative Expenses

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

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

Impairment of Goodwill

Goodwill is not amortized but evaluated at year end for potential impairment. There was no goodwill impairment made in 2020. As of December 31, 2019, goodwill was impaired $7.3 million.

Critical Accounting Policies

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

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Effective January 1, 2019, the Company adopted ASU No. 2014-09 (Topic 606) "Revenue from Contracts with Customers." The adoption of Topic 606 did not have any material impact on the Company's consolidated financial statements. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Our principal sources of revenue during the reporting period were income that resulted through our collaborative arrangements and license agreements that related to the development and commercialization of Pulmazole and our license and reimbursement arrangement that related to the JJEI Agreement. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, and collectability of the resulting receivable is reasonably assured.

During the year ended December 31, 2020, our principal source of revenue was income that resulted from the JJEI and Cipla Agreements. During the year ended December 31, 2019, our principal source of revenue was income that resulted from the Cipla Agreement.

Milestone Payments

At the inception of each arrangement that includes research or development milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. As of December 31, 2020, we have an active arrangement that contains a research or development milestone.

Royalties

For arrangements that include sales-based royalties, including milestone payments upon first commercial sales and milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have recognized an insignificant amount of royalty revenue in the fourth quarter 2020 which resulted from a licensing arrangement.

Research and Development Costs

Research and development costs are expensed as incurred and include: salaries, benefits, bonus, share-based compensation, license fees, milestone payments due under license agreements, costs paid to third-party contractors to perform research, conduct clinical trials, and develop drug materials and delivery devices; and associated overhead and facilities costs. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors, CROs and CMOs. Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of fees and costs associated with the contract that were rendered during the period and they are expensed as incurred. Research and development costs that are paid in advance of performance are capitalized as prepaid expenses and amortized over the service period as the services are provided. As of December 31, 2020, the Company has an active arrangement with JJEI that contains a research or development milestone.

Leases

At the inception of an arrangement, we determine whether the arrangement is, or contains a lease, based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and long-term lease liabilities. We have elected not to recognize on the balance sheet leases with terms of one year or less. Options to renew a lease are not included in our initial lease term assessment unless there is reasonable certainty that we will renew. We evaluate our plans to renew any material lease on a quarterly basis.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items, such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, we utilize our incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired, and liabilities assumed under the acquisition method of accounting for push-down accounting. Goodwill is not amortized but is evaluated for impairment within our single reporting unit on an annual basis during the fourth quarter, or more frequently if an event occurs or circumstances change that would more likely than not reduce the fair value of our reporting unit below our carrying amount. When performing the impairment assessment, the accounting standard for testing goodwill for impairment permits a company to first assess the qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the goodwill is impaired. If we believe, as a result of the qualitative assessment, that it is more likely than not that the fair value of goodwill is impaired, we must perform a quantitative analysis to determine if the carrying value of the goodwill exceeds the fair value of the Company. Based on a quantitative analysis, goodwill was not deemed to be impaired as of December 31, 2020. Based on a qualitative and quantitative analysis performed at the end of 2019, goodwill was deemed impaired and a charge of $7.3 million was recorded as of December 31, 2019.

Basic and Diluted Net Loss Per Share

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

Income Taxes

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

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of December 31, 2020, and 2019, we did not have any significant uncertain tax positions. We recognize interest and penalties related to uncertain tax positions in income tax expense.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

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

	Year ended December 31,		
	2020	**2019**	**Change**
Revenues	$ 12,634	$ 7,910	$ 4,724
Operating expenses			
Research and development	15,609	12,845	2,764
General and administrative	6,887	8,489	(1,602)
Impairment of Goodwill	—	7,268	(7,268)
Total operating expenses	22,496	28,602	(6,106)
Loss from operations	(9,862)	(20,692)	10,830
Other income (expense)			
Interest income	82	301	(219)
Settlement expense	—	(200)	200
Warrant inducement expense	(9,289)	—	(9,289)
Other expense, net	(239)	(5)	(234)
Loss before income taxes	$ (19,308)	$ (20,596)	$ 1,288
Net loss	$ (19,308)	$ (20,596)	$ 1,288

Revenue — Revenue was $12.6 million for the year ended December 31, 2020 as compared to $7.9 million for the year ended December 31, 2019, an increase of $4.7 million. The increase resulted from an increase in revenue recorded of $6.9 million as a result of the JJEI License Agreement which was executed in late 2019 and includes reimbursement of pass-through expenses, partially offset by a decrease in revenue recorded of $2.2 million as a result of the Cipla Agreement.

Research and development expenses — Research and development expense was $15.6 million for the year ended December 31, 2020 as compared to $12.8 million for the year ended December 31, 2019 an increase of $2.8 million. The increase was primarily due to increased spending on manufacturing, clinical, and preclinical study costs of $4.4 million and $0.3 million, on the PUR1800 and PUR3100 programs, respectively, $1.1 million on employment costs in support of our programs, $0.6 million in allocated fixed expenses and lab services which were partially offset by a decrease of $3.6 million on the Phase 2 Pulmazole clinical trial costs.

General and administrative expenses — General and administrative expense was $6.9 million for the year ended December 31, 2020, compared to $8.5 million for the year ended December 31, 2019, a decrease of $1.6 million The decrease was primarily due to decreased employment costs of $1.2 million because of lower share-based compensation expense and salary costs, $0.1 million in patent and legal expenses and $0.3 million of a milestone payment to the CFFT made in 2019.

Impairment of goodwill — In 2020 and 2019, the Company performed an impairment assessment and concluded that during 2019, the carrying amount of the goodwill exceeded its fair value and recorded the resulting impairment charges of $7.3 million. We have concluded that during 2020, goodwill was not impaired.

Warrant inducement expenses — During 2020 we executed a warrant exercise inducement transaction with existing investors who held existing and outstanding warrants that had an exercise price of $1.35 per share. Upon the exercise, warrant holders were able to purchase on a cash basis up to an aggregate of 10,085,741 shares of common stock. In consideration of the exercise, we issued to the exercise holders new warrants that had a five-year expiry and an exercise price of $1.80 per share. The fair value on the grant date of the new warrants was $9.3 million and was recorded as warrant inducement expense with a corresponding offset to paid-in-capital.

Liquidity and Capital Resources

At December 31, 2020, we had unrestricted cash of $31.7 million. We have incurred recurring losses and as of December 31, 2020 had an accumulated deficit of $234.5 million. During the year ended December 31, 2020, approximately $12.5 million was used in its operating activities. We have primarily financed operations to date through the sale of equity securities, a term loan, licensing and collaboration agreements. We will be required to raise additional capital to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels.

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

Under the JJEI License Agreement, we are also eligible to earn a $2.0 million milestone payment for the completion of the Phase 1b clinical study of PUR1800, the data of which is expected during the fourth quarter 2021. If JJEI exercises the license option under the JJEI License Agreement, we are also eligible to receive a $14.0 million option exercise payment, up to an additional $32.0 million in development milestone payments, $45.0 million in commercial milestones, as well as royalty payments ranging from 1% to 2% of sales.

We expect that our existing cash and cash equivalents at December 31, 2020 and anticipated interest income will enable us to fund our operating expenses and capital expenditure requirements for at least the 12 months following the filing date of this Annual Report on Form 10-K. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our preclinical studies and clinical trials. We are currently assessing the impact of the COVID-19 pandemic which may adversely affect our ability to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials or obtain approval of any product candidates from the U.S. Food and Drug Administration, or the FDA, and other regulatory authorities.

During the year ended December 31, 2020, we raised an aggregate of $21.0 million in net proceeds through the sale of our common stock, exercise of warrants and the exercise of pre-funded warrants (note 7 of the accompanying consolidated financial statements).

In February 2021, we raised $40.0 million in gross proceeds through the sale of our common stock.

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

	Year ended December 31,	
	2020	**2019**
Net cash (used in)/provided by operating activities	$ (12,483)	$ 3,230
Net cash used in investing activities	(281)	(58)
Net cash provided by financing activities	20,981	17,705
Net increase in cash and cash equivalents	$ 8,217	$ 20,877

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 was $12.5 million, which was primarily the result of a net loss of $19.3 million, partially offset by $11.5 million of net non-cash adjustments and $4.7 million in cash outflows associated with changes in operating assets and liabilities. Our non-cash adjustments were primarily comprised of $9.3 million in warrant inducement expense, $1.2 million of share-based compensation expense, $0.8 million of amortization of operating lease right-of-use asset and $0.2 million of depreciation and amortization. The net cash outflows associated with changes in operating assets and liabilities were primarily due to increases of $7.1 million in accounts receivable and $0.3 million in accounts payable partially offset by decreases of $11.0 million in deferred revenue, $0.6 million in operating lease liabilities and $0.5 million in accrued expenses.

Net cash provided by operating activities for the year ended December 31, 2019 was $3.2 million, which was primarily the result of a net loss of $20.6 million, offset by $10.1 million of net non-cash adjustments and $13.7 million in cash inflows associated with changes in operating assets and liabilities. Our non-cash adjustments were primarily comprised of $7.3 million of goodwill impairment, $2.0 million of share-based compensation expense, $0.6 million of amortization of operating lease right-of-use asset and $0.2 million of depreciation and amortization. The net cash inflows associated with changes in operating assets and liabilities was primarily due to $21.2 million increase in deferred revenue and $0.9 million increase in accrued expenses partially offset by decreases of $7.2 million in accounts receivable, $0.6 million in operating lease liabilities, $0.5 million in accounts payable and $0.1 million in prepaid expenses and other current assets.

