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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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 ☒

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ 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	☒	Smaller reporting company	☒
		Emerging Growth Company	☐

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

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

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, as of June 30, 2019, the last business day of registrants most recently completed second fiscal quarter, was $17,267,361.

As of March 24,2020, the registrant had 20,521,304 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of Pulmatrix, Inc.'s Definitive Proxy Statement on Schedule 14A relating to the 2020 Annual Meeting of Stockholders are incorporated by reference into PART III.

PULMATRIX, INC.

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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) on the Company’s ongoing and planned clinical trials;
- the geographic, social and economic impact of COVID-19 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 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.

The Company effected a 1-for-10 reverse stock split on February 3, 2019. All share and per share information in this Annual Report on Form 10-K has been retroactively adjusted to reflect these reverse stock splits.

"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"), and lung cancer. We are also exploring iSPERSE based therapeutics in neurological diseases.

Corporate History

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

Business Strategy

Our goal is to utilize our proprietary iSPERSE technology to develop proprietary breakthrough therapeutic products that are safe, convenient, efficiently delivered and more effective than the existing therapeutic products of respiratory diseases. In addition to our own proprietary products, we continue to pursue technology partnerships where iSPERSE can improve upon the other company's products.

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

- *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 to severe COPD patients. In 2019, Pulmatrix entered into a License, Development and Commercialization Agreement for PUR1800 with Johnson & Johnson Enterprise Innovation, Inc. ("JJEI"). In 2020, we will direct resources to advance the research and development of PUR1800, an inhaled kinase inhibitor, into a Phase 1b study in patients with stable COPD. JJEI retains an option for worldwide licensure to develop PUR1800 and other kinase inhibitors as part of its Lung Cancer Initiative.
- *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 that 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, 2019, our patent portfolio related to iSPERSE included approximately 93 granted and allowed patents, 15 of which are granted or allowed US patents, with expiration dates from 2024 to 2034, and approximately 56 additional pending patent applications in the US and other jurisdictions. Our in-licensed portfolio related to kinase inhibitors included approximately 237 granted and allowed patents, 27 of which are granted or allowed US patents, with expiration dates from 2029 to 2035, and approximately 37 additional pending patent applications in the US and other jurisdictions.

iSPERSE Technology

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

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

- *Flexible drug loading for delivery of a single microgram to tens of milligrams per dose*. iSPERSE particles can be engineered to include significantly less than one percent (1%) to greater than eighty percent (80%) active pharmaceutical ingredients ("APIs"), which allows flexibility for dosing 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 U.S. Food and Drug Administration 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 asthma and CF patients, *Aspergillus* can cause chronic infections that may be associated with worsening disease and larger declines in lung function than patients without infection. A subset of asthma and CF patients with *Aspergillus* colonization and/or infection develop ABPA, which is a complex hypersensitivity reaction to fungal antigens. ABPA is a disease resulting in mucus production, wheezing, pulmonary infiltrates, worsening bronchiectasis and fibrosis of the lung.

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

Pulmazole is our inhaled formulation of itraconazole, an anti-fungal drug commercially available as an oral drug that we are developing to treat and prevent pulmonary fungal infections. Development of Pulmazole is focused on treatment of *Aspergillus* spp. colonization and infection in patients with asthma and CF. In a Phase 1/1b clinical trial, Pulmazole appeared to be safe and well tolerated in healthy normal volunteers (Parts 1 and 2) and asthmatics (Part 3). In Part 3 of the 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® 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 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, 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 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 million of unencumbered cash available for the development of Pulmazole. Pursuant to the terms of the agreement, we dedicated $24 million of cash to the development of Pulmazole. The $24 million is expected to fund the development of Pulmazole beyond the completion of the initiated Phase 2 study. After such $24 million is exhausted, each of us and Cipla will bear 50% of any costs incurred with respect to the development, regulatory and commercialization costs of Pulmazole. The parties will share equally the total free cash flow in relation to commercialization of Pulmazole. Pulmatrix will remain responsible for the execution of the clinical development of Pulmazole, and Cipla will be responsible for the global commercialization of the product.

Competition and Market Opportunities

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

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

There is precedent for 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. Savara is developing AeroVanc, an inhaled dry powder version of vancomycin, intended for treatment of methicillin-resistant Staphylococcus aureus lung infection in patients with CF, which has begun Phase 3 clinical trials. Insmed received approval for Amikacin Liposome Inhalation Suspension (Arikayce) in September 2018 for the treatment of lung disease caused by a group of bacteria, Mycobacterium avium complex (MAC) in a limited population of patients with the disease who do not respond to conventional treatment (refractory disease). Arikayce is the first drug to be approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs, or LPAD pathway, established by Congress under the 21st Century Cures Act to advance development and approval of antibacterial and antifungal drugs to treat serious or life-threatening infections in a limited population of patients with unmet need. As required for drugs approved under the LPAD pathway, labeling for Arikayce includes certain statements to convey that the drug has been shown to be safe and effective only for use in a limited population. Arikayce also was approved under the Accelerated Approval pathway. Under this approach, the U.S. Food and Drug Administration ("FDA") may approve drugs for serious or life-threatening diseases or conditions where the drug is shown to have an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. The approval of Arikayce was based on achieving three consecutive negative monthly sputum cultures by month six of treatment. Insmed

was required by the FDA to conduct an additional, post-market study to describe the clinical benefits of Arikayce. Pulmocide Ltd has initiated a Phase 2 clinical trial in the fourth quarter of 2018 to investigate PC945, a novel triazole antifungal, for the treatment of Culture-positive Aspergillus Fumigatus infection in subjects with moderate to severe asthma. There are currently no products specifically approved for treatment of ABPA.

New methods to detect Aspergillus spp. infection in sputum have improved the sensitivity of diagnosis and clinical appreciation for these infections. Pulmonary Aspergillus spp. infections affect approximately 14 million patients worldwide according to the Global Action Fund for Fungal Infections (Improving Outcomes for Patients with Fungal Infections across the World: A Road Map for the Next Decade). The majority of these cases occur in 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 Allergic Bronchopulmonary Aspergillosis (ABPA)’. Top-line data for this study is presently anticipated during the first quarter of 2021. However, we are currently assessing the impact of the coronavirus on this study and how it could impact this timeline. An outbreak of the coronavirus in areas where we are enrolling patients for this trial could delay patient enrollment and divert healthcare resources from our study and ultimately lead to closure of clinical sites. Institutions, where seven of our clinical sites are located, recently suspended enrollment in the trial due to issues associated with coronavirus and additional institutions may follow. In addition, some patients may withdrawal from the trial due to limitations on travel and movement that have been imposed in jurisdictions in response to the coronavirus pandemic. Finally, we are working to make sure all of our trial sites are safe for patients and do not expose them to the risk of a coronavirus infection. Should we determine that continued participation in our clinical trials creates unreasonable risk of exposure to coronavirus, we intend to voluntarily suspend enrollment at such sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. We cannot predict the extent to which the coronavirus may impact our clinical trials. However, it could result in a delay or indefinite suspension of this trial. 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.

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 first of which, iSPERSE PUR1800 (previously RV1162), we plan to develop for the treatment of acute exacerbations in patients with COPD (“AECOPD”). AECOPDs can result from environmental, viral, or bacterial catalysts causing the patient to experience an increase in coughing, sputum production, and dyspnea. COPD exacerbations (worsening of respiratory symptoms) are a major contributor to health care costs as well disease progression that can lead to serious consequences such as hospitalization and death. AECOPD accounts for up to 62.5% of all hospital admissions related to COPD.

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.

Clinical Development

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

In the first half of 2020, Pulmatrix plans to initiate a Ph1b study of an iSPERSE formulation, PUR1800, in stable moderate-severe COPD patients. This study 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 (iSPERSE formulation) in stable COPD patients. As we plan a Ph1b study of PUR1800, we are assessing the impact of the coronavirus on our studies and current timeline. An outbreak of the coronavirus in areas where we plan to conduct studies of PUR1800 may delay enrollment of patients and divert healthcare resources from our studies. We cannot predict the extent to which the coronavirus 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.

New Products — PUR3000 and PUR4000

In 2019, Pulmatrix underwent an extensive landscape survey to identify new opportunities under Section 505(b)(2) of the Food, Drug, and Cosmetic Act (“FDC”), which permits the submission of a new drug application (“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, where an inhaled iSPERSE re-formulation could lead to potential clinical advantage in diseases with high unmet need. The landscape survey began by looking at the top 100 drugs by sales. The list was then filtered down to products that met three areas of focus: (1) pulmonary indications (2) neurological (CNS) indications requiring rapid onset and (3) products with poor bioavailability with associated toxicity. Following this process, we identified two products for further pre-clinical development: PUR3000 is a neurological disease product where pulmonary delivery can lead to rapid onset, meeting a significant unmet need in the market. PUR4000 is a respiratory disease product where direct product delivery to the lungs can solve poor bioavailability issues and create a potential efficacy advantage with higher drug concentrations in the lungs. We intend to prioritize one of these two compounds and commence the pre-clinical work necessary in 2020 to potentially have one Phase 1 ready asset in 2021.

Business Development

On April 15, 2019, Pulmatrix entered into the Cipla Agreement for the co-development and commercialization of Pulmazole™. Pulmatrix received an upfront payment of $22 million from Cipla in exchange for assignment of all rights for Pulmazole in relation to pulmonary indications to Cipla. Thereafter, both parties equally share all costs related to the future development and commercialization of Pulmazole, and equally share worldwide free cash flow from future sales of Pulmazole. Pulmatrix will remain responsible for the execution of the clinical

development of Pulmazole, and Cipla will be responsible for the commercialization of the product. The partnership is overseen by a Joint Steering Committee with equal representation from both companies.

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 PUR5700 programs, 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, 2019, our patent portfolio related to iSPERSE included approximately 93 granted and allowed patents, 15 of which are granted or allowed US patents, with expiration dates from 2024 to 2034, and approximately 56 additional pending patent applications in the US and other jurisdictions. Our in-licensed portfolio related to kinase inhibitors included approximately 237 granted and allowed patents, 27 of which are granted or allowed US patents, with expiration dates from 2029 to 2035, and approximately 37 additional pending patent applications in the US and other jurisdictions.

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

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

Trade Secrets

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

confidentiality agreements with our employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We have small-scale production capabilities and generally perform early process development for our product candidates to produce the quantities necessary to conduct preclinical studies of our investigational product candidates. We do not have, and do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical studies. We rely on contract manufacturing organizations ("CMOs") and third-party contractors to generate drug-loaded formulations and produce larger, pilot- scale amounts of drug substance and the drug product required for our clinical studies. We expect to continue to rely on CMOs to manufacture drug substances and drug products under the appropriate current Good Manufacturing Practices ("cGMP") conditions to perform clinical studies for the foreseeable future. We also contract with CMOs for the labeling, packaging, storage and distribution of investigational drug products. These arrangements allow us to maintain a more flexible infrastructure while focusing 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, 2019 and 2018, we spent approximately $12.8 million and $13.0 million, respectively on research and development activities.

Government Regulation

Pharmaceutical companies are subject to extensive regulation by national, state and local agencies, such as the FDA, in the United States and the European Medicines Agency in Europe. The manufacture, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the United States and various foreign countries. Additionally, in the United States, we must follow rules and regulations established by

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

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

FDA Approval Process

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

- Completion of pre-clinical laboratory and animal testing;
- The submission to the FDA of an investigational new drug (“IND”), application, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- Performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- Submission and approval of a 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 Prescription Drug User Fee Act ("PDUFA"), the FDA's goal is to complete its initial review and respond to the applicant within twelve months of submission, unless the application relates to an unmet medical need in a serious or life-threatening indication, in which case the goal may be within eight months of NDA submission. However, PDUFA goal dates are not legal mandates and FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of a NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

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

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

We rely, and expect to continue to rely, on third parties for the manufacture of clinical and future commercial, quantities of its therapeutic candidates. Future FDA and state inspections may identify compliance issues at these third-party facilities that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could

delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Many of the foregoing could limit the commercial value of an approved product or require us to commit substantial additional resources in connection with the approval of a product. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of its products under development.

Section 505(b)(2) New Drug Applications

As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2), 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, 2019 and 2018 and subsequently has not had a material effect upon our capital expenditures, earnings or competitive position.

Employees

As of December 31, 2019, we had 1 part-time and 22 full-time employees, 16 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 are located in Lexington, Massachusetts. We currently lease approximately 21,810 square feet of office and lab space in Lexington, Massachusetts under a lease that expires on December 31, 2020. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms for our future growth.

Available Information

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

ITEM 1A. RISK FACTORS.

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

Risks Related to Our Business

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

We have yet to establish any history of profitable operations. We reported a net loss of $20.6 million for both fiscal years ended December 31, 2019 and December 31, 2018. As of December 31, 2019, we had an accumulated deficit of $215.2 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 raising may be costly or difficult to obtain and could dilute our stockholders' ownership interests.

Our current capital will only be sufficient to enable us to continue operations into the second quarter of 2021. In order to fully realize all of our business objectives, absent any non-dilutive funding from a strategic partner or some other strategic transactions, we will need to raise additional capital 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 product sales. All of our product candidates are still in the preclinical or clinical development stage, and none have been approved for marketing or are currently being marketed or commercialized. Our product candidates will require significant additional development, clinical studies, regulatory clearances and additional investments of time and capital before they can be commercialized. We cannot be certain when or if any of our product candidates will obtain the required regulatory approval.

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

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

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

- be shown to be ineffective or to cause harmful side effects during preclinical testing or clinical trials;
- fail to receive regulatory approval on a timely basis or at all;
- be difficult to manufacture on a large scale;
- not be economically viable;
- not be prescribed by doctors or accepted by patients;
- fail to receive a sufficient level of reimbursement from government, insurers or other third-party payors; or
- infringe on intellectual property rights of any other party.

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

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.

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

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

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

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

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, 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, 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 pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for, or to commercialize, our products.

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

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

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

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

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

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

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

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

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market additional product candidates and technologies, 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. In 2019, we identified two potential product candidates for pre-clinical development (PUR3000 and PUR4000) with the intention of commencing the pre-clinical work necessary in 2020. We cannot guarantee that we will be able to successfully conduct the pre-clinical 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.

Business interruptions could limit our ability to operate our business.

Our operations, as well as those of any collaborators and third party contacts on which we depend, are vulnerable to damage or interruption from computer viruses, human error, natural disasters, extreme weather, electrical and telecommunication failures, international acts of terror, public health crises, such as pandemics and epidemics, and similar events. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures in China and such other countries. We initiated a Phase 2 clinical study of Pulmazole in 2019 and plan to initiate a Ph1b study of PUR1800 in the first half of 2020. We conduct our clinical trials within multiple geographies including the United States, United Kingdom, India, Poland and Australia. The extent to which the coronavirus 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 the coronavirus in areas where we are conducting trials, as hospitals and clinics in those regions may shift resources to patients affected by the disease. Institutions, where seven of our clinical sites are located for our Phase 2 clinical study of Pulmazole, recently suspended enrollment in the trial due to issues associated with coronavirus and additional institutions may follow. Additionally, if our trial participants are unable to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from the coronavirus, 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 coronavirus 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 coronavirus outbreak 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 coronavirus or any other epidemic harms the global economy generally. We cannot predict the ultimate impact of the coronavirus outbreak as consequences of such health epidemic 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.

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, or the Code, a corporation that undergoes an "ownership change" is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards or other tax attributes, or NOLs, to offset future taxable income or reduce taxes. Our past issuances of stock and other changes in our stock ownership may have resulted in ownership changes within the meaning of Section 382 of the Code; accordingly, our pre-change NOLs may be

subject to limitation under Section 382. If we determine that we have not undergone an ownership change, the Internal Revenue Service could challenge our analysis, and our ability to use our NOLs to offset taxable income could be limited by Section 382 of the Code. Future changes in our stock ownership, including in connection with our initial public offering, some of which are outside of our control, could result in ownership changes under Section 382 of the Code further limiting our ability to utilize our NOLs. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability.

Risks Related to Regulatory Matters

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

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

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

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

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

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

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

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

- injunctions or the imposition of civil or criminal penalties; or
- adverse publicity.

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

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

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

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

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

In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for, or purchase, order or recommendation of, goods or services reimbursed by any source, not just governmental payers. The scope and enforcement of these laws are uncertain and subject to change in the current environment of healthcare reform. We cannot predict the impact on our business, financial condition nor results of operations of any changes in these laws. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Law enforcement authorities are increasingly focused on enforcing these laws, and if we are challenged under 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, pre-clinical and clinical studies and human clinical trials, is a time-consuming and expensive process that takes years to complete. We anticipate that our expenses will increase substantially as we continue to advance Pulmazole in the Phase 2 trial and pursue development of PUR1800 or other iSPERSE-based product candidates and/or pursue development of iSPERSE-based pharmaceuticals in additional indications. Based upon our current expectations, we believe that our existing capital resources will enable us to continue planned operations into the second quarter of 2021. 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, 2019 of $215.2 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 or PUR1800 development activities, or reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be continued doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. If we are or become insolvent, investors in our stock may lose the entire value of their investment.

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

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

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

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

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

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

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

Risks Related to Company Common Stock

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

The stock market in general, and Nasdaq in particular, as well as biotechnology companies, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating

performance of small companies. The market price of Company Common Stock may fluctuate as a result of, among other factors:

- the announcement of new products, new developments, services or technological innovations by us or our competitors;
- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;
- announcements relating to strategic relationships, mergers, acquisitions, partnerships, collaborations, joint ventures, capital commitments, or other events by us or our competitors;
- conditions or trends in the biotechnology and pharmaceutical industries;
- changes in the economic performance or market valuations of other biotechnology and pharmaceutical companies;
- general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance or financial condition (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 pre-clinical and clinical trials;
- ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of Company Common Stock by stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- analyst research reports, recommendations and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigation related to intellectual property rights, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

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

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

As a publicly traded company, we incur significant additional legal, accounting and other expenses. The obligations of being a public reporting company require significant expenditures, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act , 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.

We no longer qualify as an "emerging growth company" and will be required to comply with certain provisions of the Sarbanes-Oxley Act and can no longer take advantage of reduced disclosure requirements.

Effective December 31, 2019 we are no longer an emerging growth company and may no longer take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, such as exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. This increase in reporting requirements will further increase our compliance burden.

As a "smaller reporting company," however, we are still able to take advantage of certain exemptions available to both emerging growth companies and smaller reporting companies, including, but not limited to, exemptions from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and an exemption from providing a "Compensation Discussion and Analysis" section in our proxy statements. Additionally, as a smaller reporting company, we need only provide two years of financial statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations"; and we need only provide three years of business development information and benefit from other "scaled" disclosure requirements that are less comprehensive than those for issuers that are not smaller reporting companies.

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).

On July 19, 2019, the Company received a letter from the Listing Qualifications Department of the NASDAQ Stock Market indicating that, based upon the closing bid price of the Company's common stock for the 30 consecutive business day period between June 6, 2019 through July 18, 2019, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). On January 16, 2020, the Company received notice from the NASDAQ Listing Qualifications Office of the NASDAQ Stock Market, indicating that the Company has regained compliance with the minimum bid price requirement under the NASDAQ Listing Rule 5550(a)(2).

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 24, 2020, 1,088,568 shares remained available to be awarded under our 2013 Employee, Director and Consultant Equity Incentive Plan (the "2013 Plan). Further, an aggregate of 2,912,419 shares of Company Common Stock could be delivered upon the exercise or conversion of outstanding stock options or restricted stock units under the Incentive Plan and other equity incentive plans we previously assumed. We may also issue additional options, warrants and other types of equity in the future as part of stock-based compensation, capital raising transactions, technology licenses, financings, strategic licenses or other strategic transactions. To the extent these options are exercised, existing stockholders would experience additional ownership dilution. In addition, the number of shares available for future grant under our equity compensation plans may be increased in the future, as our equity compensation plan contains an "evergreen" provision, pursuant to which additional shares may be authorized for issuance under the plan each year.

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters are located at 99 Hayden Avenue, Suite 390, Lexington, Massachusetts. We currently lease approximately 21,810 square feet of office space in Lexington, Massachusetts under a lease that expires on December 31, 2020. Base rent expense for the year ended December 31, 2019 was approximately $676,110. The lease agreement, as amended on October 27, 2015, provides for a base monthly rent, and we are also responsible for real estate taxes, maintenance and other operating expenses applicable to the leased premises. Our future minimum lease payments under the lease are as follows (dollars in thousands):

Year	Amount
2020	698
Total	$ 698

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 23, 2020 the last reported sale price of our common stock on the NASDAQ Capital Market was $1.30 per share.

Stockholders

As of March 24, 2020, 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, 2019.

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 respiratory diseases, including allergic bronchopulmonary aspergillosis ("ABPA") in asthmatics and in patients with cystic fibrosis ("CF"), chronic obstructive pulmonary disease ("COPD") and idiopathic pulmonary fibrosis ("IPF").

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

We do not have any products approved for sale and have not generated any revenue from product sales. We fund our operations through proceeds from issuances of common stock, 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;
- 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

On January 28, 2020, Pulmazole received Fast Track designation from the U.S. Food and Drug Administration for the treatment of ABPA.

JJEI

On December 26, 2019 the Company 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, 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 (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 will conduct a clinical and chronic toxicology program in 2020 focused on chronic obstructive pulmonary disease (COPD) and lung cancer interception.

As consideration for the Company's entry into the JJEI License Agreement, JJEI will pay the Company 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. The Company is 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 option under the JJEI License Agreement, Pulmatrix is 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, Pulmatrix 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 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.

The Company has recorded a receivable for the upfront payment of $7.2 million as of December 31, 2019. The upfront payment amount was due within 30 calendar days of the agreement's effective date and was paid in January 2020.

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 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 million of unencumbered cash available for the development of Pulmazole. Pursuant to the terms of the agreement, we dedicated $24 million of cash to the development of Pulmazole. After such $24 million is exhausted, each of us and Cipla will bear 50% of any costs incurred with respect to the development, regulatory and commercialization costs of Pulmazole. The parties will share equally the total free cash flow in relation to 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.

Financial Overview

To date, we have not generated any product sales. Our 2019 revenue was generated through the Cipla Agreement. Our 2018 revenue resulted from an award from Cystic Fibrosis Foundation Therapeutics ("CFFT"), the nonprofit drug discovery and development affiliate of the Cystic Fibrosis Foundation, to support the development of Pulmazole for the treatment of ABPA in patients with asthma and cystic fibrosis.

Research and Development Expenses

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

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with CROs or CMOs, and consultants that conduct our clinical trials and preclinical activities;
- the cost of acquiring, developing and manufacturing clinical trial materials and lab supplies;
- facility, depreciation and other expenses, which include direct and allocated expenses for rent, maintenance of our facility, insurance and other supplies; and
- costs associated with preclinical activities and 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 70%, of our staff are research and development employees. In addition, we maintain a 12,000 square foot research and development facility which includes capital equipment for the manufacture and characterization of our iSPERSE powders for our pipeline programs. As we identify opportunities for iSPERSE in 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 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 professional legal fees. Other general and administrative expenses include travel expenses, expenses related to being a publicly-traded company and professional fees for consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in the future as 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. As of December 31, 2019, and 2018, goodwill was impaired by $7.3 million and $0.1 million, respectively.

Interest Expense

Interest expense primarily reflects the amortization of debt discounts and interest expense accrued in connection with a term loan that was outstanding during the period. We incurred interest expense associated with a $7.0 million term loan, or Term loan, from Hercules Technology Growth Capital, Inc., or Hercules, until its maturity date of July 1, 2018. The loan was paid in its entirety and as of June 30, 2018, there was no further liability.

Critical Accounting Policies

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

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

Revenue Recognition

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

During the year ended December 31, 2019, our principal source of revenue was income that resulted from the Cipla Agreement. During the year ended December 31, 2018, our principle source of revenue was income for reimbursement of clinical study costs as part of a grant received from CFFT.

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, 2019, the Company has 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, 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. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

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, 2019, the Company has an active arrangement with JJEI that contains a research or development milestone.

Leases

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.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired, and liabilities assumed under the acquisition method of accounting for push-down accounting. Goodwill is not amortized but is evaluated for impairment within our single reporting unit on an annual basis during the fourth quarter, or more frequently if an event occurs or circumstances change that would more likely than not reduce the fair value of our reporting unit below our carrying amount. When performing the impairment assessment, the accounting standard for testing goodwill for impairment permits a company to first assess the qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that the goodwill is impaired. If we believe, as a result of the qualitative assessment, that it is more likely than not that the fair value of goodwill is impaired, we must perform a quantitative analysis to determine if the carrying value of the goodwill exceeds the fair value of the Company. Based on the quantitative analysis, goodwill was determined to be impaired and as of December 31, 2019, and December 31, 2018, charges of $7,268 and $69 were recorded, respectively.

Basic and Diluted Net Loss Per Share

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

Income Taxes

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

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of December 31, 2019, and 2018, 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

Year Ended December 31, 2019 Compared with Year ended December 31, 2018

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

	Year ended December 31,		
	2019	2018	Change
Revenues	$ 7,910	$ 153	$7,757
Operating expenses			
Research and development	12,845	12,966	(121)
General and administrative	8,489	7,518	971
Impairment of Goodwill	7,268	69	7,199
Total operating expenses	28,602	20,553	8,049
Loss from operations	(20,692)	(20,400)	(292)
Interest expense	—	(186)	186
Fair value adjustment of derivative liability	—	1	(1)
Interest income	301	27	274
Settlement expense	(200)	—	(200)
Other expense, net	(5)	(5)	—
Loss before income taxes	(20,596)	(20,563)	(33)
Net loss	$(20,596)	$(20,563)	$ (33)

Revenue — Revenue was $7.9 million for the year ended December 31, 2019 as compared to $0.1 million for the year ended December 31, 2018, an increase of $7.8 million. The increase in revenue was the result of recognition of income pursuant to the Cipla Agreement.

Research and development expenses — Research and development expense was $12.8 million for the year ended December 31, 2019 as compared to $13.0 million for the year ended December 31, 2018 a decrease of 0.2 million. The decrease was primarily due to decreased spend of $1.6 million in employment costs as a result of decreased share based compensation expense and $0.6 million on the PUR1800 project as a result of the completion of a pre-clinical toxicology study in 2018, partially offset by increased spend of $2.0 million on the Pulmazole project.

General and administrative expenses — General and administrative expense was $8.5 million for the year ended December 31, 2019, compared to $7.5 million for the year ended December 31, 2018, an increase of $1.0 million. The increase was primarily due to a $0.3 million royalty payment to the CFFT resulting from the Cipla Collaboration and increases of $0.3 million of legal and patent costs, $0.2 million of employment costs, and $0.2 million in professional consulting expense.

Impairment of goodwill — In 2019 and 2018, the Company performed an impairment assessment and concluded that the carrying amount of the goodwill exceeded its fair value and recorded the resulting impairment charges of $7.3 million and $0.1 million, respectively.

Interest expense — Interest expense was $0.2 million for the year ended December 31, 2018 which related to the term loan agreement that we entered into in June 2015. Final payments were made in June 2018 and, as of June 30, 2018, the term loan was paid in full.

Liquidity and Capital Resources

At December 31, 2019, the Company had unrestricted cash of $23.4 million. The Company had incurred recurring losses and as of December 31, 2019 had an accumulated deficit of $215.2 million. During the year ended December 31, 2019, approximately $3.2 million was provided by its operating activities. The Company has primarily financed operations to date through the sale of equity securities, a term loan, licensing and collaboration agreements. In 2018, the Company paid off the Term Loan in full, and the Company currently does not have a term loan outstanding. The Company 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.

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

Under the JJEI License Agreement, the Company is 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 option under the JJEI License Agreement, Pulmatrix is 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 believe that our existing resources will be sufficient to fund our planned operations into the second quarter of 2021. 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 coronavirus 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, 2019, the Company raised an aggregate of $17.7 million in net proceeds through the sale of its common stock and the exercise of pre-funded warrants (note 9 of the accompanying consolidated financial statements). Subsequent to December 31, 2019, the accounts receivable was satisfied with

the receipt of $7.2 million from JJEI (see Note 6 of the accompanying consolidated financial statements) and $0.3 million was received for the exercise of outstanding warrants and stock options.

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,	
	2019	2018
Net cash provided by/(used in) operating activities	$ 3,230	$(16,761)
Net cash used in investing activities	(58)	(19)
Net cash provided by financing activities	17,705	15,793
Net increase in cash and cash equivalents	$20,877	$ (987)

Cash Flows from Operating Activities

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.

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

Cash Flows from Investing Activities

Net cash used in investing activities for the years ended December 31, 2019 and December 31, 2018 were both less than $0.1 million and were 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, 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.

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

Financings

Based on our planned use for our existing cash resources, we believe that our available funds will enable us to support chemistry manufacturing and control activities in support of the Pulmazole program into the second

quarter of 2021. 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.

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

Reverse Stock Split

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

2019 Financings

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

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

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.

2018 Financings

At-the-Market Offering

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

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

During 2018, we sold 123,266 shares of common stock under the Sales Agreement at an average selling price of approximately $15.40 per share which resulted in gross proceeds of approximately $1.9 million and net proceeds of approximately $1.8 million after payment of 3% commission to BTIG and other issuance costs.

Public Offering

On April 3, 2018, the Company closed its firm commitment underwritten public offering in which, pursuant to the underwriting agreement (the "Underwriting Agreement") entered into between the Company and Oppenheimer & Co. Inc., as representative of the underwriters (the "Underwriters"), dated March 28, 2018, the Company issued and sold (i) 1,566,000 common units ("Common Units"), with each Common Unit being comprised of one share of the Company's common stock, par value $0.0001 per share, one Series A warrant (collectively, the "Series A Warrants") to purchase one share of common stock and one Series B warrant (collectively, the "Series B Warrants") to purchase one share of common stock, and (ii) 784,000 pre-funded units (the "Pre-Funded Units" and, together with the Common Units, the "Units"), with each Pre-Funded Unit being comprised of one pre-funded warrant to purchase one share of common stock, one Series A Warrant and one

Series B Warrant. The public offering price was $6.50 per Common Unit and $6.40 per Pre-Funded Unit, and the gross proceeds received by the Company on April 3, 2018 pursuant to such sales were $15.2 million, prior to deducting underwriting discounts and commissions and other estimated offering expenses.

In addition, on April 4, 2018, the Company closed on the sale of 115,000 additional Common Units pursuant to the Underwriters' option to purchase up to an additional 115,000 Units, which were exercised in full. After giving effect to the exercise of the Underwriters' overallotment option, the gross aggregate proceeds from the offering on April 3 and 4 were $16.0 million, prior to deducting underwriting discounts and commissions and other estimated offering expenses.

All pre-funded warrants issued in the offering were exercised in April 2018 and, as 15,000 were exercised on a cashless basis, resulted in the issuance of an additional 783,707 shares of common stock with gross proceeds of $0.1 million in the second quarter.

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

The Company agreed to pay Oppenheimer a commission of (a) 7% of the gross proceeds raised up to $5.0 million and (b) 6.5% of the gross proceeds raised in excess of $5.0 million. The Company also agreed to pay or reimburse certain expenses on behalf of Oppenheimer. A total of $1.5 million of commissions and other issuance costs were associated with the public offering.

The net proceeds to the Company from the Offering were approximately $14.6 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the Offering for research and development of its therapeutic candidates, particularly the development of Pulmazole, as well as for working capital and general corporate purposes.

Registered Direct Offering

On November 29, 2018, the Company entered into a Securities Purchase Agreement with an institutional investor (the "Purchaser"), pursuant to which the Company agreed to issue and sell an aggregate of 240,000 shares of common stock, par value $0.0001 per share, of the Company common stock at an offering price of $3.20 per share for gross proceeds of $0.8 million before the deduction of offering expenses. In addition, the Company sold pre-funded warrants (the "Pre-Funded Warrants") to purchase 697,500 shares of common stock (and the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants). The Pre-Funded Warrants were sold at an offering price of $3.10 per share for gross proceeds of $2.2 million before deduction of offering expenses.

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

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

Exercise of Warrants

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

Term Loan and Warrant

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

Commitments

We contract with various other organizations to conduct research and development activities. As of December 31, 2019, we had aggregate commitments to pay approximately $4.6 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 officers as appropriate to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

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

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

Management 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, 2019.

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, 2019 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, 2019.

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, 2019.

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, 2019.

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, 2019.

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, 2019.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

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

(1) Financial Statements:

Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
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(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)	1/30/2019	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

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
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
10.1*	Executive Employment Agreement, dated June 15, 2015, by and between Pulmatrix, Inc. and Robert W. Clarke, Ph.D.		Form 8-K (Exhibit 10.4)	06/16/15	001-36199
10.2*	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
10.7	Form of Securities Purchase Agreement		Form 8-K (Exhibit 10.1)	12/03/18	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
10.9*	General Release and Severance Agreement, dated May 16, 2019, by and between the Company and Robert Clarke, Ph.D.		Form 10-K (Exhibit 10.1)	05/16/19	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

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
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	X			
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 26, 2020

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 26, 2020
/s/ Michelle S. Siegert Michelle S. Siegert	VP, Finance, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 26, 2020
/s/ Mark Iwicki Mark Iwicki	Chairman of the Board of Directors	March 26, 2020
/s/ Richard Batycky Richard Batycky	Director	March 26, 2020
/s/ Steven Gillis, Ph.D. Steven Gillis, Ph.D.	Director	March 26, 2020
/s/ Michael J. Higgins Michael J. Higgins	Director	March 26, 2020
/s/ Amit D. Munshi Amit D. Munshi	Director	March 26, 2020

PULMATRIX, INC.

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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, 2019 and 2018, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Changes in Accounting Principles

ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards update ("ASU") No. 2016-02, *Leases (Topic 842), as amended*, effective January 1, 2019, using the modified retrospective approach.

ASU No. 2014-09

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for revenues in 2019 due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606), as amended*, effective January 1, 2019, using the modified retrospective approach.

Basis for Opinion

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

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

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

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 26, 2020

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

	December 31, 2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 23,440	$ 2,563
Accounts receivable	7,200	—
Prepaid expenses and other current assets	777	717
Total current assets	31,417	3,280
Property and equipment, net	270	394
Operating lease right-of-use asset	630	—
Long-term restricted cash	204	204
Goodwill	3,577	10,845
Total assets	$ 36,098	$ 14,723
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 600	$ 1,183
Accrued expenses	2,514	1,696
Operating lease liability	675	—
Deferred revenue	13,411	—
Total current liabilities	17,200	2,879
Deferred revenue, net of current portion	7,879	—
Total liabilities	25,079	2,879
Stockholders' Equity:		
Preferred stock, $0.0001 par value — 500,000 shares authorized at December 31, 2019 and December 31, 2018, respectively; no shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Common stock, $0.0001 par value — 200,000,000 shares authorized at December 31, 2019 and December 31, 2018, respectively; 19,994,560 and 4,923,723 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	2	—
Additional paid-in capital	226,178	206,409
Accumulated deficit	(215,161)	(194,565)
Total stockholders' equity	11,019	11,844
Total liabilities and stockholders' equity	$ 36,098	$ 14,723

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,	
	2019	2018
Revenues	$ 7,910	$ 153
Operating expenses		
Research and development	12,845	12,966
General and administrative	8,489	7,518
Impairment of goodwill	7,268	69
Total operating expenses	28,602	20,553
Loss from operations	(20,692)	(20,400)
Other income/(expense)		
Interest expense	—	(186)
Fair value adjustment of derivative liability	—	1
Interest income	301	27
Settlement expense	(200)	—
Other expense	(5)	(5)
Total other income/(expense)	96	(163)
Net loss	$ (20,596)	$ (20,563)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.23)	$ (4.98)
Weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders	16,733,909	4,126,393

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 Capital	Accumulated Deficit	Total
	Shares	Amount			
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
Stock-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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance — January 1, 2018	2,104,750	$ —	$184,139	$ (174,002)	$ 10,137
Issuance of common stock, net of issuance costs	2,044,266	—	19,219	—	19,219
Exercise of pre-funded warrants	783,707	—	78	—	78
Stock-based compensation	—	—	2,973	—	2,973
Net loss	—	—	—	(20,563)	(20,563)
Balance — December 31, 2018	4,932,723	$ —	$206,409	$ (194,565)	$ 11,844

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (20,596)	$ (20,563)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	182	231
Amortization of operating lease right-of-use asset	583	—
Stock-based compensation	2,066	2,973
Impairment of goodwill	7,268	69
Non-cash interest expense	—	35
Non-cash debt issuance expense	—	3
Fair value adjustment on derivative liability	—	(1)
Loss on disposal of property and equipment	—	8
Changes in operating assets and liabilities:		
Accounts Receivable	(7,200)	—
Prepaid expenses and other current assets	(60)	(21)
Accounts payable	(583)	726
Accrued expenses	885	(221)
Operating lease liabilities	(605)	—
Deferred revenue	21,290	—
Net cash provided by/(used in) operating activities	3,230	(16,761)
Cash flows from investing activities:		
Purchases of property and equipment	(58)	(19)
Net cash used in investing activities	(58)	(19)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrants, net	17,545	19,297
Proceeds from exercise of pre-funded warrants	160	—
Principal payments term loan	—	(3,259)
End of term loan payment	—	(245)
Net cash provided by financing activities	17,705	15,793
Net increase (decrease) in cash, cash equivalents and restricted cash	20,877	(987)
Cash, cash equivalents and restricted cash — beginning of period	2,767	3,754
Cash, cash equivalents and restricted cash — end of period	$ 23,644	$ 2,767
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ —	$ 131
Supplemental disclosures of non-cash investing and financing information:		
Operating lease right-of-use asset obtained in exchange for operating lease obligation	$ 1,213	—

See accompanying notes to consolidated financial statements

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

1. Nature of the Business and Basis of Presentation

Organization

Pulmatrix, Inc. (the "Company") was incorporated in 2013 as a Nevada corporation and converted to a Delaware corporation in September 2013. On June 15, 2015, the Company completed a merger with Pulmatrix Operating Company, Inc. changed its name from Ruthigen, Inc. to "Pulmatrix, Inc." and relocated its corporate headquarters to Lexington, Massachusetts. 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. Accordingly, all common share and per share data are retrospectively restated, including any adjustments necessary to eliminate fractional shares, to give effect of the Reverse Stock Split for all periods presented herein.

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.

Use of Estimates

In preparing consolidated financial statements in conformity with U.S. GAAP, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting period. Due to inherent uncertainty involved in making estimates, actual results may differ from these estimates. On an ongoing basis, the Company evaluates its estimates and assumptions. These estimates and assumptions include valuing equity securities in share-based payments, estimating the useful lives of depreciable and amortizable assets, 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, 2019 and 2018 the Company had a $153 letter of credit as a security deposit on its leased office and laboratory facility that expires on February 21, 2021. 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	
	2019	2018
Cash and cash equivalents	$ 23,440	$ 2,563
Restricted cash	204	204
Total cash, cash equivalents and restricted cash	$ 23,644	$ 2,767

Property and Equipment, net

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

Depreciation is provided over the following estimated useful lives:

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

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

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

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

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

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

Leases

During the quarter, 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, 2019, 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, 2019, the Company has an active arrangement that contains a research or development milestone see Note 6, *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. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

For a complete discussion of accounting for collaboration revenues, see Note 6, *Significant Agreements*.

Research and Development Costs

Research and development costs are expensed as incurred and include: salaries, benefits, bonus, stock-based compensation, license fees, milestone payments due under license agreements, costs paid to third-party contractors to perform research, conduct clinical trials, and develop drug materials and delivery devices; and associated overhead and facilities costs. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors, clinical research organizations (“CROs”) and clinical manufacturing organizations (“CMOs”). Invoicing from third-party contractors for services performed can lag several months. We accrue the costs of services rendered in connection with third-party contractor activities based on our estimate of fees and costs associated with the contract that were rendered during the period 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, 2019, the Company has an active arrangement with JJEI that contains a research or development milestone.

Stock-Based Compensation

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

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 and due to the decline in stock price, goodwill was determined to be impaired as of December 31, 2019 and December 31, 2018. A charge of $7,268 and $69 was recorded, respectively.

Recently Adopted Accounting Standards

In November 2018, the FASB issued ASU No. 2018-18, *Clarifying the Interaction between Topic 808* (Collaborative Arrangements) *and Topic* 606 (Revenue from Contracts with Customers). The amendments are effective for public business entities for fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company has early adopted ASU 2018-18 and adoption of this ASU has no significant impact on its consolidated financial statements.

In July 2018, the FASB issued ASU 2018-11, Leases, Targeted Improvements, ("ASU 2018-11"), which contains certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. ASU 2018-11 provided companies with an option to not restate comparative periods presented in the financial statements. The Company adopted this new standard on January 1, 2019 (the "adoption date") using the effective date method, for which comparative periods will be presented in accordance with the previous guidance in ASC 840, Leases. In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance, which does not require the reassessment of the following: i) whether existing or expired arrangements are or contain a lease, ii) the lease classification of existing or expired leases, and iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. As of the adoption date of January 1, 2019, the Company identified two operating lease arrangements in which it is a lessee. In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance, which does not require the reassessment of the following: i) whether existing or expired arrangements are or contain a lease, ii) the lease classification of existing or expired leases, and iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. As of the adoption date of January 1, 2019, the Company identified two operating lease arrangements in which it is a lessee. The adoption of this standard resulted in the recognition of operating lease liabilities of $1,280 and right-of-use assets of $1,213 on the Company's balance sheet, with a reclass of the existing deferred rent balance of $67 to the right-of-use assets. The adoption of the standard did not have a significant effect on the Company's statements of operations or statements of cash flows. In February 2016, the FASB issued ASU No. 2016-02, Leases. The new standard establishes a right-of-use model that requires a lessee to record a right-of-use asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. The new standard includes a short-term lease exception for leases with an original term of 12 months or less, the Company made this accounting policy election. Leases will be classified as either finance (previously referred to as capital) or operating, with classification affecting the pattern of expense recognition in the statements of operations and cash flow classification in the statements of cash flows. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. As a result, ASU 2016-02 became effective for the Company on January 1, 2019. A modified retrospective transition approach was provided for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available.

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

In July 2017, FASB issued ASU No. 2017-11, Earnings per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). ASU 2017-11 consists of two parts. The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial

instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The amendments in Part II of this Update do not require any transition guidance because those amendments do not have an accounting effect. The Company has adopted ASU 2017-11 and adoption of this ASU has no significant impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements

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 will be effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU No. 2018-13 and delay adoption of the additional disclosures until their effective date. The Company has not yet evaluated the impact of adoption of this ASU on its consolidated financial statements disclosures.

In 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 will be effective for the Company on January 1, 2020. The Company does not anticipate a material impact to its net financial position or disclosures as a result of the adoption of ASU 2018-15.

3. Accounts Receivable

Accounts receivable consisted of an upfront payment obligation from JJEI that was received in January 2020.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
	2019	2018
Prepaid insurance	$ 202	$ 243
Prepaid clinical trials	322	419
Prepaid other	221	27
Deferred operating costs	32	28
Total prepaid expenses and other current assets	$ 777	$ 717

5. Property and Equipment, Net

Property and equipment consisted of the following:

	As of December 31,	
	2019	2018
Laboratory equipment	$ 1,538	$ 1,529
Computer equipment	217	185
Office furniture and equipment	217	217
Leasehold improvements	581	579
Capital in progress	2	—
Total property and equipment	2,555	2,510
Less accumulated depreciation and amortization	(2,285)	(2,116)
Property and equipment, net	$ 270	$ 394

Depreciation and amortization expense for the years ended December 31, 2019 and 2018 was $182 and $231, respectively. During the years ended 2019 and 2018, the Company recorded gross fixed asset disposals of $13 and $993 and their related accumulated depreciation of $13 and $985, respectively.

6. Significant Agreements

License, Development and Commercialization Agreement

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 will conduct a clinical and chronic toxicology program beginning in 2020 focused on chronic obstructive pulmonary disease (COPD) and lung cancer interception.

As consideration for the Company's entry into the JJEI License Agreement, JJEI will pay 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

As of December 31, 2019, the Company has recorded a receivable for the upfront payment of $7,200, payment of which occurred in January 2020. 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. As of December 31, 2019, none of the performance obligations have been fully satisfied and $7,200 was recorded as deferred revenue, of which $5,359 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 quarter of 2021.

Collaborations

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.

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.

None of the performance obligations have been fully satisfied as of December 31, 2019. The Company received the $22,000 upfront payment in May 2019. During 2019, the Company recognized $6,298 in revenue related to the research and development services and $1,612 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, 2019 the Company recorded $14,090 in deferred revenue, of which $8,052 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.

7. Debt

Loan and Security Agreement and Warrant Agreement

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

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

8. Accrued Expenses and Other Current Liabilities

Accrued expenses consisted of the following:

	As of December 31,	
	2019	2018
Vacation	$ 42	$ 59
Wages and incentive	527	915
Clinical & consulting	1,820	517
Legal & patent	85	67
Deferred rent	—	67
Other expenses	40	71
Total accrued expenses	$2,514	$1,696

9. Common Stock

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.

Exercise of Warrants

All pre-funded warrants issued in the November 2018 securities purchase agreement with an institutional investor were exercised in 2019 and 697,500 common shares were issued. The Company recorded $70 in net proceeds.

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. The Company intends to use the net proceeds for research and development of its therapeutic candidates, particularly the development of Pulmazole, as well as for working capital and general corporate purposes.

At-the-Market Offering

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

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

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

Public Offering

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

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

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

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

The Company agreed to pay Oppenheimer a commission of (a) 7% of the gross proceeds raised up to $5,000 and (b) 6.5% of the gross proceeds raised in excess of $5,000. The Company also agreed to pay or reimburse certain expenses on behalf of Oppenheimer. A total of $1,505 of commissions and other issuance costs were associated with the public offering.

The net proceeds to the Company from the Offering were approximately $14,517, after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the Offering for research and development of its therapeutic candidates, particularly the development of Pulmazole, as well as for working capital and general corporate purposes

Registered Direct Offering

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

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

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

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

10. Warrants

A rollforward of the common stock warrants outstanding at December 31, 2019 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, 2018	328,444	—	$ 77.90	2.44	$ —
Series A warrants issued	2,465,000	—	$ 6.50		
Series A warrants expired	(2,465,000)	—	$ (6.50)		
Series B warrants issued	2,465,011	—	$ 7.50		
Pre-funded warrants issued	784,000	—	$ 6.50		
Pre-funded warrants exercised	(784,000)	—	$ (6.50)		
Warrants issued	937,500	—	$ 3.90		
Pre-funded warrants issued	—	697,500	$ 0.01		
Adjustment for reverse stock split	(11)	—			
Outstanding December 31, 2018	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	$ —

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	2019	2018
April 8, 2019	Equity	$ 0.01	Pre-funded	300,000	—
April 8, 2019	Equity	$ 1.35	April 8, 2024	12,266,665	—
April 8, 2019	Equity	$ 1.6875	April 3, 2024	797,334	—
February 12, 2019	Equity	$ 1.8313	February 7, 2024	110,922	—
February 12, 2019	Equity	$ 1.34	August 12, 2024	1,706,484	—
February 04, 2019	Equity	$ 2.125	January 30, 2024	34,605	—
January 31, 2019	Equity	$ 2.125	January 26, 2024	10,151	—
December 3, 2018	Equity	$ 3.90	June 3, 2024	937,500	937,500
December 3, 2018	Equity	$ 3.20	Pre-funded	—	697,500
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	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	2,515
March 21, 2014	Equity	$ 226.60	March 21, 2019	—	3,926
Adjustment for Reverse Stock Split					(16)
Total Outstanding				18,953,195	4,428,444

11. Share-Based Compensation

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

In addition, the Company sponsors two legacy plans under which no additional awards may be granted. As of December 31, 2019, the two legacy plans have a total of 15,865 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, 2019, the Company granted options to purchase 561,600 shares of the Company's common stock to employees and options to purchase 90,000 shares of the Company's common stock to directors. No options were granted to advisors during the period. The stock options granted vest over time (the "Time Based Options"). Time Based Options vest over either 36 or 48 months. Subject to the grantee's continuous service with the Company, Time Based Options vest in one of the following ways: (i)) 25% at the one year anniversary of the Vesting Start Date and the remainder in 36 equal monthly installments beginning in the thirteenth month after the Vesting Start Date or (ii) 25% at the time of grant and the remainder in 36 equal monthly installments beginning in the first month after the Vesting Start Date. Stock options expire ten years after the date of grant.