Cash Flows from Investing Activities

Net cash used in investing activities for the years ended December 31, 2020 and December 31, 2019 were both primarily due to purchases of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 was $21.0 million and was due to the issuance of common stock in two capital raises, exercises of warrants, pre-funded warrants and stock options.

Net cash provided by financing activities for the year ended December 31, 2019 was $17.7 million and was due to the issuance of common stock in multiple capital raises during the first half of 2019 and the exercise of pre-funded warrants.

Financings

Based on our planned use for our existing cash resources, we believe that our available funds will enable us to support administrative, preclinical, clinical, and chemistry manufacturing and control activities in support our programs for at least 12 months following the filing date of this Annual Report on Form 10-K. We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

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

2021 Financings

On February 16, 2021 we closed on a registered direct offering with certain healthcare-focused institutional investors to purchase up to an aggregate of 20,000,000 shares of our common stock at $2.00 per share. The gross proceeds were $40.0 million, prior to deducting placement agent’s fees and other offering expenses. In connection with the offering, 1,300,000 warrants with a five-year expiry were issued to placement agent designees at an exercise price of $2.50 per share. The shares of common stock were offered by Pulmatrix pursuant to a “shelf” registration statement on Form S-3 (File No. 333-230225) previously filed with the Securities and Exchange Commission (the “SEC”) on March 12, 2019 and declared effective by the SEC on March 15, 2019.

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

2020 Financings

On July 9, 2020, we entered into letter agreements with certain existing accredited investors to exercise certain existing and outstanding warrants (“Existing Warrants”) to purchase up to an aggregate of 10,085,741 shares of our common stock at the existing exercise price per share of $1.35. The Existing Warrants were issued in an underwritten public offering pursuant to a registration statement on Form S-1 (File No. 333-230395) and an additional registration statement on Form S-1 (File No. 333-230714) filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, that was consummated in April 2019. In consideration for the exercise of the Existing Warrants for cash, the exercising holders received new unregistered warrants to purchase up to an aggregate of 10,085,741 shares of common stock at an exercise price of $1.80 per share and with an exercise period of five years from July 14, 2020. The gross proceeds to the Company from the exercise were approximately $13.6 million, prior to deducting placement agent fees and offering expenses. In addition, we issued s 655,573 unregistered warrants to placement agent designees at an exercise price of $2.25 and with an exercise period of five years from July 14, 2020. All warrants issued in the financing were subsequently registered pursuant to a registration statement on Form S-3 (File No. 333-242341) which was declared effective on August 13, 2020.

On April 16, 2020, we entered into a Securities Purchase Agreement with certain institutional investors (the "Purchasers"), pursuant to which on April 20, 2020, we issued and sold in a registered direct offering (the "Offering") an aggregate of 4,787,553 shares of our common stock at an offering price of $1.671 per share, for gross proceeds of approximately $8.0 million before the deduction of placement agent fees and offering expenses. In a concurrent private placement, we issued to the Purchasers, for each share of common stock purchased in the Offering, a warrant ("Common Warrants") to purchase one share of common stock. The Common Warrants have an exercise price of $1.55 per share and are exercisable to purchase an aggregate of up to 4,787,553 shares of common stock. In addition, we issued to the placement agent for the Offering warrants to purchase 311,191 shares of common stock at an exercise price of $2.0888 per share. Both the Common Warrants and the placement agent warrants are exercisable immediately upon issuance and terminate on April 20, 2022.

2019 Financings

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

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

After giving effect to $0.7 million in commissions, fees and expenses, the two financings resulted in $3.0 million of net proceeds.

On April 8, 2019, we closed our firm commitment underwritten public offering in which, pursuant to the underwriting agreement (the "Underwriting Agreement") entered into between the Company and H.C. Wainwright & Co., LLC, as representative of the underwriters (the "Underwriters"), dated April 3, 2019, we issued and sold an aggregate of (i) 1,719,554 Common Units ("Common Units"), with each Common Unit being comprised of one share of the Company's common stock, par value $0.0001 per share and one warrant to purchase one share of common stock and (ii) 8,947,112 pre-funded units (the "Pre-Funded Units") with each Pre-Funded Unit being comprised of one pre-funded warrant to purchase one share of common stock and one common warrant to purchase a share of common stock. The public offering price was $1.35 per Common Unit and $1.34 per Pre-Funded Unit. The common warrants have an exercise price of $1.35 per share. In addition, on April 8, 2019, we closed on the sale of an additional 1,599,999 Common Units purchased pursuant to the exercise in full of the underwriter's option to purchase additional securities. Each Common Unit contains one share of common stock and one common warrant to purchase a share of common stock.

We recorded gross proceeds of $16.5 million and after commissions and fees of $1.9 million, the financing resulted in $14.6 million of net proceeds.

All of the 8,947,112 pre-funded warrants issued in the offering were exercised during 2019 which resulted in the issuance of an additional 8,647,112 shares of common stock with net proceeds of $0.1 million. The remaining 300,000 common shares underlying the outstanding pre-funded warrants were issued on January 2, 2020.

Exercise of Warrants

During January and February 2019, 697,500 pre-funded warrants were exercised, 697,500 common shares were issued and we recorded proceeds of $0.1 million.

Commitments

We contract with various other organizations to conduct research and development activities. As of December 31, 2020, we had aggregate commitments to pay approximately $1.1 million remaining on these contracts. The scope of the services under contracts for research and development activities may be modified and the contracts, subject to certain conditions, may generally be cancelled by us upon written notice. In some instances, the contracts, subject to certain conditions, may be cancelled by the third party.

Off-Balance Sheet Arrangements

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

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

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The information required by this Item 8 is included at the end of this Annual Report on Form 10-K beginning on page F-1.

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

Not applicable.

Item 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Our Principal Executive Officer and Principal Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Principal Executive Officer and Principal Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and the disposition of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP and that receipts and expenditures are being made only in accordance with authorizations of our management and board of directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

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

Management evaluates the effectiveness of our internal control over financial reporting based on the 2013 framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during our last fiscal quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2020.

ITEM 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2020.

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2020.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2020.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2020.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

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

(1) Financial Statements:

(2) Financial Statement Schedules:

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

(3) Exhibits:

See "Index to Exhibits" for a description of our exhibits.

Item 16. FORM 10-K SUMMARY

Not applicable.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
3.1	Amended and Restated Certificate of Incorporation of Pulmatrix, Inc., as amended through June 15, 2015		Form 10-Q (Exhibit 3.1)	08/14/15	001-36199
3.2	Restated Bylaws of Pulmatrix, Inc., as amended through June 15, 2015		Form 10-Q (Exhibit 3.2)	08/14/15	001-36199
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Pulmatrix, Inc., dated as of June 5, 2018		Form 8-K (Exhibit 3.1)	06/07/18	001-36199
4.1	Form of Specimen Stock Certificate		Form 8-K (Exhibit 4.1)	06/16/15	001-36199
4.2	Form of Representative's Warrant Agreement		Form S-1/A (Exhibit 4.2)	02/24/14	333-190476
4.3	Warrant Agreement, dated June 16, 2015, by and between Pulmatrix, Inc. and Hercules Technology Growth Capital, Inc.		Form 8-K (Exhibit 10.3)	06/16/15	001-36199
4.4	Form of Warrant issued in Pulmatrix Operating Private Placement, dated June 15, 2015		Form 10-Q (Exhibit 10.8)	08/14/15	001-36199
4.5	Form of Series B Warrant issued in Pulmatrix Public Offering, dated March 28, 2018		Form S-1/A (Exhibit 4.8)	03/28/18	333-223630
4.6	Form of Pre-Funded Warrant issued in Pulmatrix Public Offering, dated March 28, 2018		Form S-1/A (Exhibit 4.7)	03/28/18	333-223630
4.7	Form of Pre-Funded Warrant issued in Pulmatrix Public Offering, dated December 3, 2018		Form 8-K (Exhibit 4.1)	12/03/18	001-36199
4.8	Form of Common Warrant issued in Pulmatrix Public Offering, dated December 3, 2018		Form 8-K (Exhibit 4.2)	12/03/18	001-36199
4.9	Form of Underwriter Warrant issued in Pulmatrix Public Offering, dated January 31, 2019		Form 8-K (Exhibit 4.1)	1/30/19	001-36199
4.10	Form of Underwriter Warrant issued in Pulmatrix Public Offering, dated February 4, 2019		Form 8-K (Exhibit 4.1)	02/01/19	001-36199

4.11	Form of Common Warrant issued in Pulmatrix Direct Registered Offering, dated February 12, 2019	Form 8-K (Exhibit 4.1)	02/11/19	001-36199
4.12	Form of Placement Agent Warrant issued in Pulmatrix Registered Direct Offering, dated February 12, 2019	Form 8-K (Exhibit 4.2)	02/11/19	001-36199
4.13	Form of Common Stock Warrant issued in Pulmatrix Public Offering, dated April 1, 2019	Form S-1/A (Exhibit 4.13)	04/01/19	333-230395
4.14	Form of Pre-Funded Warrant issued in Pulmatrix Public Offering, dated April 1, 2019	Form S-1/A (Exhibit 4.11)	04/01/19	333-230395
4.15	Form of Underwriter Warrant issued in Pulmatrix Public Offering, dated April 1, 2019	Form S-1/A (Exhibit 4.12)	04/01/19	333-230395
4,16	Form of Common Warrant issued in Pulmatrix Public Offering, dated April 16, 2020	Form 8-K (Exhibit 4.1)	04/16/20	001-36199
4.17	Form of Placement Agent Warrant issued in Pulmatrix Public Offering dated April 16, 2020	Form 8-K (Exhibit 4.1)	04/20/20	001-36199
4.18	Form of Warrant Dated July 9, 2020	Form 8-K (Exhibit 4.1)	07/09/20	001-36199
10.1*	Pulmatrix, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan	Form 8-K (Exhibit 10.6)	06/16/15	001-36199
10.3*	Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan	Form S-8 (Exhibit 99.2)	07/20/15	333-205752
10.4*	Pulmatrix Inc. 2003 Employee, Director and Consultant Stock Plan	Form S-8 (Exhibit 99.3)	07/20/15	333-205752
10.5	License, Development and Commercialization Agreement, dated June 9, 2017, by and between Pulmatrix, Inc. and Respivert Ltd.	Form 10-Q (Exhibit 10.1)	08/04/17	001-36199
10.6	First Amendment to the Pulmatrix, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan, dated as of June 5, 2018	Form 8-K (Exhibit 10.1)	06/07/18	001-36199
10.8*	Amended and Restated Employment Agreement, dated June 28, 2019, by and between the Company and Teofilo Raad	Form 10-K/A (Exhibit 10.1)	06/28/19	001-36199
10.10	Development and Commercialization Agreement, dated as of April 15, 2019, by and between Cipla Technologies, LLC and Pulmatrix, Inc.	Form 10-Q (Exhibit 10.4)	08/05/19	001-36199
10.11*	Second Amendment to the Pulmatrix, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan, dated March 11, 2019	Form S-8 (Exhibit 99.3)	06/04/19	333-231935
10.12*	Third Amendment to the Pulmatrix, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan, dated as of September 6, 2019	Form 8-K (Exhibit 10.1)	09/09/19	001-36199

10.13**	License, Development and Commercialization Agreement, by and between Pulmatrix, Inc. and Johnson & Johnson Enterprise Innovation, Inc., dated as of December 26, 2019		Form 10-K (Exhibit 10.13)	03/26/20	001-36199
10.14	Collaboration and License Agreement by and between Pulmatrix, Inc. and Sensory Cloud, Inc. dated April 9, 2020		Form 8-K (Exhibit 10.1)	04/15/20	001-36199
10.15	Securities Purchase Agreement		Form 8-K (Exhibit 10.1)	04/16/20	001-36199
10.16	Form of Letter Agreement		Form 8-K (Exhibit 10.1)	07/09/20	001-36199
10.17	Offer Letter with Todd Bazemore		Form 10-Q (Exhibit 10.2)	11/12/20	001-36199
21.1	List of Subsidiaries		Form 10-K (Exhibit 21.1)	03/13/18	001-36199
23.1	Consent of Marcum LLP, independent registered public accounting firm, to the Form 10-K	X			
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101	The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statement of Changes in Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements.	X			

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

* These exhibits are management contracts

** Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

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

PULMATRIX, INC.

Date: March 23, 2021

By: */s/ Teofilo Raad*
Teofilo Raad
Chief Executive Officer and President

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

Signature	Title	Date
/s/ Teofilo Raad Teofilo Raad	Chief Executive Officer, President and Director (Principal Executive Officer)	March 23, 2021
/s/ Michelle S. Siegert Michelle S. Siegert	VP, Finance, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 23, 2021
/s/ Michael J. Higgins Michael J. Higgins	Chairman of the Board of Directors	March 23, 2021
/s/ Richard Batycky, Ph.D. Richard Batycky	Director	March 23, 2021
/s/ Todd Bazemore Todd Bazemore	Director	March 23, 2021
/s/ Christopher Cabell, M.D. Chris Cabell	Director	March 23, 2021
/s/ Mark Iwicki Mark Iwicki	Director	March 23, 2021
/s/ Amit D. Munshi Amit D. Munshi	Director	March 23, 2021

PULMATRIX, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pulmatrix, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition – Estimated Total Contract Costs

Description of the Matter

As described in Note 2 and Note 5 to the financial statements the Company recognizes revenue from non-refundable, upfront fee allocated to a license, when such license is transferred to the customer through collaboration arrangements and the customer is able to use and benefit from the license. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company uses the input method, with estimated costs to satisfy the performance obligation being the input, as the best measure of the transfer of control of the performance obligation.

Management uses significant assumptions and estimates when determining the total estimated costs expected upon satisfying the performance obligation, which in turn led to significant auditor judgment, subjectivity and effort in performing procedures to evaluate the total estimate of the costs expected upon satisfying the performance obligation.

How We Addressed the Matter in Our Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) obtaining an understanding of management's process in developing the cost estimates (ii) discussion with the Company's clinical and manufacturing personnel to understand the estimates used in developing the cost estimates (iii) evaluating the appropriateness of changes to management's estimates of total costs to satisfy the performance obligation; (iv) performing retrospective review of the estimates to determine the effectiveness of management's estimation process; (v) evaluating whether the cost estimates used by management were reasonable considering consistency with company-specific data; and (vi) determining the reasonableness of the inputs, assumptions and model used in management's estimation process..

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 23, 2021

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 31,657	$ 23,440
Accounts receivable	84	7,200
Prepaid expenses and other current assets	797	777
Total current assets	32,538	31,417
Property and equipment, net	361	270
Operating lease right-of-use asset	1,489	630
Long-term restricted cash	204	204
Goodwill	3,577	3,577
Total assets	$ 38,169	$ 36,098
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 925	$ 600
Accrued expenses	2,028	2,514
Operating lease liability	1,135	675
Deferred revenue	4,166	13,411
Total current liabilities	8,254	17,200
Deferred revenue, net of current portion	6,168	7,879
Operating lease liability, net of current portion	608	—
Total liabilities	15,030	25,079
Stockholders' Equity:		
Preferred stock, $0.0001 par value — 500,000 shares authorized at December 31, 2020 and December 31, 2019, respectively; no shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.0001 par value — 200,000,000 shares authorized at December 31, 2020 and December 31, 2019, respectively; 36,105,097 and 19,994,560 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	4	2
Additional paid-in capital	257,604	226,178
Accumulated deficit	(234,469)	(215,161)
Total stockholders' equity	23,139	11,019
Total liabilities and stockholders' equity	$ 38,169	$ 36,098

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,	
	2020	**2019**
Revenues	$ 12,634	$ 7,910
Operating expenses		
Research and development	15,609	12,845
General and administrative	6,887	8,489
Impairment of goodwill	—	7,268
Total operating expenses	22,496	28,602
Loss from operations	(9,862)	(20,692)
Other income/(expense)		
Interest income	82	301
Settlement expense	—	(200)
Warrant inducement expense	(9,289)	—
Other expense, net	(239)	(5)
Total other income/(expense)	(9,446)	96
Net loss	$ (19,308)	$ (20,596)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.67)	$ (1.23)
Weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders	28,753,310	16,733,909

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance — January 1, 2020	19,994,560	$ 2	$ 226,178	$ (215,161)	$ 11,019
Issuance of common stock, net of issuance costs	4,787,553	1	7,313	—	7,314
Exercise of warrants, net of issuance costs	11,000,487	1	13,642	—	13,643
Exercise of pre-funded warrants	300,000	—	—	—	—
Warrant inducement expense	—	—	9,289	—	9,289
Exercise of stock options	22,497	—	24	—	24
Share-based compensation	—	—	1,158	—	1,158
Net loss				(19,308)	(19,308)
Balance — December 31, 2020	36,105,097	$ 4	$ 257,604	$ (234,469)	$ 23,139

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance — January 1, 2019	4,932,723	$ —	$ 206,409	$ (194,565)	$ 11,844
Adjustment for reverse stock split	2,717	—	—	—	—
Issuance of common stock, net of issuance costs	5,714,508	1	17,544	—	17,545
Exercise of pre-funded warrants	9,344,612	1	159	—	160
Share-based compensation	—	—	2,066	—	2,066
Net loss	—	—	—	(20,596)	(20,596)
Balance — December 31, 2019	19,994,560	$ 2	$ 226,178	$ (215,161)	$ 11,019

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (19,308)	$ (20,596)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	215	182
Amortization of operating lease right-of-use asset	828	583
Stock-based compensation	1,158	2,066
Warrant inducement	9,289	—
Impairment of goodwill	—	7,268
Changes in operating assets and liabilities:		
Accounts Receivable	7,116	(7,200)
Prepaid expenses and other current assets	(20)	(60)
Accounts payable	300	(583)
Accrued expenses	(486)	885
Operating lease liabilities	(619)	(605)
Deferred revenue	(10,956)	21,290
Net cash (used in)/provided by operating activities	(12,483)	3,230
Cash flows from investing activities:		
Purchases of property and equipment	(281)	(58)
Net cash used in investing activities	(281)	(58)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	7,314	17,545
Proceeds from exercise of common stock warrants, net of issuance costs	13,643	
Proceeds from exercise of common stock options	24	
Proceeds from exercise of pre-funded warrants	—	160
Proceeds from Paycheck Protection Program loan	617	—
Repayment of Paycheck Protection Program loan	(617)	—
Net cash provided by financing activities	20,981	17,705
Net increase in cash, cash equivalents and restricted cash	8,217	20,877
Cash, cash equivalents and restricted cash — beginning of period	23,644	2,767
Cash, cash equivalents and restricted cash — end of period	$ 31,861	$ 23,644
Supplemental disclosures of non-cash investing and financing information:		
Fixed asset purchases in accounts payable	$ 25	$ —
Operating lease right-of-use asset obtained in exchange for operating lease obligation	$ 1,687	$ 1,213

See accompanying notes to consolidated financial statements

1. Nature of the Business and Basis of Presentation

Organization

Pulmatrix, Inc. (the "Company") was incorporated in 2013 as a Delaware corporation. The Company is a clinical stage biotechnology company focused on the discovery and development of a novel class of inhaled therapeutic products. The Company's proprietary dry powder delivery platform, iSPERSE™ (inhaled Small Particles Easily Respirable and Emitted), is engineered to deliver small, dense particles with highly efficient dispersibility and delivery to the airways, which can be used with an array of dry powder inhaler technologies and can be formulated with a variety of drug substances. The Company is developing a pipeline of iSPERSE-based therapeutic candidates targeted at prevention and treatment of a range of respiratory and other diseases and infections with significant unmet medical needs.