The following table summarizes stock option activity for the year ended December 31, 2019:

	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	$ —
Exercisable — December 31, 2019	401,453	$ 23.14	7.71	$ —

The estimated fair values of employee stock options granted during the year ended December 31, 2019 and 2018, were determined on the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	For the year ended December 31,	
	2019	2018
Expected option life (years)	6.02	5.58%
Risk-free interest rate	2.22%	2.77%
Expected volatility	74.14%	79.67%
Expected dividend yield	0%	0%

The risk-free interest rate was obtained from U.S. Treasury rates for the applicable periods. The Company's expected volatility was based upon the historical volatility for industry peers and used an average of those

volatilities. The expected life of the Company's options was determined using the simplified method as a result of limited historical data regarding the Company's activity. The 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, 2019, there was $746 of unrecognized stock-based compensation expense related to unvested stock options granted under the Company's stock award plans. This expense is expected to be recognized over a weighted-average period of approximately 1.88 years.

The following table presents total stock-based compensation expense for the years ended December 31, 2019 and 2018, respectively:

	For the years ended December 31,	
	2019	2018
Research and development	$ 156	$ 970
General and administrative	1,910	2,003
Total stock-based compensation expense	$ 2,066	$ 2,973

12. Commitments and Contingencies

Research and Development Activities

The Company contracts with various other organizations to conduct research and development activities. As of December 31, 2019, we had aggregate commitments to pay approximately $4,569 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 Company currently leases approximately 21,810 square feet of office and lab space in Lexington, Massachusetts under a lease that expires on December 31, 2020. 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 as of December 31, 2019 were as follows:

	As of December 31, 2019
Lease Cost	
Fixed lease cost	$ 654
Variable lease cost	—
Total lease cost	$ 654
Other information	
Short term, immaterial office equipment lease obligation	$ 5
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 676
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	$ 1,213
Weighted-average remaining lease term — operating leases	1 year
Weighted-average discount rate — operating leases	7.44%

	As of December 31, 2019
Balance Sheet Classification:	
Right-of-use Assets	
Operating Lease Assets	$ 630
Total Lease Assets	$ 630

Maturities of lease liabilities due under these lease agreements as of December 31, 2019 are as follows:

	Operating Leases
Maturity of lease liabilities	
2020	$ 698
Total lease payments	698
Less: interest	(23)
Total lease liabilities	$ 675

	Operating Leases
Reported as of December 31, 2019	
Lease liabilities — short term	$ 675
Lease liabilities — long term	—
Total	$ 675

The Company adopted ASU 2016-02 on January 1, 2019 as noted above, and as required, the following disclosure is provided for periods prior to adoption. Future annual minimum lease payments due under the Company's operating leases as of December 31, 2018 were as follows:

	Operating Leases
2019	$ 676
2020	698
Total lease payments	$ 1,374

13. Income Taxes

The Company had no income tax expense due to operating losses incurred for the year ended December 31, 2019 and 2018.

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:

	2019	2018
Income tax computed at federal statutory tax rate	21.0%	21.0%
State taxes, net of federal benefit	3.9%	6.2%
Research and development credits	2.0%	1.9%
Expiration of stock options	(7.3)%	0.0%
Write-down of goodwill assets	(7.4)%	(0.1)%
Permanent differences	(0.6)%	(0.5)%
Limitations on Credits and Net Operating Losses	(171.3)%	0.0%
Other	(1.4)%	(0.3)%
Change in valuation allowance	161.1%	(28.2)%
Total	0.0%	0.0%

The significant components of the Company's deferred tax assets as of December 31, 2019 and 2018 were as follows:

	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 9,077	$ 37,640
Research and development credit carryforwards	382	3,170
Capitalized start-up expenses	711	851
Stock Compensation	1,031	2,589
Lease Liability	184	—
Other	382	520
Total deferred tax assets	11,767	44,770
Deferred tax liabilities:		
Right of Use Asset	(172)	—
Total deferred tax liabilities	(172)	—
Valuation allowance	(11,595)	(44,770)
Net deferred tax liabilities	$ —	$ —

At December 31, 2019, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately $37,602 and $18,674 respectively, which were available to reduce future taxable

income. Federal net operating losses generated after January 1, 2018 may be carried forward indefinitely, however, utilization of these carryforwards is limited 80% of the Company's taxable income each year. Federal and state net operating loss carryforwards of $7,500 and $18,674 respectively, will expire at various dates from 2023 through 2039. $30,102 of the federal net operating losses, generated in 2018 and 2019, can be carried forward indefinitely. The Company has research and development credits for federal and state income tax purposes of approximately $318 and $81, respectively, which expire at various dates from 2022 through 2039.

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, 2019 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, 2019 and 2018. The valuation allowance decreased by $33,175 during the year ended December 31, 2019, primarily due to the reduction of tax credit and loss carryforwards that were determined to be limited under Sections 382 and 383 of the internal revenue code for future utilization by the Company.

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

The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company files income tax returns in the United States for federal and state income taxes. In the normal course of business, the Company is subject to examination by tax authorities in the United States. Since the Company is in a loss carry-forward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carry-forward is utilized. The Company's returns remain subject to federal and state audits for the years 2016 through 2019. 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, 2018	$ 1,109
Additions for current year tax positions	115
Additions for prior year tax positions	20
Balance — December 31, 2018	1,244
Additions for current year tax positions	87
Reductions for prior year tax positions	(1,244)
Balance — December 31, 2019	$ 87

The Company's total uncertain tax positions decreased during the year ended December 31, 2019 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,	
	2019	2018
Options to purchase common stock	900,003	972,573
Warrants to purchase common stock	18,653,195	3,730,944
Total	19,553,198	4,703,517

15. Subsequent Events

On December 31, 2019, 300,000 pre-funded warrants were exercised, and the Company collected proceeds of $3. Common shares were issued on January 2, 2020.

During January and February 2020, 176,747 warrants issued in April 2019 were exercised, and the Company collected proceeds of $239.

On January 3, 2020, 19,997 stock options were exercised, and the Company collected proceeds of $21.

On January 9, 2020, the Company granted 2,098,304 stock option awards to directors, employees and consultants.

On January 28, 2020, pursuant to the payment terms of the License, Development and Commercialization agreement, the Company received a milestone payment from JJEI of $7,200.

On February 4, 2020, 146,084 warrants issued in February 2019 were exercised cashlessly, and 30,000 shares were issued.

The Company has evaluated its events subsequent to December 31, 2019 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.

RESEARCH AND OPTION TO LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

between

JOHNSON & JOHNSON ENTERPRISE INNOVATION, INC.

and

PULMATRIX, INC.

DATE: December 26, 2019

PLEASE NOTE: CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

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LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

This License, Development, and Commercialization Agreement is made and effective as of December 26, 2019 (the "Effective Date"), and is between Johnson & Johnson Enterprise Innovation, Inc., a company incorporated in New Jersey and having a principal place of business at 1 Johnson and Johnson Plaza, New Brunswick, NJ 08940 ("Licensee" or "JJEI") and Pulmatrix, Inc., a company incorporated in the State of Delaware and having a place of business at 99 Hayden Avenue, Suite 390, Lexington, MA 02421 ("Licensor" or "Pulmatrix"). Licensor and Licensee are each referred to herein as a "Party" and are together referred to herein as the "Parties". Capitalized terms used in this Agreement shall have their respective meanings set forth in Article 1 (Definitions) below or, if not set forth in Article 1 (Definitions), the meaning designated elsewhere in this Agreement.

RECITALS

1. Licensor and Respivert Ltd. ("Respivert"), a subsidiary of Janssen Biotech, Inc. and an Affiliate of Licensee are currently parties to a License, Development, and Commercialization Agreement, dated June 9, 2017 (the "Exclusive License Agreement") pursuant to which Respivert has, among other things, granted Licensor an exclusive license to certain Patent rights and Know-How related to Compounds, and Licensor has, among other things, developed licensed products pursuant to the Exclusive License Agreement. Respivert has acknowledged and consented to Licensor entering into this Agreement as described in Appendix 8 (Side Letter).
2. Licensor desires to provide an assignment option to Licensee of all of Licensor's rights under the Exclusive License Agreement.
3. Licensor and Licensee desire to engage in the Clinical Study and the Toxicology Study, pursuant to a Research Plan, as further described in this Agreement and in the Research Plan.
4. Licensee, together with its Affiliate companies, possesses biological and other research, development, and commercialization capabilities, as well as proprietary technology in a broad range of therapeutic fields, and is interested in Developing and Commercializing one or more of the Compounds pursuant to the terms of this Agreement.
5. Licensor desires to assign and license certain rights, on an exclusive basis as set forth in this Agreement, to the Compounds and certain Technology and Know-How to Licensee, and Licensee desires to receive from Licensor an assignment and license to such Compounds, Technology, and Know-How.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the receipt, sufficiency, and adequacy of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

Capitalized terms used in this Agreement shall have their respective meanings set forth below or, if not set forth below, the meaning designated elsewhere in this Agreement. Whether stated expressly or not herein, any citation to any statute or regulation shall be deemed to include any amendment, replacement, or reenactment thereof for the time being in force.

1.1 “**Active Development**” means that at any given time Licensee, Sublicensee, or a delegated Affiliate shall use Commercially Reasonable Efforts to engage in one or more of the following Development activities for Licensed Products: formulation development, study/protocol design activity, awaiting protocol approval from the applicable institutional review board or FDA, patient recruitment, patient treatment, data analysis, report writing for any Clinical Trial, regulatory files being drafted or pending, pricing or marketing approvals pending, Manufacturing investment work, synthetic process development, drug synthesis, packaging development, manufacturing scale-up and validation, preclinical or in vitro characterization and go/no go decision awaited from a formal research and development committee within Licensee to initiate any of the preceding activities.

1.2 “**Active Pharmaceutical Ingredient**” or “**API**” means any substance or combination of substances used in a finished pharmaceutical product, intended to furnish pharmacological activity or to otherwise have a direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to have direct effect in restoring, correcting, or modifying physiological functions in human beings.

1.3 “**Affiliate**” means with respect to any Person, any other Person that directly or indirectly controls, is controlled by, or is under direct or indirect common control with such Person. For the purposes of this definition, the term “control” (including, with correlative meanings, the term “controlled by” and “under common control with”) as used with respect to any Person, means the possession of at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, or the power to direct or cause the direction of the management and policies of the other Person, or the power to elect or appoint at least fifty percent (50%) of the members of the governing body of the other Person through the ownership of the outstanding voting securities or by contract or otherwise. “Affiliate” of, or an entity

1.4 “**Agreement**” means this agreement, together with any other documents incorporated herein by reference, including its schedules and Appendices, as the same may be amended from time-to-time.

1.5 “**Applicable Law**” means all laws, statutes, rules, regulations, including any applicable rules, regulations, guidelines, or other requirements set forth by the Regulatory Authorities with jurisdiction over the activities performed under this Agreement, applicable to each of the Parties with respect to each such Party’s performance of their respective obligations under this Agreement, that may be in effect from time-to-time.

1.6 “**BLA**” means a biological license application filed pursuant to 42 USC Section 262 et. seq. including all documents, data, and other information concerning a Licensed Product which are necessary for, or included in, FDA approval to market a Licensed Product and all supplements and amendments, including supplemental biological license applications, that may be filed with respect to the foregoing as more fully defined in 21 C.F.R. §600 et seq.

1.7 “**Business Day**” means a day on which banking institutions in New York, N.Y. are open for business.

1.8 “**Calendar Quarter**” means a financial quarter based on the J&J Universal Calendar (a copy of which is attached hereto as Appendix 4 (Johnson & Johnson Universal Calendar)) for that year and is used by JJEI or its Affiliates for internal and external reporting purposes; provided, however, that the first (1st) Calendar Quarter for the first (1st) Calendar Year extends from the Effective Date to the end of the then-current Calendar Quarter and the last Calendar Quarter extends from the first (1st) day of such Calendar Quarter until the effective date of the termination or expiration of this Agreement.

1.9 "**Calendar Year**" means a year based on the J&J Universal Calendar for that year (a copy of which for 2019/2020 is attached hereto as Appendix 4 (Johnson & Johnson Universal Calendar)). The last Calendar Year of the Term begins on the first (1st) day of the J&J Universal Calendar Year for the year during which termination or expiration of the Agreement will occur, and the last day of such Calendar Year will be the effective date of such termination or expiration. The first (1st) Calendar Year will begin on the Effective Date and end on the last day of the first (1st) full Calendar Year thereafter.

1.10 "**Clinical Study**" shall have the meaning set forth under the Research Plan attached hereto as Appendix 3 (Research Plan).

1.11 "**Clinical Trial**" means any research study of a therapeutic product with human subjects designed to provide specific data to determine either or both the safety and/or efficacy of such product.

1.12 "**Combination Product**" means a product offering sold under a single price consisting of a Licensed Product in combination with, or supplied with, one or more other products containing one or more additional APIs, whether or not such other products are sold separately.

1.13 "**Commercially Reasonable Efforts**" means reasonable and good faith efforts by a Party to accomplish such objective as that Party would normally use to accomplish a similar objective under similar circumstances.

1.14 "**Commercialize**" or "**Commercialization**" means any and all activities directed to marketing, promoting, detailing, distributing, importing, having imported, exporting, having exported, selling or offering to sell, or otherwise exploiting, a pharmaceutical product following receipt of Regulatory Approval for such product in the applicable country, including conducting pre-and post-Regulatory Approval activities, including studies reasonably required to increase the market potential of the product and studies to provide improved formulation and delivery, and launching and promoting such product in each country.

1.15 "**Compound Patents**" means the patents licensed by Licensor under the Exclusive License Agreement, including those listed on Appendix 1A (Compound Patents).

1.16 "**Compounds**" means experimental narrow spectrum kinase inhibitor compounds designated as RV568, RV1162, and RV7031, and their salts, isomers, enantiomers, different physical forms (including amorphous forms), and polymorphs.

1.17 "**Control**" or "**Controlled**" means possession of the ability to grant a license or sublicense of Patents, Know-How, or other intangible rights as provided for herein without violating the terms of any contract or other arrangements with any Third Party.

1.18 "**Cover**" means, with respect to any subject matter, that the Manufacturing, using, selling, offering for sale, making, having made , or otherwise exploiting of such subject matter would, but for the licenses granted in this Agreement, infringe a claim of a Patent right in the country in which the activity occurs.

1.19 "**Currency Hedge Rates**" means the J&J currency hedge rate, which is the result of the effectively performed currency hedging at J&J for the then-current Calendar Year, as updated pursuant to Section 6.13 (Currency Exchange) and will be set up once a Calendar Year and will remain constant throughout such Calendar Year. The Currency Hedge Rate is calculated as a weighted average hedge rate of the outstanding external foreign currency forward hedge contracts of J&J with Third Party banks.

1.20 “**Development**” or “**Develop**” means all internal and external research, development, and regulatory activities related to pharmaceutical or biologic products, including (i) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities, and Clinical Trials and (ii) preparation, submission, review, and development of data or Information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic Product, but excluding activities that are directed to Manufacturing, Medical Affairs, or Commercialization. Development will include development and regulatory activities for additional forms, formulations, or Indications for a pharmaceutical or biologic Product after receipt of Regulatory Approval of such Product (including label expansion), including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved formulation or Indication (such as post-marketing studies and observational studies, if required by any Regulatory Authority in any region in the Territory to support or maintain Regulatory Approval for a pharmaceutical or biologic Product in such region). “Develops,” “Developing,” and “Developed” (and any similar derivatives of “Develop”) will be construed in accordance with this Section 1.20.

1.21 “**Development Milestone Event**” has the meaning set forth in Section 6.4 (Development Milestone Payments).

1.22 “**Development Milestone Payment**” has the meaning set forth in Section 6.4 (Development Milestone Payments).

1.23 “**Dollars**” means the legal currency of the United States.

1.24 “**Effective Date**” shall have the meaning set forth in the preamble to this Agreement.

1.25 “**EMA**” means the European Medicines Agency or any successor agency that is responsible for reviewing applications seeking approval for the sale of pharmaceuticals in the European Union.

1.26 “**FDA**” means the United States Food and Drug Administration or any successor agency.

1.27 “**Field**” means the diagnosis, treatment, palliation, amelioration, or prevention of (i) respiratory disease, condition, or symptom, and (ii) cancer or any related symptom, in humans or animals. “Respiratory disease, condition or symptom” is intended to include any disease, condition, or symptom that is (a) related to the respiratory system, or (b) diagnosed, treated, palliated, ameliorated, or prevented by an Active Pharmaceutical Ingredient delivered by the respiratory pathway, for example, including oral or nasal inhalation. Notwithstanding the foregoing, the Field does not include diagnosis, treatment, palliation, amelioration, or prevention of any gastrointestinal and/or ophthalmology Indications in humans, but the Field does include any cancer or related Indication, including without limitation any tumor suppression-related Indication in oncology such as cancers of the gastrointestinal tract and eye.

1.28 “**Financial Records**” has the meaning set forth in Section 6.12 (Financial Records).

1.29 “**First Commercial Sale**” means, with respect to a Licensed Product on a country-by-country basis, the first (1st) sale by JJEI or its Affiliates, Sublicensees, or, with respect to a Generic Equivalent, the first (1st) sale by a Third Party, in each case, in an arms-length transaction to a Third Party (other than a Sublicensee) for use or consumption by the general public of that Licensed Product or Generic Equivalent in a country after all required Regulatory Approvals for commercial sale of that Licensed Product or Generic Equivalent have been obtained in such country. A sale of a Licensed

Product for: (i) Clinical Trial purposes; (ii) compassionate use, named patient sales, or patient assistance programs; (iii) similar uses in a limited number to support Regulatory Approvals, such as test marketing programs or other similar programs or studies (provided that the Licensed Product is not otherwise generally available for purchase in such country); or (iv) early access programs, in each case ((i) – (iv)), will not constitute a First Commercial Sale of such Licensed Product. In addition, sales of a Licensed Product by and between JJEI and its Affiliates or Sublicensees will not constitute a First Commercial Sale.

1.30 "**Generic Equivalent**" means a product that is being sold in a country without infringing a claim of a Licensed Patent covering a Licensed Product being sold hereunder by Licensee, which would have infringed such claim of a Licensed Patent, or which would have prevented a Third Party from selling the product, if such claim of a Licensed Patent were in force in that country.

1.31 "**Governmental Authorities**" means any court, tribunal, arbitrator, agency, commission, department, ministry, official, authority, or other instrumentality of any national, state, county, city, or other political subdivision.

1.32 "**Improvements**" means any adaptation, change, modification, redesign, change in formulation, dosage, or mode of delivery, any additional Indications in the Field, and any change in a Compound, the Technology, or the Licensed Product resulting from a change in the Manufacturing process, which utilizes or is derived from information Controlled by Licensor or its Affiliates during the Term.

1.33 "**Indication**" means a recognized disease or condition as identified in a NDA or BLA for a Licensed Product.

1.34 "**Information**" means all information including, but not limited to, screens, assays, models, inventions, practices, methods, knowledge, Know-How, skill, experience, test data including pharmacological, toxicological, and clinical test data, analytical and quality control data, marketing, pricing, distribution, costs, sales, Manufacturing secrets and procedures, secret processes, reports, plans, designs, prototypes, test results, working drawings, methods including testing methods, formulas, recipes, material and performance specifications, and current accumulated experience acquired as a result of technical research or otherwise, and patent and legal data or descriptions (to the extent that disclosure thereof would not result in loss or waiver of privilege or similar protection) and methods as each of the foregoing relate to the Licensed Product and is Controlled by a Party or its Affiliates.

1.35 "**iSPERSE Patents**" means any Patents owned or controlled by Licensor covering the iSPERSE Technology and not containing claims to iSPERSE Technology in combination with a Compound, including those listed in Appendix 1B (iSPERSE Patents).

1.36 "**iSPERSE Technology**" means Licensor's proprietary platform for inhaled drug delivery based on the following unique properties: dense, high drug load, engineered particles with highly efficient dispersibility and delivery to the airways.

1.37 "**Know-How**" means all Information, including Manufacturing secrets and procedures.

1.38 "**Licensed Patent**" means all patents that (a) are Controlled by Licensor as of the Effective Date; and (b) are necessary and useful for the Development, Manufacture, use, or Commercialization of the Compounds, Technology, and the Licensed Products. Licensed Patents, including all patents that claim iSPERSE Technology in combination with a Compound and those listed in Appendix 1C (Licensed Patents), but excluding the Compound Patents and the iSPERSE Patents.

1.39 "**Licensed Product**" means any product containing a Compound as an API, either alone or in combination with one or more other APIs, in any formulation, dosage form, or method of delivery, that the sale, Manufacture, importation, or use, but for the license rights granted in this Agreement, would directly infringe, or contribute to, or induce the infringement of a Valid Claim of a Licensed Patent.

1.40 "**Licensee Indemnitees**" has the meaning set forth in Section 9.1.1.

1.41 "**Licensee Know-How**" means Know-How which (i) Licensee discloses to Licensor under this Agreement or under the Confidentiality Agreement between the Parties dated August 12, 2019, and (ii) is within the Control of Licensee during the Term of the Agreement.

1.42 "**Licensee Patent**" means the rights granted by any Governmental Authority under a Patent owned or Controlled by Licensee during the Term claiming a method, apparatus, material, Manufacture, or business method relating to a Licensed Product.

1.43 "**Licensor Indemnitees**" has the meaning set forth in Section 9.1.2.

1.44 "**Licensor Know-How**" means Know-How that (a) Licensor discloses to Licensee under this Agreement or under the Confidentiality Agreement between the Parties dated August 12, 2019, (b) is within the Control of Licensor during the Term of the Agreement, and (c) and that is not generally known to the public at the time it is disclosed to Licensee or its Affiliates.

1.45 "**Licensor Materials**" means the Compounds, physical API, formulated API bulk material and on-hand intermediaries required for the Manufacture of Compounds, in the quantities listed in Appendix 2 (Licensor Materials and Technology).

1.46 "**Losses**" has the meaning set forth in Section 9.1.1.

1.47 "**Manufacture**" means activities that are directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping or storage of any pharmaceutical or biologic product (or any components or process steps involving any product or any companion diagnostic), placebo or comparator agent, as the case may be, including process, development, qualification, validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization and stability testing, but excluding activities that are directed to Development, Commercialization or Medical Affairs. "Manufacturing" and "Manufactured" and any similar derivatives of "Manufacture" will be construed in accordance with this Section 1.47.

1.48 "**Medical Affairs**" means activities conducted by a Party's medical affairs departments (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies) and charitable donations to the extent related to medical affairs and not to other activities that do not involve the promotion, marketing, sale or other Commercialization of products and are not conducted by a Party's medical affairs (or equivalent) departments.

1.49 "**NDA**" means a new drug application filed pursuant to 21 U.S.C. Section 505(b)(1), as amended from time-to-time, or equivalent submissions with similar requirements in other countries including all documents, data, and other Information concerning a Licensed Product which are necessary for or included in FDA approval to market a Licensed Product and all supplements and amendments, including supplemental new drug applications, that may be filed with respect to the foregoing as more fully defined in 21 C.F.R. §314.50 et. seq., as amended from time-to-time, or equivalent submissions with similar requirements in other countries.