On February 5, 2019, the Company effectuated a 1-for-10 reverse stock split of its issued and outstanding shares of common stock (the "Reverse Stock Split") pursuant to which every 10 shares of the Company's issued and outstanding common stock were automatically converted into 1 share of common stock.

2. Summary of Significant Accounting Policies and Recent Accounting Standards

Basis of Presentation

Principles of Consolidation

The consolidated financial statements represent the consolidation of the accounts of the Company and its subsidiary in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP"). All intercompany accounts and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

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

Concentrations of Credit Risk and Off-Balance Sheet Arrangements

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

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

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents are held in U.S. banks and consist of liquid investments and money market funds with a maturity from date of purchase of 90 days or less that are readily convertible into cash. Cash and cash equivalents consist of cash, checking accounts and money market accounts. Restricted cash consists of cash deposited with a financial institution for $204.

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

At December 31, 2020 and 2019, the Company had a $153 letter of credit as a security deposit on its leased office and laboratory facility that was renewed and currently expires on August 14, 2022. The letter of credit is secured by a deposit in a money market account, as well as $51 deposited in a money market account as security for a credit card.

The following table provides a reconciliation of cash, cash equivalents and restricted cash as reported in the consolidated balance sheets that sum to the total of the same amounts in the statement of cash flows.

	Year Ended	
	2020	2019
Cash and cash equivalents	$ 31,657	$ 23,440
Restricted cash	204	204
Total cash, cash equivalents and restricted cash	$ 31,861	$ 23,644

Property and Equipment, net

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

Depreciation and amortization is provided over the following estimated useful lives:

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

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

Impairment of Long-Lived Assets

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

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

Fair Value of Financial Instruments

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

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

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

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

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

Leases

During 2019, the Company adopted ASC Topic 842, *Leases*, effective January 1, 2019, using the modified retrospective approach through a cumulative-effect adjustment and utilizing the effective date as its date of initial application, with prior periods unchanged and presented in accordance with the guidance in Topic 840, Leases ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. Options to renew a lease are not included in the Company's initial lease term assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its material leases on a quarterly basis.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items, such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASC 842, components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g. common area maintenance, consumables, etc.), and non-components (e.g. property taxes, insurance, etc.) Then the contract consideration (including any related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, a certain policy election is available in which an entity may elect to not separate lease and non-lease components. Rather, each lease component and the related non-lease components would be accounted for together as a single component. The Company has elected to account for the lease and non-lease components as a combined lease component.

Revenue Recognition

Effective January 1, 2019, the Company adopted ASC 606, using the modified retrospective transition method. Under this method, results for reporting periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with ASC Topic 605, *Revenue Recognition* (ASC 605). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses. If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a promise or performance obligation is distinct from the other promises, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining promise, whether the value of the promise is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Research and Development Services. The promises under the Company's collaboration agreements may include research and development services to be performed by the Company on behalf of the partner. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts. Reimbursements from and payments to the partner that are the result of a collaborative relationship with the partner, instead of a customer relationship, such as co-development activities, are recorded as a reduction to research and development expense.

Customer Options. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options that are not determined to be material rights are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised. As of December 31, 2020, the Company does not have any active arrangements that contain customer options.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. As of December 31, 2020, the Company has an active arrangement that contains a research or development milestone see Note 5, *Significant Agreements*.

Royalties. For arrangements that include sales-based royalties, including milestone payments upon first commercial sales and milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. As of December 31, 2020, the Company has an active licensing arrangement that contains royalty provisions and is recognizing royalty revenue as a result.

For a complete discussion of accounting for collaboration revenues, see Note 5, *Significant Agreements*.

Research and Development Costs

Research and development costs are expensed as incurred and include: salaries, benefits, bonus, share-based compensation, license fees, milestone payments due under license agreements, costs paid to third-party contractors to perform research, conduct clinical trials, and develop drug materials and delivery devices; and associated overhead and facilities costs. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors, clinical research organizations ("CROs") and clinical manufacturing organizations ("CMOs"). Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of fees and costs associated with the contract that were rendered during the period and they are expensed as incurred. Research and development costs that are paid in advance of performance are capitalized as prepaid expenses and amortized over the service period as the services are provided. As of December 31, 2020, the Company has an active arrangement with JJEI that contains a research or development milestone.

Share-Based Compensation

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

Share-based payments to non-employees are recognized as services are rendered, generally on a straight-line basis. The Company believes that the fair values of these awards are more reliably measurable than the fair values of the services rendered.

Common Stock Warrants

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

Basic and Diluted Net Loss Per Share

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

Income Taxes

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

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

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired, and liabilities assumed under the acquisition method of accounting for push-down accounting. Goodwill is not amortized but is evaluated for impairment within the Company's single reporting unit on an annual basis during the fourth quarter, or more frequently if an event occurs or circumstances change that would more likely than not reduce the fair value of the Company's reporting unit below its carrying amount. When performing the impairment assessment, the accounting standard for testing goodwill for impairment permits a company to first assess the qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the goodwill is impaired. If the Company believes, as a result of the qualitative assessment, that it is more likely than not that the fair value of goodwill is impaired, the Company then must perform a quantitative analysis to determine if the carrying value of the goodwill exceeds the fair value of the Company. Based on the quantitative analysis done during the fourth quarter in 2020, goodwill was determined not to be impaired. Based on a qualitative and quantitative analysis done during 2019, goodwill was determined to be impaired and at December 31, 2019, a charge of $7,268 was recorded.

Recently Adopted Accounting Standards

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The new standard will align the requirements for capitalizing implementation costs for hosting arrangements (services) with costs for internal-use software (assets). As a result, certain implementation costs incurred in hosting arrangements will be deferred and amortized. The new standard became effective for the Company on January 1, 2020. The Company has adopted ASU 2018-13, and adoption of this ASU has no significant impact on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement*. ASU 2018-13 modifies the disclosure requirements for fair value measurements by removing, modifying or adding certain disclosures. The amendments in ASU 2018-13 became effective for fiscal years beginning after December 15, 2019. The Company has adopted ASU 2018-13, and adoption of this ASU has no significant impact on its condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, *"Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)"* ("ASU 2020-06"). ASU 2020-06, which simplifies the guidance on accounting for convertible debt instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature. As a result, the Company will not separately present in equity an embedded conversion feature in such debt. Instead, we will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. We expect the elimination of these models will reduce reported interest expense and increase reported net income for the Company's convertible instruments falling under the scope of those models before the adoption of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and the treasury stock method will be no longer available. The provisions of ASU 2020-06 are applicable for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements.

During the year ended December 31, 2020, other than ASUs 2020-06, there have been no new, or existing recently issued, accounting pronouncements that are of significance, or potential significance, that impact the Company's consolidated financial statements.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
	2020	**2019**
Prepaid insurance	$ 276	$ 202
Prepaid clinical trials	317	322
Prepaid other	130	221
Deferred operating costs	74	32
Total prepaid expenses and other current assets	$ 797	$ 777

4. Property and Equipment, Net

Property and equipment consisted of the following:

	As of December 31,	
	2020	**2019**
Laboratory equipment	$ 1,702	$ 1,538
Computer equipment	302	217
Office furniture and equipment	217	217
Leasehold improvements	596	581
Capital in progress	25	2
Total property and equipment	2,842	2,555
Less accumulated depreciation and amortization	(2,481)	(2,285)
Property and equipment, net	$ 361	$ 270

Depreciation and amortization expense for the years ended December 31, 2020 and 2019 was $215 and $182, respectively. During the years ended 2020 and 2019, the Company recorded gross fixed asset disposals of $19 and $13 and their related accumulated depreciation of $19 and $13, respectively.

5. Significant Agreements

License, Development and Commercialization Agreement with JJEI

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

The RespiVert License Agreement terminates upon the expiration of the Company's obligation to pay royalties for all licensed products, unless earlier terminated. In addition, the RespiVert License Agreement may be terminated (i) by the Company for any reason upon 120 days' advance notice to RespiVert; (ii) by RespiVert upon receipt of notice from the Company of either voluntary or involuntary insolvency proceedings of the Company; and (iii) by either party for a material breach which remains uncured following the applicable cure period.

Under the terms of the RespiVert License Agreement, the Company paid RespiVert an up-front, non-refundable license fee of $1,000 in partial consideration for the rights granted by RespiVert to the Company and will pay RespiVert designated amounts when any licensed product achieves certain developmental milestones. On December 26, 2019, the Company entered into a License, Development and Commercialization Agreement (the "JJEI License Agreement") with JJEI pursuant to which the Company provided JJEI an assignment option of all of its rights under the RespiVert License Agreement.

Under the terms of the JJEI License Agreement, the Company granted JJEI an option to acquire (1) the Company's rights to an intellectual property portfolio of materials and technology related to narrow spectrum kinase inhibitor compounds (the "Licensed Product") and (2) an exclusive, worldwide, royalty bearing license to PUR1800, the Company's inhaled iSPERSE drug delivery system as formulated with one of the kinase inhibitor compounds. The Company began a chronic toxicology program in 2020 and will begin a clinical study in early 2021 which is focused on chronic obstructive pulmonary disease ("COPD") and lung cancer interception.

As consideration for the Company's entry into the JJEI License Agreement, JJEI paid the Company an upfront fee of $7,200 to conduct the research on the Phase 1b clinical study and will also fund $3,400 for the toxicology study costs. The Company is also eligible to earn a $2,000 milestone payment for the completion of the Phase 1b study of the Licensed Product. If JJEI exercises the option, Pulmatrix is eligible to receive a $14,000 option exercise payment, up to an additional $32,000 in development milestone payments, $45,000 in commercial milestones, as well as royalty payments ranging from 1% to 2% of sales.

Under the JJEI License Agreement, JJEI will have three months from the later of (1) the completion of a Phase 1b clinical study for the Licensed Product and JJEI's receipt of audited final reports and (2) JJEI's receipt of audited draft reports for the chronic toxicology program of the Licensed Product to exercise the option. If the option is not exercised, Pulmatrix may terminate the JJEI License Agreement by providing a 30 day written notice, and all licenses revert back to Pulmatrix. The agreement may otherwise be terminated by JJEI for any reason upon 90 days advance notice, or upon notice of the Company's entering into insolvency or bankruptcy proceedings. Either party may terminate the agreement for material breach of contract that is not cured within 60 days.

Accounting Treatment

Revenue associated with the combined research and development services for the Product and the irrevocable license to the Assigned Assets is recognized as revenue as the research and development services are provided using an input method, according to the ratio of costs incurred to the total costs expected to be incurred in the future to satisfy the performance obligation. In management's judgment, this input method is the best measure of the transfer of control of the performance obligation. The amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company's consolidated balance sheet. During 2020, the Company recognized $1,647 in revenue related to the toxicology study costs and $5,207 in revenue related to the license agreement in the Company's consolidated statement of operations. As of December 31, 2020, $1,993 was recorded as deferred revenue, all of which is current. The Company expects to recognize the deferred revenue according to costs incurred, over the remaining research term, which is expected to be completed during the third quarter of 2021.

Collaborations - Development and Commercialization Agreement with Cipla

On April 15, 2019 ("Effective Date"), the Company entered into a Development and Commercialization Agreement (the "Cipla Agreement") with Cipla Technologies, LLC. (Cipla") for the worldwide development and commercialization of Pulmazole (the "Product"), an inhaled formulation of the anti-fungal drug itraconazole (developed using iSPERSE technology designed to treat allergic bronchopulmonary aspergillosis ("ABPA") in patients with asthma.

Pursuant to the Cipla Agreement, the Company is responsible for the development of the Product in accordance with the development plan, which includes completion of the Phase 2 ABPA study, as well as any additional Phase 2/2b and/or Phase 3 clinical studies that may be required for regulatory approval. In addition, the Company will be responsible for submission of investigational new drug ("IND") applications, annual reports and other regulatory filings to the extent required to conduct the development activities, including any clinical studies. Subsequent to regulatory approval of the Product for marketing in the U.S. or in any other country, Cipla will be responsible for the implementation of the commercialization plan, including all activities, arrangements and other matters related to commercialization.

The Company received a non-refundable upfront payment of $22,000 under the Cipla Agreement (the "Upfront Payment"). Upon receipt of the Upfront Payment, the Company irrevocably assigned to Cipla the following assets, solely to the extent that each covers the Product in connection with any treatment, prevention, and/or diagnosis of diseases of the pulmonary system ("Pulmonary Indications"): all existing and future technologies, current and future drug master files, dossiers, third-party contracts, regulatory filings, regulatory materials and regulatory approvals, patents, and intellectual property rights, as well as any other associated rights and assets directly related to the Product, specifically in relation to Pulmonary Indications (collectively, the "Assigned Assets"), excluding most specifically the Company's iSPERSE technology. A portion of the Upfront Payment was deposited by the Company into a bank account, along with an equal amount from the Company, and will be dedicated to the development of the Product (the "Initial Development Funding"). After the Initial Development Funding is depleted, the Company and Cipla will each be responsible for 50% of the development costs actually incurred (the "Co-Development Phase").

The Company and Cipla have established a joint steering committee (the "JSC"). The JSC will, among other powers and responsibilities, direct the further development and commercialization activities, including all budgetary activities in relation to the Product. The JSC will oversee the performance of the Company and Cipla under the Cipla Agreement and will provide a forum for sharing advice, progress and results relating to such activities. The JSC is also responsible for reviewing and approving the development plan developed by the Company, and the commercialization plan developed by Cipla.

The Cipla Agreement will remain in effect in perpetuity, unless otherwise earlier terminated in accordance with its terms. In the event of circumstances affecting the continuity of development of the Product in line with the Cipla Agreement, the JSC will evaluate the cause and effect and make a recommendation as to the most optimal option available to Cipla and the Company. In any event, either the Company or Cipla may elect to terminate (a "Terminating Party") its obligation to fund additional costs and expenses for the development and/or commercialization of the Product. If the non-Terminating Party wishes to continue the development of the Product, it will have the right to purchase the rights of the Terminating Party in the Product at fair market value. If both the Company and Cipla abandon the development program, the Company and Cipla shall make commercially reasonable efforts to monetize the Product and development program in connection with the Pulmonary Indications. The Company and Cipla will equally share the proceeds.

The Cipla Agreement also contains customary representations, warranties, and covenants by both parties, as well as customary provisions relating to indemnification, confidentiality and other matters.

In July of 2019, the Company initiated a Phase 2 clinical study for Pulmazole, our formulation of inhaled itraconazole, an anti-fungal drug that is only commercially available as an oral drug. Due to delays in patient enrollment in the Phase 2 clinical study, exacerbated by the ongoing COVID-19 pandemic, Cipla informed us that it desired to amend the Cipla Agreement. In connection with our renegotiation of the Cipla Agreement, on July 10, 2020, the Pulmatrix/Cipla steering committee recommended the termination of the Phase 2 study due the COVID-19 pandemic.

The Company conducted a Type C meeting with the FDA on January 27, 2021 and leveraging the insights gained from this meeting, now plan to commence the Phase 2b study when the risks of study conduct presented by the ongoing COVID-19 pandemic is reduced to an acceptable level. The Phase 2b study design includes a 16-week dosing regimen as well as an exploration of potential efficacy endpoints, whereas the terminated Phase 2 study comprised only a 4 week dosing regimen with safety and tolerability as its primary endpoint. The longer dosing regimen of the planned new Phase 2b study is supported by the 6-month inhalation toxicology study in dogs completed in April 2020.

In addition to the planned new Phase 2b study, as part of the contemplated amendments to the Cipla Agreement, the Company may assign to Cipla the exclusive rights to develop and commercialize Pulmazole in India, South Africa and other regional markets where Cipla has strong clinical development and business capabilities. The Company has not agreed to any amendments to the Cipla Agreement as of the date of the filing this Annual Report. However, it is expected that discussions regarding amendments to the Cipla Agreement will continue. No assurance can be given that the Company will be able to reach a mutually acceptable arrangement with Cipla for the conduct of the Phase 2b clinical study in the future. Accordingly, if the Company is unable to agree with Cipla on such matters such as cost sharing for the new study, further development of Pulmazole may be suspended.

Accounting Treatment

The Company concluded that because both it and Cipla are active participants in the arrangement and are exposed to the significant risks and rewards of the collaboration, the Company's collaboration with Cipla is within the scope of ASC 808 Collaborative Arrangements ("ASC 808") for accounting purposes. Contemplating the guidance of ASU 2018-18, the Company concluded that because Cipla contracted with the Company to obtain research and development services and an irrevocable license to the Assigned Assets, each of which is an output of the Company's ordinary activities in exchange for consideration, Cipla is a customer. Therefore, in order to determine the appropriate treatment for the research and development services and the license grant, the Company has applied the guidance in ASC 606 Revenue from Contracts with Customers ("ASC 606") to account for and present consideration received from Cipla. Accordingly, the Company identified the following material promises under the arrangement: (1) the research and development services for the Product and (2) an irrevocable license to the Assigned Assets. The Company determined that the research and development services and license to the Assigned Assets are considered highly interdependent and highly interrelated and combined into a single performance obligation because it is impossible for Cipla to benefit from the license to the Assigned Assets without the performance by Pulmatrix of the research and development services. Such research and development services are highly specialized and proprietary to Pulmatrix and therefore not available to Cipla from any other third party.