1.50 “**Net Sales**” means the gross amounts invoiced on sales of a Licensed Product by JJEI, or any of its Affiliates or Sublicensees (excluding any Third Party distributor or Compulsory Sublicensee) to a Third Party purchaser (including any Third Party distributor), less the following customary and commercially reasonable deductions (without duplication), determined in accordance with GAAP and internal policies and actually taken, paid, accrued, allocated, or allowed based on good faith estimates:

a. trade, cash, or quantity discounts, allowances and credits, excluding commissions for Commercialization;

b. excise taxes, use taxes, tariffs, sales taxes and customs duties, or other government charges imposed on the sale of Licensed Product (including VAT, but only to the extent that such VAT taxes are not reimbursable or refundable), specifically excluding, for clarity, any income taxes assessed against the income arising from such sale;

c. compulsory or negotiated payments and cash rebates or other expenditures to Governmental Authorities (or designated beneficiaries thereof) in the context of any national or local health insurance programs or similar programs, including pay-for-performance agreements, risk sharing agreements as well as government levied fees as a result of the Affordable Care Act and other similar legislation and foreign equivalents;

d. rebates, chargebacks, administrative fees, and discounts (or equivalent thereof) to managed health care organizations, group purchasing organizations, insurers, pharmacy benefit managers (or equivalent thereof), specialty pharmacy providers, Governmental Authorities, or their agencies or purchasers, reimbursers or trade customers, as well as amounts owed to patients through co-pay assistance cards or similar forms of rebate to the extent the latter are directly related to the prescribing of the Licensed Product;

e. outbound freight, shipment, and insurance costs to the extent included in the price and separately itemized on the invoice price;

f. retroactive price reductions, credits, or allowances actually granted upon claims, rejections, or returns of Licensed Product, including for recalls or damaged or expired goods, billing errors and reserves for returns;

g. any invoiced amounts that are not collected by the selling Party or its Affiliates, including bad debts, unless otherwise recovered; and

h. any deductions in the context of payments that are due or collected significantly after invoice issuance, provided that such payments are included in revenue, if collected.

Net Sales will include named patient sales only if the applicable Licensed Product is sold at a price greater than the applicable cost of goods (as determined in accordance with GAAP). Net Sales will not include transfers or dispositions for: (i) Clinical Trial purposes; (ii) compassionate use or patient assistance programs; (iii) similar uses in a limited number to support Regulatory Approvals or as required by any Governmental Authority, such as test marketing programs or other similar programs or studies, provided that the Licensed Product is not otherwise generally available for purchase in such country; (iv) early access programs; or (v) free samples or donations. In addition, Net Sales will not include transfers or dispositions of a Licensed Product by and among JJEI and its Affiliates and Sublicensees.

All aforementioned deductions will only be allowable to the extent they are commercially reasonable by JJEI and will be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount verifiable based on JJEI's and its Affiliates' and Sublicensee's reporting system. All such discounts, allowances, credits, rebates, and other deductions will be fairly and equitably allocated between the Licensed Product and other products of JJEI and its Affiliates and Sublicensees such that the Licensed Product does not bear a disproportionate portion of such deductions.

If a Licensed Product is sold as part of a Combination Product in a given country in the Territory, then Net Sales for such Combination Product in such country will be determined as follows:

A. In the event that any Licensed Product is sold in the form of Combination Products containing one or more other products, if the licensed Compound is sold separately and all other products in such Combination Product are sold separately, then Net Sales for the determination of royalties of Combination Products will be calculated by multiplying Net Sales of such Combination Product by the fraction A/(A+B) where A is the average Net Sales price of the licensed Compound component contained in the Combination Product in the applicable country and B is the sum of the average Net Sales prices of all other product components included in the Combination Product in the applicable country.

B. If the licensed Compound is sold separately, but not all other products in a Combination Product are sold separately, then Net Sales for the determination of royalties of Combination Products will be calculated by multiplying Net Sales of such Combination Product by the fraction A/C where A is the average Net Sales price of the licensed Compound component in the Combination Product in the applicable country and C is the average Net Sales price of the entire Combination Product in the applicable country.

C. If the licensed Compound is not sold separately, but all other products in a Combination Product are sold separately, then Net Sales for such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction (C-B)/C where B is the sum of the average Net Sales prices of all other product components included in the Combination Product in the applicable country and C is the average Net Sales Price of the entire Combination Product in the applicable country.

D. If Net Sales of a Combination Product cannot be determined using the methods A through C above, then the Parties will negotiate in good faith, at the latest six (6) months before the expected launch of such Combination Product, an allocation of Net Sales of such Combination Product to the respective API components or product components thereof, as the case may be, based on the fair market value of such components for the purposes of determining a Licensed Product specific or licensed API specific allocated Net Sales, and if the Parties are unable to agree on such a reasonable allocation no later than three (3) months prior to the estimated launch date of such Combination Product, then Net Sales of such Combination Product will be calculated based on JJEI's good faith estimate of the fair market value of the licensed Compound and each of the other product components included in such Combination Product when sold in such country. Payments related to such Combination Product under this Agreement, including royalty payments, will be calculated, due, and payable based only on such allocated Net Sales.

1.51 “**Patents**” shall mean all patents and patent applications, including any continuations, continuations-in-part, divisions, provisionals, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal, or extension (including any supplemental patent certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

1.52 “**Person**” shall mean an individual, corporation, partnership, joint venture, limited liability entity, Governmental Authority, unincorporated organization, trust, trustee, association, or other entity.

1.53 “**Phase III Clinical Trial**” means a randomized, well-controlled Clinical Trial in humans of the efficacy and safety of a Licensed Product alone or in combination with another active agent, which is prospectively designed to demonstrate statistically whether the Licensed Product, alone or in combination with another active agent, is safe and effective for use in a particular Indication, as more fully defined in 21 C.F.R. § 312.21(c), as amended from time-to-time, and equivalent submissions with similar requirements in other countries in the Territory in a manner intended to be sufficient to be sufficient to obtain Regulatory Approval to market that research and development candidate.

1.54 “**Product**” means a pharmaceutical product in any dosage form intended for the prevention, treatment, or diagnosis of disease in humans or animals.

1.55 “**Program**” shall mean a program of research devised and developed by Licensor and Licensee for Licensor to perform a Clinical Study and a Toxicology Study, both as defined in the Research Plan, and as more fully described in the Research Plan.

1.56 “**Program Budget**” has the meaning set forth in Section 2.4.3 (Funding).

1.57 “**Related Party**” and “**Related Parties**” means each of Licensor’s and Licensee’s Affiliates and Sublicensees.

1.58 “**Regulatory Approval**” means, with respect to a pharmaceutical Product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the Manufacture, distribution, use, marketing, and sale of such Product in such jurisdiction in accordance with Applicable Laws. In jurisdictions where the applicable Regulatory Authority sets the pricing or reimbursement authorizations necessary for the general marketing and sale of such Product in the marketplace, Regulatory Approval will not be deemed to have occurred unless and until final approval with respect to pricing or reimbursement has been granted by the applicable Regulatory Authority. “Regulatory Approval” does not include authorization by a Regulatory Authority to conduct named patient, compassionate use, or other similar activities.

1.59 “**Regulatory Approval Application**” means an application for Regulatory Approval required before commercial sale or use of a Licensed Product in a regulatory jurisdiction.

1.60 “**Regulatory Authority**” means any Governmental Authority, including the FDA, EMA, or Koseisho (i.e., the Japanese Ministry of Health and Welfare, or any successor agency thereto), or any other equivalent Governmental Authority, that has responsibility for granting any licenses or approvals or granting pricing or reimbursement approvals necessary for the marketing and sale of a pharmaceutical Product in any country.

1.61 “**Research Plan**” means the Parties’ plan for the Development activities to be conducted by Licensor during the Research Term with respect to the Clinical Study and the Toxicology Study (funded by Licensor and Licensee, respectively), as described in Appendix 3 (Research Plan), attached hereto (Research Plan).

1.62 “**Sales Milestone Event**” has the meaning set forth in Section 6.5 (Sales Milestones).

1.63 “**Sales Milestone Payment**” has the meaning set forth in Section 6.5 (Sales Milestones).

1.64 “**Sublicensee**” shall mean, with respect to a particular Licensed Product, a Third Party to whom Licensee has granted a license or sublicense under any Licensee Patents, Licensor Know-How, Licensed Patents or other intellectual property licensed to Licensee hereunder, to make, use, and sell such Licensed Product. As used in this Agreement, “Sublicensee” shall also include a Third Party to whom Licensee has granted the right to distribute a Licensed Product.

1.65 “**Technology**” means any and all inventions, whether or not patentable, discoveries, ideas, Know-How, or any other intellectual property, that Licensor owns, controls, or has access to, that covers or is necessary or reasonably useful for the research, Development, Manufacture, or Commercialization of any Compound or Licensed Product in the Field pursuant to this Agreement.

1.66 “**Term**” shall have the meaning ascribed thereto in Section 10.1 (Term).

1.67 “**Territory**” means the entire world.

1.68 “**Third Party**” means an individual, corporation, or any other entity other than Licensor and Licensee, and any of their Related Parties.

1.69 “**Toxicology Study**” shall have the meaning set forth in the Research Plan, attached hereto as Appendix 3 (Research Plan).

1.70 “**Valid Patent Claim**” means a claim in any Licensed Patent, which claim has not expired or been held invalid by a non-appealed or unappealable decision by a court or other appropriate body of competent jurisdiction. In addition, and when referring to the European Union or to any of its member states, a claim shall not be a Valid Patent Claim unless it is issued or pending in its regional or national phase, in each and all members of the European Union or the European Patent Convention, whichever has the largest number of member states, as of the Effective Date of this Agreement. For the purpose of royalty determination and payment, any claim being prosecuted in a pending patent application shall be deemed to be a “Valid Patent Claim” provided such claim is not pending for more than six (6) years from the earliest filing date of the patent application in which case it shall cease to be considered a Valid Patent Claim until the patent issues.

ARTICLE 2

RESEARCH PROGRAM

2.1 **Scope; Research Plan; Program**. The Parties wish to engage in the Program, as set forth in Appendix 3 (Research Plan) (as such Program may be updated by mutual written agreement between the Parties from time to time).

2.1.1 Each Party’s shall perform its obligations under the Research Plan and this Agreement in compliance with applicable local, state, and federal laws, regulations, and ordinances, including the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations, the Medicare/Medicaid Anti-kickback Statute, Health Insurance Portability and Accountability Act of 1996 (HIPAA), the False Claims Act, applicable state fraud and abuse laws, the AMA Guidelines on Gifts to Physicians from Industry, the Economic Espionage Act of 1996 and applicable laws and government regulations relating to services and the privacy, professional confidentiality and security thereof.

2.1.2 Each Party certifies that it is not debarred by a competent health authority (including, if applicable, the US FDA) or by the Professional Council of Physicians. The Parties shall not knowingly employ, contract with, or retain any person, directly or indirectly, to perform work under the Agreement if such a person is or if it becomes aware that such person becomes debarred by a competent health authority (including, if applicable, the US FDA) or by the Professional Council of Physicians. Upon written request from either Party shall, within ten (10) calendar days, provide written confirmation that it has complied with the foregoing obligation.

2.1.3 Each Party agrees to notify the other Party of any final adverse action, discovery of contract with an excluded entity or individual, or exclusion within thirty (30) calendar days of such action which relates to this Agreement or the personnel working on the Research Plan.

2.1.4 The Physician Payments Transparency Requirements of the Patient Protection and Affordable Care Act of 2010 (codified at 42 U.S.C. 1320a-7h) and implementing regulations, require certain pharmaceutical, medical device, and other companies to annually report to the Centers for Medicare and Medicaid Services (CMS) certain information about payments and transfers of value provided directly or indirectly to U.S. physicians and teaching hospitals, which CMS will make publicly available. This includes any payments or transfers of value that Licensee provides indirectly through Licensor to U.S. physicians and teaching hospitals. As required by law, Licensee will report to CMS information about payments and transfers of value that Licensor provides to U.S. physicians and teaching hospitals pursuant to this Agreement. This includes any portion of any payment or transfer of value that Licensee furnishes to Licensor which Licensor then provides directly or indirectly to U.S. physicians or teaching hospitals, including its employees, agents, or contractors. Information that Licensee must report includes the identity and business address of each relevant U.S. physician or teaching hospital, the value and purpose of any payments or transfers of value that are furnished, and any other information as may be required by law. To enable Licensee to comply with its legal obligations, Licensor, in a reporting form mutually agreed by the Parties, shall track, maintain, and report to Licensee information and data related to any payments or transfers of value that Licensor provides to U.S. physicians and teaching hospitals under this Agreement. Licensor shall provide such reports in a timely manner. Licensee may also report information about payments or transfers of value provided to U.S. physicians and teaching hospitals under this Agreement as otherwise required by law and Licensee reserves the right to post such information on a website accessible to the public such information, as required by law.

2.1.5 Licensor represents and warrants that any payment made hereunder is the fair-market value for carrying out the Research Plan hereunder. Further, Licensor represents and warrants that any payment to a Third Party entity for work under this arrangement represents fair-market value and has been negotiated in an arms-length transaction, and that all such payments have not been determined in a manner that takes into account the volume or value of any referrals or other business otherwise generated between Licensor and Licensee. For clarity, nothing contained in this Agreement shall be construed in any manner as an obligation or inducement for any Licensor personnel who are healthcare professionals to recommend that patients purchase any products of Licensee or of any of its Affiliates.

2.2 **Scientific Steering Committee**. Promptly after the Effective Date, the Parties shall form a steering committee consisting of three (3) representatives from each Party (the “Steering Committee”) to monitor and manage the scientific progress of the Program and for the purpose set forth in Section 2.4.3(c) (Funding). The Steering Committee shall meet from time-to-time promptly after the date of a written request by either Party and shall operate by consensus. Steering Committee meetings may be conducted in person, via video conference, or by teleconference. Either Party may change its Steering Committee members upon written notice to the other Party. Except as provided in Section 2.4.3(c) (Funding) with respect to a permitted increase in the Program Budget, the Steering Committee shall have no power to amend or waive compliance with this Agreement or to amend the Research Plan.

2.3 **Program Intellectual Property Disputes**. The Parties shall use reasonable, good faith efforts to address all issues concerning the inventorship and ownership of, or any rights to, intellectual property Developed in connection with this Agreement in a fair and equitable manner and in accordance with the requirements of United States law to achieve the goals of the Research Plan. If a Dispute arises concerning the intellectual property and the Parties are unable to resolve the Dispute within thirty (30) calendar days' after commencing discussions, either Party may begin the alternative Dispute resolution procedure set out in Article 12 (Dispute Resolution).

2.4 **Performance under Program**

2.4.1 Each Party will use Commercially Reasonable Efforts to perform its obligations as described in the Research Plan. The Parties acknowledge and agree, however, that no outcome or success is or can be assured and that failure to achieve desired results do not in and of itself constitute a breach or default of any obligation in this Agreement. Any amendments to the Research Plan must be approved in writing by both Parties.

2.4.2 In the course of performance of the Research Plan, either Party may request a change thereto if the requesting Party believes that the Research Plan will not satisfy the objective, provide the measurable outcomes, or achieve the Program deliverables as described in the Research Plan. In response to such request, the Parties shall promptly discuss how to address such deficiency. If the changes to the Research Plan requested are acceptable to the other Party, the Parties shall execute an amendment to the Research Plan to reflect any material changes thereto. Additionally, Licensee may, on an ongoing basis, review and provide commentary and feedback on the protocol for the Clinical Study included in the Research Plan in order to ensure that the protocol and the Research Plan meet Licensee's requirements for the Program set forth in Appendix 3 (Research Plan). Licensor shall use Commercially Reasonable Efforts to review and include any such commentary and feedback in the protocol for the Clinical Study and provide responses to Licensee with respect to Licensee's commentary and feedback.

2.4.3 Funding. Prior to Licensee's election to excise the Option, Licensor and Licensee shall fund the Program in accordance with the requirements of the Research Plan. The Research Plan shall, include a total of the approved costs, fees, and expenses to be paid by the Parties hereunder (the "Program Budget").

(a) Licensor shall be responsible for all costs incurred in its performance of the Development activities set out in the Research Plan in relation to the Clinical Study. Such activities may include, but are not limited to: data collection, analysis, and report writing; and clinical laboratory work, each as further described in the Research Plan.

(b) Licensee shall be responsible for all direct costs incurred in Licensor's performance of the Development activities set out in the Research Plan in the relation to the Toxicology Study in an amount up to three million three hundred seventy-one thousand fifteen U.S. Dollars ($3,371,015). Such activities may include: Development activities related to test method development and stability testing, toxicology and/or toxicity studies, formulation, process development, manufacturing scale-up, qualification and validation, and quality assurance/quality control (to the extent related to the Toxicology Study).

(c) In the event that the actual costs of the Program are expected to exceed the Program Budget, the Steering Committee shall, upon the request of Licensor, promptly meet and convene to discuss the Program Budget. Any changes to the Project Budget require the approval of the Steering Committee; provided that changes to the Program Budget by up to seven and one-half percent (7.5%) may be approved by the Steering Committee without any requirement to amend this Agreement.

In the event that the increase in costs exceeds seven and one-half percent (7.5%) of the Program Budget, then the parties may mutually agree (although neither party is required to do so) to any necessary increase in the Program Budget and, if the parties are unable to agree on an increase in the budget, then this Agreement shall remain in effect in accordance with its terms.

2.4.4 Reports. During the term of the Program as described in the Research Plan (the "Research Term"), Licensor shall provide written reports to Licensee within fifteen (15) calendar days' of the end of each Calendar Quarter of Licensor's work pursuant to the Program. Licensor shall provide Licensee a final written report within thirty (30) calendar days of the completion of the Research Term.

2.4.5 Exclusivity; Independent Development. This Agreement shall in no way preclude Licensee from independently Developing, having Developed, or acquiring any other materials or programs, irrespective of their similarity with any Technology, or the Program, nor shall it preclude or restrict Licensee from selling, licensing, sublicensing, or otherwise using or disposing of, Products derived from its own technology, without any accountability, liability, or obligation whatsoever to Licensor.

2.4.6 Research Term Extensions. The Parties may agree to extend the Research Term by mutual written agreement and will discuss any requested extension in good faith. It is not anticipated that the Research Term will be extended unless Licensee agrees to fund additional research activities that were not contemplated by the Parties as part of the Program when the Research Plan was created; provided, however, that if any functions, activities, tasks, subtasks, responsibilities, deliverables, and other services not specifically described in the Research Plan or this Agreement are inherent, reasonably necessary, or a customary part of the Program, or are needed to successfully deliver the deliverables of the Program as required under this Agreement, they shall be deemed to be included within the Program to be delivered to Licensee for the fees set forth in this Agreement and included in the Program Budget, as if such functions, activities, tasks, subtasks, responsibilities, deliverables, and other services were specifically described herein. Subject to the foregoing, if either Party considers an extension of the Research Term is necessary or desirable to achieve the Program's goals, then the Parties shall discuss in good faith an extension to the Research Term and additional research, if any, to be funded by Licensee during the extension.

2.4.7 Research-Term Regulatory Matters. During the Research Term, Licensor shall have sole responsibility for all Regulatory Approvals and any regulatory filings, submissions, and other regulatory materials, including CTA and relevant Regulatory Authority correspondence, associated with the Clinical Study and the Toxicology Study.

ARTICLE 3

OPTION, ASSIGNMENT, AND LICENSE RIGHTS

3.1 **Assignment Option**

3.1.1 Licensor hereby grants, and shall grant, to Licensee an exclusive option, exercisable by Licensee in its sole discretion, commencing on the Effective Date and expiring three (3) months from the later of (i) receipt of the final report for the Clinical Study, or (ii) receipt of the audited draft reports for the Toxicology Study ("Option Period"), as such Option Period may be extended upon the mutual agreement of the Parties, to obtain an assignment of all rights and interest that Licensor has pursuant to the Exclusive License Agreement, including all rights with respect to the Compound Patents, and including with respect to the license for licensed products pursuant to Article 2 of the Exclusive License Agreement, development of licensed products pursuant to Article 3 of the Exclusive License

Agreement, commercialization of licensed products pursuant to Article 4 of the Exclusive License Agreement, and all other rights and interests associated therewith, as further described in the Exclusive License Agreement ("Option"). Licensee may exercise the Option by delivering to Licensor during the Option Period, and any mutually agreed extension thereof, irrevocable written notice of Licensee's intent to enter into the assignment and by signing the assignment agreement attached hereto as Appendix 6 (Assignment Agreement) (the "Assignment Agreement"), which Licensor will sign within two (2) Business Days after receipt and return a fully signed Assignment Agreement to Licensee immediately thereafter. Upon the effective date of the assignment as reflected in the Assignment Agreement, (i) Licensee shall have accepted such assignment and agreed to assume and fully perform all of Licensor's obligations and liabilities pursuant to the Exclusive License Agreement, (ii) each of Licensee and Licensor shall have consented to the assignment, and (iii) Licensor shall have represented and warranted to Licensee that (a) no interest in the assigned rights has been previously assigned to any Person, whether in accordance with or in breach of the Exclusive License Agreement, (b) all rights and interests in and to the assigned rights are assignable free and clear of any liens, without any further action or consent, and (c) the rights and interests being assigned to Licensee hereby constitute all of the rights and interest in and to the assigned rights. The Option is irrevocable subject only to Licensor's termination of this Agreement pursuant to Section 10.3 (Termination for Breach). The exercise of the Option by Licensee hereunder shall be irrevocable.

3.1.2 Upon Licensee's exercise of the Option, Licensee shall have and shall retain sole and exclusive responsibility for complying with all Applicable Laws that govern the Licensed Products and related activities.

3.1.3 During the Option Period, and any extension thereof, and throughout the Term, Licensor shall neither grant to any Person (other than Licensee), nor directly or indirectly solicit, initiate, facilitate, encourage, or participate in any discussions or negotiations with any Person concerning entering into, continuing, or consummating any transaction under which any Person other than Licensee does or will obtain any right, title, or interest in, to, or under any of the Compounds.

3.1.4 Licensee has no obligation or commitment to exercise the Option or to enter into the Assignment Agreement or any other agreement relating to the subject matter hereof.

3.2 **License for Licensed Products**

3.2.1 Subject to the terms and conditions of this Agreement and upon Licensee's exercise of the Option, Licensor hereby grants to Licensee an exclusive, worldwide license under the Licensed Patents, Licensor's Technology (other than the iSPERSE Technology), and Licensor's Know-How (other than Know-How related to the iSPERSE Technology) to Develop, discover, research, make, have made, use, sell, have sold, import, offer to sell, and otherwise exploit and Commercialize Compounds, Technology, and the Licensed Products and Improvements in the Field, in the Territory, with the right to sublicense through multiple tiers. The foregoing license shall include any Patent rights that Licensor owns or has access to that Cover the Compounds or the Licensed Products, and any methods for Manufacturing the Licensed Products.

3.2.2 Subject to the terms and conditions of this Agreement and upon Licensee's exercise of the Option, Licensor hereby grants to Licensee an exclusive, perpetual, irrevocable, worldwide license under the iSPERSE Patents, iSPERSE Technology, Improvements (to the extent provided in Section 4.3 (Access to Improvements)), and Licensor's Know-How related to iSPERSE Technology solely and exclusively to Develop, discover, research, make, have made, use, sell, have sold, import, offer to sell, and otherwise exploit and Commercialize the Licensed Products and Improvements in the Field with the right to (i) sublicense through multiple tiers, and to (ii) research and conduct Clinical

Trials necessary or useful for Licensee to practice the license described in Section 3.2.1. The foregoing license shall include (i) any Patent rights that Licensor owns or has access to that Cover the Compounds or the Licensed Products, and any methods for Manufacturing the Licensed Products including any iSPERSE Patents to the extent such Patent rights solely and exclusively Cover the Compounds and/or the Licensed Products, and (ii) to the extent provided in Section 4.3 (Access to Improvements), any Improvements to the iSPERSE Technology or Know-How related to the iSPERSE Technology developed after the Effective Date.