The Company determined the total transaction price to be $22,000 – comprised of $12,000 for research and development services for the Product and $10,000 for the irrevocable license to the Assigned Assets. Any consideration related to the Co-Development Phase has not been included in the transaction price as such amounts are subject to the variable consideration constraint. Additionally, upon Commercialization, Cipla and the Company will share equally, both positive and negative total free cash-flows earned by Cipla in respect of the Product. However, the Company has not included such free cash-flows in the transaction price as these milestones are constrained until after the commercialization of the Product.

Revenue associated with the combined research and development services for the Product and the irrevocable license to the Assigned Assets is recognized as revenue as the research and development services are provided using an input method, according to the ratio of costs incurred to the total costs expected to be incurred in the future to satisfy the performance obligation. In management's judgment, this input method is the best measure of the transfer of control of the performance obligation. The amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company's consolidated balance sheet.

The Company received the $22,000 upfront payment in May 2019. During 2020, the Company recognized $4,629 in revenue related to the research and development services and $1,120 in revenue for the irrevocable license to the Assigned Assets in the Company's consolidated statements of operations. The aggregate amount of the transaction price related to the Company's unsatisfied performance obligations and at December 31, 2020 the Company recorded $8,341 in deferred revenue, $2,173 of which is current. The Company expects to recognize the deferred revenue according to costs incurred, over the remaining research term, which is expected to be completed during the second half of 2023.

Collaboration and License Agreement with Sensory Cloud

On April 9, 2020, the Company entered into a Collaboration and License Agreement (the "Sensory Cloud Agreement") with Sensory Cloud, Inc. ("Sensory Cloud"). Under the terms of the Agreement, the Company has granted Sensory Cloud an exclusive, worldwide, royalty bearing license to PUR003 and PUR006, the Company's proprietary aerosol salt solution for delivery or administration to or through the nasal passages, as well as related patents and know-how, for use in the field (the "Licensed Product"). PUR003 and PUR006, also known as NasoCalm, was originally developed by the Company as a potential anti-infective biodefense medical countermeasure product. Sensory Cloud will be using NasoCalm, now integral in their product FEND, a hypertonic calcium chloride salt solution with nasal mister. For purposes of the Sensory Cloud Agreement, the field means the formulation and commercialization of over-the-counter products for the prophylaxis, prevention and treatment of upper and lower respiratory disease that are delivered or administered to or through the nasal passages. The license granted to Sensory Cloud does not cover the development or commercialization of any prescription products.

Under the terms of the Agreement, Sensory Cloud may develop other over-the-counter Licensed Products that contain other active pharmaceutical ingredients or therapeutic agents and combine the Licensed Product with one or more of Sensory Cloud's proprietary delivery devices. In addition, Pulmatrix has granted Sensory Cloud an exclusive right of first refusal to any new over-the-counter products in the field that may be developed by Pulmatrix.

During the term of the Sensory Cloud Agreement, neither party may alone or with, through or for the benefit of any third party, with respect to any Licensed Product in the field, pursue any research, development or commercialization activities specifically directed to development or commercialization of any Licensed Product.

Pulmatrix shall be entitled to royalties on net sales of Licensed Product in each country in which there is a valid claim of a patent within the licensed intellectual property covering the Licensed Product. Pulmatrix' rights to receive such royalties commences upon the first commercial sale of a Licensed Product in any such country and terminates upon the expiration of the last valid claim in such territory. The royalty rates are as follows: (1) 7% of net sales during calendar year 2020, (2) 14% of net sales during calendar year 2021, and (3) 17% of net sales during calendar year 2022 and each calendar year thereafter during the royalty term. In addition, Pulmatrix shall be entitled to receive a milestone payment of $1,000 following the achievement of aggregate net sales of all Licensed Products of $20,000.

The Agreement shall terminate at such time that Pulmatrix would no longer be entitled to royalties because there are no longer any valid claims of a patent within the licensed intellectual property covering any Licensed Product. Upon there being no more such royalty payments owed by Sensory Cloud for a Licensed Product, the licenses granted by Pulmatrix to Sensory Cloud shall become fully paid up, royalty free, perpetual, irrevocable and non-exclusive licenses to such Licensed Product. The Agreement may also be terminated earlier by Sensory Cloud for convenience and by Sensory Cloud or Pulmatrix for material breach or upon the bankruptcy or insolvency of the other party.

Accounting Treatment

Royalty revenues from the Company's agreements with third parties are recognized when the Company can reasonably determine the amounts earned. This will be upon notification from Sensory Cloud, which is typically during the quarter following the quarter in which the sales occurred. The Company does not participate in the selling or marketing of products for which it receives royalties. No provision for uncollectible accounts is established upon recognition of revenues. Sensory Cloud commenced their product launch in October 2020 and delivered the net sales report within the 90-day term following the end of the fourth quarter. Immaterial royalty revenue was recorded for the fourth quarter 2020.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following:

	As of December 31,	
	2020	**2019**
Vacation	$ 56	$ 42
Wages and incentive	813	527
Clinical & consulting	1,010	1,820
Legal & patent	129	85
Other expenses	20	40
Total accrued expenses	$ 2,028	$ 2,514

7. Common Stock

2020

On July 9, 2020, the Company entered into letter agreements with certain existing accredited investors to exercise certain existing and outstanding warrants ("Existing Warrants") to purchase through a cash exercise up to an aggregate of 10,085,741 shares of the Company's common stock at the existing exercise price of $1.35 per share. The Existing Warrants were issued in an underwritten public offering pursuant to a registration statement on Form S-1 and an additional registration statement on Form S-1 filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, that was consummated in April 2019

In consideration for the exercise of the Existing Warrants for cash, the Company agreed to issue the exercising holders new unregistered warrants ("Inducement Warrants") in three tranches which occurred on July 13, 2020, July 23, 2020, and August 7, 2020, to purchase up to an aggregate of 10,085,741 shares of common stock at an exercise price of $1.80 per share and with an exercise period of five years from July 14, 2020. The gross proceeds to the Company from the exercise of 10,085,741 warrants was approximately $13,616. After deducting placement agent fees and offering expenses of approximately $1,112, the Company recorded net proceeds of $12,504.

As compensation, the Company issued warrants to designees of the placement agent on substantially the same terms as the Inducement Warrants to purchase up to an aggregate of 655,573 shares of common stock in two tranches which occurred on July 13, 2020 and August 7, 2020, at an exercise price per share of $2.25 with an exercise period of five years from July 14, 2020.

All Inducement Warrants and the placement warrants were registered pursuant to a registration statement on Form S-3, which was declared effective on August 13, 2020. At issuance, the Inducement Warrants and the placement agent warrants had a weighted average fair value of approximately $0.92 and $0.87 per award, respectively. These weighted average fair values were estimated using the Black-Scholes option-pricing model with the following assumptions: expected life of 5 years, expected volatility of 99.0%, risk-free interest rate of 0.28% and expected dividend yield of 0.0%. The weighted average grant date fair value of approximately $9,289 associated with the Inducement Warrants, was recorded as a warrant inducement expense in the accompanying statements of operations with an offset to additional paid-in capital.

Exercise of Warrants

During 2020 the Company issued 11,300,487 shares of common stock upon exercise of 10,085,741 warrants issued in the July 2020 warrant exercise inducement to purchase 10,085,741 shares of common stock, 1,117,184 warrants issued in the April 2019 public offering to purchase 914,746 shares of common stock and 300,000 pre-funded warrants issued in the April 2019 public offering to purchase 300,000 shares of common stock. The Company collected net proceeds of $13,643 upon the exercise of these warrants.

Registered Direct Offering

On April 20, 2020, the Company sold 4,787,553 shares at $1.671 per share, pursuant to a securities purchase agreement, dated as of April 16, 2020, by and among the Company and certain institutional investors, for gross proceeds of approximately $8,000. After deducting placement agent fees and offering expenses of approximately $686, the Company recorded net proceeds of $7,314. In a concurrent private placement, the Company issued warrants to purchase an aggregate of up to 4,787,553 shares of its common stock to investors with an exercise price of $1.55 per share and an expiration date of April 20, 2022. In addition, the Company issued warrants to purchase up to 311,191 shares of its common stock to the designees of the placement agent with an exercise price of $2.0888 per share and an expiration date of April 20, 2022. The investor and placement agent warrants have a fair value of approximately $0.64 and $0.54 per share, respectively.

Exercise of Stock Options

During 2020, stock options to buy 22,497 shares were exercised, and the Company collected proceeds $24.

2019

Confidential Marketed Public Offering ("CMPO")

On January 31, 2019 and February 4, 2019, the Company closed two CMPOs, pursuant to which the Company sold 156,118 and 532,353 shares of common stock, respectively, at $1.70 per share and issued warrants to exercise 10,151 and 34,605 shares of common stock, respectively, to underwriters at an exercise price of $2.125 per share with expiration dates of January 26, 2024 and January 30, 2024, respectively. The underwriter warrants had a fair value of $0.9332 and $1.1946 per share at the January 31, 2019 and February 4, 2019 issuance date, respectively. Prior to deducting fees and commissions for both offerings, the Company recorded aggregate gross proceeds of approximately $1,170.

Registered Direct Offering

On February 12, 2019, the Company sold 1,706,484 shares at $1.465 per share. In this registered direct offering, the Company issued warrants to purchase 1,706,484 shares of its common stock to investors with an exercise price of $1.34 and a fair value of $0.5962 per share, with an expiration date of August 12, 2024. In addition, the Company issued warrants to purchase 110,922 shares of its common stock to underwriters with an exercise price of $1.8313 per share and an expiration date of February 7, 2024. The underwriter warrants had a fair value of $0.5314 per share at the issuance date. The Company recorded gross proceeds of approximately $2,500.

After giving effect to approximately $691 of fees and expenses associated with the CMPOs and the Registered Direct offering, the Company recorded net proceeds of approximately $2,979.

Public Offering

On April 8, 2019, the Company closed its underwritten public offering in which, pursuant to the underwriting agreement entered into between the Company and H.C. Wainwright & Co., LLC, as representative of the underwriters, dated April 3, 2019, the Company issued and sold an aggregate of (i) 1,719,554 common units, with each common unit being comprised of one share of the Company's common stock, par value $0.0001 per share and one warrant to purchase one share of common stock and (ii) 8,947,112 pre-funded units with each pre-funded unit being comprised of one pre-funded warrant to purchase one share of common stock and one common warrant to purchase one share of common stock. The public offering price was $1.35 per common unit and $1.34 per pre-funded unit. The common warrants have an exercise price of $1.35 per share. In addition, on April 8, 2019, the Company closed on the sale of an additional 1,599,999 common units purchased pursuant to the exercise in full of the underwriter's option to purchase additional securities. Each common unit contains one share of common stock and one common warrant to purchase a share of common stock. The common warrants issued on April 8, 2019 have a fair value of $0.997 per share.

Warrants were also issued to the underwriters to purchase 797,334 shares of common stock with an exercise price of $1.6875 and a fair value of $1.2632 per share. Both the common and underwriter warrants have an exercise term of five years and are exercisable immediately following their issuance.

All pre-funded warrants issued in the offering were exercised during 2019. 8,647,112 shares of common stock were issued in 2019 and 300,000 shares of common stock were issued in January 2020 which resulted in net proceeds of $90.

After giving effect to the exercise of the Underwriters' overallotment option, the gross aggregate proceeds from the offering on April 8 was $16,470, prior to deducting underwriting discounts and commissions and other estimated offering expenses. The Company agreed to pay H.C. Wainwright & Co, LLC a commission of 7% of the gross proceeds and also agreed to pay or reimburse certain expenses on behalf of H.C. Wainwright. A total of $1,904 of commissions and other issuance costs were associated with the public offering.

During 2019, after giving effect to fees, commissions and other expenses of approximately $2,595, the Company recorded net proceeds of $17,705 for the sale of the CMPOs, the registered direct offering, the public offering and the pre-funded warrant exercises.

Exercise of Warrants

All pre-funded warrants issued in the November 2018 securities purchase agreement with an institutional investor were exercised in 2019, 697,500 common shares were issued, and the Company recorded $70 in net proceeds. Of the 8,947,112 pre-funded warrants issued as a result of the April 8, 2019 public offering, 8,647,112 were exercised during 2019 and 300,000 were exercised in 2020. The Company recorded $90.

8. Warrants

A rollforward of the common stock warrants outstanding at December 31, 2019 and 2020 is as follows.

	Number of Common Warrants	Number of Pre-funded Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2019	3,730,944	697,500	$ 10.78	4.30	$ —
Warrants issued	14,926,161	—	$ 1.37		
Pre-funded warrants issued	—	8,947,112	$ 0.01		
Pre-funded warrants exercised	—	(9,344,612)	$ (0.01)		
Expirations	(3,926)	—	$ 226.60		
Adjustment for reverse stock split	16	—			
Outstanding December 31, 2019	18,653,195	300,000	$ 3.61	4.17	$ —
Warrants issued	15,840,058	—	$ 1.75		
Warrants exercised	(11,202,925)	—	$		
Pre-funded warrants exercised		(300,000)	$ (0.01)		
Expirations	(5,515)	—	$ 102.27		
Outstanding December 31, 2020	23,284,813	—	$ 3.41	3.3	$ —

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

				Number of Shares Underlying Warrants For the Year Ended December 31,	
Issue Date	Classification	Exercise Price	Expiration Date	2020	2019
August 7, 2020	Equity	$ 1.80	July 14, 2025	1,814,815	
August 7, 2020	Equity	$ 2.25	July 14, 2025	218,713	
July 23, 2020	Equity	$ 1.80	July 14, 2025	1,550,000	
July 13, 2020	Equity	$ 2.25	July 14, 2025	436,860	
July 13, 2020	Equity	$ 1.80	July 14, 2025	6,720,926	
April 20, 2020	Equity	$ 1.55	April 20, 2022	4,787,553	
April 20, 2020	Equity	$ 2.0888	April 20, 2022	311,191	
April 8, 2019	Equity	$ 0.01	Pre-funded	—	300,000
April 8, 2019	Equity	$ 1.35	April 8, 2024	1,336,777	12,266,665
April 8, 2019	Equity	$ 1.6875	April 3, 2024	797,334	797,334
February 12, 2019	Equity	$ 1.8313	February 7, 2024	110,922	110,922
February 12, 2019	Equity	$ 1.34	August 12, 2024	1,433,447	1,706,484
February 04, 2019	Equity	$ 2.125	January 30, 2024	34,605	34,605
January 31, 2019	Equity	$ 2.125	January 26, 2024	10,151	10,151
December 3, 2018	Equity	$ 3.90	June 3, 2024	937,500	937,500
April 3, 2018	Equity	$ 7.50	April 3, 2023	2,350,011	2,350,011
April 4, 2018	Equity	$ 7.50	April 4, 2023	115,000	115,000
August 31, 2015	Equity	$ 118.00	August 31, 2020	—	3,000
June 15, 2015	Equity	$ 75.50	Five years after milestone achievement	319,008	319,008
June 15, 2015	Equity	$ 83.50	June 16, 2020	—	2,515
Total Outstanding				23,284,813	18,953,195

9. Share-Based Compensation

The Company sponsors the Pulmatrix, Inc. 2013 Employee, Director and Consultant Equity Incentive Plan (the "2013 Plan"). As of December 31, 2020, the 2013 Plan provided for the grant of up to 4,060,000 shares of the Company's common stock, of which 1,090,350 shares remained available for future grant. As of December 31, 2019, the 2013 Plan provided for the grant of up to 4,060,000 shares of the Company's common stock, of which 3,121,545 shares remained available for future grant.

In addition, the Company sponsors two legacy plans under which no additional awards may be granted. As of December 31, 2020, the two legacy plans have a total of 7,001 options outstanding all of which are fully vested and for which common stock will be delivered upon exercise.

Options

During the year ended December 31, 2020, the Company granted options to purchase 2,089,304 shares of the Company's common stock to employees, options to purchase 215,000 shares of the Company's common stock to directors and options to purchase 40,000 shares of the Company's common stock were granted to advisors. The stock options granted vest over time (the "Time Based Options"). Time Based Options vest over either 36 or 48 months. Subject to the grantee's continuous service with the Company, Time Based Options vest in one of the following ways: (i) 25% at the one year anniversary of the Vesting Start Date and the remainder in 36 equal monthly installments beginning in the thirteenth month after the Vesting Start Date or (ii) in 48 equal monthly installments beginning on the first monthly anniversary after the Vesting Start Date or (iii) 25% at the time of grant and the remainder in 36 equal monthly installments beginning in the first month after the Vesting Start Date. Stock options expire ten years after the date of grant.

The following table summarizes stock option activity for the years ended December 31, 2019 and 2020:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding — January 1, 2019	972,569	$ 23.85	8.46	$ —
Granted	651,600	$ 1.06		
Exercised	—	—		
Forfeited or expired	(724,166)	$ (18.54)		
Outstanding — December 31, 2019	900,003	$ 11.63	8.52	$ —
Granted	2,344,304	$ 1.52		
Exercised	(22,497)	$ (1.06)		
Forfeited or expired	(321,973)	$ (14.53)		
Outstanding — December 31, 2020	2,899,837	$ 3.22	8.75	$ 60
Exercisable — December 31, 2020	991,443	$ 6.44	8.33	$ 24

The estimated fair values of employee stock options granted during the year ended December 31, 2020 and 2019, were determined on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	For the year ended December 31,	
	2020	2019
Expected option life (years)	5.93	6.02
Risk-free interest rate	1.57%	2.22%
Expected volatility	93.93%	74.14%
Expected dividend yield	0%	0%

The risk-free interest rate was obtained from U.S. Treasury rates for the applicable periods. The Company's expected volatility was based upon the weighted average of historical volatility for industry peers and its own volatility. The expected life of the Company's options was determined using the simplified method as a result of limited historical data regarding the Company's activity. The dividend yield considers that the Company has not historically paid dividends and does not expect to pay dividends in the foreseeable future.

As of December 31, 2020, there was $2,108 of unrecognized stock-based compensation expense related to unvested stock options granted under the Company's stock award plans. This expense is expected to be recognized over a weighted-average period of approximately 2.7 years.

The following table presents total stock-based compensation expense for the years ended December 31, 2020 and 2019, respectively:

	For the years ended December 31,	
	2020	2019
Research and development	$ 185	$ 156
General and administrative	973	1,910
Total stock-based compensation expense	$ 1,158	$ 2,066

10. Commitments and Contingencies

Research and Development Activities

The Company contracts with various other organizations to conduct research and development activities. As of December 31, 2020, we had aggregate commitments to pay approximately $1.1 million remaining on these contracts. The scope of the services under contracts for research and development activities may be modified and the contracts, subject to certain conditions, may generally be cancelled by us upon written notice. In some instances, the contracts, subject to certain conditions, may be cancelled by the third party.