3.2.3 To the extent that formulation of a Compound with the iSPERSE Technology is required in order for Licensee to Develop, discover, research, make, have made, use, sell, have sold, import, offer to sell, and otherwise exploit and Commercialize Compounds, Technology, and the Licensed Products and Improvements in the Field, in the Territory, pursuant to the licenses granted in Sections 3.2.1 and 3.2.2, Licensee may (i) enter into a separate written agreement with Licensor for Licensor to perform such services subject to terms mutually agreed by the Parties, or (ii) perform such formulations itself or through a Third Party in Licensee's sole discretion.

3.2.4 The exclusive license granted under Section 3.2.1 shall mean such license rights are exclusive to Licensee for the Term of this Agreement in the Field and the Territory and have not previously been subject to any licensing, assignment, or other encumbrance prior to the Effective Date that would contravene Licensee's right to practice exclusively under the Licensed Patents and Know-How in the Territory.

3.2.5 Licensee may sublicense its rights to Licensed Product to Third Parties without Licensor's prior written approval; provided, however, that any such sublicense occurs pursuant to a written agreement that subjects such Sublicensee to any relevant restrictions in this Agreement. In addition, and notwithstanding the foregoing, Licensee may, without the need for approval by Licensor, distribute Licensed Product through a Third Party, granting any necessary licenses or sublicenses using Third Party distributors.

3.2.6 Licensee may exercise its rights and perform any or all of its obligations under this Agreement, through its Affiliates; provided that, any such Affiliates are bound by applicable terms and conditions of this Agreement to the same extent as Licensee. Licensee is responsible for its sublicensees' (including Affiliates, as applicable) compliance with applicable terms and conditions of this Agreement, and any act or omission of a sublicensee or Affiliate that would be a material breach of this Agreement if committed by Licensee will be deemed to be a material breach by Licensee.

ARTICLE 4

DEVELOPMENT OF LICENSED PRODUCTS

4.1 **Licensee's Right to Select Licensed Products**. After Licensee exercises the Option pursuant to Section 3.1 (Assignment Option), Licensee shall be solely responsible for and shall have the sole right to Develop, and seek Regulatory Approval for, the Licensed Product, including making all Regulatory Approval Applications and obtaining, holding, and maintaining all Regulatory Approvals throughout the Territory during the Term.

4.2 **Licensor's Responsibilities**. After Licensee exercises the Option pursuant to Section 3.1 (Assignment Option), Licensor shall use Commercially Reasonable Efforts to assist Licensee, at Licensee's sole expense, in Licensee's Development activities relating to any Licensed Product, as reasonably requested by Licensee, by providing Licensee any relevant Licensor Know-How relating to Licensed Products being Developed by Licensee.

4.3 **Access to Improvements**. After Licensee exercises the Option, Licensor shall promptly identify to Licensee and disclose to Licensee, during the Term, all Improvements that directly relate to making, Developing, using, or selling Licensed Products, to which Licensor or its Affiliates have or obtain rights to practice. During the Term, Licensor shall furnish Licensee with Licensor Know-How concerning such Improvements. Licensor shall provide reasonable technical assistance at no additional cost to enable Licensee to utilize such Improvements if Licensee elects to do so; provided that Licensee shall promptly reimburse Licensor for any reasonable out-of-pocket expenses incurred by Licensor in providing such assistance. Such Improvements and Know-How shall be automatically deemed to be within the scope of the assignments and licenses herein granted without payment of any additional compensation.

4.4 **Licensee Development Efforts**. Licensee agrees to use Commercially Reasonable Efforts to Develop Licensed Products. Evidence that Licensee is using the efforts described in this Section to Develop a Licensed Product shall be that such Licensed Product is in Active Development. Without limiting the foregoing, Licensee shall also use its Commercially Reasonable Efforts to obtain any go/no-go decisions from any formal research and development committee within Licensee.

4.5 **Filing Reports**. Any reports made to Regulatory Authorities in the Territory in connection with any Licensed Product hereunder, including adverse reaction reports, after Licensee has exercised the Option, if ever, shall be made exclusively by Licensee or its designee.

ARTICLE 5

OPTION-TERM COMMERCIALIZATION OF LICENSED PRODUCTS

5.1 **Manufacture of Licensed Product**. Licensee or its Affiliates shall be responsible for Manufacturing and supplying the Licensed Products in the Territory by itself or through one or more Third Party Manufacturers for commercial sale of Licensed Product in the Territory. Licensee shall be solely responsible for ensuring that the Licensed Products and any APIs or other components are Manufactured in accordance with all Applicable Laws.

5.2 **Commercial Responsibilities**. Licensee agrees to use Commercially Reasonable Efforts to Commercialize Licensed Products.

5.3 **Licensee's Marketing Obligations For Licensed Products**. All business decisions, including the design, sale, price, and promotion of Licensed Products, including decisions whether to market any particular Licensed Product in a given country, shall be within the sole discretion of Licensee. Licensee shall also be solely responsible for compliance with any applicable legal and/or regulatory requirements, restrictions and/or prohibitions that govern the marketing, advertising, promotion and/or sale of the Licensed Products. Licensee shall annually report to Licensor on Licensee's developments with respect to achievement of Development Milestone Events and Sales Milestone Events, consistent with Licensee's marketing obligations as required hereunder.

5.4 **Trademarks**. Licensee shall select its own trademarks under which it will market the Licensed Products, and no right or license is granted to Licensor hereunder with respect to such trademarks.

ARTICLE 6

FINANCIALS AND REPORTING

6.1 **Upfront Payment**. Licensee will pay to Licensor an upfront payment of seven million two hundred thousand U.S. Dollars ($7,200,000) as a one-time, non-refundable, non-creditable upfront payment in consideration of the rights granted to Licensee under this Agreement within thirty (30) calendar days' after the Effective Date.

6.2 **Option Fee**. Licensee will pay a non-refundable license fee of fourteen million U.S. Dollars ($14,000,000) within thirty (30) calendar days' after Licensee exercises the Option and the assignment becomes effective pursuant to the terms of this Agreement.

6.3 **RV1162 Phase Ib Completion Milestone**. Licensee will pay a non-refundable milestone payment of two million U.S. Dollars ($2,000,000) within thirty (30) calendar days' after receipt of an invoice following completion of the Clinical Study as defined and described in the Research Plan, Licensor's providing of a final report with respect to same to Licensee, which report shall conform in form and substance to the requirements established by Licensee within ninety (90) calendar days after the Effective Date. For the avoidance of doubt, the foregoing payment shall not be payable by Licensee to Licensor if the Clinical Study is not completed according to the Research Plan.

6.4 **Development Milestone Payments**. Licensee will make one-time, non-refundable, non-creditable milestone payments (each, a "Development Milestone Payment") to Licensor upon the first (1st) achievement by Licensee or its Affiliates or Sublicensees of each of the milestone events (each, a "Development Milestone Event") set forth in TABLE 1 (Development Milestones) below. For the avoidance of doubt, each Development Milestone Payment hereunder will be payable only once. If one or more Development Milestone Events are skipped for a Licensed Product, then such skipped Development Milestone Event will be payable upon the first (1st) achievement of the subsequent Development Milestone Event by a Licensed Product, except that a Development Milestone Event that is specific to one territory will not be deemed to be skipped solely because a subsequent Development Milestone Event was achieved in a different territory (e.g., receipt of Regulatory Approval of a Licensed Product outside of the United States will not be deemed to trigger a Development Milestone Payment for receipt of Regulatory Approval of such Licensed Product in the United States if such Regulatory Approval of such Licensed Product has not yet occurred in the United States). Licensee will notify Licensor in writing of the achievement of a Development Milestone Event by Licensee or its Affiliates or Sublicensees no later than thirty (30) calendar days' after Licensee becomes aware of the achievement thereof. Thereafter, Licensor will provide Licensee with an invoice for the corresponding Development Milestone Payment, and Licensee will pay to Licensor such Development Milestone Payment within ninety (90) calendar days' after its receipt of an invoice for such Development Milestone Payment.

Table 1 – Development Milestones and Payments

Development Milestone Event	**Development Milestone Payment (U.S. Dollars)**
Dosing of the first (1st) patient with the first (1st) Licensed Product in the first Phase III Clinical Trial	$ [ ]
Regulatory Approval of the first (1st) Licensed Product for a first (1st) Indication in the United States	$ [ ]
Regulatory Approval of the first (1st) Licensed Product for a first (1st) Indication outside of the United States	$ [ ]

6.5 **Sales Milestones**. Licensee will make one-time, non-refundable, non-creditable sales milestone payments (each, a "Sales Milestone Payment") to Licensor upon the achievement by Licensee or its Affiliates or Sublicensees of each of the sales-based milestones events (each, a "Sales Milestone Event") set forth in TABLE 2 (Sales Milestones) below with respect to aggregate annual worldwide Net Sales of Licensed Products. Each of the Sales Milestone Payments set forth below will be payable only one time, for the first (1st) Calendar Year in which the corresponding Sales Milestone Event is achieved. As part of the royalty report delivered pursuant to Section 6.11 (Quarterly Royalty Reports), Licensee will notify Licensor in writing of the achievement of a Sales Milestone Event by Licensee or its Affiliates or Sublicensees no later than ninety (90) calendar days' after the end of the Calendar Quarter in which such Sales Milestone Payment is payable pursuant to the preceding sentence. Licensee shall pay to Licensor the corresponding Sales Milestone Payment within ninety (90) calendar days' after the end of the Calendar Quarter during which the corresponding Sales Milestone Event is achieved.

Table 2. – Sales Milestones and Payments

Sales Milestone Event	**Sales Milestone Payment (U.S. Dollars)**
First (1st) Calendar Year in which annual aggregate worldwide Net Sales of all Licensed Products equal or exceed $[ ]U.S. Dollars	$ [ ]
First (1st) Calendar Year in which annual aggregate worldwide Net Sales of all Licensed Products equal or exceed $[ ] U.S. Dollars	$ [ ]
First (1st) Calendar Year in which annual aggregate worldwide Net Sales of all Licensed Products equal or exceed $[ ] U.S. Dollars	$ [ ]

6.6 **Royalty Rate for Licensed Products**. Licensee shall pay Licensor a royalty based on Net Sales of Licensed Products that include the iSPERSE Technology sold by Licensee, according to the following schedule:

6.6.1 [ ] on annual aggregate worldwide Net Sales less than [ ];

6.6.2 [ ]on annual aggregate worldwide Net Sales of [ ] to [ ];

6.6.3 [ ] on annual aggregate worldwide Net Sales of more than [ ].

6.6.4 For the purpose of this Section, Net Sales will be determined on a Calendar Year basis.

6.6.5 The above volumes of Net Sales shall not be interpreted as an indication of the potential Net Sales for any Licensed Product and the Parties acknowledge that it is uncertain that any Licensed Product will have Net Sales resulting in the payment of royalties pursuant to this Agreement.

6.7 **Royalty Rate Reduction**

6.7.1 Generic Equivalent. If, in any royalty reporting period, an unlicensed Third Party commences selling a Product that is a Generic Equivalent of the Licensed Product in a country in the Territory, then the applicable royalty rate under Section 6.6 (Royalty Rate for Licensed Products) shall be reduced by one-half in such country.

6.7.2 Third Party Patents. If a Patent of a Third Party should exist in any country during the Term of this Agreement covering the Manufacture, use, or sale of any Licensed Product, and if it should prove in Licensee's reasonable judgment (as supported by an opinion from outside patent counsel which counsel is acceptable to both Parties) impractical or impossible for Licensee or its Sublicensee to continue the activity or activities licensed hereunder without obtaining a royalty bearing license from such Third Party under such Patent or Patents in such country, then Licensee shall be entitled to a credit against the royalty payments due hereunder of an amount equal to the royalty paid to such Third Party, not to exceed fifty percent (50%) of the royalty rate due under this Agreement, arising from the Manufacture, use or sale of the Licensed Product in such country.

6.7.3 Compulsory License. If at any time and from time-to-time a Governmental Authority in any country, grants or compels JJEI or an Affiliate to grant a compulsory license to a Third Party to Manufacture, use, or sell any Licensed Product ("Compulsory Sublicensee"), with respect to which royalties would be payable pursuant to Section 6.6 (Royalty Rate for Licensed Products) hereof, then Licensee may reduce the royalty on sales in such country of such Licensed Product according to the rates specified in Section 6.7.2 (Third Party Patents).

6.8 **Currency Restrictions**. All payments hereunder, including royalty payments, shall be paid in U.S. Dollars. If, at any time, legal restrictions prevent the prompt remittance of part of or all of the royalties with respect to any country where Licensed Products are sold, Licensee shall have the right and option to make such payments by depositing the amount thereof in local currency to Licensor's accounts in a bank or depository in such country.

6.9 **Royalty Period**. The royalty payments set forth above shall be payable on a country-by-country basis from the date of First Commercial Sale of a Licensed Product in such country until the later of: (i) ten (10) years from the date of First Commercial Sale of a Licensed Product in such country; or (ii) the expiration of the last Valid Claim of a Licensed Patent or licensed iSPERSE Patent that Covers the Licensed Product in such country and such Valid Claim would constitute the type of claim that is listable in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (regardless of the country or jurisdiction in which the patent is filed). Once Licensee has paid Licensor for the full term of the periods of time set forth in (i) and (ii) above for a Licensed Product on a country-by-country basis, it shall have a perpetual, paid up, no fee, royalty-free license pursuant to Section 3.2 (License for Licensed Products) under Licensor Know-How for any Licensed Product in such country notwithstanding any changes, Improvements, or modifications to Licensed Products that are incorporated into such products after the First Commercial Sale in a relevant country.

6.10 **Mode of Payment**. All payments to Licensor hereunder shall be made by ACH electronic funds transfer of U.S. Dollars in the requisite amount to the account designated by Licensor; provided, however, that any notice by Licensor of a change in such account shall not be effective until thirty (30) calendar days' after receipt thereof by Licensee. Unless otherwise set forth herein or mutually agreed by the Parties, all payments to be made hereunder by Licensee to Licensor, and Licensor's receipt of all payments hereunder, shall be made in accordance with the invoicing and payment requirements set forth in Appendix 5 (Invoicing and Payment).

6.11 **Quarterly Royalty Reports**. During the Term, commencing with the First Commercial Sale of each Licensed Product, and for so long as royalty payments are to be made under this Agreement, Licensee shall furnish or cause to be furnished to Licensor on a quarterly basis within ninety (90) calendar days' after the last day of the Calendar Quarter to which the report relates, a written report or reports as of the end of each Calendar Quarter showing:

6.11.1 the Net Sales of each Licensed Product in each country in the world during the applicable Calendar Quarter;

6.11.2 the royalties, payable in U.S. Dollars, payable under this Agreement resulting from those Net Sales and the basis for calculating those royalties;

6.11.3 the exchange rates and other methodologies used, if any, converting into U.S. Dollars, from the currencies in which sales were made.

6.12 **Financial Records**. Licensee shall keep accurate records, including gross invoiced sales, Net Sales, and royalty payments, ("Financial Records"), in accordance with U.S. generally accepted accounting practices, in sufficient detail to enable the amounts due hereunder to be determined and verified by Licensor.

6.13 **Currency Exchange**. In the case of sales of any Licensed Product outside the United States, royalty payments by Licensee to Licensor shall be converted to Dollars in accordance with Licensee's current customary and usual procedures for calculating same which are the following: the rate of currency conversion shall be calculated using the average exchange rates as calculated and utilized by Licensee's and its Affiliate's reporting systems and published accounts.

6.14 **Audit**. Financial Records under this Agreement shall be open during reasonable business hours for a period of two (2) years from creation of individual records for examination. Upon the written request of Licensor, but not more often than once in any twelve (12) month period and with at least four (4) weeks' notice, at Licensor's expense, Licensee shall permit an independent public accounting firm of national prominence selected by Licensor and acceptable to Licensee, and subject to such public accounting firm entering into a separate confidentiality agreement with Licensee in Licensee's discretion, to have access during normal business hours to those records of Licensee as may be reasonably necessary for the sole purpose of verifying the accuracy of the Net Sales report, and royalty calculation conducted by Licensee pursuant to this Agreement.

6.14.1 Licensee shall include in each sublicense or Commercialization agreement entered into by it pursuant to this Agreement, a provision requiring, among others, the Sublicensee or Commercialization partner to keep and maintain adequate Financial Records pursuant to such sublicense or Commercialization agreement and to grant access to such records by the aforementioned independent public accountant for the reasons specified in this Agreement.

6.14.2 The report prepared by such independent public accounting firm, a copy of which shall be sent or otherwise provided to Licensee by such independent public accountant at the same time as it is sent or otherwise provided to Licensor, shall contain the conclusions of such independent public accountant regarding the audit and will specify that the amounts paid to Licensor pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment.

6.14.3 If such independent public accounting firm's report shows any underpayment, Licensee shall remit or shall cause its Sublicensees or Commercialization partners to remit to Licensor within thirty (30) calendar days' after Licensee's receipt of such report, (i) the amount of such underpayment, and (ii) if such underpayment exceeds ten percent (10%) of the total amount owed for the Calendar Year then being audited, the reasonable and necessary fees and expenses of such independent public accountant performing the audit, subject to reasonable substantiation thereof. If such independent public accounting firm's report shows any overpayment, Licensee shall receive a credit equal to such overpayment against the royalty otherwise payable to Licensor.

6.15 **Taxes**

6.15.1 Licensee will make all payments to Licensor under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

6.15.2 Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by Licensee on behalf of Licensor to the appropriate Governmental Authority, and Licensee will furnish Licensor with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Licensor. If any such Tax is assessed against and paid by Licensee, then Licensor will indemnify and hold harmless Licensee from and against such Tax.

6.15.3 Licensee and Licensor will cooperate with respect to all documentation required by any taxing authority or reasonably requested by Licensee to secure a reduction in the rate of applicable withholding taxes.

6.15.4 If Licensee had a duty to withhold taxes in connection with any payment it made to Licensor under this Agreement but Licensee failed to withhold, and such taxes were assessed against and paid by Licensee, then Licensor will indemnify and hold harmless Licensee from and against such taxes (including interest). If Licensee makes a claim under this Section 6.15.4, it will comply with the obligations imposed by Section 6.15.2 as if Licensee had withheld taxes from a payment to Licensor.

6.15.5 Amounts payable under this Agreement do not include any sales, use, excise, value added or other applicable taxes, tariffs or duties. If any taxing authority imposes a VAT, GST, sales, use, service, consumption, business or similar tax with respect to the work undertaken under this Agreement, then Licensee agrees to pay that amount if specified in a valid invoice or supply exemption documentation. For avoidance of doubt, Licensor will not be entitled to pass on to Licensee, and Licensee will not be obligated to pay or bear, any tax that is based on Licensor's real, personal or intangible property (whether owned or leased), corporate structure, franchise, continuing business operations, income, gross receipts, capital stock, net worth or imposed with respect to Licensor's engagement of employees or independent contractors or that Licensor incurs upon subcontracting any work hereunder, in whole or in part, to any affiliated or non-affiliated Third Party. To the extent that Licensor does not provide Licensee a valid invoice (i.e., an invoice compliant with this Agreement and the applicable Statement of Work and the rules and regulations of the jurisdiction of both Licensor and Licensee, including separate identification of the tax where legally required), Licensor shall be responsible for any penalty resulting directly from such noncompliance. The parties will cooperate in good faith to minimize taxes to the extent legally permissible.

ARTICLE 7

CONFIDENTIALITY

7.1 **Confidentiality Obligations**. The Parties agree that, during the Term and for five (5) years thereafter, either Party that receives Information (a "Receiving Party") and other confidential and proprietary information and materials furnished to it by the other Party (a "Disclosing Party") pursuant to this Agreement or any Information developed during the Term (collectively "Confidential Information"), shall keep confidential by the Receiving Party and the Receiving Party shall not publish or otherwise disclose and shall not use for any purpose, except as expressly permitted hereunder or required hereunder to perform the Receiving Party's obligations under this Agreement, such Confidential Information. Confidential Information shall not include information that: (i) was already known to the Receiving Party, other than under an obligation of confidentiality from the Disclosing Party or from any other party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of the Receiving Party in breach of this Agreement or any other agreement; (iv) was subsequently lawfully disclosed to the Receiving Party by a Third Party without the obligation to keep the information confidential; (v) can be shown by written records to have been independently developed by or for the Receiving Party without reference to the Confidential Information received from the Disclosing Party and without breach of or reliance on any of the provisions of this Agreement; or (vi) is information that the Disclosing Party has specifically agreed in writing that the Receiving Party may disclose, and then only to the extent of such permissive disclosure.

7.2 **Written Assurances and Permitted Uses of Confidential Information**

7.2.1 Each Party shall inform its employees and consultants who perform work under this Agreement of the obligations of confidentiality specified in Article 7 (Confidentiality), and all such persons shall be bound by the terms of this Article 7 (Confidentiality) or obligations of confidentiality substantially similar, and at least as protective of the Disclosing Party's Confidential Information, as those set forth herein, as applicable.

7.2.2 The Receiving Party may disclose Confidential Information to the extent the Receiving Party is compelled to disclose such information by a court or other tribunal of competent jurisdiction, provided, however, that in such case the Receiving Party shall give prompt notice to the Disclosing Party so that the Disclosing Party may seek a protective order or other remedy from said court or tribunal. In any event, the Receiving Party shall disclose only that portion of the Confidential Information that, in the opinion of its legal counsel, is legally required to be disclosed and will exercise reasonable efforts to ensure that any such information so disclosed will be accorded confidential treatment by said court or tribunal. Furthermore, disclosed Confidential Information pursuant to this Section 7.2.2 shall remain the Confidential Information of the Disclosing Party and shall not become non-confidential information as a result of such disclosure.

7.2.3 To the extent it is reasonably necessary or appropriate to fulfill its obligations and exercise its rights under this Agreement, either Party may disclose Confidential Information to its Affiliates on a need-to-know basis on the condition that such Affiliates agree to keep the Confidential Information confidential for the same time periods and to the same extent as such Party is required to keep the Confidential Information confidential under this Agreement, and to any Regulatory Authorities to the extent reasonably necessary to obtain Regulatory Approval.

7.2.4 The existence and the terms and conditions of this Agreement that the Parties have not specifically agreed to disclose pursuant to this Section 7.2 (Written Assurances and Permitted Uses of Confidential Information) shall be treated by each Party as Confidential Information of the other Party.

7.3 **Publication**. Each Party shall submit any proposed scientific publication containing Confidential Information of the other Party relating to the Research Plan at least thirty (30) calendar days' in advance of submission of an abstract of a proposed publication, if any, and again at least thirty (30) calendar days' in advance of submission of the scientific publication, to allow such other Party to review such planned public disclosure. The reviewing Party will promptly review such publication and make any objections that it may have to the publication of the Confidential Information contained therein. Should the reviewing Party make an objection to the publication of the Confidential Information or require its modification, then the Parties will discuss the merits of publishing and any such modifications; provided, however, that in any case, no publication of Confidential Information of the other Party shall take place under this Section without the other Party's prior written approval thereof or unless the obligations of confidentiality as to such Confidential Information shall be waived or disclosure of Confidential Information of the other Party is authorized under Article 7 (Confidentiality).

7.4 **Publication of Clinical Trial Results**. In connection with the licenses hereunder, Licensor agrees that it will and it will cause any of its licensors, to agree to, permit Licensee and its Affiliates to register and publish data from any Clinical Trials conducted using a Licensed Product in accordance with Licensee's policies on Clinical Trials, notwithstanding the provisions of Section 7.1 (Confidentiality Obligations). Licensor further agrees to provide, or to cause any of its licensors to provide to, Licensee and its Affiliates such reasonable assistance as Licensee and its Affiliates may require in connection with fulfilling its publication requirements. Notwithstanding anything to the contrary in this Agreement, Licensee and its Affiliates' publication of Clinical Trial data will not result in a breach of any provision of this Agreement, including without limitation, the obligations of confidentiality and non-use.