Operating Leases

The Company has limited leasing activities as a lessee and are primarily related to its corporate headquarters located at 99 Hayden Avenue, Suite 390, Lexington, Massachusetts. The lease is for approximately 22,119 square feet of office and lab space under a lease that originally expired on December 31, 2020. On April 23, 2020, an extension to our lease for office and lab space was signed between us and 99 Hayden LLC and will expire on June 30, 2022.

The lease provides for base rent, and the Company is responsible for real estate taxes, maintenance, and other operating expenses applicable to the leased premises.

The Company also leases small office equipment which is primarily short-term or immaterial in nature. Therefore, no right-of-use assets and lease liabilities are recognized for these leases.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

Effective January 1, 2019, the Company used the modified retrospective approach through a cumulative-effect adjustment and utilizing the effective date as its date of initial application, with prior periods unchanged and presented in accordance with the guidance in ASC 840. As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

Since the Company elected to account for each lease component and its associated non-lease components as a single combined lease component, total contract consideration was allocated to the combined lease component.

The expected lease terms include non-cancelable lease periods. Renewal option periods were not included in the determination of the lease terms as they were not reasonably certain to be exercised.

The components of lease expense for the Company for the years ended December 31, 2020 and 2019 were as follows:

	For the years ended December 31,	
	2020	2019
Lease Cost		
Fixed lease cost	$ 909	$ 654
Variable lease cost	421	381
Total lease cost	$ 1,330	$ 1,035
Other information		
Immaterial office equipment lease obligation, 4 year lease	$ 15	$ 5
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 698	$ 676
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 1,687	$ 1,213
Weighted-average remaining lease term — operating leases	1.5 years	
Weighted-average discount rate — operating leases	5.23%	7.44%

	For the years ended December 31,	
	2020	2019
Balance Sheet Classification:		
Right-of-use Assets		
Operating Lease Assets	$ 1,489	$ 630
Total Lease Assets	$ 1,489	$ 630

Maturities of lease liabilities due under these lease agreements as of December 31, 2020 are as follows:

	Operating Leases
Maturity of lease liabilities	
2021	$ 1,194
2022 (half year)	615
Total lease payments	1,809
Less: interest	(66)
Total lease liabilities	$ 1,743

	Operating Leases
Reported as of December 31, 2020	
Lease liabilities — short term	$ 1,135
Lease liabilities — long term	608
Total	$ 1,743

11. Income Taxes

The Company had no income tax expense due to operating losses incurred for the year ended December 31, 2020 and 2019.

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

	2020	2019
Income tax computed at federal statutory tax rate	21.0%	21.00%
State taxes, net of federal benefit	3.10%	3.90%
Research and development credits	2.60%	2.00%
Expiration of stock options	(2.30)%	(7.30)%
Write-down of goodwill assets	—	(7.40)%
Non-deductible warrant inducement	(10.10)%	—
Permanent differences	(0.40)%	(0.60)%
Limitations on Credits and Net Operating Losses	(5.30)%	(171.30)%
Other	(0.80)%	(1.40)%
Change in valuation allowance	(7.80)%	161.10%
Total	0.0%	0.0%

The significant components of the Company's deferred tax assets as of December 31, 2020 and 2019 were as follows:

	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 8,732	$ 9,077
Research and development credit carryforwards	356	382
Capitalized start-up expenses	572	711
Stock Compensation	664	1,031
Lease Liability	476	184
Other	2,716	382
Total deferred tax assets	13,516	11,767
Deferred tax liabilities:		
Right of Use Asset	(407)	(172)
Total deferred tax liabilities	(407)	(172)
Valuation allowance	(13,109)	(11,595)
Net deferred tax liabilities	$ —	$ —

At December 31, 2020, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately $38,220 and $11,168 respectively, which were available to reduce future taxable income. The Company has unlimited federal net operating loss carryforwards of $26,752 and federal and state net operating loss carryforwards of $11,468 and $11,168 respectively, will expire at various dates from 2023 through 2040. The Company has research and development credits for federal and state income tax purposes of approximately $278 and $99, respectively, which expire at various dates from 2022 through 2040.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception which it believes has resulted in changes in control as defined by Sections 382 and 383 of the Internal Revenue Code. The Company has completed an assessment through December 31, 2020 to determine the impact of the Section 382 and 383 ownership changes and has reduced their income tax credit and loss carryforwards.

Management of the Company evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and determined that it is more likely than not that the Company will not recognize the benefits of the deferred tax assets. As a result, a full valuation allowance was recorded as of December 31, 2020 and 2019. The valuation allowance increased by $1,514 during the year ended December 31, 2020, primarily due to the recognition of deferred revenue for income tax purposes that continues to be deferred by the Company.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted March 27, 2020. Among the business provisions, the CARES Act provided for various payroll tax incentives, changes to net operating loss carryback and carryforward rules, business interest expense limitation increases, and bonus depreciation on qualified improvement property. Additionally, the Consolidated Appropriations Act of 2021 was signed on December 27, 2020 which provided additional COVID relief provisions for businesses. The Company has evaluated the impact of both Acts and has determined that any impact is not material to its financial statements.

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

The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company files income tax returns in the United States for federal and state income taxes. In the normal course of business, the Company is subject to examination by tax authorities in the United States. Since the Company is in a loss carry-forward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carry-forward is utilized. The Company's returns remain subject to federal and state audits for the years 2017 through 2020. However, carryforward attributes from prior years may still be adjusted upon examination by tax authorities if they are used in an open period.

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

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

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

	Gross Uncertain Tax Position
Balance — January 1, 2019	$ 1,244
Additions for current year tax positions	87
Reductions for prior year tax positions	(1,244)
Balance — December 31, 2019	87
Additions for current year tax positions	34
Reductions for prior year tax positions	(121)
Balance — December 31, 2020	$ -

The Company's total uncertain tax positions decreased during the year ended December 31, 2020 as a result of the reduction of tax credit and loss carryforward that were determined to be limited for future utilization by the Company under Sections 382 and 383. None of the uncertain tax positions that, if realized, would affect the Company's effective tax rate in future periods due to a valuation allowance provided against the Company's net deferred tax assets.

14. Net Loss Per Share

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

	As of December 31,	
	2020	2019
Options to purchase common stock	2,899,837	900,003
Warrants to purchase common stock	23,284,813	18,653,195
Total	26,184,650	19,553,198

15. Subsequent Events

On February 24, 2021, 18,965 warrants issued in April 2019 were exercised, the Company issued 18,965 shares of common stock and collected $26 in net proceeds.

On February 16, 2021, the Company closed on a registered direct offering with certain healthcare-focused institutional investors for the sale of 20,000,000 shares of its common stock for gross proceeds of $40,000, prior to deducting placement agent's fees and other offering expenses. In connection with the offering, 1,300,000 warrants with a five-year expiry were issued to placement agent designees at an exercise price of $2.50 per share. The shares of common stock were offered by Pulmatrix pursuant to a "shelf" registration statement on Form S-3 (File No. 333-230225) previously filed with the Securities and Exchange Commission (the "SEC") on March 12, 2019 and declared effective by the SEC on March 15, 2019.

On February 13, 2021, 100,000 warrants issued in February 2019 were exercised, the Company issued 100,000 shares of common stock and collected $134 in net proceeds.

On February 12, 2021, 25,000 warrants issued in July 2020 were exercised, the Company issued 25,000 shares of common stock and collected $45 in net proceeds.

On January 28, 2021, the Company granted 993,587 stock options to directors and employees.

The Company has evaluated its events subsequent to December 31, 2020 to the date these consolidated financial statements were issued, and has determined that, other than what was disclosed above, it does not have any subsequent events to disclose in these consolidated financial statements.

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Pulmatrix, Inc. on Forms S-1 (File Nos. 333-223630, 333-230670, 333-239431, and 333-230395, and the related registration statement (No. 333-230714) filed under Rule 462(b)), S-3 (File Nos. 333-212546, 333-230225 and 333-242341) and Forms S-8 (File Nos. 333-195737, 333-205752, 333-207002 333-212547, 333-216628, 333-225627, 333-231935, and 333-252439) of our report, dated March 26, 2020 with respect to our audits of the consolidated financial statements of Pulmatrix, Inc. as of December 31, 2020 and 2019 and for each of the two years in the period ended December 31, 2020, which report is included in this Annual Report on Form 10-K of Pulmatrix, Inc. for the year ended December 31, 2020.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 23, 2021

Exhibit 31.1

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

I, Teofilo Raad, President and Chief Executive Officer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pulmatrix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2021

/s/ Teofilo Raad
Teofilo Raad
President & Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Michelle S. Siegert., Vice President of Finance, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pulmatrix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2021

/s/ Michelle S. Siegert
Michelle S. Siegert
Vice President of Finance
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Pulmatrix, Inc. (the "Company") for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Teofilo Raad, as the President & Chief Executive Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2021

/s/ Teofilo Raad
Teofilo Raad
President & Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Pulmatrix, Inc. (the "Company") for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, Michelle S. Siegert, as the VP, Finance of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2021

/s/ Michelle S. Siegert
Michelle S. Siegert
Vice President of Finance
(Principal Financial Officer)

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