7.5 **Public Announcements**. Neither Party shall originate any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to this Agreement, including its existence, the subject matter to which it relates, performance under it, or any of its terms, to any amendment hereto or performances hereunder, without the prior written consent of the other Party, except for such announcements that are required by law to be made or that are otherwise agreed to by the Parties in writing. Such announcements shall be brief and factual. If a Party decides to make an announcement required by law, it shall give the other Party at least ten (10) Business Days' advance written notice, where possible, of the text of the announcement so that the other Party shall have an opportunity to comment upon the announcement. To the extent that the receiving Party reasonably requests the deletion of any information in the materials, the disclosing Party shall delete such information unless, in the opinion of the disclosing Party's legal counsel, such information is legally required to be fully disclosed.

ARTICLE 8

PATENTS AND INTELLECTUAL PROPERTY

8.1 **Ownership; Inventions**. Licensee shall own and retain all rights, title, and interest in and to inventions and Licensee Improvements arising after Licensee exercises the Option. Licensor shall have no license, right, or interest whatsoever in or to any and all such inventions or Licensee Improvements, except as expressly set forth in this Agreement. To the extent that any Licensee Improvements are to the iSPERSE Technology generally (and not specifically applicable only to a Licensed Product), Licensee grants to Licensor a non-exclusive, sublicensable, worldwide, fully paid-up and royalty free license to any such Licensee Improvements to the iSPERSE Technology.

8.2 **Prosecution and Maintenance of Licensed Patents**. Upon Licensee's exercise of the Option, and thereafter during the Term of this Agreement, Licensee shall, at Licensee's expense, prepare, file, prosecute, and maintain the Licensed Patents. Licensee will, directly or via its counsel, consult with Licensor and keep Licensor reasonably informed with respect to matters relating to the preparation, filing, prosecution, and maintenance of the Licensed Patents, including copying Licensor on correspondence

sent to and received from patent offices. Notwithstanding the foregoing, Licensee shall have the option to abandon the prosecution of individual Licensed Patents upon at least thirty (30) calendar days' notice to Licensor, at which point Licensor shall have the right to prepare, file, prosecute, and maintain such abandoned Licensed Patents at Licensor's expense.

8.3 **Prosecution and Maintenance of iSPERSE Technology Patents**. Notwithstanding patent prosecution and maintenance terms set forth in Section 8.2 (Prosecution and Maintenance of Licensed Patents) or anything to the contrary contained in this Agreement, during the Term, Licensor will, at its own expense, prepare, file, prosecute, and maintain any iSPERSE Patents.

8.4 **Prosecution and Maintenance of Licensee Patents**. During the Term, Licensee will, at its own expense, prepare, file, prosecute, and maintain Licensee Patents and use reasonable efforts to file initially all such patent applications in countries in which Licensee would file patent applications in its normal business practice for comparable technology.

8.5 **Infringement Claims by Third Parties**

8.5.1 Notice. If the Development, Manufacture, use, sale, offer to sell, or Commercialization of any Licensed Product results in a claim or a threatened claim by a Third Party against a Party hereto for patent infringement or for inducing or contributing to patent infringement ("Infringement Claim"), the Party first having notice of an Infringement Claim shall promptly notify the other in writing. The notice shall set forth the facts of the Infringement Claim in reasonable detail.

8.5.2 Defense. Licensee will have the right, but not the obligation, to defend any suit resulting from an Infringement Claim at its expense. Licensor will cooperate and assist Licensee in any such litigation at Licensee's expense. Licensor may participate in, but not control, the defense or settlement of any such matter with counsel of its own choosing, at Licensor's sole expense.

8.5.3 Settlement. In the event that the development, Manufacture, use, sale, offer for sale, or Commercialization of the Licensed Product in a country would infringe a Third Party Patent and a license to such Third Party Patent is available, and Licensee in its sole discretion seeks such a license, the Parties agree:

(a) Licensee shall be responsible for all costs associated with acquiring such Third Party license; and

(b) Licensee shall use reasonable efforts to obtain required licenses under the Third Party Patents and the Parties agree that Licensee shall have the sole discretion to determine whether or not any offered terms of such Third Party license are reasonable and whether or not to enter into any such Third Party license.

8.6 **Infringement Claims Against Third Parties**

8.6.1 In the event that there is infringement or apparent infringement by a Third Party of any Patent, technology, or other intellectual property licensed to Licensee hereunder, Licensee shall notify Licensor in writing to that effect. If, prior to the expiration of one hundred and twenty (l20) calendar days' from the date of such notice, Licensor obtains a discontinuance of such infringement or brings suit against the Third Party infringer, then the obligation of Licensee to pay royalties under such Licensed Patent shall continue unabated. Licensor shall bear all the expenses of any suit brought by it and shall retain all damages or other monies awarded or received in settlement of such suit. Licensee will cooperate with Licensor in any such suit, at Licensor's expense, and shall have the right to consult with Licensor and be represented by its own counsel.

8.6.2 Should Licensor elect not to take any action, or fails to take any action within one hundred and twenty (120) calendar days' following notice by Licensee of an apparent infringement, Licensee shall have the right, at its expense, to take whatever steps in its own and sole discretion it deems advisable including settlement or the filing of suit for damages or to enjoin such sales or offers for sale by such Third Party, and Licensee shall be relieved of all obligation to make payment of further royalties under the Patent being infringed until such time as either the Third Party infringement has ceased or suit for infringement has been finally determined in accordance with Section 8.6.3. Licensor agrees to perform all acts which are or may become necessary to vest in Licensee the right to institute any such suit and will, upon reasonable notice, cooperate and, to the extent deemed necessary or desirable by Licensee and at Licensee's expense, participate in any suit to enjoin such infringement and to collect, for Licensee's sole and exclusive benefit, any and all damages, profits, and awards of any nature recoverable for such infringements. Licensee shall incur no liability to Licensor as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding the Patent invalid or unenforceable.

8.6.3 Royalties which are based solely on an infringed Licensed Patent which accrue during the pendency of any suit for infringement brought by Licensee shall be held in escrow by Licensee until a final decision is rendered by a court of competent jurisdiction from which no appeal can be or is taken. In the event the Patent, technology, or other intellectual property under which such royalties are payable is held to be invalid, the accrued royalties shall be retained by Licensee to offset litigation expenses. In the event the validity of the intellectual property that is the subject matter of the claim is upheld, the accrued royalties shall be paid to Licensor, and any damages or other monies awarded or received in settlement of such suit shall be retained by Licensee in satisfaction of its litigation expenses.

8.7 **Notices Relating to the Act**. Licensor shall notify Licensee of the issuance of each U.S. patent included among the Licensed Patents, giving the date of issue and Patent number for each such Patent. Licensor and Licensee each shall immediately give notice to the other of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" (as used in this Section 8.7 (Notices Relating to the Act), the "Act"), including, but not necessarily limited to, notices pursuant to §§101 and 103 of the Act from Persons who have filed an abbreviated NDA ("ANDA") or a 505(b)(2) application claiming that a Licensed Patent is invalid or that infringement will not arise from the Development, Manufacture, use, sale, offer of sale, or Commercialization of any Licensed Product by a Third Party.

8.7.1 If Licensee decides not to bring infringement proceedings against the entity making such a certification, Licensee shall give notice to Licensor of its decision not to bring suit within twenty-one (21) calendar days' after receipt of notice of such certification.

8.7.2 Licensor may then, but is not required to, bring suit against the party that filed the certification.

8.7.3 Any suit shall either be in the name of Licensee or in the name of Licensor, or jointly in the name of Licensee and Licensor, as may be required to effectively institute and maintain such suit.

8.7.4 For purposes of this Section, the Parties agree to execute the legal papers necessary for the prosecution of any such suit as may be reasonably needed.

8.8 **Patent Term Extensions**. Licensor hereby authorizes Licensee to (i) provide in any NDA a list of Patents which includes the Licensed Patents that relate to such Product and such other information as Licensee believes is appropriate, (ii) commence suit for infringement of Licensed Patents under § 271(e) (2) of Title 35 of the United States Code, and (iii) exercise any rights that may be exercisable by Licensor as Patent owner under the Act, including applying for an extension of the term of any Patent included in Licensed Patents. In the event that Applicable Law in any country provides for the extension of the term of any Patent included among Licensed Patents, such as under the Act, the Supplementary Certificate of Protection of the Member States of the European Union, and other similar measures in any other country, Licensor shall apply for and use its reasonable efforts to obtain such an extension or, should the law require Licensee to so apply, Licensor hereby gives permission to Licensee to do so. Licensee and Licensor agree to cooperate with one another in obtaining such extension. Licensor agrees to cooperate with Licensee or its Sublicensee, as applicable, in the exercise of the authorization granted herein and shall execute such documents and take such additional action as Licensee may reasonably request in connection therewith, including, if necessary, permitting itself to be joined as a Party in any suit for infringement brought by Licensee hereunder.

8.9 **Validity of Licensed Patents**. In the event that a declaratory judgment action alleging invalidity of any of the Licensed Patents is brought against either Party, Licensor shall have the right, but not the obligation, to assume the sole defense of the action at its own expense. If Licensor elects not to assume such defense, Licensee may assume sole defense at its own expense.

ARTICLE 9

INDEMNIFICATION

9.1 **Research and Development Indemnification**

9.1.1 Licensor agrees to indemnify, defend, and hold harmless Licensee, and its Affiliates, and each of their agents, employees, and directors (the “Licensee Indemnitees”), from and against any and all actions, claims, damages, injuries, losses, costs, and expenses (including reasonable attorney’s fees and disbursements) (“Losses”) arising from or alleged or claimed to arise from personal injury, death, or damage to property, including arising from any materials that are transferred by Licensor to Licensee under this Agreement and regardless of when Manufactured, sustained by any Person resulting from any intentionally wrongful act or omission or negligence arising after the Effective Date of Licensor or its employees or agents in performing its responsibilities pursuant to this Agreement, or any material breach by Licensor of its obligations under this Agreement.

9.1.2 Licensee shall indemnify, defend, and hold harmless Licensor, and their agents, employees, and directors (the “Licensor Indemnitees”) from and against any and all Losses resulting directly from the manufacture, use, or sale of Licensed Products by Licensee, except to the extent such Losses result from the negligence or willful misconduct of, or any material breach of this Agreement by, the Licensor Indemnitees.

9.1.3 Licensee agrees to indemnify, defend, and hold harmless the Licensor Indemnitees from and against any and all Losses arising from or alleged or claimed to arise from personal injury, death, or damage to property sustained by any Person resulting from any intentionally wrongful act or omission or negligence of Licensee or its employees or agents in performing its responsibilities pursuant to this Agreement or any material breach by Licensee of its obligations under this Agreement.

9.2 **Indemnification Procedure**. Upon the assertion of any indemnified claim or suit pursuant to Sections 9.1.1, 9.1.2, or 9.1.3 of Section 9.1 (Research and Development Indemnification), the indemnified Party shall promptly notify the indemnifying Party thereof and shall permit the indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration) and shall cooperate as requested (at the expense of the indemnifying Party) in the defense of the claim. The indemnifying Party shall not settle any indemnified claim or suit without the prior written consent of the indemnified Party, unless the indemnified Party has waived its rights to indemnification hereunder.

9.3 **Insurance Proceeds**. Any indemnification hereunder shall be made net of any insurance proceeds recovered by the indemnified Party; provided, however, that if, following the payment to the indemnified Party of any amount under this Article 9 (Indemnification), such indemnified Party recovers any insurance proceeds in respect of the claim for which such indemnification payment was made, the indemnified Party shall promptly pay an amount equal to the amount of such proceeds (but not exceeding the amount of such indemnification payment) to the indemnifying Party.

ARTICLE 10

TERM AND TERMINATION

10.1 **Term**. This Agreement shall commence on the Effective Date and shall remain in effect until the expiration of Licensee's obligation to pay royalties for all Licensed Products, unless earlier terminated as provided in this Article 10 (Term and Termination) (the "Term").

10.2 **Termination of this Agreement by Licensee for any Reason**. Licensee may terminate this Agreement for any reason upon ninety (90) calendar days' advance written notice to Licensor. In such case, Licensee shall pay to Licensor any outstanding fees and expenses then due and owing to Licensor in accordance with the payment terms pursuant to this Agreement.

10.3 **Termination for Breach**. The failure by a Party to comply with any of the material obligations contained in this Agreement shall entitle the other Party to give notice to have the default cured. If such default is not cured within sixty (60) calendar days' after the receipt of such notice, or if by its nature such default could not be cured within sixty (60) calendar days' in the non-breaching Parties' reasonable judgment, the notifying Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies that may be available to it, to terminate this Agreement. Provided, however, that in the event of a good faith Dispute with respect to the existence of a material breach or cure thereof, the sixty (60) day cure period shall be tolled until such time as the Dispute is resolved pursuant to Article 12 (Dispute Resolution) herein.

10.4 **Termination for Failure to Exercise Option**. If Licensee has not exercised the Option within the Option Period then, upon expiration of the Option Period, Licensor may elect to terminate this Agreement by providing Licensee with written notice thirty (30) calendar days' prior to the date such termination will become effective. If Licensee elects the Option within thirty (30) calendar days' after receipt of such notice, then the Option shall be deemed exercised pursuant to Section 3.1 (Assignment Option) of this Agreement and any termination by Licensor shall not be effective.

10.5 **Termination for Bankruptcy**

10.5.1 If (i) Licensor makes any general assignment for the benefit of its creditors, (ii) a petition is filed by or against Licensor, or any proceeding is initiated against Licensor as a debtor, under any bankruptcy or insolvency law, (iii) Licensor petitions for or acquiesces to the appointment of any receiver, trustee, or any similar officer to take possession, custody, or control of all or any part of Licensor's assets or property, or (iv) Licensor commences under the laws of any jurisdiction any

proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation, or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above, Licensor shall provide prompt written notice thereof to Licensee and Licensee may terminate this Agreement in its entirety (including the licenses granted herein) on or after the receipt of such written notice.

10.5.2 All rights and licenses granted by Licensor or any other applicable successor of licensor under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined in the Bankruptcy Code. The Parties agree that Licensee and its Affiliates and any Sublicensees, shall retain and may fully exercise and enforce all of its respective rights and elections under the Bankruptcy Code, including in the event any proceeding shall be instituted by or against Licensor seeking to adjudicate Licensor as bankrupt or insolvent, or seeking liquidation, winding up, reorganization, arrangement, adjustment, protection, relief or composition of Licensor or Licensor's debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking an entry of an order for relief or the appointment of a receiver, trustee, or other similar official for Licensor or any substantial part of Licensor's property, or Licensor shall take any action to authorize any of the foregoing actions (each a "Proceeding" for purposes of this Section 10.5.2). Licensor hereby agrees that in the event of any such Proceeding during the Term, and anytime thereafter, with respect to the licenses granted pursuant to Section 3.2 (License for Licensed Products), to create and provide current copies to Licensee or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such intellectual property. In any event, Licensee will have (i) the right to a complete duplicate of (or complete access to, as appropriate) all intellectual property (as defined in the Bankruptcy Code) and embodiments of intellectual property, which shall be promptly delivered to Licensee upon any rejection of this Agreement by or on behalf of Licensor, upon written request therefor by Licensee, and (ii) the right to continue to commercialize the Licensed Products using Licensor's Patent Rights, Technology, and Know-How granted under this Agreement, and all versions and derivatives thereof to which Licensee would otherwise have been entitled under this Agreement, in accordance with the terms and conditions of this Agreement. All rights, powers, and remedies of Licensee provided under this Section 10.5.2 are in addition to and not in substitution for any and all other rights, powers, and remedies now or hereafter existing at law or in equity in the event of any commencement of a bankruptcy proceeding by or against Licensor.

10.6 **Effect of Termination**. In the event of termination by Licensee under Section 10.2 (Termination of this Agreement by Licensee for any Reason), or by Licensor under Section 10.3 (Termination for Breach) or Section 10.4 (Termination for Failure to Exercise Option), all rights licensed by Licensor to Licensee herein shall revert to Licensor. In addition, in the event of a termination as described in the foregoing sentence, Licensee shall grant to Licensor a non-exclusive, sublicensable, worldwide, fully paid-up and royalty free license to any data resulting from the Toxicology Study described in the Research Plan.

10.7 **No Waiver**. The right of a Party to terminate this Agreement, as provided in this Article 10 (Term and Termination), shall not be affected in any way by its waiver or failure to take action with respect to any prior default.

10.8 **Consequences of Termination**. Except as otherwise provided herein, upon termination of this Agreement, all remaining records and materials in either Party's possession or control containing the other Party's Confidential Information and to which the Party with possession and control does not retain rights hereunder, shall promptly be returned. Notwithstanding the foregoing, one copy of such records may be retained by legal counsel for the former Party.

10.9 **Results of Termination by Licensee**. In the event of termination of this Agreement by Licensee pursuant to Section 10.3 (Termination for Breach) or 10.5 (Termination for Bankruptcy), the rights granted to Licensee in Article 3 (Option, Assignment, and License Rights) hereof shall survive termination. In addition, the Licensor's right to the option fee under Section 6.2 (Option Fee), milestone payments under Sections 6.3 (RV1162 Phase Ib Completion Milestone), 6.4 (Development Milestone Payments), and 6.5 (Sales Milestones), and royalty payments pursuant to Section 6.6 (Royalty Rate for Licensed Products), as well as terms of the Agreement associated with the payment of such payments, shall survive any such termination, provided that the royalty rates set forth in Sections 6.6 (Royalty Rate for Licensed Products) shall be reduced by fifty percent (50%).

10.10 **Survival of Obligations**. The termination or expiration of this Agreement shall not relieve the Parties of any obligations accruing prior to such termination, and any such termination shall be without prejudice to the rights of either Party against the other. The provisions of Article 1 (Definitions), Article 3 (Option, Assignment, and License Rights) (pursuant to Section 10.7 (No Waiver)), Article 6 (Financials and Reporting) (pursuant to Section 10.7 (No Waiver)), Article 7 (Confidentiality), Article 8 (Patents and Intellectual Property), Article 9 (Indemnification), Section 10.5 (Termination for Bankruptcy), Section 10.6 (Effect of Termination), Section 10.7 (No Waiver), Section 10.8 (Consequences of Termination), Section 10.9 (Results of Termination by Licensee), this Section 10.10 (Survival of Obligations), Article 12 (Dispute Resolution), and Article 13 (Miscellaneous Provisions) shall survive any termination of this Agreement.

10.11 **Termination Not Sole Remedy**. Termination is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as agreed to otherwise herein.

ARTICLE 11

REPRESENTATIONS AND WARRANTIES

11.1 **Authority**. Each Party represents and warrants that as of the Effective Date, it has the full right, power, and authority to enter into this Agreement and that this Agreement has been duly executed by such Party and constitutes a legal, valid, and binding obligation of such Party, enforceable in accordance with its terms.

11.2 **No Conflicts**. Each Party represents and warrants that the execution, delivery, and performance of this Agreement by such Party does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

11.3 **No Existing Third Party Rights**. Each Party represents and warrants that it has not, and during the Term will not, grant any right to any Third Party relating to its respective technology in the Field which would conflict with the rights granted to the other Party hereunder.

11.4 **Patents and Know-How Warranties**. To the best of its knowledge, as of the Effective Date, each Party represents and warrants that (i) any Patent, Technology, Know-How, or other intellectual property right owned or controlled by such Party is not currently being infringed by any Third Party, and (ii) the practice of such rights does not infringe any property right of any Third Party.

11.5 **Control of Know-How**. Licensor and Licensee each represent and warrant that it owns or Controls all of the rights, title, and interest in and to the Licensor Know-How and the Licensee Know-How, respectively.

11.6 **Licensor Intellectual Property Representations**. Licensor represents and warrants that (i) each of the Patents, Technology, and Know-How being licensed or assigned to Licensee pursuant to this Agreement is exclusively owned or Controlled by Licensor or its wholly-owned subsidiaries, is in good standing, and is not subject to any litigation or administrative proceeding, including opposition, re-examination, reissue, or post-issuance PTO review proceeding including interference, IPR, PGR, or related proceedings, (ii) no notice has been received from a Third Party by Licensor or its Affiliates regarding any of the Patents, Technology, or Compounds being licensed or assigned to Licensee under this Agreement, and (iii) there are no Third Party Patents in any country that would be infringed by making, having made, using, offering for sale, selling, importing, or Commercializing the Licensed Products under this Agreement.

11.7 **Disclaimer of Warranties**. EXCEPT AS SET FORTH ABOVE, NEITHER PARTY MAKES ANY REPRESENTATIONS AND EXTENDS NO OTHER WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE LICENSED PATENTS, KNOW-HOW, TECHNOLOGY, AND PRODUCTS LICENSED HEREUNDER, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

11.8 **Continuing Representations**. The representations and warranties of each Party contained in this Article 11 (Representations And Warranties) shall survive the execution and delivery of this Agreement and shall remain true and correct at all times during the Term with the same effect as if made on and as of such later date.

ARTICLE 12

DISPUTE RESOLUTION

12.1 **Resolution of Disputes**. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy, or claim arising from or related to this Agreement or the breach thereof (each a “Dispute”). If the Parties initially are unable to resolve a Dispute despite using reasonable efforts to do so, either Party may, by written notice to the other, have the Dispute referred to their respective senior management designated below or their respective successors, for attempted resolution by negotiation in good faith. The attempted resolution will take place no later than thirty (30) calendar days’ following receipt of such notice. The designated management are as follows:

For Licensee: Avrum Spira, Vice President, Global Head Lung Cancer Initiative

For Licensor: Ted Raad, Chief Executive Officer

12.1.1 If the Parties are unable to resolve the Dispute, controversy, or claim within sixty (60) calendar days’ following the day on which one Party provides written notice of the Dispute to the other in accordance with Section 12.1 (Resolution of Disputes), and a Party wishes to pursue the matter, each such Dispute, controversy, or claim that is not an Excluded Claim will be finally resolved by mediation followed by binding arbitration as set forth below. As used in this Section, the term “Excluded Claim” means a Dispute, controversy, or claim that concerns the validity or infringement of a Patent, trademark, or copyright.

12.2 **Mediation**. The Parties shall first attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then current Mediation Procedure of the International Institute for Conflict Prevention and Resolution (“CPR Mediation Procedure”) (www.cpradr.org) before initiating arbitration. The CPR Mediation Procedure shall control, except where it conflicts with these

provisions, in which case these provisions control. The mediator shall be chosen pursuant to CPR Mediation Procedure. The mediation shall be held in New York, New York. Either Party may initiate mediation by written notice to the other Party of the existence of a Dispute. The Parties agree to select a mediator within twenty (20) calendar days' after the notice and the mediation will begin promptly after the selection. The mediation will continue until the mediator, or either Party, declares in writing, no sooner than after the conclusion of one full day of a substantive mediation conference attended on behalf of each Party by a senior business Person with authority to resolve the Dispute, that the Dispute cannot be resolved by mediation. In no event, however, shall mediation continue more than sixty (60) calendar days from the initial notice by a Party to initiate meditation unless the Parties agree in writing to extend that period. Any period of limitations that would otherwise expire between the initiation of mediation and its conclusion shall be extended until twenty (20) calendar days' after the conclusion of the mediation.

12.3 **Arbitration**. If the Parties fail to resolve the Dispute in mediation, and a Party desires to pursue resolution of the Dispute, the Dispute shall be submitted by either Party for resolution in arbitration pursuant to the then current CPR Non-Administered Arbitration Rules ("CPR Rules") (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The arbitration will be held in New York, New York. All aspects of the arbitration shall be treated as confidential. The arbitrators will be chosen from the CPR Panel of Distinguished Neutrals, unless a candidate not on such panel is approved by both Parties. Each arbitrator shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law department of over twenty five (25) lawyers or who was a judge of a court of general jurisdiction. To the extent that the Dispute requires special expertise, the Parties will so inform CPR prior to the beginning of the selection process. The arbitration tribunal shall consist of three arbitrators, of whom each Party shall designate one in accordance with the "screened" appointment procedure provided in CPR Rule 5.4. The chair will be chosen in accordance with CPR Rule 6.4. If, however, the aggregate award sought by the Parties is less than five million Dollars ($5,000,000) and equitable relief is not sought, a single arbitrator shall be chosen in accordance with the CPR Rules. Candidates for the arbitrator position(s) may be interviewed by representatives of the Parties in advance of their selection, provided that all Parties are represented. The Parties agree to select the arbitrator(s) within forty five (45) calendar days' of initiation of the arbitration. The hearing will be concluded within nine (9) months after selection of the arbitrator(s) and the award will be rendered within sixty (60) calendar days' of the conclusion of the hearing, or of any post-hearing briefing, which briefing will be completed by both sides within forty five (45) calendar days' after the conclusion of the hearing. In the event the Parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practical. The hearing will be concluded in ten hearing days or less. Multiple hearing days will be scheduled consecutively to the greatest extent possible. A transcript of the testimony adduced at the hearing shall be made and shall be made available to each Party. The arbitrator(s) shall be guided, but not bound, by the CPR Protocol on Disclosure of Documents and Presentation of Witnesses in Commercial Arbitration (www.cpradr.org) ("Protocol"). The Parties will attempt to agree on modes of document disclosure, electronic discovery, witness presentation, etc. within the parameters of the Protocol. If the Parties cannot agree on discovery and presentation issues, the arbitrator(s) shall decide on presentation modes and provide for discovery within the Protocol, understanding that the Parties contemplate reasonable discovery. The arbitrator(s) shall decide the merits of any Dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The arbitrator(s) may not apply principles such as "amiable compositeur" or "natural justice and equity". The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing and shall endeavor to decide such motions as would a United States District Court Judge sitting in the jurisdiction whose substantive law governs. The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The Parties consent to the jurisdiction of the United States District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of

judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion. Each Party has the right to seek from the appropriate court provisional remedies such as attachment, preliminary injunction, replevin, etc. to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the Dispute. Rule 14 of the CPR Rules does not apply to this Agreement. EACH PARTY HERETO WAIVES: (A) ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY, (B) WITH THE EXCEPTION OF RELIEF MANDATED BY STATUTE, ANY CLAIM TO PUNITIVE, EXEMPLARY, MULTIPLIED, INDIRECT, CONSEQUENTIAL, OR LOST PROFITS/REVENUES DAMAGES, AND (C) ANY CLAIM FOR ATTORNEY FEES, COSTS AND PREJUDGMENT INTEREST.

ARTICLE 13

MISCELLANEOUS PROVISIONS

13.1 **Entire Agreement**. This Agreement and each of the Appendices hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter of this Agreement and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. Promptly following the execution of this Agreement, the Parties shall jointly issue the press release attached hereto as Appendix 7 (Press Release).

13.2 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.3 **Binding Effect**. This Agreement and the rights granted herein shall be binding upon, and shall inure to the benefit of, Licensor, Licensee and their respective lawful successors and permitted assigns.

13.4 **Assignment**. Neither Party shall assign this Agreement without the prior written consent of the other Party (such consent not to be unreasonably withheld) except that a Party may assign this Agreement to an Affiliate or to a successor in connection with the merger, consolidation or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

13.5 **No Implied Licenses**. No rights to any other patents, know-how, or technical information, or other intellectual property rights, other than as explicitly identified herein, are granted or deemed granted by this Agreement. No right, expressed or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party or its Affiliates in connection with the performance of this Agreement.

13.6 **No Waiver**. No waiver, modification, or amendment of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.

13.7 **Force Majeure**. The failure of a Party to perform any obligation under this Agreement by reason of force majeure such as acts of God, acts of governments, terrorism, riots, wars, strikes, accidents, or deficiencies in materials or transportation or other causes of a similar magnitude beyond its control shall not be deemed to be a breach of this Agreement. The Party which is affected by any force majeure shall contact the other Party for discussion of possible emergency measures.

13.8 **Independent Contractors**. Both Parties are independent contractors and not agents or employees of the other Party under this Agreement. Nothing contained in this Agreement is intended nor is to be construed so as to constitute Licensor or Licensee as partners or joint venturers with respect to this Agreement. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any other contract, agreement or undertaking with any Third Party except as may be explicitly provided for herein or authorized in writing.

13.9 **Notices and Deliveries**. Any notices, request, delivery, approval, or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given when it is received, whether delivered in person, by email or delivery by registered letter (or its equivalent) or delivery by certified overnight courier service, to the Party to which it is directed at its address shown below or such other address as such Party shall have last given by notice to the other Parties.

If to Licensor:	Pulmatrix, Inc. ATTN: Ted Raad 99 Hayden Ave. Suite 390 Lexington, MA 02421 traad@pulmatrix.com
with a copy to:	Haynes and Boone, LLP ATTN: Greg Kramer & Rick Werner 30 Rockefeller Plaza 26th Floor New York, NY 10112 greg.kramer@haynesboone.com
If to Licensee:	Johnson & Johnson Enterprise Innovation, Inc. ATTN: Christopher Stevenson 50-100 Holmers Farm Way High Wycombe Buckinghamshire United Kingdom HP12 4EG csteve22@ITS.JNJ.com
with a copy to:	Morrison & Foerster LLP ATTN: Matthew Karlyn 200 Clarendon Street Boston, MA 02116 MKarlyn@mofo.com

13.10 **Headings; Interpretation**. The headings in this Agreement are for reference only and will not affect the interpretation of this Agreement. For purposes of this Agreement (a) the words “include,” “includes,” and “including” will be deemed to be followed by the words “without limitation,” (b) the word “or” is not exclusive, and (c) the words “herein,” “hereof,” “hereby,” “hereto,” and

“hereunder” refer to this Agreement as a whole. Unless the context otherwise requires, references herein: (x) to sections and exhibits mean the sections of and exhibits attached to, this Agreement; (y) to an agreement, instrument, or other document means such agreement, instrument, or other document as amended, supplemented, or modified from time-to-time to the extent permitted by the provisions thereof; and (z) to a statute means such statute as amended from time-to-time and includes any successor legislation thereto and any regulations promulgated thereunder. This Agreement will be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted.

13.11 **Severability**. In the event that any provision of this Agreement shall, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid or unenforceable provision had not been included herein.

13.12 **Applicable Law**. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, without reference to any laws of the state of New York that would require the application of the laws of another jurisdiction.

13.13 **Advice of Counsel**. Licensee and Licensor have each consulted with counsel of their choice regarding this Agreement, and each acknowledges and agrees that this Agreement shall not be deemed to have been drafted by one Party or another and will be construed accordingly.

13.14 **Counterparts; Electronic Signatures**. This Agreement may be executed in two or more counterparts, or facsimile versions, each of which shall be deemed to be an original, and all of which together shall be deemed to be one and the same agreement. The Parties acknowledge and agree that (a) this Agreement and any amendments to the Agreement, can be entered into electronically and enforceable in accordance with laws applicable to the recognition of electronic signatures, including without limitation the Electronic Signatures in Global and National Commerce Act (the E-SIGN Act); (b) the electronic signature utilizing the designated method constitutes the individual’s signature, acceptance, and agreement the same as if actually signed in writing; (c) this Agreement shall constitute “original” documents when printed from electronic files and records established and maintained by either Party in the normal course of business; and (d) the individual signing this Agreement electronically is authorized to enter into this Agreement on behalf of the Party to this Agreement.

13.15 **Waiver**. Except as specifically provided for herein, the waiver from time-to-time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party’s rights or remedies provided in this Agreement.

13.16 **Compliance with Laws**. The Parties shall comply with all Applicable Laws of the United States and applicable European countries and supra-governmental organizations and all jurisdictions and any Governmental Authority or court thereof in connection with this Agreement and the transactions contemplated thereby.

THE REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK
SIGNATURES ARE ON THE NEXT PAGE

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which shall for all purposes be deemed to be an original.

JOHNSON & JOHNSON ENTERPRISE INNOVATION, INC.

By: _____

Name: _____

Title: _____

Date: _____

PULMATRIX, INC.

By: _____

Name: _____

Title: _____

Date: _____

APPENDICES

Appendix Number	Appendix Title
1A	Compound Patents
1B	iSPERSE Patents
1C	Licensed Patents
2	Licensor Materials and Technology
3	Research Plan
4	Johnson & Johnson Universal Calendar
5	Invoicing and Payment
6	Assignment Agreement
7	Press Release
8	Side Letter

APPENDIX 1A

COMPOUND PATENTS

Appendix 1A (Compound Patents) is attached hereto and incorporated herein by this reference.

APPENDIX 1B

iSPERSE PATENTS

Appendix 1B (iSPERSE Patents) is attached hereto and incorporated herein by this reference.

APPENDIX 1C

LICENSED PATENTS

Appendix 1C (Licensed Patents) is attached hereto and incorporated herein by this reference.

APPENDIX 2

LICENSOR MATERIALS AND TECHNOLOGY

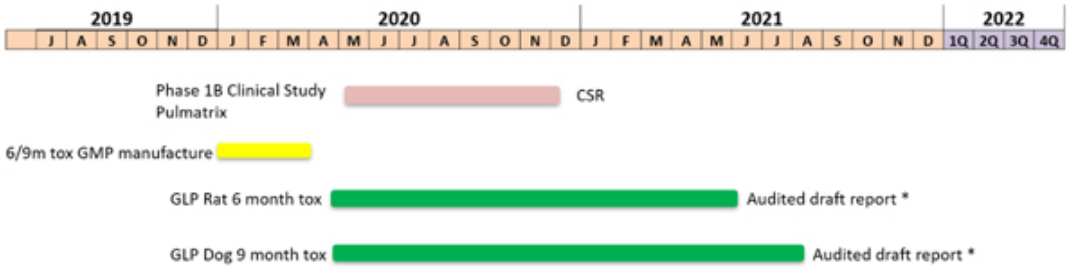
RV1162

PUR1800 (iSPERSE formulation of RV1162)

APPENDIX 3

RESEARCH PLAN

Project Plan



* Timings subject to slot availability

Project Summary

The research plan consists of four main activities;

1) Conduct of a Phase 1 study with RV1162 in patients with COPD
2) Manufacture of RV1162 for GLP toxicology studies
3) Conduct of a GLP 6 month rat inhaled toxicology study inc. SEND data report
4) Conduct of a GLP 9 month dog inhaled toxicology study inc. SEND data report

Research Plan Budget

Pass Through Costs	Description	USD Amount
	GMP Manufacture	$530,500.0
	26-Week Inhalation Toxicity Study in Rats	$979,137.0
	Rat SEND Data	$32,535.0
	39-Week Inhalation Toxicity Study in Dogs	$2,969,238.0
	Dog SEND Data	$24,605.0
	Shipping	$8,000.0
	Peer Review of 2 Tox Safety Studies	$27,000.0
Total		$4,571,015.0
	JJEI Funded	**$3,371,015.0**
	Pulmatrix Funded	**$1,200,000.0**

All pass through costs as incurred should be billed to JJEI, and reflect actuality.

- GLP manufacture of 1.5 kg of RV1162 and 1kg of placebo for use in safety studies
- 26-Week Inhalation Toxicity Study in Rats with a 6 Week Recovery Period, testing RV1162 – Outline study plan

Outline study plans

26-Week Inhalation Toxicity Study in Rats with an 6-Week Recovery Period

GLP Compliant

Test Item:	PUR1800				
Duration:	32 weeks				
Route:	Daily (182 doses) for at least 26 weeks *via* nose-only inhalation (1-hour) exposure with an 6-week recovery period				
Species:	Albino rat				
Age at start of treatment:	~ 6 weeks				
Aerosol Generation:	RBG				
Atmosphere Analysis:	Gravimetric concentrations: at least once during each exposure. Particle size distribution analysis: On at least one occasion for each Group during week 1 and monthly thereafter				
Groups:	1	2	3	4	5
Treatment (µg/kg/day):	Air Control	Placebo Control	60	120	240
Animals – main M/F:	15/15	15/15	15/15	15/15	15/15
Animals – recovery M/F:	5/5	5/5	-	-	5/5
Toxicokinetics M/F:	6/6	6/6	12/12	12/12	12/12

Serial Observations:		
	Occasions (Week)	**Details**
Bodyweights:	-2 to 32	Weekly
Food consumption:	-2 to 32	Weekly
Clinical observations:	Daily/weekly	Daily Mortality check Twice daily cage side observations (am/pm) Post-dose observations (1 to 2 h post dose)
Physical examination:	Pre-test Weekly	All animals All surviving animals
Ophthalmology:	Pre-treatment Study termination	All animals All main study and recovery animals (recovery optional if no term findings)

Hematology, Coagulation, Clinical Chemistry and Urinalysis:	Study termination	All main study and recovery animals (recovery optional if no term findings) Parameters in accordance with CRO standards
Toxicokinetics:	Dose Days	Groups 1 & 2 – 1 time point on Days 2, 91 and 182 (3/sex/group/time point) Samples 36 Groups 3, 4 & 5 - 6 time points on Days 1, 91 and 182 (3/sex/group/time point) Samples 324 Total samples = 372
	Recovery	Groups 1 & 2 – No Samples Groups 3, 4 & 5 – 1 time point on Recovery Days 28 and 56 (3/sex/group/time point) Samples 36 Total samples = 36
Lung Collection (TK animals)	Dose Days	Groups 1 & 2 – Term only (3/sex/group) Samples 12 Groups 3, 4, & 5 – Pre-dose on Days 2 & at term (24h after last dose) (3/sex/group/time point) Samples 36 Total samples = 48
	Recovery	Groups 1 & 2 – No Samples Groups 3, 4 & 5 – Recovery Days 28 & 56 (3/sex/group/time point) Samples 36 Total samples = 36
Necropsy and Organ Weights:		All main study and recovery animals Parameters in accordance with CRO standards
Bone Marrow Smears		All animals. Prepared, not evaluated.
Histopathology:		All main study and recovery animals Full histopathological examination including all parameters in accordance with CRO standards for control and high-dose animals only. Respiratory tissues only for mid- and low-dose animals with optional full histopathology.

Analytical Support:		
Dose Formulation:		As supplied by customer
Dose Confirmation:		None
Plasma Bioanalysis (LC/MS or ELISA)		All samples shipped to customer designated laboratory Samples as indicated under "Toxicokinetics" Assumes one analyte
Toxicokinetic Interpretation:		Parameters: C_{max}, T_{max}, AUC_{24}, k, $t_{½}$ Assessment: dose proportionality, sex differences, accumulation. 18 profiles

Reporting:	
Audited Draft Report:	Available 16 weeks from study termination
SEND Data:	Included in price

- 39-Week Inhalation Toxicity Study in Dogs with a 6-Week Recovery Period, testing RV1162

GLP Compliant

Test Item	PUR1800				
Duration:	45 weeks				
Route:	Daily (273 doses) for at least 39 weeks *via* oronasal inhalation (1-hour)				
Species:	Purebred Beagles				
Age at start of treatment:	4 to 6 Months Old				
Aerosol Generation:	RBG				
Atmosphere Analysis:	Gravimetric concentrations: At least 2 times during each exposure. Particle size distribution analysis: On at least one occasion for each Group during each of weeks 1, 8, 16 and 26 of treatment				
Groups:	1	2	3	4	5
Treatment (µg/kg/day):	Air Control	Placebo Control	40	80	120
Main Study Animals (M/F):	4/4	4/4	4/4	4/4	4/4
Recovery Animals (M/F):	2/2	2/2	-	-	2/2

Serial Observations:		
	Occasions (Week)	**Details**
Bodyweights:	-2 to 45	Weekly
Food consumption:	-2 to 45	Daily (visual)
Clinical observations:	Daily/weekly	Daily Mortality check Twice daily cage side observations (am/pm) Post-dose observations (1 to 2 h post dose) Weekly physical exam
Ophthalmology:	Pre-test Study Termination	All main study animals and spares All main study and recovery animals (recovery optional pending term results)
ECG snapshot assessment: **(Qualitative)**	Pre-test Study termination	All animals All animals (recovery optional pending term results)
Hematology, Coagulation, Clinical	Pre-test Study termination	All main study animals and spares All main study and recovery animals

Chemistry and Urinalysis:		(recovery optional pending term results) Parameters in accordance with CRO standard practice

Toxicokinetics:	Dose Days	Groups 1 & 2 – 2 time points on Days 1, 90 and 273 Samples: 144 (432 collected) Groups 3, 4 & 5 - 6 time points on Days 1, 90 and 273 Samples: 504 Total number of samples analyzed 648
	Recovery	Groups 1 & 2 – No Samples Groups 3, 4 & 5 – 1 time point on Recovery Days 7, 14, 28 and 56 Samples: 48 Total samples = 48

Lung Bioanalysis Collection		One lobe isolated and collected at necropsy for all animals Total number of samples 60

Necropsy and Organ Weights:	Termination	All main study and recovery animals Parameters in accordance with CRO standard practice
Bone Marrow Smears		All animals. Prepared, not evaluated.
Histopathology:		All animals Parameters in accordance with CRO standard practice

Analytical Support:		
Dose Formulation:		As supplied by customer
Dose Confirmation:		None
Plasma Bioanalysis (LC/MS or ELISA)		All samples shipped to customer designated laboratory Samples as indicated under "Toxicokinetics" Assumes one analytes
Toxicokinetic Interpretation:		Parameters: C_{max}, T_{max}, $AUC_{0\text{-}24h}$, k, t½ Assessment: dose proportionality, sex differences, accumulation. 84 profiles

Reporting:	
Audited Draft Report:	Available 16 weeks from study termination

SEND Data:	Included in price

- Clinical Study: Phase 1b randomized, double-blind, placebo-controlled, 3-way crossover study to assess the safety, tolerability and pharmacokinetics of RV1162, a narrow spectrum kinase inhibitor (NSKI) administered as a dry powder for inhalation once daily for 14 consecutive days, in adult patients with stable chronic obstructive pulmonary disease. (refer to protocol synopsis below).

1. PROTOCOL SYNOPSIS

Protocol Number	601-0016
Title	A Phase 1b randomized, double-blind, placebo-controlled, 3-way crossover study to assess the safety, tolerability and pharmacokinetics of RV1162, a narrow spectrum kinase inhibitor (NSKI) administered as a dry powder for inhalation once daily for 14 consecutive days, in adult patients with stable chronic obstructive pulmonary disease.
Investigational Product	RV1162 (iSPERSE™ Dry Powder Formulated RV1162 NSKI) Placebo
Indication	Acute exacerbations of chronic obstructive pulmonary disease (AECOPD)
Number of Subjects	Approximately 15 subjects will be randomized into the study to achieve at least 12 evaluable subjects. Subjects who discontinue the study may be replaced at the discretion of the Sponsor.
Number of Study Centers	1 (UK)
Objectives	Primary Determine the safety and tolerability of 14 daily doses of inhaled RV1162 in adult subjects with stable COPD. Secondary Characterize the systemic and sputum pharmacokinetics (PK) of single and multiple doses of inhaled RV1162 in adult subjects with stable COPD. Exploratory Characterize pharmacodynamic (PD) effects of 14 daily doses of inhaled RV1162 in adult subjects with stable COPD via kinase phosphorylation, total and differential inflammatory cell counts, and cytokine expression in sputum samples.
Overview of Study Design	Safety, tolerability, and pharmacokinetics (PK) will be assessed following 14 daily doses of RV1162 or placebo. This is a randomized, placebo-controlled, double-blind 3-arm crossover study in which RV1162 or placebo is dosed daily for 14 consecutive days in adult subjects with stable COPD over three discrete treatment periods. The three treatment arms are as follows:

Arm	Period 1	Period 2	Period 3
1	Placebo	RV1162 250 µg	RV1162 500 µg
2	RV1162 250 µg	Placebo	RV1162 500 µg
3	RV1162 250 µg	RV1162 500 µg	Placebo

The study design is as follows:

- Informed Consent: Before any study specific procedures or study requirements are conducted on or expected of a subject, the subject must review and sign an IEC/IRB/REC-approved informed consent form.
- Screening: Subjects will be screened for eligibility to participate in the study within 28 days before randomization (i.e. Treatment Period 1, Day 1).
- Treatment Periods:
  - Period 1: On Day 1 all subjects who are eligible for entry into the study will be randomized to receive either placebo or one of two nominal doses of RV1162 (RV1162 250 µg or RV1162 500 µg) for 14 consecutive days.
  - Period 2: Following a washout period of at least 28 days after the completion of Period 1 dosing, subjects will receive one of the treatments not received during Period 1 for 14 consecutive days.
  - Period 3: Following a washout period of at least 28 days after the completion of Period 2 dosing, subjects will receive the last remaining treatment not received during Periods 1 or 2 for 14 consecutive days.
- End of Study: Subjects will return to the study site 28 days after the last dose of the last Treatment Period for an End of Study visit for a safety assessment and collection of sputum PD samples.

Overview of Study Assessments

Screening

Screening procedures will be performed within 28 days prior to randomization (i.e. Treatment Period 1, Day 1). After informed consent is obtained, the following procedures and assessments will be performed:

Alcohol breath test and urine drug screening, medical history, physical examination, measurement of height and weight, vital signs, triplicate 12-lead electrocardiogram (ECG), spirometry (pre and post bronchodilator), pulse oximetry, device training and safety laboratory samples for heamatology, serum chemistry, coagulation, and urinalysis, as well as a serum pregnancy test for women of childbearing potential (WOCBP). In addition, an induced sputum sample will be obtained to confirm subjects are able to produce an adequate sputum sample for processing (the definition of ‘adequate’ will be confirmed in the Study Reference Manual).

Screening procedures (including informed consent) can be performed over more than 1 day. Repeat of study procedures is permitted on the day and/or on another day (as appropriate) at the discretion of the investigator. In the event of a repeat being required for the screening PD sputum sample there must be at least 48 hours between attempts.

Clinical safety laboratory samples (clinical chemistry, haematology, and urinalysis) must be performed within 7 days of Treatment Period Day 1; if this interval is exceeded, sampling must be repeated.

Baseline Visit (Day -3 to Day -1)

Subjects will attend to perform a baseline sputum induction. If an adequate sample is not obtained a repeat may be performed; however, there must be at least 48 hours between attempts.

If the subject cannot provide an adequate sputum sample on the repeat attempt, they will not continue to Treatment.

Treatment Periods 1, 2, and 3

The treatment will be divided across three discrete Treatment Periods, with a washout period of at least 28 days starting after the completion of the Treatment Period dosing between each Treatment Period.

Day 1

Eligible subjects will attend the clinic on Day 1 and the following pre-dose assessments to confirm eligibility and establish baseline values will be performed:

Vital sign measurement, pulse oximetry, spirometry, triplicate 12-lead ECG measurements, device training and safety laboratory and PK blood samples.

Subjects will be randomized to one of three study treatment arms at the beginning of Treatment Period 1.

Once all pre-dose assessments are complete, all subjects will receive their first inhaled dose for that Treatment Period of RV1162 or placebo under supervision.

All subjects will have been fasted for at least 6 hours prior to receiving study medication on Day 1. Water will be restricted from 1-hour pre-dose until 1-hour post-dose.

Subjects will remain in the clinic for monitoring for 12 hours following dosing. Study procedures will be performed and samples will be collected at timepoints as per the Schedule of Study Assessments up to 12 hours post dose.

Subjects will be discharged from the clinic after the 12-hour post-dose assessments and asked to return to the clinic the next morning. Subjects may stay overnight in the study centre if required for logistical reasons.

	Day 2 Subjects will attend the unit and perform pre dose procedures as per the Schedule of Study Assessments and assessed for eligibility to receive the next dose. Subjects will receive their Day 2 dose of study medication. Study procedures will be performed, and samples will be collected at timepoints as per the Schedule of Study Assessments up to 1-hour post dose. Supervised administration of the second inhaled dose on Day 2 of each Treatment Period will be performed. Following these assessments, the subject will be discharged from the clinic if they have no clinically significant adverse events, monitoring findings, or other safety concerns with instructions to continue daily dosing. Subjects will dose at home on Days 2 to 6 of each treatment period. A telephone follow-up call will be performed for review of safety, tolerability and compliance with study medication. Day 7 Subjects will attend the unit and perform pre-dose procedures as per the Schedule of Study Assessments and assessed for eligibility to receive the next dose. Subjects will receive their Day 7 dose of study medication. Study procedures will be performed, and samples will be collected at timepoints as per the Schedule of Study Assessments up to 12 hours post dose. Day 14 Subjects will attend the unit and perform pre-dose procedures as per the Schedule of Study Assessments and assessed for eligibility to receive the next dose. Subjects will receive their Day 14 will be collected at timepoints as per the Schedule of Study Assessments up to 12 hours post dose. Washout Period There will be a washout interval of at least 28 days between the last dose of a Treatment Period and the first dose of the next Treatment period. End of Study Visit All subjects will return for an End of Study visit days after the last dose of the last Treatment Period. Study procedures will be performed, and samples will be collected as per the Schedule of study assessments All subjects, including subjects who withdraw prematurely for any reason, will be asked to complete the End of Study visit. Subjects who withdraw for an AE will be followed until the AE has resolved, becomes stable and not reversible, or for 28 days, whichever is shortest.
Treatment Groups	Placebo RV1162 250 µg nominal dose RV1162 500 µg nominal dose

Investigational Product	RV1162 RV1162 (iSPERSE™ Dry Powder Formulated RV1162) is an inhalation powder containing RV1162, a narrow spectrum kinase inhibitor (NSKI) with activity against p38, Src and Syk kinases that is manufactured by Lonza (Bend Oregon USA, Tampa Florida USA, and Burton, UK) as pre-metered size 3 hydroxypropylmethelcellulose (HPMC) capsules containing the RV1162 drug substance and the excipients mannitol, sodium sulfate and polysorbate 80. RV1162 capsules will be provided in 250 µg and 500 µg RV1162 dose strengths. Each capsule of RV1162 is filled with iSPERSE powder comprised of RV1162, sodium sulfate, mannitol, and polysorbate 80. Each capsule of Placebo is filled with iSPERSE powder comprised of sodium sulfate, mannitol, and polysorbate 80. The clinical site will receive blinded dosing kits containing a sufficient quantity of packaged capsules and dry powder inhalers (Monodose Inhaler RS01 Model 7 high-resistance, Plastiape SA) to support the 14 days of dosing. RV1162 and Placebo will be administered to each subject via the included dry powder inhaler in accordance with the supplied instructions.
Eligibility Criteria	**Inclusion Criteria** Subjects must meet all the following: 1. Male or female subjects aged 40 to 75 years of age with a body mass index ³ 17 and £ 35 kg/m2. 2. Female subjects must be either of non-childbearing potential or if of childbearing potential use a highly effective birth control method. 3. Male subjects with female partners of childbearing potential must be vasectomised with documented medical assessment of the surgical success or use highly effective contraception together with their female partner(s). 4. Subject must agree not to donate semen or ova/oocytes during the study and for 60 days after the last dose of IMP. 5. Confirmed diagnosis by a physician of COPD with symptoms compatible with COPD for at least 1 year prior to screening. 6. Severity of Disease: subjects who conform to the current severity classification for GOLD Grade II/III disease in terms of post-bronchodilator spirometry at screening: • Post-salbutamol FEV_1/FVC ratio of £ 0.70. • Post-salbutamol FEV_1 ³ 40 % and £ 80 % of predicted normal values calculated using ECCS reference equations (Quanjer, 1993). • Current or previous smoker with a smoking history of ³ 10 pack years (1 pack year = 20 cigarettes smoked per day for 1 year or equivalent). 7. Normal blood pressure, defined as a systolic value of 90 mmHg to 160 mmHg and diastolic value of 60 mm Hg to 90 mm Hg, at screening and prior to randomisation.

8. Normal heart rate, defined as ≥ 60 and ≤ 100 beats per minute at screening and prior to randomisation.
9. Able to provide written Informed Consent Form (ICF) prior to participation in any study-related activities, and to comply with the requirements of the study.
10. Able to perform technically acceptable spirometry at screening.
11. Able to produce a sputum sample of adequate quality at the Screening or Baseline visit.
12. Able to demonstrate the correct inhalation technique for use of delivery device during the study at screening and prior to randomization.

Exclusion Criteria

Subjects who meet any of the following are not eligible:

1. Upper or lower respiratory tract infection or exacerbation of COPD from 4 weeks prior to the screening visit through to randomisation.
2. Clinically significant abnormal values at screening that, in the opinion of the PI, would make the subject inappropriate for the study or put the subject at undue risk, specifically liver function tests (LFTs) >3 x upper limit of normal (ULN); hemoglobin <10 gm/dL; absolute neutrophil count (ANC) <1000; white blood cells (WBC) >20,000; Platelets <100,000 and >500,000; prothrombin time (PT) >14 seconds.
3. History of drug or alcohol abuse within the past 2 years.
4. History of regular alcohol consumption within 6 months of the study defined as an average weekly intake of >21 units for males, or >14 units for females, where one unit is equivalent to 8 g of alcohol: a half-pint (~240 mL) of beer, 1 glass (125 mL) of wine or 1 (25 mL) measure of spirits.
5. Positive alcohol breath test result at screening or prior to randomization.
6. Positive urine drugs of abuse test result (unless in the opinion of the investigator this can be explained by the subject's current medications) at screening or prior to randomisation; unexpected or unexplained positive results may require discussion with sponsor.
7. Current users of e-cigarettes or nicotine replacement products and those who have used these products within the last 12 months prior to screening or prior to randomisation.
8. Known sensitivity to the study drug or any of the excipients of the formulation, or history of clinically significant sensitivity to any agent that, in the opinion of the PI, would make participation in the study inadvisable.
9. Donated blood or blood products or had substantial loss of blood (more than 500 mL) within 3 months before the first administration of study drug, or intention to donate blood or blood products during the study.

10. Participated in an interventional study involving an experimental therapeutic agent within 3 months of screening.
11. Women who have a positive serum b-human chorionic gonadotropin (hCG) pregnancy test at screening or a positive urinary hCG pregnancy test prior to randomisation, is pregnant, lactating, or planning to become pregnant during the study.
12. Positive test for human immunodeficiency virus (HIV) 1 and 2 antibodies, hepatitis B virus (HBV) infection, or hepatitis C antibodies.
13. Planned surgery or procedures during the participation of the study and for 14 days after the conclusion of study participation.
14. Employee of the Investigator or study centre with direct involvement in the proposed study or other studies under the direction of that Investigator or study centre, as well as family members of the employees or the Investigator.
15. Current or chronic history of liver disease or known hepatic or biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones).
16. The subject is unable or unwilling to comply fully with the study protocol.
17. Subject is mentally or legally incapacitated.
18. Unable or unwilling to undergo multiple venepuncture procedures or the subject has poor access to veins suitable for cannulation.
19. Any other reason that, in the opinion of the PI, would make participation in the study inadvisable.
20. A history of life-threatening COPD including Intensive Care Unit admission and/or requiring intubation within the last 5 years.
21. A history of > 1 hospitalisation for COPD in the previous 1 year prior to screening.
22. Evidence of cor pulmonale or clinically significant pulmonary hypertension.
23. Requires routine treatment for COPD using one (or more) of the following therapies within the 6 weeks before screening:
    - Oral b2 agonists
    - Methyl xanthines
    - PDE inhibitors
    - Oral leukotriene inhibitors
    - Antibiotic therapies for acute infections; chronic antibiotic use for prophylaxis, e.g. macrolides, is acceptable.

24. Other respiratory disorders: Subjects with a current diagnosis of asthma, active tuberculosis, lung cancer, bronchiectasis, sarcoidosis, lung fibrosis, interstitial lung diseases, or other active pulmonary diseases other than COPD.
25. Subjects with a history of chronic uncontrolled disease including, but not limited to, cardiovascular, endocrine, neurological, hepatic, gastrointestinal, renal, hematologic, urologic, immunologic, or ophthalmic diseases that, in the opinion of the PI, would make participation in the study inadvisable.
26. Subjects with a history of sleep apnoea requiring non-invasive ventilation or supplemental oxygen during sleep.
27. Previous lung resection or lung reduction surgery.
28. Active participation in a pulmonary rehabilitation program.
29. Has had major surgery within 6 weeks before screening.
30. A disclosed history, or one known to the Investigator, of significant noncompliance in previous investigational studies or with prescribed medications.
31. History of unstable or uncontrolled hypertension or has been diagnosed with hypertension in last 3 months.
32. Requires supplemental oxygen, even on an occasional basis.

Criteria for Evaluation	**Safety and Tolerability of RV1162:**
	Vital signs, physical examinations, and medical history
	12-lead ECG
	Heamatology, serum chemistry, and coagulation laboratory tests
	Urinalysis and urine drug screen
	Serum (screening) and urine (Day 1) pregnancy tests in WOCBP
	Pulse oximetry
	Spirometry
	Pharmacokinetics:
	Blood samples for systemic RV1162 levels:
	Treatment Period Day 1 at pre-dose, 0.25, 0.75, 2, 4, 8, and 12 h post-dose
	Treatment Period Day 2 at 24 h post-dose but prior to Dose 2
	Treatment Period Day 7 at pre-dose, 0.25, 0.75, 2, 4, 8, and 12 h post-dose
	Treatment Period Day 14 at pre-dose, 0.25, 0.75, 2, 4, 8, and 12 h post-dose
	End of Study 28 days after the last dose of the last Treatment Period
	Sputum samples for airway RV1162 PK levels:
	Treatment Period Day 2 at 24 h after Dose 1 but prior to Dose 2
	Treatment Period Day 7 prior to Dose 7
	Treatment Period Day 14 prior to Dose 14
	End of Study 28 days after the last dose of the last Treatment Period
	Sputum samples for PD evaluations:
	Day -3 to Day -1 of each Treatment Period
	Treatment Period Day 7 pre-dose
	Treatment Period Day 14 pre-dose
	End of Study 28 days after the last dose of the last Treatment Period

Statistical Methods	Sample size estimation This study is not powered for any formal hypothesis test. The sample size of 15 subjects has been chosen to minimise exposure while allowing an adequate assessment of safety and sputum PK. Pharmacokinetic Parameters: PK concentrations and PK parameters will be listed and summarised using descriptive statistics. Safety Parameters: Safety data analysis will be performed on all subjects in the safety population. Individual and summary vital signs, ECG parameters, spirometry, pulse oximetry and safety laboratory data will be listed and presented in tabular form with mean, median, standard deviation and range (min and max) as appropriate. Categorical variables will be summarised using frequency tables (frequency and percentage). All safety data (scheduled and unscheduled) will be presented in the data listings. For the laboratory safety data, out-of-range values will be flagged in the data listings and a list of clinically significantly abnormal values will be presented. In addition, clinically significant abnormal values will be summarised as appropriate.

TABLE 1: SCHEDULE OF STUDY ASSESSMENTS

Visit	Screening	Treatment Periods 1, 2 and 3- Washout of at least 21 days between treatment periods					End of Study[1]
Study Day	Within 28 days of TP1 Day 1	Day -3 to Day -1	Day 1	Day 2	Day 7+1	Day 14+1	Day 28+2
Informed consent	X						
Medical history	X						
Physical examination[2]	X		X	X	X	X	X
Vital signs[3,4]	X		X	X	X	X	X
Pulse oximetry	X		X	X	X	X	X
Pregnancy test[5]	X		X				X
FSH (postmenopausal females only; if required)	X						
12-lead ECG[6]	X		X	X	X	X	X
Serum chemistry, haematology, coagulation, and urinalysis[11]	X		X		X	X	X
Urine for drugs of abuse	X		X		X	X	X
Spirometry[7]	X		X	X	X	X	X
Sputum PD[8]	X	X			X	X	X
Study drug administration			X	X	X	X	
Blood RV1162 PK[9]			X	X	X	X	X
Sputum RV1162 PK[10]				X	X	X	X
Device Training	X		X		X	X	
AEs & Con Meds	From consent and throughout the study						

1 Subjects will return to the clinic at End of Study 28 days after the last dose for safety assessments and collection of PK plasma and sputum and PD sputum samples; if subject withdraws from the study early every effort will be made for the subject to complete an End of Study visit.
2 Full PE, including height and weight, at screening, Day 1 of each Treatment Period, and at End of Study; brief examination on Day 2, Day 7 and Day 14.
3 Blood pressure, pulse rate, respiratory rate, and oral temperature.
4 Vital signs performed at screening and pre-dose, then post-dose every 15 minutes for 1 hour, then hourly at 2, 3, and 4 hours, and then at 8 and 12 hours after Day 1 dose of each Treatment Period; pre-dose and 1 hour post-dose after Day 2 dose of each Treatment Period, and pre-dose and 1, 4, 8, and 12 hours post-dose after Day 7 and Day 14 dose of each Treatment Period.
5 Serum pregnancy at screening, urine pregnancy on Day 1 of each Treatment Period and at End of Study.
6 12-lead ECG performed in triplicate; performed at screening, pre-dose and 1, 4, and 8 hours post-dose after Day 1 dose of each Treatment Period, pre-dose and 1 hour post-dose after Day 2 dose of each Treatment Period, and pre-dose and 1, 4, 8, and 12 hours post-dose after Day 7and Day 14 dose of each Treatment Period.
7 Spirometry performed at screening , pre-dose and 1, 2, 4, 8, and 12 hours post-dose after Day 1 dose of each Treatment Period, pre-dose and 1 hour post-dose after Day 2 dose of each Treatment Period, and pre-dose and 1, 4, 8, and 12 hours post-dose after Dose 7 and Day 14 dose of each Treatment Period.
8 Sputum collection will be performed at Screening and/or Baseline to ensure subjects can produce adequate sample; PD sputum sample collected at baseline visit between Day -3 and Day -1 of each Treatment Period, pre dose on Day 7 and Day 14 of each Treatment Period and at the End of Study Visit.
9 Blood PK samples collected pre-dose and 0.25, 0.75, 2, 4, 8, and 12 hours post-dose on Day 1, Day 7, and Day 14 of each Treatment Period, and prior to Day 2 dose of each Treatment Period.
10 Sputum PK samples collected pre-dose on Day 2 (24 hours post dose and prior to Day 2 dose) and pre-dose Days 7 and 14 of each Treatment Period.
11 Clinical safety laboratory samples (clinical chemistry, haematology, coagulation, and urinalysis) must be performed within 7 days of Day 1, Period 1; if this interval is exceeded, sampling must be repeated.

APPENDIX 4

JOHNSON & JOHNSON UNIVERSAL CALENDAR

2019 UNIVERSAL CALENDAR

	M	T	W	T	F	S	S
	31						
JANUARY		1	2	3	4	5	6
(4 Weeks)	7	8	9	10	11	12	13
	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30	31			
FEBRUARY					1	2	3
(4 Weeks)	4	5	6	7	8	9	10
	11	12	13	14	15	16	17
	18	19	20	21	22	23	24
	25	26	27	28			
					1	2	3
MARCH	4	5	6	7	8	9	10
(5 Weeks)	11	12	13	14	15	16	17
	18	19	20	21	22	23	24
	25	26	27	28	29	30	31
	1	2	3	4	5	6	7
APRIL	8	9	10	11	12	13	14
(4 Weeks)	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30					
MAY			1	2	3	4	5
(4 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26

	M	T	W	T	F	S	S
	1	2	3	4	5	6	7
JULY	8	9	10	11	12	13	14
(4 Weeks)	15	16	17	18	19	20	21
	22	23	24	25	26	27	28
	29	30	31				
AUGUST				1	2	3	4
(4 Weeks)	5	6	7	8	9	10	11
	12	13	14	15	16	17	18
	19	20	21	22	23	24	25
	26	27	28	29	30	31	
							1
SEPTEMBER	2	3	4	5	6	7	8
(5 Weeks)	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
	30						
OCTOBER		1	2	3	4	5	6
(4 Weeks)	7	8	9	10	11	12	13
	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30	31			
NOVEMBER					1	2	3
(4 Weeks)	4	5	6	7	8	9	10
	11	12	13	14	15	16	17
	18	19	20	21	22	23	24

	27	28	29	30	31		
						1	2
JUNE	3	4	5	6	7	8	9
(5 Weeks)	10	11	12	13	14	15	16
	17	18	19	20	21	22	23
	24	25	26	27	28	29	30

	25	26	27	28	29	30	
							1
DECEMBER	2	3	4	5	6	7	8
(5 Weeks)	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	29

2020 UNIVERSAL CALENDAR

	M	T	W	T	F	S	S
	30	31					
JANUARY			1	2	3	4	5
(4 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30	31		
FEBRUARY						1	2
(4 Weeks)	3	4	5	6	7	8	9
	10	11	12	13	14	15	16
	17	18	19	20	21	22	23
	24	25	26	27	28	29	
							1
MARCH	2	3	4	5	6	7	8
(5 Weeks)	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
	30	31					
APRIL			1	2	3	4	5
(4 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26

	M	T	W	T	F	S	S
	29	30					
JULY			1	2	3	4	5
(4 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30	31		
AUGUST						1	2
(4 Weeks)	3	4	5	6	7	8	9
	10	11	12	13	14	15	16
	17	18	19	20	21	22	23
	24	25	26	27	28	29	30
	31						
SEPTEMBER		1	2	3	4	5	6
(5 Weeks)	7	8	9	10	11	12	13
	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30				
OCTOBER				1	2	3	4
(4 Weeks)	5	6	7	8	9	10	11
	12	13	14	15	16	17	18
	19	20	21	22	23	24	25

	27	**28**	**29**	**30**			
MAY					**1**	**2**	**3**
(4 Weeks)	**4**	**5**	**6**	**7**	**8**	**9**	**10**
	11	**12**	**13**	**14**	**15**	**16**	**17**
	18	**19**	**20**	**21**	**22**	**23**	**24**
	25	**26**	**27**	**28**	**29**	**30**	**31**
JUNE	**1**	**2**	**3**	**4**	**5**	**6**	**7**
(5 Weeks)	**8**	**9**	**10**	**11**	**12**	**13**	**14**
	15	**16**	**17**	**18**	**19**	**20**	**21**
	22	**23**	**24**	**25**	**26**	**27**	**28**

	26	**27**	**28**	**29**	**30**	**31**	
NOVEMBER							**1**
(4 Weeks)	**2**	**3**	**4**	**5**	**6**	**7**	**8**
	9	**10**	**11**	**12**	**13**	**14**	**15**
	16	**17**	**18**	**19**	**20**	**21**	**22**
	23	**24**	**25**	**26**	**27**	**28**	**29**
	30						
DECEMBER		**1**	**2**	**3**	**4**	**5**	**6**
(6 Weeks)	**7**	**8**	**9**	**10**	**11**	**12**	**13**
	14	**15**	**16**	**17**	**18**	**19**	**20**
	21	**22**	**23**	**24**	**25**	**26**	**27**
	28	**29**	**30**	**31**			
					1	**2**	**3**

APPENDIX 5

INVOICE AND PAYMENT

Invoices shall be due and payable within ninety (90) calendar days' after Licensee's receipt thereof, unless otherwise set forth in this Agreement. Provider shall establish a profile with Johnson & Johnson Accounts Payable at www.ap.jnj.com and shall submit invoices electronically to Accounts Payable. When logging into the website, Provider will be prompted for its supplier number, which can be found on the purchase order. All invoices will be paid via electronic funds transfer on the first (1st) and third (3rd) Monday of the month, in arrears. Payments due on a holiday will be paid on the next Business Day.

Copies of all invoices shall be sent concurrently to Karen Shakespeare, at kshakesp@ITS.JNJ.com. All invoices must reference a valid JJEI Purchase Order (P.O.) number which will be provided by JJEI. JJEI reserves the right to return to Provider unprocessed and unpaid invoices that do not reference such P.O. number. All invoices and payments shall be in U.S Dollars ($USD).

APPENDIX 6

ASSIGNMENT AGREEMENT

Appendix 6 (Assignment Agreement) is attached hereto and incorporated herein by this reference.

APPENDIX 7

PRESS RELEASE

December XX, 2019

Pulmatrix Announces Kinase Inhibitor Licensing Agreement with Lung Cancer Initiative at Johnson & Johnson

LEXINGTON, Mass., Dec. XX, 2019 /PRNewswire/ — Pulmatrix, Inc. (NASDAQ: PULM), a clinical stage biopharmaceutical company developing innovative inhaled therapies to address serious pulmonary diseases, today announced that it has entered into a licensing and development agreement with the Lung Cancer Initiative at Johnson & Johnson*. Through the agreement, the Lung Cancer Initiative gains an option to access a portfolio of narrow spectrum kinase inhibitors intended for development in lung cancer interception.

“Pulmatrix’s iSPERSE™ platform has the ability to enhance the safety and efficacy profile of promising drug candidates,” said Ted Raad, Chief Executive Officer of Pulmatrix. “We applied the iSPERSE™ technology to RV1162/PUR1800, the lead in-licensed inhibitor and helped unlock its clinical potential by improving the product’s profile from the original formulation. In 2020, we anticipate clinical data from the first of these inhibitors in a disease area with significant unmet medical need. We look forward to collaborating with the Lung Cancer Initiative at Johnson & Johnson as we advance this important program. Additionally, in 2020, we anticipate data from our phase 2 Pulmazole program and we plan to introduce new proprietary, wholly owned iSPERSE enabled 505(b)(2) assets to our pipeline.”

Under the terms of the agreement, the Lung Cancer Initiative will pay a $7.2 million upfront payment and an additional $2 million milestone payment upon completion of the ongoing Phase 1b study of RV1162/PUR1800 in stable COPD patients, on-track for year-end 2020. If the Lung Cancer Initiative exercises the option on RV1162/PUR1800 and the portfolio of these kinase inhibitors, Pulmatrix is eligible for up to $91M in additional development and commercial milestones, as well as royalty payments.

About Pulmatrix

Pulmatrix is a clinical stage biopharmaceutical company developing innovative inhaled therapies to address serious pulmonary disease using its patented iSPERSE™ technology. The Company’s proprietary product pipeline is focused on advancing treatments for serious lung diseases, including Pulmazole, an inhaled anti-fungal for patients with allergic bronchopulmonary aspergillosis (“ABPA”), and PUR1800, a narrow spectrum kinase inhibitor for patients with obstructive lung diseases including asthma and chronic obstructive pulmonary disease (“COPD”). Pulmatrix’s product candidates are based on iSPERSE™, its proprietary engineered dry powder delivery platform, which seeks to improve therapeutic delivery to the lungs by maximizing local concentrations and reducing systemic side effects to improve patient outcomes.

FORWARD-LOOKING STATEMENTS

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements of historical fact, and may be identified by 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 are intended to identify forward-looking statements. Such forward-looking statements are based on the beliefs of management

as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including, but not limited to, delays in planned clinical trials; the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of therapeutic candidates; the ability to obtain appropriate or necessary governmental approvals to market potential products; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; the Company's ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to the Company's products, including patent protection. A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company's filings with the SEC, including its annual report on Form 10-K filed with the Securities and Exchange Commission on February 19, 2019, as amended on July 24, 2019, as may be supplemented or amended by the Company's Quarterly Reports on Form 10-Q. The Company disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

* Johnson & Johnson Enterprise Innovation Inc. is the legal entity to the agreement.

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Investor Contact
Timothy McCarthy, CFA
212.915.2564
tim@lifesciadvisors.com

APPENDIX 8

SIDE LETTER

Appendix 8 (Side Letter) is attached hereto and incorporated herein by this reference.

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 No. 333-230670), S-3 (File No. 333-230225) and Forms S-8 (File Nos. 333-195737, 333-205752, 333-207002 333-212547, 333-216628, 333-225627, and 333-231935) of our report, dated March 26, 2020 with respect to our audits of the consolidated financial statements of Pulmatrix, Inc. as of December 31, 2019 and 2018 and for each of the two years in the period ended December 31, 2019, which report is included in this Annual Report on Form 10-K of Pulmatrix, Inc. for the year ended December 31, 2019.

Our report on the consolidated financial statements refers to a change in the method of accounting for leases effective January 1, 2019, due to the adoption of Accounting Standards update ("ASU") No. 2016-02, *Leases (Topic 842), as amended*, and a change in the method of accounting for revenues effective January 1, 2019, due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606), as amended*.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 26, 2020

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 26, 2020

/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 26, 2020

/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, 2019 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 26, 2020

/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, 2019 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 26, 2020

/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.